FY 2016-2017

Office of Enforcement and Compliance Assurance National Program Manager Guidance

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Table of Contents

I. EPA Overview to the FY 2016-2017 NPM Guidance

The *EPA Overview* to the National Program Manager (NPM) Guidances communicates important agency-wide information and should be reviewed in conjunction with this fiscal year (FY) 2016-2017 NPM Guidance as well as other applicable requirements. Read the overview at: http://www2.epa.gov/planandbudget/national-program-manager-guidances.

II. Introduction

This National Program Manager Guidance applies to the Office of Enforcement and Compliance Assurance (OECA), all U.S. Environmental Protection Agency (EPA) regional enforcement programs, and states and federally-recognized Indian tribes (tribes) implementing EPA-approved inspection and enforcement programs[1]. OECA coordinates with the EPA program offices, regions, states and local agencies and engages in consultation and coordination with tribal governments as it designs, develops, implements and oversees national compliance and enforcement programs. Regional offices also work with states and local agencies and consult with tribes to implement and review these programs.[2] Headquarters and regional program coordination includes providing assistance on regulatory interpretations and applicability issues upon request from regions, states, tribes and local agencies. *OECA's National Program Manager (NPM) Guidance* provides clear direction for FY 2016-2017. It identifies the national compliance and enforcement priorities, discusses national direction for all compliance assurance programs, identifies activities to be carried out by authorized programs, and describes how the EPA should work with states and tribes to ensure compliance with environmental laws. Once implemented, the priorities and activities described in the NPM Guidance serve to protect the Nation's environment and public health and provide a level playing field for responsible businesses. Most of the work in the NPM Guidance is accomplished under the Agency's Goal 5 - "Protecting Human Health and the Environment by Enforcing Laws and Assuring Compliance" in the FY 2014-2018 EPA Strategic Plan.

The EPA's national enforcement and compliance assurance program continues to assure compliance with federal environmental statutes using a variety of tools, including civil and criminal enforcement. These tools advance OECA's overall national goals for:

- Tough civil and criminal enforcement for violations that threaten communities and the environment.
- Next Generation Compliance: achieving greater compliance and protection using advanced monitoring and information technologies. Next Generation Compliance tools are intended to supplement and advance strong enforcement programs.
- Strong EPA/State/Tribal environmental protection: working together toward shared environmental goals.

[1] When referring to states and tribes throughout this NPM guidance, OECA is referring to states and tribes authorized to implement federal programs.

[2] EPA consults with tribes consistent with the EPA Policy on Consultation and Coordination with Indian Tribes and Executive Order 13175.

To help achieve these enforcement goals, OECA will continue to focus on high priority work where significant environmental risk and noncompliance patterns are known to exist or where there are important opportunities to improve performance. This work includes:

1. Implementing Clean Air Act National Enforcement Initiatives;
2. Implementing Clean Water Act National Enforcement Initiatives;
3. Assuring Safe Drinking Water;
4. Reducing Pollution from Mineral Processing Operations;
5. Assuring Energy Extraction Sector Compliance with Environmental Laws;
6. Implementing the Clean Water Act Action Plan;
7. Advancing Next Generation Compliance; and
8. Strengthening State Performance and Oversight.

These priorities continue from FY 2015.

As part of the process for identifying national priorities, OECA and the EPA regions sought early input from states, tribes and associations on priorities, suggestions for FY 2017-2019 National Enforcement Initiatives and the remaining content of the FY 2016-2017 NPM Guidance. The EPA took this input into account when developing the NPM Guidance and responded to each state, association and tribal partnership group who provided comments. Several sections of the NPM Guidance were influenced by stakeholder comments, including comments to continue our safe drinking water priority area and other priorities, and comments related to the sections on the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and Resource Conservation and Recovery Act (RCRA) Underground Storage Tanks program. Stakeholders submitted several ideas for the FY 2017-2019 National Enforcement Initiatives, which are still under discussion. OECA will identify the FY 2017-2019 national initiatives in an FY 2017 Addendum to the NPM Guidance. The EPA looks forward to working together with its state and tribal partners to achieve our shared environmental goals, including Next Generation Compliance.

Robust compliance monitoring and enforcement continue and are critically important for addressing violations and promoting deterrence. But this alone will not solve our noncompliance problems. To address these problems, OECA is continuing to implement Next Generation Compliance which will enable the EPA and states to better address large regulated universes with approaches that go beyond traditional single facility inspections and enforcement. Advances in emissions monitoring and information technology are foundations of this new approach. The EPA will increase the use of advanced monitoring technologies, and other Next Generation Compliance tools, in rules, permits and inspections to detect, correct and report pollution problems. Use of advanced emissions/pollutant detection technology will make pollution that is currently “invisible,” “visible.” Industry can then more effectively prevent and reduce pollution and often make their operations more efficient. Developing more effective regulations and permits using electronic reporting, public accountability and third party verification, and continuing to develop innovative enforcement approaches and increase transparency are all encompassed under Next Generation Compliance. The EPA, states, and other partner agencies continue to implement this transformation together -- realizing both efficiencies and cost savings in the longer term while protecting public health and the environment.

Next Generation Compliance complements the Agency-wide E-Enterprise for the Environment[3] effort described in EPA's Overview to the FY 2016-2017 NPM Guidance. Both focus on expanding electronic reporting, advanced monitoring and transparency. Appendix 1 to this Guidance identifies examples of projects in which OECA is participating or leading which align with the E-Enterprise goals. Over the period of this NPM Guidance, EPA will complete or modify some of these activities, and develop and/or implement new projects. OECA encourages states and tribes to coordinate with EPA on these projects where they see the same or complementary priorities, processes, or objectives.

During FY 2016-2017, regional enforcement programs will also work with their state, tribal, and local partners to implement each region's Climate Change Adaptation Plan in conjunction with *the U.S. Environmental Protection Agency, Climate Change Adaptation Plan,* available at: www.epa.gov/climatechange/impacts-adaptation/fed-programs/Final-EPA-Adaptation-plans.html. OECA will strive to integrate climate adaptation planning into its programs, policies, and operations where appropriate to protect human health and the environment as the climate changes.

It's important to note that, in 2014, OECA issued updated Compliance Monitoring Strategies (CMSs) which provide increased compliance monitoring flexibility for the Clean Water Act, the Resource Conservation and Recovery Act, and the Clean Air Act programs. They were issued after OECA held a national dialogue about flexibility in the CMSs and how compliance monitoring activities could be further expanded while maintaining program integrity. The revised CMSs provide increased flexibility to EPA and state agencies when conducting compliance monitoring activities through an expanded set of tools for determining compliance and to address local pollution and compliance concerns. The revised strategies provide additional flexibility to address the most important pollution problems within each media program, an expanding universe of regulated entities and resource limitations. In response to state comments and at the request of the states, OECA also developed more specific guidance on the process for states to request alternative CMS plans and for regions to review and approve state alternative plans. This guidance has been distributed to states and associations is accessible at: http://www2.epa.gov/compliance/resources-and-guidance-documents-compliance-monitoring

OECA and the Office of Pesticides Programs (OPP) jointly issue FIFRA Cooperative Agreement Guidance, which explicitly discusses parameters for flexibility. The FIFRA Cooperative Agreement Guidance attempts to balance support for National Pesticide Program priorities, goals and performance measures, with providing flexibility to grantees to focus on those national program areas which present the greatest concern locally. The specific parameters for flexibility are discussed in the Guidance Framework on page 2 of the FIFRA Cooperative Agreement Guidance (http://www2.epa.gov/sites/production/files/2014-10/documents/15-17guidance.pdf). Grantees may also negotiate a Performance Partnership Grant (PPG) in lieu of pesticide program and enforcement cooperative agreements. Under the PPG system, regions and grantees should continue to use our FIFRA Cooperative Agreement Guidance to ensure that program areas are addressed consistent with the Guidance.

[3] See "About E-Enterprise for the Environment" at http://www2.epa.gov/e-enterprise/about-e-enterprise-environment

OECA, in coordination with the EPA regions, established the Regional Strategic Plan process to provide a vehicle for meaningful and efficient strategic planning dialogue at senior management levels in the regions and within OECA across all civil regulatory enforcement programs. The Regional Strategic Plans provide a concise overview of regional strategy and rationale for deployment of enforcement resources consistent with national priorities, regional priorities, state oversight and resource constraints. The Regional Strategic Planning process seeks to align priorities with ACS commitments, recognizing the need to focus on the highest priority work; flexibility and elevation of issues are integral parts of that planning process.

Finally, beyond the discussion of Regional Plans, in implementing the NPM Guidance, if issues or questions arise beyond those discussed above, OECA has also established general guidelines for seeking approval for flexibilities and elevating issues, as needed. If resources do not allow for activities in the Guidance to be implemented, then EPA regional management should raise the specific activities for discussion with the appropriate OECA Office Director(s) (ODs). If agreement cannot be reached at the OD level, then the discussion will be elevated to the Assistant Administrator's office. Similarly, delegated or authorized state, tribal or local agencies that are facing resource challenges can raise specific activities for discussion with the appropriate senior regional manager(s) when developing their annual work plans with the EPA regions. The appropriate OECA Office Director is ready to assist if regional management wants to discuss any state, tribal or local issues with OECA. These guidelines are necessary to help ensure EPA consistency, as appropriate, in implementing critical activities across media programs and ensuring a level playing field nationally.

III. National Areas of Focus

Every three years, the EPA selects National Enforcement Initiatives (NEIs) to address specific environmental problems, risks, or patterns of noncompliance. These initiatives are reevaluated every three years in order to assure that federal enforcement resources are focused on the most important environmental problems where noncompliance is a significant contributing factor, and where federal enforcement attention can have a significant impact. After reviewing input from tribes, states and other external stakeholders, OECA chose the FY 2014-2016 NEIs which conclude at the end of FY 2016. Although the initiatives have made substantial progress in addressing noncompliance within their respective sectors, more work remains to be done in FY 2016.

The next cycle of National Enforcement Initiatives will be implemented in FY 2017-2019. OECA solicited early input on these initiatives from states, tribes, associations and tribal partnership groups. OECA intends to seek additional comment from all interested parties through a Federal Register (FR) Notice to be published in 2015. OECA will take into account all early input received to date and in response to the FR Notice during the process of selecting the FY 2017-2019 national initiatives; discussions are still underway. The FY 2017-2019 national initiatives will be identified in the FY 2017 Addendum to this National Program Manager (NPM) Guidance; the Addendum will be published around April, 2016. The FY 2017 Addendum will highlight any significant changes or new decisions impacting FY 2017 which could not be predicted when EPA released the final FY 2016-2017 NPM Guidance.

This section discusses each of OECA's FY 2014-2016 NEIs, as well as other national priorities for FY 2016-2017, and identifies critical supporting activities, responsibility for implementation, and associated measures for tracking. If resources do not allow for activities in the guidance to be implemented, then regional management should raise the specific activities for discussion with the appropriate OECA Office Director(s) per the discussion above. Similarly, delegated or authorized state, tribal or local agencies that are facing resource challenges can raise specific activities for discussion with the appropriate senior regional manager(s) when developing their annual work plans with the EPA regions.

1. Implementing Clean Air Act (CAA) National Enforcement Initiatives

Description: The following is a discussion of work in 2 CAA-specific National Enforcement Initiative areas.

Cutting Toxic Air Pollution that Affects Communities' Health:

In 1990, Congress identified hazardous air pollutants (HAPs), currently totaling 187, that present significant threats to human health and have adverse ecological impacts (http://www.epa.gov/ttn/atw/188polls.html). The CAA and EPA's regulations impose strict emission control requirements (known as "Maximum Achievable Control Technology" or "MACT") for these pollutants, which are emitted by a wide range of industrial and commercial facilities. The EPA will target and reduce emissions of toxic air pollutants in three areas where the agency has determined there are high rates of noncompliance: (A) leak detection and repair; (B) reduction of the volume of waste gas to flares and improvements to flare combustion efficiency; and (C) excess emissions, including those associated with startup, shut down and malfunction. Through this Air Toxics Initiative, the EPA will undertake compliance monitoring and enforcement activities to maximize environmental and human health benefits, which is particularly important for disproportionately burdened communities. OECA will utilize innovative monitoring and evaluation techniques and partner with the EPA's Office of Air and Radiation (OAR) and Office of Research and Development. OECA will also provide equipment and training to inspectors to enhance the effectiveness of on-site activities.

Reducing Widespread Air Pollution from the Largest Sources, Especially the Coal-fired Utility, Cement, Glass, and Acid Sectors:

The New Source Review/Prevention of Significant Deterioration (NSR/PSD) requirements of the CAA require certain large industrial facilities to install state-of-the-art air pollution controls when they build new facilities or make "significant modifications" to existing facilities. However, many industries have not complied with these requirements, leading to excess emissions of air pollutants such as sulfur dioxide, nitrogen oxides and particulate matter. These pollutants can be carried long distances by the wind and can have significant adverse effects on human health, including asthma, respiratory diseases and premature death. These effects may be particularly significant for communities overburdened by exposure to environmental risks and vulnerable populations, including children. In recent years, the EPA has made considerable progress in reducing excess pollution by bringing enforcement actions against coal-fired power plants, cement manufacturing facilities, sulfuric and nitric acid manufacturing facilities, and

glass manufacturing facilities. However, work remains to be done to bring these sectors into compliance with the CAA and protect communities burdened with harmful air pollution.

Activities:

EPA regions will:

- Implement the strategy for the Air Toxics National Enforcement Initiative.
- Implement the strategy for the National Enforcement Initiative on New Source Review – Coal Fired Electric Utilities, Cement, Glass, Sulfuric and Nitric Acid.

Measures: For the Air Toxics Initiative, see Annual Commitment System (ACS) measures PBS-ATX03 and ATX04. For the initiative addressing the largest sources, see ACS measures PBS-NSR01-NSR09. Both sets of measures are in Appendix 2, pages 1-2.

2. Implementing Clean Water Act (CWA) National Enforcement Initiatives

Description: The following is a discussion of work in 2 CWA-specific National Enforcement Initiative areas.

Keeping Raw Sewage and Contaminated Stormwater Out of Our Nation's Waters:

The EPA will continue its enforcement focus on reducing discharges of raw sewage and contaminated stormwater into our nation's rivers, streams and lakes. This National Enforcement Initiative focuses on reducing discharges from combined sewer overflows (CSOs), sanitary sewer overflows (SSOs), and municipal separate storm sewer systems (MS4s) by obtaining cities' commitments to implement timely, affordable solutions to these problems. In FY 2012, the EPA developed the Integrated Municipal Stormwater and Wastewater Planning Approach Framework, posted at http://www.epa.gov/npdes/pubs/integrated_planning_framework.pdf, to provide further guidance on developing and implementing effective integrated planning solutions to municipal wastewater and stormwater management. This approach allows municipalities to prioritize CWA requirements in a manner that addresses the most pressing public health and environmental protection issues first, while maintaining existing regulatory standards. All or part of an integrated plan may be incorporated into the remedy of enforcement actions. These remedies may include expansion of collection and treatment system capacity and flow reduction measures including increased use of green infrastructure and other innovative approaches. The EPA is committed to working with communities to incorporate green infrastructure, such as green roofs, rain gardens, and permeable pavement into permitting and enforcement actions to reduce stormwater pollution and sewer overflows where applicable. Regions should consider and promote the opportunity to utilize green infrastructure controls in municipal enforcement actions. See information on green infrastructure at http://water.epa.gov/infrastructure/greeninfrastructure/index.cfm. Building on the Integrated Planning Framework, EPA released the Financial Capability Assessment Framework (FCA Framework) in November of 2014. The FCA Framework provides clarifications on the flexibilities built into EPA existing guidance on how to evaluate financial capability when developing Clean Water Act compliance schedules. As envisioned by that guidance, it also

provides examples of additional information that could be submitted to give a more complete picture of a permittee's unique circumstances so as to better inform schedule development.

Preventing Animal Waste from Contaminating Surface and Ground Waters:

Concentrated animal feeding operations (CAFOs) are a subset of livestock and poultry animal feeding operations (AFOs) that meet the regulatory thresholds of number of animals for various animal types. The EPA's goal is to take action to reduce animal waste pollution from livestock and poultry operations that impair our nation's waters, threaten drinking water sources, and adversely impact vulnerable communities. EPA's regulations require permit coverage for any CAFO that discharges manure, litter, or process wastewater into waters of the U.S. CAFOs that discharge to U.S. waters but do not have National Pollutant Discharge Elimination System (NPDES) permits are in violation of the CWA. The EPA will continue to focus federal enforcement investigations primarily on existing large and medium CAFOs identified as discharging without a permit to waters of the U.S., particularly in areas impacted by CAFO/AFO wastes. In addition, EPA's resources will be used to assure that CAFOs that already have permits are in compliance with those permits. Each EPA region, in coordination with the states and tribes where appropriate, will consider a variety of factors to prioritize its CAFO activities. These factors include, but are not limited to, identifying watersheds or water bodies where CAFO/AFO wastes are negatively affecting surface water quality, proximity of CAFOs to drinking water sources and vulnerable communities, and status of states or tribes with NPDES-authorized CAFO programs.

Activities:

EPA regions, coordinating with their states and tribes where appropriate, will:

- Implement the strategy for the Municipal Infrastructure National Enforcement Initiative.
- Identify appropriate opportunities for implementing EPA's Integrated Municipal Stormwater and Wastewater Planning Approach Framework.
- Work with permittees to foster better understanding of EPA approaches to Financial Capability Assessment (FCA) through the implementation of the FCA Framework.
- Implement the strategy for the Concentrated Animal Feeding Operation (CAFO) National Enforcement Initiative.

Measures: For the initiative addressing raw sewage and contaminated storm water, see ACS measures PBS M105-M108 in Appendix 2, page 2. For the CAFO initiative, see ACS measures PBS-CAF002, CAF007 and CAF008 in Appendix 2, page 2.

3. Assuring Safe Drinking Water

Description: The EPA's focus on public water systems (PWS), including those in Indian country, protects the public from the potential acute and chronic health effects of drinking water that fails to comply with the Safe Drinking Water Act (SDWA). The EPA's Enforcement

Response Policy (ERP)[4] has the ultimate goal of returning non-compliant PWS's to compliance. The ERP establishes a holistic approach for prioritizing systems to address through an enforcement action. Those PWS's that reach a score of 11 or higher are identified as an enforcement priority and must return to compliance or be issued a formal enforcement action within six months. Scores for each PWS with unresolved violations are based upon the number, severity and length of violations.

A quick response to violations of the National Primary Drinking Water Regulations decreases the risks to public health and allows primacy agencies flexibility to use a variety of tools such as assistance and informal enforcement actions to bring the PWS back into compliance. Primacy agencies should be proactive in addressing violations to prevent systems from reaching a score of 11 or greater. This approach is especially important in Indian country, as it allows for timely and appropriate consultation and coordination with the tribal government as soon as a violation is identified. It is also particularly important in responding to violations at small systems, which may require more assistance to return to compliance.

The EPA realizes that some small systems remain in persistent noncompliance despite primacy agency efforts. EPA, states and tribes will be working together to explore root causes of noncompliance and options for resolving them in a concerted effort to ensure that all available tools, resources and partners are engaged to help these systems operate safely, comply with SDWA, and become sustainable, if possible.

EPA's Enforcement and Compliance History Online (ECHO) makes public access to PWSs' compliance status more readily available and highlights the importance of accurate and complete data. Inaccurate and incomplete data limits EPA's and the public's understanding of the state of compliance with the Safe Drinking Water Act. This in turn limits the EPA's ability to identify priorities, and evaluate program needs and effectiveness consistently and appropriately. OECA continues to coordinate with and support OW to improve data quality. EPA regions, states, territories and tribes should continue their efforts to improve the completeness, accuracy and timeliness of data reported.

Activities:

EPA regions will:

- Ensure that primacy agencies fulfill the enforcement conditions of their primacy agreements.
- Promote accurate, timely and complete reporting by each primacy agency, including the EPA.
- Ensure that primacy agencies implement the ERP, and use the Enforcement Targeting Tool (ETT).
- Collaborate with primacy agencies to ensure that the PWSs with the most serious violations are addressed and returned to compliance in a timely and appropriate manner, particularly

[4] The ERP is available at http://www2.epa.gov/enforcement/proposed-revision-enforcement-response-policy-public-water-system-supervision-pwss

where PWSs are in substantial noncompliance with state, territorial, or tribal enforcement orders.

- Using the quarterly ETT, hold in-depth regular discussions with primacy agencies regarding compliance and enforcement matters. These exchanges should include progress in returning systems to compliance, monitoring implementation of orders, number of systems addressed, number of systems in violation, and overall performance in implementing the ERP.
- Apply the ERP in Indian country, Wyoming, and the District of Columbia. When serving as the primacy agency for Indian country, ensure the ERP timeline for return to compliance (RTC) is accomplished while simultaneously implementing *OECA's Guidance on the Enforcement Principles Outlined in the 1984 Indian Policy (January 17, 2001),* which can be found at: http://www2.epa.gov/enforcement/transmittal-final-guidance-enforcement-principles-outlined-1984-indian-policy-january-17. Application of the guidance, which contains threshold criteria for EPA's consideration of formal civil enforcement actions, including appropriate consultation and compliance assistance, should not result in a lesser degree of human health and environmental protection in Indian country than elsewhere in the United States and must address and resolve drinking water violations on a schedule consistent with the ERP.
- When appropriate, authorize state and tribal inspectors to conduct inspections on EPA's behalf. Ensure that state and tribal inspectors who conduct inspections on EPA's behalf are trained and credentialed consistent with agency guidance, including the *Guidance for Issuing Federal EPA Inspector Credentials to Authorize Employees of State/Tribal Governments to Conduct Inspections on Behalf of EPA* (2004). Consistent with the EPA Order 3510, annually conduct an inventory of federal credentials which includes an annual physical possession check of 10 percent of the federal credentials issued to state and tribal inspectors and a count of unused credentials stock.
- Coordinate internally among enforcement programs in all media to protect drinking water sources.
- Perform the activities listed below under "State, territories and tribes with primacy" in circumstances where the EPA is the primacy agency.

States, territories and tribes with primacy will:

- Fulfill the enforcement conditions of their primacy agreements.
- Use the ETT and implement the ERP to ensure that priority systems, within six months of having reached a score of 11, either return to compliance or receive formal enforcement actions that compel the systems to return to compliance in a timely fashion.
- Work to reduce their backlog of systems that have already been at a score of 11 or higher for more than six months.
- Return to compliance or address violations at non-complying PWSs before they become priority systems with a focus on schools and child care facilities, as resources allow.
- Report compliance and enforcement data to ensure that it is entered into SDWIS in a complete, accurate and timely manner.
- Coordinate internally among enforcement programs in all media to protect drinking water sources.

Measures: See ACS measure SDWA02 in Appendix 2, page 3.

4. Reducing Pollution from Mineral Processing Operations

Description: The following is a discussion of work in this National Enforcement Initiative area.

Mining and mineral processing facilities generate more toxic and hazardous waste than any other industrial sector, based on the EPA's Toxic Release Inventory. Many of these facilities have impacted surrounding communities and continue to pose high risk to human health and the environment. For example, over 120 mining and mineral processing sites are on the Superfund National Priorities List and more sites are being added every year, including operating facilities. The EPA has spent over $2.4 billion to address the human health and environmental threats to communities as a result of mining and mineral processing. In some cases, the EPA had to sample drinking water wells due to potential impacts to children in low income communities. At some sites, EPA's inspections have found significant non-compliance with hazardous waste and other environmental laws. Some of the more serious cases required alternative drinking water supplies or removal of lead-contaminated soil from residential yards. In other cases, toxic spills into waterways from mining and mineral processing caused fish kills and impacted the livelihood of low income communities. The EPA will continue its enforcement initiative to bring these facilities into compliance with the law and protect the environment and nearby communities.

Activities:

EPA regions will:

- Implement the strategy for reducing pollution through the Mineral Processing National Enforcement Initiative.

Measures: See ACS measure PBS-MNP05 in Appendix 2, page 2.

5. Assuring Energy Extraction Sector Compliance with Environmental Laws

Description: The following is a discussion of work in this National Enforcement Initiative area.

Vast natural gas reserves, unlocked through technological advances, are a key part of the nation's energy future. The full promise of this resource will be realized only if it is developed responsibly in a manner that protects the nation's air, water, and land.

OECA initiated the Energy Extraction National Enforcement Initiative in FY 2011 to address environmental compliance concerns with land-based natural gas extraction and production, and ensure that natural gas development proceeds in a manner protective of human health and the environment. The EPA will continue to monitor and assess compliance with regulatory requirements, and utilize a range of legal authorities to address violations.

In addition, EPA will continue to utilize Next Generation technologies and reporting techniques to assess and quantify emissions at land-based natural gas extraction and production facilities, and develop and use innovative compliance and enforcement approaches.

Activities:

EPA regions will:

- Implement the Strategy for the Land-Based Gas Extraction and Production National Enforcement Initiative.

Measures: See ACS measures PBS-EE01 and EE03 in Appendix 2, page 3.

6. Implementing the Clean Water Act (CWA) Action Plan

Description: OECA, together with the EPA regions, the Office of Water, states and tribes with program authorization, continues to implement the CWA Action Plan issued in October 2009. The CWA Action Plan Steering Committee oversees implementation of the Action Plan through regular communication with and feedback to the EPA/state workgroups who are leading the individual action items associated with the four fundamental changes. The changes are designed to revamp the NPDES permitting, compliance and enforcement program to better address today's serious water quality problems. They are:

1. Switch from existing paper reporting to electronic reporting, resulting in increased efficiency and improved transparency of the NPDES program.
2. Use *Next Generation Compliance* approaches to create a new paradigm in which regulations and permits improve compliance via public accountability, self-monitoring, self-certification, electronic reporting and/or other innovative methods.
3. Address the most serious water pollution problems by re-tooling key NPDES permitting and enforcement practices, while continuing to vigorously enforce against serious violators.
4. Conduct comprehensive and coordinated permitting, compliance, and enforcement programs to improve state and EPA performance in protecting and improving water quality. (Related activities are discussed under *Strengthening State Performance and Oversight*, pages 15-16.)

The EPA will engage in appropriate consultation and coordination with tribes on the Clean Water Act Action Plan consistent with the EPA Policy on Consultation and Coordination with Indian Tribes.

Activities:

EPA regions should:

- Prepare for implementation of the Proposed NPDES Electronic Reporting Rule, including working to:
  a. Actively market NetDMR, NeT and other e-reporting tools to the regulated community. Train permittees;

b. Ensure state and regional general permit requirements are entered into the Integrated Compliance Information System (ICIS) (or the state NPDES program data management system);
c. Review state and regional general permit paper forms to evaluate consistency with Appendix A in the Proposed NPDES e-reporting rule.
d. Ensure states are preparing for the implementation of the electronic reporting rule by adopting the use of EPA electronic reporting tools (NetDMR, NeT), or developing their own state e-reporting tools; and
e. Coordinate closely with the Office of Compliance to individually evaluate their states' readiness to implement the electronic reporting rule, including: Cross-Media Electronic Reporting Regulation (CROMERR) compliant electronic reporting tools compliant with EPA's electronic reporting regulations; state system readiness; and level of participation using the state e-reporting tools (e.g., 90 percent participation by NPDES-regulated facilities).

- Require electronic reporting, as appropriate, for all permits written by the regions and all data required by enforcement actions, where appropriate and in accordance with national guidance.
- Provide relevant feedback to permitting offices regarding permit prioritization and modifications to consider when new permits are developed or a permit is renewed. Request that permit writers consider including e-reporting and comments provided by inspectors and/or enforcement personnel in developing appropriate permit conditions.
- Actively participate in CWA Action Plan projects including those to address effluent violations reported on Discharge Monitoring Reports (DMRs) using new strategies and tools. Consider innovative approaches to deal with more routine paperwork violations.
- Participate with OECA in an effort to draft a new NPDES enforcement framework (*i.e.*, criteria and method) for identifying and addressing serious violations that supports the principles described in the 2009 CWA Action Plan. Staff and managers in regions, states and tribes with program approval are encouraged to participate actively in this workgroup to develop this framework.
- Include in targeting, monitoring, enforcement and state oversight the complete array of the NPDES regulated universe, going beyond the historic focus on traditional NPDES majors. Use targeting tools, such as the DMR Pollutant Loading Tool, to determine the source, location and amount of discharged pollutants, including a subset of non-major facilities (www.epa.gov/pollutantdischarges).

State and EPA representatives on the CWA Action Plan Steering Committee and the various associated workgroups should:

- Attend and participate in regular meetings.
- Assist in numerous aspects of workgroup responsibility including, as appropriate, drafting work products and deliverables and identifying appropriate timing for raising issues with the Steering Committee.
- Represent states and regions, respectively, by engaging and providing meaningful input and direction on implementation issues.

States should:

- Work towards implementation of e-reporting.

- Educate and train regulated community.
- Develop e-reporting tools or use EPA tools (NetDMR; NeT).

7. Advancing Next Generation Compliance

Description: The health and environmental benefits envisioned by our statutes, regulations, and state and tribal programs are not being fully achieved. Although the available data is incomplete, high noncompliance is evident in much of the data we do have. State and federal resources for onsite compliance assistance, individual inspections, and enforcement actions are not adequate to address the large universe of regulated sources, especially the numerous small sources that are important contributors to environmental problems. Robust compliance monitoring and enforcement are critically important for identifying and addressing violations and promoting deterrence. While individual facility inspections and enforcement actions remain a critically important part of addressing noncompliance, this alone is not sufficient to achieve the improvements in compliance we need. Field operations and EPA regulations must consider emerging approaches and technology to be effective and efficient. Together with the program offices, regions, and states, OECA is implementing *Next Generation Compliance,* which takes advantage of advances in emissions monitoring and information technology. EPA has completed a Next Generation Compliance Strategic Plan and is proceeding to implement the Plan. See http://www2.epa.gov/compliance/next-generation-compliance. The EPA is visiting states to discuss Next Generation Compliance and its benefits for states, to learn from states, and to explore possible collaborative projects to test or pilot Next Generation Compliance approaches. As of November 2014, the EPA has visited 8 states and expects to visit around 20 states by end of FY 2015. While there are no Next Generation Compliance implementation requirements for states, OECA and the regions need to perform work in five areas:

1. **Design more effective regulations and permits that are easier to implement, with a goal of improved compliance and environmental outcomes.** OECA is working with the program offices and regions to design more effective regulations and permits that include Next Generation Compliance tools and approaches that will drive us towards better compliance and environmental outcomes. We are looking to pilot the use of Next Generation Compliance tools in air, water, and waste permits in FY 2015 and FY 2016.
2. **Use and promote advanced emissions/pollutant detection technology so that regulated entities, the government, and the public can more easily see pollutant discharges, environmental conditions and noncompliance.** This technology will make "visible" pollution that is currently "invisible." Industry can more effectively prevent and reduce pollution, and often make their operations more efficient, while government can better target significant pollution and noncompliance problems. Private sector development of monitoring technology that can be used by the public could empower citizens and encourage industry and government to reduce pollution. In addition, advanced monitoring technology, coupled with electronic reporting, will produce more complete universe data on regulated sources, their emissions and discharges, and environmental conditions. This data will support the development of new and improved compliance measures, allowing for more evidence-based approaches to compliance work and better assessment of compliance rates.

3. **Shift toward electronic reporting by regulated entities so that we have more accurate, complete, and timely information on pollution sources, pollution, and compliance, saving time and money while improving effectiveness and public transparency.** Electronic reporting should not be simply emailing files to the government. It is taking advantage of advances in IT to improve and streamline information submission, improving government while saving money and making the data more available for public use. For example, electronic "smart" tools will be deployed that guide the regulated entity through the reporting process. Error prevention and two-way communication can be integrated into reporting tools, allowing electronic compliance assistance, alerts on new regulations, and helping to ensure that only necessary data is collected.
4. **Expand transparency** by making the information we have today more accessible, and making new information obtained from advanced emissions monitoring and electronic reporting publicly available. This will empower communities to play an active role in compliance oversight and improve the performance of both the government and regulated entities.
5. **Develop and use innovative enforcement approaches to achieve more widespread compliance**. We are developing new enforcement approaches that help to increase the effectiveness of our compliance work, such as greater use of fenceline monitoring and publication of pollution information, to both track pollution that is important to communities and to engage the community in monitoring compliance. We are also using advanced monitoring and electronic reporting in our enforcement investigations and settlements and making greater use of targeted deterrence approaches, and self and third party certification tools, to help drive better compliance and reduce pollution.

Next Generation Compliance complements the E-Enterprise for the Environment effort. Both focus on expanding electronic reporting, advanced monitoring, and transparency. Engaging states on our Next Generation Compliance work will help reinforce state-EPA collaboration under E-Enterprise. OECA is undertaking E-Enterprise aligned work with state involvement and input; examples include leading the NPDES electronic reporting pilot, as well as serving as a key participant in the Import-Export Hazardous Waste Rulemaking with e-reporting. OECA and the Office of Air and Radiation (OAR) are also co-sponsors of a proposal to develop an Advanced Monitoring Integration Strategy, to be developed jointly between EPA and states. OECA is also participating on the scoping teams for Smart Tools for Inspectors and Pesticides Label Matching.

Activities:

EPA regions should:

- When participating on regulation development workgroups, provide real-world inspection, compliance monitoring, and enforcement knowledge and advocate for Next Generation Compliance Rule Effectiveness approaches in the agency's rules.
- Actively participate in agency and OECA workgroups related to implementing Next Generation Compliance components, such as electronic reporting, advanced monitoring and enforcement settlements.

- Identify and implement best practices to improve rule and permit implementation. Include Next Generation Compliance principles, tools, and approaches when issuing permits, reviewing permits, and training permit writers.
- Work with OECA to ensure inspectors are trained in the effective use of advanced monitoring equipment.
- Incorporate Next Generation Compliance tools such as electronic reporting, advanced monitoring at the facility and fence-line, third party verification, and public accountability in enforcement settlements pursuant to the January 2015 OECA Memorandum on Use of Next Generation Compliance Tools in Civil Enforcement Settlements. OECA will highlight examples of EPA enforcement cases that use different Next Generation Compliance approaches, especially those that maximize environmental and human health benefits for overburdened communities, including the protection of children's health, and address potential disproportionate impacts to these communities.
- Actively market electronic reporting and e-tools to the regulated community and states.
- Identify and use innovative enforcement approaches.
- Coordinate with OECA and the national and regional Field Operation Guidelines Workgroups to develop smart mobile tools for our inspectors that improve the quality of our inspections and allow us to electronically submit inspection reports.

States and tribes are encouraged to:

- Expand their understanding and use of Next Generation Compliance by participating in OECA Next Generation Compliance visits.
- Share with the EPA examples of current state or tribal efforts that demonstrate Next Generation Compliance tools in operation today to be included in a compilation of Next Generation Compliance NPDES Examples.
- To the extent interested, collaborate with OECA in designing and implementing Next Generation Compliance demonstration projects, evaluation projects or CWA Action Plan pilots.

8. Strengthening State Performance and Oversight

Description: Our nation's environmental laws are based on the principle of cooperative federalism under which the EPA and states work in partnership to protect human health and the environment. Most major federal environmental laws require the EPA to establish minimum, nationwide standards, and then allow the agency to delegate authority to implement these standards to the states. The EPA retains broad enforcement authority under federal law, and provides oversight of delegated state programs.

As part of its oversight responsibilities, the EPA must clearly articulate expectations for state program performance and evaluate the states in a fair, consistent and equitable manner. This National Program Manager Guidance, working in conjunction with national enforcement policies and program grant agreements, is one place where these expectations are articulated. To evaluate state enforcement performance, states and the EPA worked in partnership to create the State Review Framework (SRF). The SRF is designed to ensure the EPA conducts oversight evaluations of state CWA, CAA and RCRA compliance and enforcement programs in a nationally consistent and efficient manner. Where regions directly implement the federal

program in states that do not have authorized programs, OECA conducts the SRF review of the regions' program using the same process and procedures as for all SRF reviews. A national approach to enforcement of the nation's environmental laws assures that: (1) all states are treated equitably and held to the same standards as the EPA regions; (2) a level playing field exists across states and for regulated businesses; (3) the public has similar protection from impacts of pollution regardless of where they live or work; and (4) timely compliance with national environmental laws and regulations is widely achieved.

In FY 2013, OECA, the EPA regions, and states incorporated program changes that will improve SRF effectiveness while reducing the resources necessary to conduct reviews. Also, in 2013, OECA issued the *National Strategy for Improving Oversight of State Enforcement Performance*. The National Strategy clarifies that an integral part of the SRF is a consistent national approach for dealing with significant state enforcement performance issues, once they have been identified. The National Strategy describes three sets of actions aimed at improving state enforcement performance to achieve the above-stated goals: (1) an escalation approach to problem-solving; (2) the regular and periodic State Review Framework evaluation process; and (3) transparency efforts.

Activities:

EPA regions will:

- Conduct all Round 3 SRF reviews of state CAA, CWA, and RCRA enforcement programs scheduled for 2016 and 2017, following Round 3 headquarters guidance issued in December 2013 and available on the ECHO SRF page.
- Enter complete draft and final SRF reports, including data metric analyses, file reviews, recommendations and state comments into the SRF Tracker.
- Monitor progress of states in carrying out the recommendations and record progress quarterly in the SRF Tracker.
- Implement the *National Strategy for Improving Oversight of State Enforcement Performance*.
- Use data verification and annual data metric analyses to inform regular discussions with states and to track performance.
- Focus oversight resources on the most pressing performance problems in states, working with them to demonstrably improve state performance. Where progress toward resolving significant state performance issues is not being made, regions should escalate their responses in accordance with OECA's escalation strategy described in the *National Strategy for Improving Oversight of State Enforcement Performance*.
- Ensure commitments to implement recommendations for program improvements are captured in appropriate negotiated PPAs, PPGs, categorical grant agreements or other written documents.
- Implement any regional components to address agreed-upon national focus issues under the National Approach to Common State Enforcement Program Issues (Common Issues) project.
- Per the June 22, 2010 memorandum from Cynthia Giles and Peter Silva "Interim Guidance to Strengthen Performance in the NPDES Program" and the October 22, 2010 memorandum from Lisa Lund and Jim Hanlon "Using the Results of NPDES Permit and Enforcement

Reviews to Address Significant Issues," regions should convene routine and regular meetings between the EPA region and authorized state to discuss progress towards meeting annual permitting and enforcement commitments and how the state has been performing overall.
- Review the number of Significant Non-compliers (SNCs)/High Priority Violators (HPVs) identified (and percent of universe) by state and the number (and percent) addressed in a timely and appropriate manner.

State and local agencies should:
- Work cooperatively with the EPA regions to conduct SRF reviews as scheduled.
- Implement recommendations within agreed upon time frames in the final SRF reports provided to the state or local agency.
- Implement additional necessary work to resolve issues impeding effective implementation of their enforcement program.
- Where EPA's review of state-EPA MOAs determined that MOAs might require revision, updating or supplementation, states should work cooperatively with the EPA regions to identify and complete appropriate actions by the end of FY 2017.

Measures: See ACS measure SRF01 in Appendix 2, page 3.

IV. Program-Specific Guidance

This section provides critical national direction on specific program areas not addressed in the preceding section. For each program area, the guidance identifies critical supporting activities, responsibility for implementation and associated measures for tracking implementation. If resources do not allow for activities in the guidance to be implemented, then regional management should raise the specific activities for discussion with the appropriate OECA Office Director(s). Similarly, delegated or authorized state, tribal or local agencies that are facing resource challenges can raise specific activities for discussion with the appropriate senior regional manager(s) when developing their annual work plans with the EPA regions. This discussion is necessary to help ensure national consistency, as appropriate, in implementing critical activities across media programs and ensuring a level playing field nationally.

1. Field Operations Group (FOG) Guidelines

Description: The EPA created a Field Operations Group (FOG) to promote national consistency among the Agency's field activities. The EPA's FOG developed ten operational guidelines (referred to as the FOG Guidelines) for field activities to ensure consistency in managing field practices and to reduce potential vulnerabilities. The FOG Guidelines apply to any field sampling, measurements, and observations used by the EPA for any purpose, such as ambient monitoring, research, clean-ups, risk management, studying new/revised regulations, screening, compliance monitoring, and enforcement. In March 2013, EPA's Deputy Administrator directed all EPA organizations conducting field activities to implement a sustainable management system that incorporates the ten Field Operations Group guidelines no later than February 15, 2016. Additional information is available at: http://www.epa.gov/irmpoli8/policies/2105-p-02.pdf

Activities:

Regions and Headquarters offices should:

- Complete development and implementation of policies, procedures and systems that fully address the ten Field Operations Group (FOG) Guidelines by the February 2016 deadline established by the Deputy Administrator.
- Prepare for and participate in FOG gap assessments.
- Once completed, conduct regional and HQ field activities (e.g., compliance inspections and sampling) in accordance with the established procedures.
- Implement process and procedures under Guidelines 9 and 10 to audit progress in implementing Guidelines 1 – 8, and address any needed corrective actions.
- Provide training to new staff on the FOG guidelines and the established procedures, and annual refresher training to existing staff.

2. Environmental Justice

Description: In addition to being the National Program Manager for the agency's Environmental Justice Program, OECA oversees the implementation of environmental justice (EJ) within the compliance and enforcement program. In its enforcement role, OECA ensures that facilities in communities overburdened by environmental problems are complying with the law. OECA aggressively applies regulatory tools to protect these communities, engages our regional, federal, state and tribal partners to meet community needs, and fosters community involvement in the EPA's decision-making processes by making information available, as appropriate. To ensure long-term, effective consideration of EJ within the enforcement and compliance program, OECA also leverages other initiatives and priorities that promote action in communities, such as Next Generation Compliance, EPA's Cross-Agency Strategies and EPA strategies for protecting children's environmental health, as appropriate.

Activities:

EPA headquarters and regions will:

- Consider EJ in the implementation of the National Enforcement Initiatives (NEIs), consistent with the strategies for each NEI, to maximize environmental and human health benefits for overburdened communities.
- Specifically consider overburdened communities and potential disproportionate impacts to these communities, including those in Indian country, when selecting enforcement actions to address other important compliance problems. Targeting evaluations should always use the best available data and methods to achieve enforcement program objectives.
- Review civil enforcement cases to be initiated in FY 2016 and 2017 for potential EJ concerns using the agency's EJSCREEN tool, and record the results of these reviews in ICIS, in accordance with the *Internal Technical Directive: Reviewing EPA Enforcement Cases for Potential Environmental Justice Concerns and Reporting Findings to the ICIS Data System* (April 2013).
- Identify specific opportunities to work with other federal agencies, state and local governments, tribal governments, and/or the business community to leverage the benefits to

communities resulting from enforcement activities. Document and share recommendations and best practices for taking action on these opportunities.

- Where appropriate, design compliance and enforcement actions to gain the greatest possible environmental benefits in overburdened communities. For example, this could include use of multi-media inspections and/or process inspections to comprehensively address potential impacts from violations at a given facility, or incorporation of Next Generation Compliance principles, tools or approaches.
- Seek appropriate remedies in enforcement actions to benefit overburdened communities and address environmental justice concerns. Increase efforts to address environmental justice concerns through appropriate injunctive relief, including seeking mitigation actions to redress harm caused by the violations being resolved, and/or by encouraging defendants to consider performing beyond-compliance Supplemental Environmental Projects (SEPs) related to the violations.
- Consider activities to effectively reach large numbers of small sources with environmental violations that have significant local impacts on overburdened communities.
- Identify and address EJ concerns as appropriate when consulting with tribal governments.
- Enhance communication with communities with EJ concerns and the public about enforcement strategies and actions that may affect them, consistent with the confidentiality requirements needed to protect the integrity of the enforcement process.
- Specifically provide opportunities for community input on EJ concerns and remedies to be sought in enforcement actions affecting communities through the EPA's website, local information repositories, and other appropriate means.
- Effectively communicate the benefits of our enforcement actions for vulnerable and overburdened communities, consistent with the internal memorandum entitled *Guidance on Characterizing and Communicating Environmental Justice Benefits Achieved in Enforcement Actions* (September 2011).
- Identify opportunities for the compliance and enforcement program to advance the EPA's Cross-Agency Strategy on *Working to Make a Visible Difference in Communities*, as appropriate.
- Coordinate with states, tribes and other partners to implement these activities, as appropriate.

Measures: See ACS measure EJ01in Appendix 2, pages 3-4. [Note: Although we are tracking this measure, there is no specific target number or trend we expect to achieve. EJ is one of many factors the Agency considers in bringing an enforcement action.]

3. Federal Facilities

Description: The EPA's compliance and enforcement program is managed by the Federal Facilities Enforcement Office (FFEO) and involves more than 30,000 federal facilities and installations spread across nearly 30 percent of the nation's territory, among which are some 10,000 currently regulated under the agency's various statutes. The EPA holds these federal agencies accountable to the same standard of environmental compliance as other members of the regulated community. This equal accountability is required by CERCLA, envisioned by most other statutes and affirmed under Presidential executive order. Federal agencies are now expected to go beyond compliance and serve as an example to others regarding environmental

stewardship and management, as Presidential Executive Order No. 13514 on federal environmental sustainability makes clear. The federal facilities enforcement and compliance program is described at http://www.epa.gov/compliance/federalfacilities/index.html. The agency's primary focus in this sector has been on monitoring and enforcement, given the extensive compliance assistance now offered by others, especially at ***FedCenter***, http://www.fedcenter.gov/, the sector's on-line environmental stewardship and compliance assistance center sponsored by more than a dozen federal agencies.

Throughout FY 2014 and FY 2015, EPA's federal facilities enforcement and compliance program, in conjunction with the regions, has reassessed its national Program Agenda, its traditional Integrated Strategies and other program components in an effort to "right-size" its activities in the face of recent resource reductions. In FY 2015, FFEO sought to more closely align its various federal facility sector activities, including its Annual Commitment System (ACS) obligations, with EPA's National Enforcement Initiatives (NEIs) and other Agency-wide and regional environmental enforcement priorities whenever possible. As FFEO completes its "right-sizing" efforts, the EPA, in addition to increased emphasis on the NEIs and other Agency and regional environmental enforcement priorities, will continue its focus on a set of previously identified federal facility enforcement priority areas as established in FFEO's FY 2015 Program Agenda, and identified in the activities below. FY 2016 commitments will reflect continued emphasis on some priority areas, while new priority areas may also be identified.

Activities:

EPA regions should:

- Consult with FFEO on all federal facility enforcement actions. FFEO will focus its resources to make these consultations timely and effective, and bring clear value to these regional actions.
- Utilize FFEO's new inspection targeting capabilities for improved monitoring, especially of vulnerable communities associated with federal facilities.
- Target federal facilities as part of implementing EPA's National Enforcement Initiatives, regional priorities, federal facility enforcement priority areas or targets established in Regional (Enforcement) Plans.
- Sustain a vigorous enforcement program at federal facilities, by integrating, as appropriate National Areas of Focus/National Enforcement Initiatives, federal facility enforcement priority areas and regional priorities into the region's inspection and enforcement efforts. These priority areas align enforcement, compliance, and stewardship activities for maximum effect and help achieve environmental and health benefits by addressing those problems that matter to communities.
- Continue to pursue *federal facility enforcement priority areas* dealing with vulnerable communities (where environmental justice issues are often most prevalent), CAA 122 (r) risk management plans, RCRA (medical waste and LQGs), SDWA, industrial stormwater, climate change/flood plain areas and Government Owned/Contractor Operated/Government Owned/Privately Operated (GOCO/GOPO) facilities and other potential areas still under consideration by FFEO and the Regional Federal Facility Program Managers.

- Continue to use FFEO's contractor inspection program and inspector travel funding support to the fullest extent possible as incorporated in the Regional Federal Facility Enforcement Plans.
- Continue to implement a 2011 enforcement settlement with the Department of the Interior's Indian Affairs program for violations at its schools and water treatment plants across Indian country.
- Adopt creative work sharing arrangements and exploit new Agency initiatives, such as the One EPA Skills Marketplace and SharePoint, to more fully utilize EPA resources to address compliance and enforcement needs at federal facilities.
- Foster collaboration between OECA, FFEO, and the regions to identify and implement Next Generation Compliance opportunities under advanced monitoring, electronic reporting, transparency and innovative enforcement, to create more effective and efficient enforcement in this sector.
- Encourage the use of Supplemental Environmental Projects (SEPs) in settlements, consistent with the SEP Policy, and as resources allow, as a means to achieve greater human health and environmental outcomes.
- FFEO will continue to provide targeting, contractor inspection and travel funding support to the Regions to the fullest extent possible. Regions will incorporate their future activities for the federal facility ACS commitment in their Regional (Enforcement) Plans.
- Promote greater public awareness and consider greater public engagement through increased transparency of federal facility compliance activity, violations and enforcement actions, including press releases for enforcement actions.
- Project at mid-year the number of formal: (1) federal facility enforcement case initiations; and (2) federal facility settlements for FY 2016. (These projections, which need not include Records of Decision at federal facility CERCLA sites, are not commitments but rather indicators of regional progress.)

States and EPA regions should:

- Continue to ensure adequate coverage of the federal facility sector through compliance monitoring and enforcement activity. Coordinate inspections, compliance monitoring or enforcement activity where appropriate. Regions should be a resource when questions of enforcement authorities arise, including questions of sovereign immunity.

Measures: See ACS measure FED-FAC05 in Appendix 2, page 4.

4. CWA National Pollutant Discharge Elimination System (NPDES) Program for Compliance Assurance and Enforcement

Description: There are essential activities under the Clean Water Act NPDES program that help ensure compliance with the Clean Water Act (CWA) and associated regulations.

Activities:

Authorized states and territories and EPA regions with direct implementation responsibilities (e.g., non-authorized states, federal facilities and Indian country) should:

- Target serious sources of pollution and serious violations. Use appropriate tools, including those developed pursuant to the CWA Action Plan and the NPDES Compliance Monitoring Strategy (NPDES CMS) (issued July 21, 2014) for the Core Program and Wet Weather Sources to target the most significant sources of pollutants affecting those water bodies and watersheds where compliance and enforcement tools will be effective in addressing the problem. Give priority to discharges that affect: (1) water bodies that are not meeting water quality standards; (2) drinking water sources; or (3) individual communities. Available tools include ambient monitoring data, the Discharge Monitoring Report (DMR) Pollutant Loading Tool and the Clean Water Act Inspection Targeting Model (available to EPA and states by logging in at Enforcement and Compliance History Online (ECHO), http://echo.epa.gov/), as well as GIS resources on EPA's GeoPlatform.
- Develop annual compliance monitoring plans that take advantage of the flexibility available in the NPDES CMS (http://www2.epa.gov/sites/production/files/2013-09/documents/npdescms.pdf)
- Ensure that all available data regarding violations are evaluated to determine the seriousness of the violation. Take appropriate enforcement responses, consistent with national policy, to address violations discovered. Ensure that civil enforcement actions are taken, where appropriate, to address serious violations contributing to a community's water quality problems.
- Ensure compliance with civil judicial consent decrees and administrative orders where applicable.
- Implement targeted "real time" (quick response) enforcement activities to address CWA violations impacting communities' waters where appropriate.
- Ensure all required compliance and enforcement data are input or transmitted to the national data base (ICIS-NPDES) in a timely manner consistent with EPA national policy and, if promulgated, the NPDES e-reporting rule. All other data related to compliance and enforcement should be tracked and managed, as appropriate, to allow the region or state to effectively manage their program. The EPA encourages authorized states to expand their use of the national database to include compliance and enforcement data that pertains to the entire NPDES universe.
- Continue implementation of integrated planning in accordance with EPA's 2012 *Integrated Municipal Stormwater and Wastewater Planning Approach Framework*, available at http://www.epa.gov/npdes/pubs/integrated_planning_framework.pdf.
- Continue implementing the Federal Facility Enforcement Priority Area for Industrial Stormwater.

EPA regions should also:

- Implement existing CWA compliance and enforcement strategies for specific geographic areas, as applicable, including the Chesapeake Bay Compliance and Enforcement Strategy and other region-specific initiatives.
- Conduct a sufficient number of NPDES oversight inspections to ensure the integrity and quality of each authorized state's or tribe's compliance monitoring program. See Part 2 of the NPDES CMS for more discussion of oversight inspections.
- Ensure the full regulated universe of NPDES permittees is addressed in the state's CMS plan, focusing on the most important sources and most serious noncompliance. Provide annual CMS plans for each authorized state and for regional direct implementation areas to OECA by December 31 of each year.

- Provide draft alternative plans to OECA for consultation and review by August 15 of each year (in advance of the beginning of the plan coverage year), or a later date if agreed to by the region and OECA. Work with OECA as needed to address national consistency and program integrity issues identified through OECA's review of draft alternative plans.
- Track compliance monitoring activities and submit annual end of year reports for each state and for regional direct implementation to OECA by December 31 of each year. End of year reports should account for all compliance monitoring activities conducted in the prior year in accordance with the NPDES CMS.
- Coordinate with their authorized states to ensure that state partners who do not directly input data into ICIS-NPDES continue to use the National Environmental Information Exchange Network to report data to the EPA.
- Utilize multi-sector general permit (MSGP) violation and benchmark data when available through ICIS-NPDES to support monitoring, targeting and enforcement in areas where the EPA has direct implementation authority.
- Routinely review all DMRs and non-compliance reports received for compliance with permit requirements where the region directly implements the program, including Indian country.
- Work with OECA to identify and evaluate new priority areas that could become CWA enforcement initiatives in the future. Assist OECA in collecting and reviewing data about core program areas that warrant further review and consideration as national initiatives.
- Directly implement the CWA/NPDES program in Indian country unless and until a tribe obtains program authorization. When directly implementing the program apply the NPDES CMS, applicable enforcement response policies, and the *Guidance on the Enforcement Principles Outlined in the 1984 Indian Policy (January 17, 2001)* (http://www2.epa.gov/enforcement/transmittal-final-guidance-enforcement-principles-outlined-1984-indian-policy-january-17). The latter policy contains procedures for consultation with federally-recognized tribes in the civil compliance monitoring and enforcement context and contains threshold criteria for EPA's consideration of formal civil enforcement actions. The threshold criteria are not intended to, and should not result in, a lesser degree of human health and environmental protection in Indian country than elsewhere in the United States.
- When appropriate, credential state and tribal inspectors to conduct compliance evaluations on the EPA's behalf. Ensure that state and tribal inspectors who conduct inspections on EPA's behalf are trained and credentialed consistent with agency guidance, including the *Guidance for Issuing Federal EPA Inspector Credentials to Authorize Employees of State/Tribal Governments to Conduct Inspections on Behalf of EPA* (2004) EPA Order 3500.1: Training Requirements for EPA Personnel Who Are Authorized to Conduct Civil Compliance Inspections/Field Investigations and EPA Inspector Supervisors (June 19, 2014), and EPA Order 3510: EPA Federal Credentials for Inspections and Enforcement of Federal Environmental Statutes and Other Compliance Responsibilities (October 31, 2012).
- Consistent with the EPA Order 3510, annually conduct an inventory of federal credentials which includes an annual physical possession check of 10 percent of the federal credentials issued to state and tribal inspectors and a count of unused credentials stock.
- Fully implement and oversee the pretreatment program:
  - In non-authorized states and in Indian country, oversee all approved POTW pretreatment programs consistent with the NPDES CMS, including audits and inspections, and inspect

Industrial Users (IUs) that discharge into POTWs without approved pretreatment programs.
    - In states authorized to implement the pretreatment program, evaluate the effectiveness of the state's (i.e., the approval authority) program by inspecting and auditing POTWs with approved pretreatment programs (i.e., control authorities). In conjunction with POTW inspections, ensure that POTWs with control authority are carrying out their responsibilities, including annual inspections and sampling of all Significant Industrial Users (SIUs).
    - Where states are the control authority, assess each state program's performance in conducting annual inspections and sampling of all SIUs.
- Coordinate with the Center of Excellence for Biosolids to respond to work that may arise in this program and to access biosolid program annual reports that may be needed to support regional compliance monitoring activities, such as targeting for pretreatment inspections.
- Investigate the CWA compliance status of surface mining facilities within each region, including mountaintop removal mining operations. Evaluate the compliance status of such facilities with respect to NPDES permitting requirements and CWA section 404 permitting requirements. Take appropriate enforcement actions in response to CWA violations.
- Oversee compliance with the Vessel General Permit through coordination with the U.S. Coast Guard, as necessary, in implementing the Vessel General Permit MOU, reviewing Coast Guard deficiency data, and conducting joint inspections.
- Support the agency's Next Generation Compliance initiative by promoting advanced monitoring, electronic reporting, and transparency to improve compliance with regulations and enhance the ability to identify violations that may harm public health and/or the environment. Develop innovative regulation design and enforcement approaches to ensure regulations promote compliance and are implementable.
- Conduct SRF consistent with the schedule outlined in the agreed-upon ACS commitments. Provide recommendations and conduct follow-up as appropriate in accordance with national SRF guidance.

Measures: See ACS measure CWA07 in Appendix 2, page 4.

5. CWA Section 404 - Discharge of Dredge and Fill Material

Description: The compliance and enforcement activities related to CWA Section 404 which should be implemented are described below.

Activities:

EPA regions should:

- Work with OECA in implementing the Section 404 Enforcement and Coordination Strategy.
- Coordinate, as appropriate, with other federal agencies [i.e., U.S. Army Corps of Engineers (Corps), Natural Resources Conservation Service (NRCS), U.S. Fish and Wildlife Service (USFWS), and National Marine Fisheries (NMFS)] which have significant roles in wetlands protection through the use of MOUs/MOAs or other appropriate mechanisms.

- Meet with Corps Districts on an annual basis to establish regional priorities and communicate priorities to OECA.
- Review field level agreements with Corps Districts, and revise them to ensure consistency with the Section 404 Enforcement and Coordination Strategy, as appropriate.
- Utilize the Office of Water's DARTER (Data on Aquatic Resources Tracking for Effective Regulation) system as well as ICIS (Integrated Compliance Information System) to identify and track potential repeat violators. (ICIS continues to be the data base of record for tracking EPA information on CWA Section 404 enforcement actions.)
- In addition to working with the Corps on developing cases under the 1989 MOA, regions should explore methods to effectively leverage other program resources (such as GIS and remote sensing resources, NWI map updates, and reports or studies of known stressors to wetlands in their regions) to more systematically identify potential serious Section 404 violations, target areas or sectors of known wetland stressors, and take appropriate enforcement responses to address these violations. Share effective techniques with OECA for use in developing the national aquatic resources (including wetlands) enforcement strategy.
- Utilize existing regional cross training opportunities as well as opportunities identified by OECA to cross-train inspectors and to train other federal and state agencies and stakeholders to identify CWA Section 404 violations.

6. CWA Section 311 – Oil Pollution Act

Description: The compliance and enforcement activities which should be implemented to help ensure compliance with the Oil Pollution Act are described below.

Activities:

EPA regions should, where appropriate:

- Participate in judicial enforcement cases to address spills from inter-state pipelines and others, such as production facilities, on a company-wide basis. Ensure these spill cases include company-wide injunctive relief requirements to prevent future spill violations at all facilities of the owner or operator.
- Participate in judicial enforcement cases to address facility response plan (FRP) violations at facilities owned or operated by the same company. Ensure these FRP cases include company-wide injunctive relief requirements to improve facility response planning and implementation at all facilities of the owner or operator.
- Target and investigate facilities subject to the EPA spill prevention and facility response planning regulations, including offshore platforms within EPA jurisdiction, and take appropriate enforcement responses to address non-compliance with these regulatory requirements.
- As necessary, target, investigate, and develop enforcement actions to address discharge violations (spills) wherever the violation occurs, whether or not the spill occurred at a facility subject to the EPA's spill prevention or facility response planning regulations.
- Conduct spill enforcement investigations to identify noncompliance and build cases for enforcement actions.

- Whenever enforcement is pursued at facilities subject to EPA regulations, the case development staff should evaluate all potential violations of CWA Section 311 and underlying regulations and include claims in the enforcement case to address all noncompliance in these areas. Include penalties, injunctive relief and/or enforceable administrative obligations to prevent future violations from similar causes across all facilities of the same owner or operator.
- Participate in OECA-led coordination and strategy meetings, as appropriate.

7. SDWA Underground Injection Control (UIC) Program

Description: The EPA plans to focus UIC enforcement efforts on violations that pose the greatest threat to public health and shift away from enforcement work on more routine violations. Data generally show good compliance at most facilities that the EPA inspects, supporting a strategy of focusing our attention on the worst problems. Additionally, the agency will invest in new pollution detection and e-reporting technologies to more effectively address the large universe of pollution sources and empower communities.

The EPA has approved primacy by rule for injection well Classes I - V for 33 states and three territories and, it shares responsibility in seven states and two tribes. EPA implements the UIC program for injection well Classes I - V in 10 states, two territories, the District of Columbia, and for most of Indian country. For Class VI Geologic Sequestration injection wells, the EPA implements the program in all states, tribes, and territories.

Activities:

EPA regions should:
- Directly implement the program where the EPA retains primacy.

Authorized state and tribal programs should:
- Implement the UIC program consistent with their specific authorization codified in 40 CFR Part 147.

8. CAA Program for Compliance Assurance and Enforcement

Description: The CAA compliance assurance and enforcement activities, described below, should be implemented to help ensure compliance with the CAA and implementing regulations.

Activities:

Delegated state, tribal and local agencies and EPA regions should:
- Implement programs in accordance with existing national compliance and enforcement policy and guidance [e.g., the CAA Stationary Source Compliance Monitoring Strategy

(CMS)[5], the CAA National Stack Testing Guidance, the Area Source Implementation Guidance, the Timely and Appropriate Enforcement Response to High Priority Violations (HPV Policy)[6], the asbestos NESHAP Demolition and Renovation Enforcement Strategy and the Guidance on Federally-Reportable Violations for Clean Air Act Stationary Sources[7]] to address air pollution problems that adversely affect impacted communities.

- Identify and evaluate all violations, determine an appropriate response, address and ultimately resolve air violations in order to bring sources into compliance which includes taking timely and appropriate actions against facilities determined to have High Priority Violations.
- Initiate civil and criminal enforcement actions, as appropriate, and whenever necessary to protect communities.
- Ensure complete, accurate and timely compliance and enforcement data is reported into the Integrated Compliance Information System (ICIS) consistent with agency policies, the "Air Stationary Source Compliance and Enforcement Information Reporting" Information Collection Request (ICR) and agreements incorporated in documents such as Memorandums of Understanding (MOUs), State Enforcement Agreements (SEAs), EPA-Tribal Enforcement Agreements, Performance Partnership Agreements (PPAs)/Performance Partnership Grants (PPGs) or Section 105 grant agreements. This reporting effort includes the verification of data used by the State Review Framework (SRF) and made available to the public.
- Negotiate settlements and track compliance with consent decrees and administrative orders and take all necessary actions to ensure compliance with the terms of enforcement actions.
- Incorporate new technologies and innovative compliance monitoring approaches in compliance monitoring programs, as appropriate and where feasible.
- Continue work with EPA headquarters to provide input into the design and development of future versions of ICIS as it pertains to CAA compliance and enforcement information.

EPA regions should also:

- Work collaboratively with OECA and OAR to identify and address, as appropriate, noncompliance issues that arise in the Greenhouse Gas (GHG) Reporting Program.
- Identify the most important air pollution problems and the most serious violations, using targeting tools and other information, including, but not limited to, the National Air Toxics Assessment (NATA) data, chemical toxicity data, non-attainment areas, and EJ SCREEN. Consider EJ information, children's health, tips/complaints, and community input.
- Conduct evaluations as outlined in the agreed-upon ACS commitments, initiate enforcement actions to address non-compliance, and seek penalties, where appropriate, consistent with the

[5]The CAA Stationary Source Compliance Monitoring Strategy is accessible at http://www2.epa.gov/compliance/clean-air-act-stationary-source-compliance-monitoring-strategy

[6]The revised HPV policy, issued August 25, 2014, is accessible at http://www2.epa.gov/enforcement/air-enforcement-policy-guidance-and-publications

[7] The Guidance on Federally-Reportable Violations for Clean Air Act Stationary Sources is dated September 23, 2014 and is accessible at http://www2.epa.gov/compliance/guidance-federally-reportable-violations-stationary-air-sources

CAA Civil Penalty Policy (including the Amendments) and in accordance with the 2013 Civil Monetary Penalty Inflation Adjustment Rule.

- As the successor to the Air Facility System (AFS), ICIS is the data system of record for the national CAA stationary source compliance and enforcement program. The regions should continue to report all federal evaluations and enforcement actions, including FRVs, HPVs and penalties, into ICIS.
- Continue any on-going investigations and initiate new ones, as appropriate. Report both initiated and completed investigations in AFS. Reported investigations should meet the definition in the CMS and minimum data requirements.
- Review state implementation plan (SIP) submissions for enforceability and approve/disapprove as necessary.
- When reviewing Title V permits consistent with national guidance, ensure permits do not shield sources subject to a pending or current CAA enforcement action or investigation. Also ensure that consent decree requirements, including required schedules of compliance, are incorporated into underlying federally enforceable non-Title V and Title V permits. Furthermore, ensure the delegated agencies/tribes are reviewing Title V certifications consistent with the CMS.
- Conduct all RMP inspections in accordance with "Guidance for Conducting Risk Management Program Inspections Under Clean Air Act Section 112(r)" (EPA 550-K-11-001, January, 2011). Evaluate facilities that experience significant chemical accidents to determine compliance with CAA sections 112(r)(1) and (7) and pursue appropriate enforcement responses for violations.
- All inspections at RMP facilities with Program 2 and/or 3 processes must evaluate a facility's compliance with some or all of the accident prevention and emergency response program requirements of Subparts C, D and E of 40 CFR Part 68, in addition to evaluating compliance with other 40 CFR Part 68 requirements as time and resources allow. For inspections at multi-process or high-risk facilities, conduct inspections where the field portion of the inspection involves the appropriate number of inspectors/technical experts and time to evaluate the RMP program compliance and chemical safety at the facility, as stated above. For inspections at larger and more-complex facilities, regions should devote additional staff and/or time as appropriate to the size and complexity of the facility.
- Continue implementing the June 30, 2010 memorandum titled '*Identification of Facilities Subject to 40 CFR Part 68'*. Settle or litigate cases filed in years prior to FY 2016.
- Directly implement the CAA in Indian country unless and until a tribe obtains program approval and apply the various compliance monitoring strategies, enforcement response policies, and the OECA *Guidance on the Enforcement Principles Outlined in the 1984 Indian Policy (January 17, 2001) (*http://www2.epa.gov/enforcement/transmittal-final-guidance-enforcement-principles-outlined-1984-indian-policy-january-17.) This guidance contains procedures for consultation with tribes in the civil compliance monitoring and enforcement context and contains threshold criteria for EPA's consideration of formal civil enforcement actions. The guidance criteria are not intended to, and should not, result in a lesser degree of human health and environmental protection in Indian country than elsewhere in the United States.
- When appropriate, authorize state and tribal inspectors to conduct compliance evaluations on the EPA's behalf. Ensure that state and tribal inspectors who inspect on EPA's behalf are trained and credentialed per the *Guidance for Issuing Federal EPA Inspector Credentials to*

Authorize Employees of State/Tribal Governments to Conduct Inspections on Behalf of EPA (2004).

- Consistent with the EPA Order 3510, annually conduct an inventory of federal credentials which includes an annual physical possession check of 10 percent of the federal credentials issued to state and tribal inspectors and a count of unused credentials stock.
- In accordance with the HPV Policy, have frequent discussions with delegated agencies to ensure consistent implementation of the Policy, including consideration of the Watch List replacement tool when available.
- Negotiate facility-specific CMS plans with all delegated agencies and ensure delegated agencies are aware of the flexibilities available within the CMS. Evaluate progress throughout the year and work with delegated agencies to revise such CMS plans as necessary. Work with headquarters to ensure that when delegated agencies use the flexibilities offered in the CMS to tailor their strategy to state/tribal/local specific circumstances, such use of flexibility is taken into account to accurately represent delegated agency performance in program reviews and to the public.
- Conduct a sufficient number of oversight inspections to ensure the integrity and quality of each authorized state's or tribe's compliance monitoring program.
- In follow-up to annual planning meetings with senior federal and state management, convene routine and regular (several times per year) meetings with senior state management to assess progress in how the state has been performing overall in its implementation of the program.
- Ensure facility performance data is accessible to the public consistent with agency policy and regulations.
- Support the agency's Next Generation Compliance by identifying and promoting advanced monitoring and electronic reporting to improve compliance and enhance the ability to identify violations that may harm public health and/or the environment. Increase transparency and improve targeting for noncompliance. Develop innovative enforcement approaches and participate in agency rulemaking workgroups to ensure regulations are designed to promote compliance and are implementable.
- Conduct SRF consistent with the schedule outlined in the agreed-upon ACS commitments. Provide recommendations and conduct follow-up as appropriate in accordance with national SRF guidance.

Measures: See ACS measures CAA04 and CAA06 in Appendix 2, page 5.

9. RCRA Subtitle C Hazardous Waste Program

Description: The critical compliance monitoring and enforcement activities for the Resource Conservation and Recovery Act (RCRA) Subtitle C Hazardous Waste Program are described below.

Activities:

Authorized states and EPA regions, in their oversight and direct implementation roles, including in Indian country, should:

- Address RCRA problems that matter to communities, especially tips and complaints, and identify and follow-up on the highest priority concerns.
- Meet statutory requirements to conduct a minimum number of thorough inspections annually including financial assurance requirements for Treatment, Storage, and Disposal Facilities (TSDF), operated by federal, state/local governments, and biennially for non-governmental TSDFs.
- Follow the RCRA Compliance Monitoring Strategy (CMS) available at http://www2.epa.gov/compliance/compliance-monitoring-strategy-resource-conservation-and-recovery-act. Note: states may use the flexibilities described in the RCRA CMS for Large Quantity Generators (LQGs) and TSDFs.
- Undertake timely and appropriate enforcement actions that produce significant environmental benefits.
- Complete on-going work in the mining/mineral processing priority area, consistent with the national strategy, unless continued noncompliance is detected.
- Consider the following focus areas as a high priority when developing strategies for targeting compliance assurance work and annual plans for respective activities in the regions:
    - Improper treatment at TSDFs/Waste Analysis Plans at TSDFs: Ensure proper characterization of incoming wastes, treatment and stabilization techniques, and the sampling and analysis of hazardous waste treated to meet the Land Disposal Restriction (LDR) treatment standards for land disposal.
    - RCRA AA/BB/CC: Ensure compliance with RCRA air emission requirements.
- Where resources allow and given regulated universe considerations of any particular region/state, other potential focus areas for regional and state consideration are:
    - Surface Impoundments: hazardous waste in unlined surface impoundments.
    - Zinc Hazardous Secondary Materials Recyclers: zinc fertilizer manufacturing that use hazardous waste; sham recycling and recycling.
    - RCRA Corrective Action: facilities that have not made meaningful progress in achieving remedial objectives, and on financially marginal or bankrupt facilities. Monitor compliance with orders and permits, identify substantial noncompliance with such instruments, and take enforcement actions where appropriate.
    - Mercury from specific sources: sectors such as universal waste lamp handlers and recyclers.

EPA regions should also:

- Ensure that the most serious instances of noncompliance are addressed through planning with states, state oversight, regular (e.g. quarterly) meetings, targeted inspections and enforcement, and through direct implementation in states and Indian country.
- Conduct a sufficient number of oversight inspections to ensure the integrity and quality of each state's compliance monitoring program.
- Support the agency's Next Generation Compliance by promoting advanced monitoring and electronic reporting to improve compliance and enhance the ability to identify violations that may harm public health and/or the environment. Increase transparency and improve targeting for noncompliance. Develop innovative enforcement approaches and participate in agency rulemaking workgroups to ensure regulations are designed to promote compliance and are implementable.

- Conduct SRF consistent with the schedule outlined in the agreed-upon ACS commitments. Provide recommendations and conduct follow-up as appropriate in accordance with national SRF guidance.
- Take enforcement action, consistent with national policy, where states are not addressing serious noncompliance or when federal enforcement may provide a more comprehensive response than an individual state response (for example on issues that involve multiple states).
- Use electronic reporting tools as feasible when monitoring compliance with orders/permits.
- Screen for potential environmental justice concerns at RCRA facilities.
- Support, and encourage states to support RCRA inspector training development.
- Ensure regional direct implementation in states and Indian country includes applying the RCRA compliance monitoring strategies and enforcement policies and OECA's *Guidance on the Enforcement Principles Outlined in the 1984 Indian Policy (January 17, 2001)* (http://www2.epa.gov/enforcement/transmittal-final-guidance-enforcement-principles-outlined-1984-indian-policy-january-17), which contains procedures for consultation with federally-recognized tribes in the civil compliance monitoring and enforcement context and threshold criteria for the EPA's consideration of formal civil enforcement actions. The threshold criteria should not result in a lesser degree of human health and environmental protection in Indian country than elsewhere in the United States.
- Ensure that state and tribal inspectors who inspect on behalf of the EPA are trained and credentialed consistent with agency guidance, including the *Guidance for Issuing Federal EPA Inspector Credentials to Authorize Employees of State/Tribal Governments to Conduct Inspections on Behalf of EPA* (2004). Consistent with the EPA Order 3510, annually conduct an inventory of federal credentials which includes an annual physical possession check of 10 percent of the federal credentials issued to state and tribal inspectors and a count of unused credentials stock.
- As necessary, work with OECA to identify and evaluate program areas that could become national priorities/enforcement initiatives in the future.
- Participate in the development and implementation of nationally consistent field mobility business solutions such as electronic inspection software.

Measures: See ACS measures RCRA02 and RCRA02s in Appendix 2, pages 6-7. Measures RCRA 01, RCRA 01s, RCRA03 support the statutory and regulatory requirements and are listed on pages 5-7.

10. RCRA Underground Storage Tank (UST) Subtitle I Program

Description: A major focus of the RCRA UST program is to maintain an enforcement presence concerning leak prevention, leak detection, corrective action, closure and financial responsibility violations. States have primary responsibility for determining facility compliance, ensuring adequate inspection coverage of the regulated universe, taking appropriate actions in response to non-compliance and playing a vital role in alerting the EPA to regulatory implementation problems. The agency's enforcement activities will focus on addressing violations that pose the greatest threat to human health and the environment where a federal response is necessary and maintaining compliance monitoring and enforcement resources to

directly implement the UST program in Indian country. The enforcement program will also continue to support the Office of Underground Storage Tanks' efforts on the implementation of the new final UST regulations such as helping to develop innovative approaches to promote and maintain compliance using next generation compliance and enforcement methods. The Leaking UST (LUST) program will continue its emphasis on corrective action and petroleum brownfields, and efforts to reduce the backlog of LUST sites. OECA headquarters has been involved in supporting work on abandoned tanks, bankruptcy, responsible party (RP) search, ability-to-pay (ATP), and enforcement at RP-lead cleanups.

Activities:

EPA regions will focus on:

- Owners and operators of USTs located in Indian country. Regional direct implementation in Indian country should take place pursuant to the applicable enforcement policies and *OECA's Guidance on the Enforcement Principles Outlined in the 1984 Indian Policy (January 17, 2001),* which contains procedures for consultation with federally-recognized tribes in the civil compliance monitoring and enforcement context and threshold criteria for EPA's consideration of formal civil enforcement actions. The threshold criteria should not result in a lesser degree of human health and environmental protection in Indian country than elsewhere in the United States.
- UST inspections that will produce the greatest environmental and human health benefits. Factors to consider in identifying facilities for inspection under the UST program include:
    - Owners and operators managing UST facilities in multiple states;
    - Mid-level distributors operating multiple UST facilities;
    - Problem non-compliers (i.e. repeat violators; owners/operators who fail to cooperate in an effort to return to compliance);
    - Owners and operators of facilities with USTs that endanger sensitive ecosystems or sources of drinking water;
    - Corporate, government-owned and federal central fueling facilities; and
    - Owners and operators of UST facilities in areas with potential environmental justice concerns.
- Ensuring timely and accurate reporting of state/tribal performance data (following guidance provided by OUST) and entering federal inspection and enforcement data into ICIS.
- Issuance of enforcement actions and assessment of penalties, as appropriate. Focus on developing large complex cases involving noncompliance on a corporate-wide basis or noncompliance in multi-state operations. Regions will consult with the states when they plan to use delivery prohibition in those states, when appropriate, to address significant noncompliance.
- Where action is appropriate in smaller cases (e.g. in Indian Country), regions will consider utilizing cost-effective tools such as field citations or expedited settlements, when appropriate.
- Regions should encourage their states to optimize deterrence from the impact of enforcement utilizing efficiencies within their authority including the use of delivery prohibition and addressing noncompliance on a corporate-wide basis statewide or other opportunities.

11. RCRA Corrective Action

Description: RCRA corrective action is implemented by the EPA and 44 authorized states and territories. On April 27, 2010, OECA and OSWER jointly issued the "*National Enforcement Strategy for Corrective Action"* (NESCA). This strategy encourages the EPA and states to continue to work in partnership to achieve the 2020 Corrective Action goals and emphasizes the need for close communication and coordination between the EPA and states to meet these goals. NESCA provides guidance to regions and states for targeting enforcement efforts and addressing special considerations that arise in the enforcement arena, such as ensuring enforceable requirements and deadlines in permits and orders are clearly identified, focusing on companies having financial difficulties, using CERCLA authorities, where appropriate, ensuring institutional controls are effective and enforceable and long-term stewardship requirements are met, and increasing the transparency and community involvement of enforcement efforts. OECA will continue to provide training to regions and states on how to review financial assurance submissions for compliance, and in particular, the financial test and corporate guarantee. In addition, OECA has updated its Model 3008(h) administrative order on consent (AOC) and will explore updating or developing other model orders.

To help achieve the RCRA Corrective Action program goals and ensure that meaningful progress is being made at facilities subject to corrective action, regions and authorized states should work closely together and continue implementing NESCA in FY 2016-2017. On September 27, 2012, the EPA issued a NESCA assessment report that recommended the following future actions: increase emphasis on communication and coordination within the EPA and with state partners, explore opportunities for compliance monitoring, and increase the state role in corrective action compliance monitoring and enforcement (see http://www2.epa.gov/sites/production/files/documents/nesca-assessment-2012.pdf). In FY 2016 and 2017, OECA will continue to implement the next steps included in the September 27, 2012 NESCA assessment report with an emphasis on enhancing compliance monitoring in the corrective action program. OECA's compliance monitoring activities will include continuing its Corrective Action inspection training efforts, encouraging long-term stewardship inspections and addressing environmental justice issues through Corrective Action inspections and enforcement actions, as appropriate.

Activities:

Authorized states and regions should:

- Enhance coordination within your offices and amongst regulatory partners. When permits or orders are being developed, renewed or modified, coordinate to ensure that they contain clear schedules for corrective action and enforcement processes as appropriate.
- Emphasize compliance monitoring, including reviewing permits and orders to determine whether noncompliance with cleanup milestones exists, and taking appropriate action in cases of noncompliance.
- When establishing potential enforcement targets, regions are encouraged to focus attention on identifying and addressing disproportionate impacts on minority, low income, tribal and other vulnerable populations.
- Leverage federal, state, tribal, local and other partnerships to maximize resources; improve cleanups using greener and more resilient and sustainable practices; and revitalize sites through policy, guidance and, when appropriate, agreements and comfort letters.

- Implement specific actions designated in EPA's Climate Change Adaptation Plan to more fully integrate climate change adaptation activities, greener remediation, and sustainability efforts into the cleanup enforcement program (e.g. consent decrees, comfort letters or other enforcement instruments), where appropriate.

Measures: See ACS measure HQ-VOL in Appendix 2, page 7.

12. TSCA Chemical Risk Reduction Programs

Description: The EPA regions and when authorized, states and tribes are expected to implement the National Compliance Monitoring Strategy (CMS) for the four major Toxic Substances Control Act (TSCA) programs. The New and Existing Chemical program (core TSCA) and PCB programs are generally implemented by the EPA. The asbestos program, and the Lead-based Paint program are implemented by the EPA except where states or tribes have been authorized to implement those programs in lieu of the Agency.

The CMS creates a "One-TSCA" program framework for regional compliance monitoring programs that gives each region the flexibility to shift its priority focus as needed to address its most significant compliance, human health, and environmental issue(s). It is important for each region to be knowledgeable about the array of environmental problems across their region and the regulated universe subject to each of its TSCA focus areas (e.g., the universe size, constituent sectors), compliance levels, the roles and effectiveness of authorized state and tribal programs and to consider and address the potential impact that directing most of its resources to its priority issue(s) likely will have on its other TSCA programs and activities. With these factors in mind, the regions are to develop a plan for their inspections and other compliance activities based on the resources available and that prioritizes the problems to be addressed along with how the regions are providing oversight of state programs. If a region chooses not to develop a plan for its TSCA programs then the region shall use the following distribution for resource allocation.

For FY 2016-2017, 90 percent of the region's overall TSCA resources should focus on the lead compliance assurance program. However, up to 20 percent of these same resources may be shifted by the region to other TSCA compliance assurance activities consistent with this NPM Guidance. The intent here is to provide flexibility for regional TSCA initiatives and to take into account unique regional situations while still maintaining a national TSCA program. Where regions choose to exercise this flexibility they should provide a rationale and articulate how this flexibility is consistent (or why inconsistent) with the CMS.

A. TSCA Lead Risk Reduction Program

Description: In 1992, Congress enacted Title X: Residential Lead-Based Paint Hazard Reduction Act. Among other things, The Act authorized four key programs for EPA to implement: the Section 1018 – Lead-Based Paint Risk Disclosure Program; the Lead-Based Paint Activities Program; the Lead-Based Paint Pre-Renovation Education Program; and the Lead-Based Paint Renovation, Repair and Painting Program. The EPA will focus its efforts on addressing the most serious violations of the Lead-Based Paint Renovation, Repair and Painting

Program in order to protect children's health. For FY 2016-2017, 90 percent of the region's TSCA resources should focus on the lead compliance assurance program.

Activities:

EPA regions should:

- Focus primarily on compliance with the LBP Renovation, Repair and Painting (RRP) Rule /Pre-Renovation Education (PRE) Rule. With regard to the regions' lead based paint compliance efforts, regions should direct 95 percent of their efforts in the lead program towards RRP/PRE, and no more than 5 percent to new § 1018-only compliance. Regions should prioritize their activities to assure compliance with RRP work practices requirements. Regions may employ targeting that, while focusing on RRP/PRE, allows for concomitant compliance monitoring with other LBP rules (the § 1018 and § 402 Abatement rules), as appropriate.
- Implement the program priorities and activities, including those set out in detail in the National Compliance Monitoring Strategy (CMS) for Lead Based Paint (LBP)[8], to balance the various types of inspections and other compliance assurance activities. The effective and efficient targeting of inspections, particularly work practice inspections, requires that the regions know the regulated universe, and prioritize the problems to be addressed. Regions should attempt to maximize their enforcement presence by focusing on larger violators, as appropriate.
- Use the inspection targeting principles set forth in the CMS with a focus on monitoring contractors' actual compliance with required work practices. Focus efforts in high-priority lead "hot spots" as described in the CMS [e.g., geographical areas with evidence or indicators of significant or wide-spread Elevated Blood Lead Levels (EBLLs)].
- Respond appropriately to tips and complaints and actively follow-up on the highest priorities.
- Coordinate with OECA to bundle press activities related to cases from multiple regions, as appropriate.
- Partner with state and local government code enforcement and building permit programs and state/local health departments to conduct joint inspections.
- Partner with health departments and health care providers to identify lead hot spots and individual properties associated with EBLL children.
- Initiate civil enforcement actions, consistent with national policy, to eliminate any regional inspection backlog and expeditiously bring facilities into compliance.
- Work with their LBP program to encourage states to seek authorization for the RRP program.
- Conduct appropriate oversight of authorized state § 402 and § 406 programs.
- Consistent with the EPA Order 3510, conduct an annual inventory of federal credentials which includes a physical possession check of 10 percent of the federal credentials issued to state inspectors and a count of unused credentials stock.

[8] Please see Compliance Monitoring Strategy for the Toxic Substances Control Act (September 16, 2011), including Appendix E – Lead-based Paint Program and Appendix F – Lead-based Paint Program Resources, at: http://www2.epa.gov/sites/production/files/2014-01/documents/tsca-cms.pdf.

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- Enter all federal inspection and enforcement cases into the national database ICIS in a timely and accurate manner.
- As necessary, work with OECA to identify and evaluate program areas that could become national priorities/enforcement initiatives in the future.

Measures: See ACS measures TSCA 01OC and TSCA 02OC in Appendix 2 on pages 7-8. The Lead Based Paint component of ACS commitment TSCA 01OC will serve as an OECA FY 2016 measure of compliance work being done to protect children's health.

B. TSCA New and Existing Chemicals Programs

Description: The TSCA New and Existing Chemicals Program is exclusively a federal program that provides for review of the risk of chemicals prior to their manufacture and importation to prevent unreasonable risk to human health and the environment and requires a series of notifications and submissions from regulated industry. For FY 2016-2017, 90 percent of the region's TSCA resources should focus on the lead compliance assurance program[9]. However, up to 20 percent of these same resources may be shifted by the region to other TSCA compliance assurance activities consistent with this NPM Guidance. The intent here is to provide flexibility for regional TSCA initiatives and to take into account unique regional situations. Where regions choose to exercise this flexibility they should provide a rationale and articulate how this flexibility is consistent (or why inconsistent) with the Compliance Monitoring Strategy (CMS) for the Toxic Substances Control Act.

Activities:

EPA regions opting to engage in compliance monitoring and assurance activities for TSCA New and Existing Chemicals should:

- Focus on chemical manufacturing (including importing), distribution, processing, use, or disposal of new chemicals. Focus monitoring and enforcement efforts on ensuring facility compliance with TSCA § 5 - new chemicals requirements such as Pre-manufacturing Notice (PMN); Significant New Use Rules (SNUR's); Low Volume Exemptions (LVE's), and on chemicals of concern including short chained and other chlorinated paraffins, fractions, Work Plan and other priority or Action Plan chemicals or targets.
- Implement the Compliance Monitoring Strategy for the Toxic Substances Control Act (September 16, 2011)[10] including Appendix B which addresses New and Existing Chemicals.
- Obtain information through inspections and/or subpoena as appropriate. Increase the use of TSCA subpoenas for investigation of potential noncompliance.
- Initiate civil enforcement actions, as appropriate, to bring facilities into compliance, consistent with national policy.

[9] Please see the description section for the TSCA Chemical Risk Reduction Programs on page 34.
[10] The TSCA CMS, including Appendix B, can be found at: http://www2.epa.gov/sites/production/files/2014-01/documents/tsca-cms.pdf.

- Target existing chemical reporting and record keeping requirements such as TSCA § 4, 8 and the 2016 Chemical Data Reporting Rule.
- Evaluate and prioritize tips and complaints and follow-up as appropriate. Regions not implementing this program should refer tips and complaints to the Waste and Chemical Enforcement Division within the Office of Civil Enforcement.
- Strengthen program integrity through enhanced chemical data collection, reporting and coordination between headquarters and regions. In particular, increase coordination on targeting between OPPT, OECA and the participating regions to focus on the chemical manufacturing sector. Additionally, coordinate when setting program priorities and communicating best practices.
- Enter all federal inspection and enforcement cases into the national database ICIS in a timely and accurate manner.

Measures: See ACS measures TSCA 01OC and TSCA 02OC in Appendix 2 on pages 7-8.

C. TSCA PCB Program

Description: The TSCA PCB enforcement program is a federal only program. However, nine states through cooperative agreements inspect on behalf of the EPA. TSCA and EPA's implementing regulations aim to minimize risks posed by the use, storage, handling, and disposal of PCBs and PCB-containing items. The EPA's enforcement program will focus its PCB enforcement resources on nationally-significant situations involving the greatest threats to health in each region. The EPA will pursue nationally-significant PCB civil and criminal violations that may present a significant risk of injury to health or the environment and maintain some field presence at EPA-approved commercial PCB storage and disposal facilities. For FY 2016-2017, 90 percent of the region's TSCA resources should focus on the lead compliance assurance program[11]. However, up to 20 percent of these same resources may be shifted by the region to other TSCA compliance assurance activities consistent with this NPM Guidance. The intent here is to provide flexibility for regional TSCA initiatives and to take into account unique regional situations. Where regions choose to exercise this flexibility they should provide a rationale and articulate how this flexibility is consistent (or why inconsistent) with the Compliance Monitoring Strategy (CMS) for the Toxic Substances Control Act. OECA will continue to evaluate enforcement options for PCBs in building materials used in schools and will update existing guidance or provide new guidance at a later date.

Activities:

<u>EPA regions opting to engage in compliance monitoring and assurance activities for the TSCA PCB program</u> should:

- Address nationally-significant PCB civil and criminal violations that may present a significant risk to human health or the environment, consistent with national policy.
- Dependent on regional resources devoted to this program, focus inspections, case development and enforcement on the following areas of potential significant risk:

[11] Please see the description section for the TSCA Chemical Risk Reduction Programs on page 34.

1. PCB treatment, storage and/or disposal facilities targeted based on potential for releases, cumulative burden on EJ communities, or associated with approvals (permitting):
    a. At facilities conducting approved PCB treatment, storage, disposal, or cleanups (the regions should inspect all approved commercial PCB treatment, storage, and disposal facilities at least once every three years);
    b. As appropriate, at oil recyclers through coordinated joint TSCA/RCRA PCB inspections to efficiently use resources.
2. Non-TSD Locations:
    a. Natural gas pipelines;
    b. Used oil facilities that receive and dilute PCB contaminated oil, and related possible distribution in commerce, contamination, decontamination, and disposal;
    c. Follow-up where improperly or unmanifested PCB waste was turned away by disposal sites and was either returned to the generator or taken in by the storer/ disposer, as well as facilities that have the potential to receive unmanifested shipments;
    d. Potential PCB-containing abandoned buildings, textile mills, and other facilities located in close proximity to residential communities assuming the existence and location of these facilities is known to the EPA region.
3. Follow-up on tips/complaints that involve potential for illegal disposal and significant risk.
4. As appropriate, coordinating joint TSCA/RCRA PCB inspections at oil recyclers to efficiently use resources.

- Taking into account the aforementioned focus for the FY 2016-2017 program, implement the Compliance Monitoring Strategy for the Toxic Substances Control Act (September 16, 2011) including Appendix C – PCBs[12].
- Monitor, evaluate and take action on compliance requirements/submittals/schedules under Consent Decrees and Consent Agreements.
- Ensure that any state and tribal inspectors who inspect on behalf of the EPA are trained and credentialed consistent with agency guidance, including the *Guidance for Issuing Federal EPA Inspector Credentials to Authorize Employees of State/Tribal Governments to Conduct Inspections on Behalf of EPA* (2004).
- Consistent with the EPA Order 3510, conduct an annual inventory of federal credentials which includes a physical possession check of 10 percent of any federal credentials issued to state and tribal inspectors and a count of unused credentials stock.
- Enter all federal inspection and enforcement cases into the national database ICIS in a timely and accurate manner.

States with EPA cooperative agreements should:

- Implement the agreed-upon work plan in their cooperative agreements.

Measures: See ACS measures TSCA 01OC and TSCA 02OC in Appendix 2 on pages 7-8.

[12] The TSCA CMS, including Appendix C, can be found at: http://www2.epa.gov/sites/production/files/2014-01/documents/tsca-cms.pdf.

D. TSCA Asbestos Program/AHERA

Description: Since 1986, the Asbestos Hazard Emergency Response Act (AHERA) amended TSCA to require schools to inspect their buildings for asbestos-containing materials and implement asbestos-management programs. The EPA will focus its efforts on addressing the most egregious violations of AHERA in order to protect human health and the environment. For FY 2016-2017, 90 percent of the region's TSCA resources should focus on the lead compliance assurance program[13]. However, up to 20 percent of these same resources may be shifted by the region to other TSCA compliance assurance activities consistent with this NPM Guidance. The intent here is to provide flexibility for regional TSCA initiatives and to take into account unique regional situations. Where regions choose to exercise this flexibility they should provide a rationale and articulate how this flexibility is consistent (or why inconsistent) with the Compliance Monitoring Strategy (CMS) for the Toxic Substances Control Act.

Activities:

EPA regions opting to engage in compliance monitoring and assurance activities for the TSCA Asbestos/AHERA program should:

- Address the most egregious violations of AHERA consistent with national policy.
- For states and tribes that do not have a cooperative agreement with the EPA, taking into account regional resources devoted to this program, investigate and respond appropriately (including taking enforcement action as appropriate) within a reasonable amount of time to tips/complaints containing allegations that provide a reasonable basis to believe that a violation has occurred.
- For states and tribes that do not have a cooperative agreement with the EPA, taking into account regional resources devoted to this program, consider conducting compliance inspections at state and local government facilities to monitor compliance with the asbestos worker protection requirements in states where state and local government employees are not protected by the OSHA Asbestos Standards.
- In states that have non-waiver status, review and evaluate inspection reports for enforcement action.
- Taking into account the aforementioned focus for the FY 2016-2017 program, implement the Compliance Monitoring Strategy for the Toxic Substances Control Act (September 16, 2011) including Appendix D – Asbestos[14].
- Ensure that any state and tribal inspectors who inspect on behalf of the EPA are trained and credentialed consistent with agency guidance, including the *Guidance for Issuing Federal EPA Inspector Credentials to Authorize Employees of State/Tribal Governments to Conduct Inspections on Behalf of EPA* (2004).
- Consistent with the EPA Order 3510, conduct an annual inventory of federal credentials which includes a physical possession check of 10 percent of the federal credentials issued to state and tribal inspectors and a count of unused credentials stock.

[13] Please see the description section for the TSCA Chemical Risk Reduction Programs on page 34.
[14] The TSCA CMS, including Appendix D can be found at: http://www2.epa.gov/sites/production/files/2014-01/documents/tsca-cms.pdf.

- Enter all federal inspection and enforcement cases into the national database ICIS in a timely and accurate manner.

Waiver and non-waiver states are expected to:

- Within a reasonable period of time, investigate and respond appropriately to any tips/complaints containing allegations that provide a reasonable basis to believe that a violation has occurred.
- Conduct inspections in each state to assure equitable protection and ensure compliance with the TSCA asbestos regulations.
- In waiver states, take appropriate enforcement action under state law.
- In non-waiver states, submit completed inspection reports to the EPA region for review and enforcement action as appropriate, consistent with the state's cooperative agreement. Consider conducting compliance inspections at state and local government facilities to monitor compliance with the asbestos worker protection requirements in states where state and local government employees are not protected by the OSHA Asbestos Standards.

Measures: See ACS measures TSCA 01OC and TSCA 02OC in Appendix 2 on pages 7-8.

13. FIFRA Program for Compliance Assurance and Enforcement

Description: The EPA will generally prioritize its compliance monitoring activities based on risk to human health and the environment. The region's FIFRA resources should include a balance of compliance and enforcement activities covering: worker protection, pesticide registration and labeling, product efficacy (including enforcement follow-up of efficacy failures of antimicrobial products) and compositional integrity, producing establishment registration and reporting, import and export requirements, unreasonable adverse effects reporting, and other noncompliant pesticides. For FY 2016-2017, the three FIFRA Focus Areas are: a) Product Integrity; b) Border Compliance; and c) Worker Protection Standards; implementation of the FIFRA Focus Areas will generally be done through direct implementation activities or in support of state and tribal programs.

Activities:

For its direct implementation program, EPA regions should:

- Participate in the three FIFRA Focus Areas: a) Product Integrity; b) Border Compliance; and c) Worker Protection Standards, discussed below.
- Conduct inspections and perform sampling in support of the Focus Areas and other core FIFRA program areas, as appropriate, and in accordance with any final FIFRA Compliance Monitoring Strategy.
- Initiate enforcement actions, consistent with the FIFRA ERPs and with emphasis on addressing risk, obtaining appropriate deterrence, and optimizing environmental benefits.
- Apply the various FIFRA enforcement policies and OECA's Guidance on the Enforcement Principles Outlined in the 1984 Indian Policy (January 17, 2001) (http://www.epa.gov/compliance/resources/policies/state/84indianpolicy.pdf) when doing

direct implementation in Indian country to ensure adequate human health and environmental protection in Indian country as elsewhere in the United States.
- Ensure timely and accurate entry of federal inspection and enforcement data into ICIS.

For its support of state and tribal programs, EPA regions should:
- Encourage state and tribal involvement in supporting the EPA Focus Area activities, as appropriate and consistent with the cooperative agreement guidance.
- Negotiate, oversee implementation of and review state and tribal performance under pesticide enforcement cooperative agreements following existing policies and guidance.
- Work with EPA Headquarters to document and improve upon current procedures and training to conduct: (1) program evaluations; and (2) grant performance evaluations, incorporating existing relevant protocols to the extent possible. Oversight resources should be focused on the most pressing performance problems and work to demonstrably improve state/tribal performance. Participate in development of FIFRA state performance dashboards based on 5700 data.
- Convene routine and regular meetings between the region and state or tribe to discuss how the state or tribe has been performing overall in its implementation of the program, and in respect to its negotiated cooperative agreement. When appropriate and consistent with the Interpretive Rule and other national policy, take enforcement to address serious violations in the absence of appropriate state or tribal response or when significant state or tribal cases are referred to EPA for enforcement.
- Ensure timely and accurate reporting of state and tribal performance data.

Measures: See ACS measure FIFRA-FED1 in Appendix 2, page 8.

A. Pesticide Product Integrity

Description: Pesticides are registered after undergoing a significant review and risk/benefit analysis intended to ensure that human health and environmental risks are adequately mitigated through the Agency's registration and related labeling process. This focus area will address pesticides which potentially present significant risks to human health and the environment while safeguarding the basic integrity of the pesticide registration process. For this focus area, regions would be expected to monitor compliance against four prongs of product integrity: (1) product registration, (2) label/labeling compliance, (3) composition compliance, and (4) product efficacy, (apply only in cases dealing with the on-going antimicrobial testing program (ATP)).

Activities:

EPA regions should:
- Conduct producer establishment inspections known to produce (1) supplemental distributor products, (2) RUP or Tox-1 pesticides, or (3) pesticides of regulatory concern.
- Collect samples and submit to laboratory for formulation analysis to ensure product composition complies with terms of registration.
- Initiate enforcement actions, as appropriate, to address violations of registration, composition, and labeling requirements to ensure optimum deterrence effect and enforcement

impact, including enforcement actions that address corporate-wide noncompliant behavior and high-risk unregistered pesticide products.
- Address ATP efficacy failures through enforcement actions, in collaboration with OPP.

Measures: See ACS measure FIFRA-FED1 in Appendix 2, page 8.

B. Border Compliance

Description: The EPA's enforcement program addresses the illegal importation of unregistered or otherwise noncompliant pesticide products into the United States by bringing enforcement actions against importers and others and working with other governments, agencies and stakeholders to prevent and reduce risks of unsafe products entering our country, with special emphasis on enforcing against importers of high-risk unregistered pesticides. Illegal pesticide imports may present significant human health and environmental risks and have been linked to poisonings of children and pets, so prevention before they enter the United States is critical. The EPA regions are the primary source of inspections and enforcement for this area. States may become involved through region-to-state referrals to monitor post-entry import compliance or states may encounter imported products during the course of other compliance monitoring inspections. Regions should make their states aware of the EPA's strong interest in import compliance and encourage collaboration with the EPA when situations warrant. This work helps to further the work of the Interagency Working Group on Import Safety established by Executive Order 13439 and the current "One U.S. Government at the Border" initiative. Currently, the EPA staff manually review FIFRA Notices of Arrival (NOAs) for pesticide products and devices entering the U.S. and provide direction and guidance to Customs and Border Protection (CBP) as to whether the product should be allowed to enter U.S. commerce. The planned transition to an automated processing system in FY 2016 [Automated Commercial Environment in the International Trade Data System (ACE/ITDS)] creates opportunities to reduce the investment in manual processing of Notices of Arrival (NOAs). Once fully functional, ACE/ITDS will process the majority of NOAs, significantly reducing the need for manual review and approval by the EPA.

Activities:

Focus on importers with a history of noncompliance or significant importation activity from countries frequently associated with noncompliant shipments. EPA regions should:
- Monitor import compliance through inspections at:
  - Entry ports, when appropriate.
  - Designated destination points (conducted after the imported products have been released by CBP and have entered into U.S. commerce, Foreign Trade Zones being used for storage, processing or packaging prior to release into U.S. commerce).
- Collect samples and submit to laboratory for formulation analysis to ensure product composition complies with terms of registration.
- Screen NOAs for potential Confidential Statement of Formula discrepancies relating to source of active ingredient and countries of origin. Where potential discrepancies are noted,

follow-up investigations may be warranted at U.S. registered agents for foreign producers and domestic producing establishments.
- Take enforcement actions, as appropriate, to ensure optimum deterrence effect and enforcement impact, including enforcement actions that address corporate-wide noncompliant behavior and high-risk unregistered pesticide products.
- Participate in Commercial Targeting and Analysis Center (CTAC) National Operations initiatives, as appropriate.

Measures: See ACS measure FIFRA-FED1 in Appendix 2, page 8.

C. Worker Protection Standards

Description: Addressing disproportionate risks of agricultural farm workers, handlers and pesticide applicators to pesticide exposure continues to remain a focus area for the EPA. Although most states have "primacy" to enforce pesticide use, including worker protection standards (WPS), regions should seek opportunities for federal cases to support state efforts. Where the EPA directly implements FIFRA, such as in Indian country and states without primacy status, EPA regions should monitor compliance and enforce pesticide use requirements, although tribes with cooperative enforcement agreements may conduct inspections under their own tribal codes. Regions are expected to place emphasis on farming activities that involve frequent use of highly toxic pesticides or significant worker exposure, such as fruit and vegetable production and on-farm fumigation. In FY 2016 and FY 2017, OECA will continue to address WPS noncompliance, but adjust the activities in several ways as described below.

Activities:

EPA regions should:
- Monitor compliance and initiate enforcement in states and tribal lands where the EPA has direct implementation authority, placing emphasis on commercial applicators.
- Collaborate with states to monitor WPS compliance associated with the use of specific products of concern on specific farm commodities where worker exposure is of special concern (regions should encourage states to identify enforcement cases that could benefit from federal enforcement by the regional office).
- Conduct federal compliance monitoring inspections of products subject to the new WPS labeling requirements.
- Increase oversight of state activities addressing WPS use related violations consistent with EPA authorities under FIFRA Section 26 and 27.

Measures: See new ACS measure FIFRA-FED2 in Appendix 2, page 8. The measure reads as follows: For EPA regions with direct implementation responsibilities in Indian country and states without primacy, project the number of regional (federal) FIFRA inspections focused on the Worker Protection Standard (WPS).

14. CERCLA

Description: The EPA's CERCLA Enforcement program ensures prompt site cleanup and uses an "enforcement first" approach that maximizes the participation of liable and viable parties in performing and paying for cleanups. The Superfund enforcement program protects communities by requiring responsible parties to conduct cleanups which helps preserve federal dollars for sites where there are no viable contributing parties. The EPA identifies potentially responsible parties and negotiates cleanup agreements at hazardous waste sites and, where negotiations fail, either takes enforcement actions to require cleanup or expends Superfund appropriated dollars to clean up the sites. In some cases, the EPA takes both actions. When the EPA uses appropriated dollars, it takes action against any viable responsible parties to recover cleanup costs.

Activities:

EPA regions will:

- Maintain focused enforcement efforts to compel cleanup early in the pipeline at non-emergency removal action and remedial investigation/feasibility study (RI/FS) stages; expedite remedial action by holding parties accountable to negotiation timeframes and scheduled cleanup commitments; and rejuvenate the process for identifying responsible parties at the site assessment stage where it appears likely that a removal or remedial response will be necessary.
- Continue to focus on activities that maximize PRP involvement in all phases of response at Superfund sites.
- Focus Superfund enforcement resources on the highest-priority sites and those enforcement activities that achieve the biggest return on our investment based on environmental risk.
- Use Federal Facility Agreements (FFAs) or other applicable enforcement authorities (such as imminent and substantial endangerment orders in applicable circumstances), when federal facilities are not complying with the terms of the agreements or with other legal requirements. Additionally, regions and headquarters offices must collaborate to establish new agreements. The EPA has CERCLA Section 121 interagency agreements, known as FFAs, in place at all but one of 176 federal facility NPL sites. Those agreements govern the cleanups conducted by the facilities, delineate EPA's oversight of those cleanups and identify procedures for resolving disputes and ensuring accountability.
- Better utilize FFAs to make site performance data available to the public and otherwise empower citizen involvement to enhance cleanup oversight and accountability.
- Implement the "nationally significant" consultation procedures; since all federal facility enforcement actions are "nationally significant" by OECA policy and require consultation with headquarters. This consultation will be even more important as the regions contemplate new work in this program.
- Ensure that institutional controls are implemented at all appropriate sites including those in potential environmental justice areas of concern.
- Provide site-specific fact sheets, which include enforcement information that is finalized and available to the public on regional web pages.
- Leverage federal, state, tribal, local and other partnerships to maximize resources; improve cleanups using greener and more resilient and sustainable practices; and revitalize sites through policy, guidance and, when appropriate, agreements and comfort letters.

- Implement specific actions designated in the EPA's Climate Change Adaptation Plan to more fully integrate climate change adaptation activities, greener remediation, and sustainability efforts into the cleanup enforcement program (e.g. consent decrees, comfort letters or other enforcement instruments), where appropriate.

Measures: See ACS measures OSRE-01, OSRE-02 and HQ-VOL in Appendix 2, pages 7-8.

15. EPCRA 313 Toxics Release Inventory

Description: The EPA and the public rely on EPCRA 313 for information on chemical releases entering the environment. The EPA must ensure that companies report accurately and within required time frames so the publicly available database remains timely, accurate and inclusive. Regions should ensure the compliance of facilities that may be contributing to pollution problems that matter to their respective communities, and develop enforcement cases that produce significant environmental benefits.

Activities:

EPA regions should:

- Physically inspect, send information requests or show cause letters, or use other agreed upon compliance monitoring activities (pursuant to the national dialogue on EPCRA 313 compliance monitoring) to determine the compliance of enforcement targets developed by OECA/Office of Environmental Information (OEI) in collaboration with the regions. If a region, based on its own regional priorities, decides not to use OECA/OEI targets, and develops its own enforcement targets, the region should notify Headquarters of its intent, be able to summarize areas of enforcement targets and describe the improved enforcement outcomes of the regional targeting. Address the following categories of concern as resources allow:
  - Potential never-reporters (such as targeting facilities in the same sectors where a facility may not have reported but a similar facility in the same sector did report);
  - Potential data quality issues (such as facilities with significant changes in release estimates or other waste management amounts from one year to the next or facilities in the same sector where a facility reports significantly more/less than a similar facility in the sector);
  - Potential non/late-reporters (facilities that report in one year but failed to report the following year or any prior year up to the past five years);
  - Additional OECA-provided targeting focusing on revisions, communities, chemicals, sectors of concern or new regulations, failures to comply with Notices of Noncompliance for non-certification and failures to correct Notices of Significant Errors. Regions may focus on facilities whose releases have the most impact on the TRI database (which is approximately 90 percent of the releases to be entered into the database). This will allow the regions flexibility in selecting their targets.
- Track and prioritize tips and complaints and follow-up, as needed.
- Work with the Air, RCRA and Water compliance and enforcement programs to add EPCRA questions to information requests where appropriate, evaluate the responses and take

appropriate enforcement actions, consistent with national policy, or combine with other enforcement actions.

- Respond to OECA's requests for reviewing draft TRI regulations for enforceability, the revised draft section 313 enforcement response and penalty policy and any other documents or proposed actions where OECA requests regional input on enforcement matters.
- Provide legal and technical enforcement case support; obtain additional information through investigations, show cause letters, subpoenas and other actions, as appropriate, or determine that follow-up is not necessary.
- Enter all federal enforcement cases into national databases in a timely and accurate manner.
- As necessary, work with OECA to identify and evaluate program areas that could become national priorities/enforcement initiatives in the future.

Measures: See ACS measures EPCRA 01 and 02 in Appendix 2, page 8.

16. EPCRA 304, 311/312 and CERCLA 103

Description: Chemical release notification and emergency preparedness are addressed under EPCRA 304, 311 and 312 and CERCLA 103. The EPA and the public rely on EPCRA for information on chemical releases entering the environment, and on the storage of chemicals at facilities. The EPA, states, tribes, local entities, and communities rely on the combined EPCRA and CERCLA information to prepare local chemical emergency response plans, and to more safely and adequately respond to chemical emergencies. EPCRA sections 311 and 312 will continue to require facilities to develop or have available Safety Data Sheets and to provide annual reports on a facility's chemical inventory directly to state and local emergency response entities. The statute authorizes citizen suits and civil suits by state or local governments against owners or operators of a facility for failure to comply with specific EPCRA provisions. Regarding federal enforcement, the EPA will focus resources on the highest priority violations, and be available to respond to significant enforcement issues (e.g. violations that create significant risks to communities, workers and first responders or state or tribal requests for federal action against recalcitrant facilities). Furthermore, the EPA will leverage agency-wide resources, as appropriate, to address this program; both OSWER and OECA agree that Risk Management Plan inspections should also include an evaluation of the facility's compliance with EPCRA sections 304 and 311/312 and CERCLA 103.

Activities:

EPA regions should:

- Use screening and targeting tools to focus limited federal resources on national and regional priority areas. In targeting for inspections, regions should consider the presence of significant quantities of CERCLA hazardous or EPCRA extremely hazardous chemicals, proximity to population centers, a history of significant accidental releases and any other information that indicates a facility may be high-risk.
- Evaluate compliance with applicable EPCRA and CERCLA requirements during CAA section 112(r) inspections.

- Within a reasonable period of time, evaluate and respond, if appropriate (including taking enforcement action where appropriate) to any tip or complaint containing allegations that provides a reasonable basis to believe that a violation has occurred.
- Evaluate certain continuous release submissions for accuracy and compliance and take appropriate enforcement actions for non-compliance.
- Focus resources on the highest priority violations and respond to significant enforcement issues.
- Enter timely, complete and accurate data into national databases.

17. Federal Activities

Description: The Office of Federal Activity's (OFA's) work focuses on three areas: fostering compliance and pollution prevention through international cooperation; assisting other federal agencies in making environmentally sound decisions which include early public involvement and transparency by complying with the National Environmental Policy Act (NEPA); and guiding the EPA's own compliance with NEPA and applicable statutes and Executive Orders.

Activities:

EPA regions should work to assure international compliance and prevent illegal trans-boundary movement of hazardous waste by:

- Improving environmental performance and cooperation in accordance with Goal 5 of the U.S./Mexico Border 2020 Plan (Regions 6 and 9).
- Enhancing enforcement, compliance, and capacity building efforts with Mexico and Canada relating to trans-boundary compliance monitoring on the U.S. borders for hazardous waste, e-waste, ozone depleting substances, selected chemicals and products (e.g., mercury), engine imports that are non-compliant with air emission standards and other regulated substances (border regions).
- Improving performance of joint responsibilities along the border and ports of entry into the United States by working with the Bureau of Customs and Border Protection (CBP) through appropriate contact channels (all regions).
- Promoting international environmental enforcement by supporting foreign capacity building efforts, as appropriate, and through participation in relevant organizations and networks, such as the Enforcement Working Group of the North American Commission for Environmental Cooperation (CEC) and the International Network for Environmental Compliance and Enforcement (INECE) and, in particular, its Seaport Environmental Security Network (regional participation as appropriate).
- Reviewing the permit and compliance status of U.S. receiving facilities, utilizing established guidance, in connection with 100 percent of the notifications for the import of hazardous waste they receive from EPA headquarters and, based on the review, recommending consent or objection to notifications within the time periods allowed under applicable international agreements (all regions).
- As a regular part of regional inspection activities, conducting periodic inspections of U.S. facilities which receive imported hazardous waste (TSDFs) and generators and other primary

exporters of hazardous waste, cathode ray tubes (CRTs) and spent lead acid batteries (SLABs), based on information provided by OFA which identifies those facilities participating in import and export shipments.

EPA regions should implement the National Environmental Policy Act (NEPA) by:

- Fulfilling EPA's obligations under NEPA and Section 309 of the Clean Air Act by reviewing and commenting on all major proposed federal actions to promote identification, elimination or mitigation of significant adverse effects, and making the comments available to the public.
- Providing recommendations to assist federal decision-makers in ensuring that projects likely to have significant impacts (e.g., transportation, mountaintop mining, and energy) receive sound environmental analysis, use cooperation among agencies to resolve differences, consider environmental justice, incorporate innovation and support public involvement through a more streamlined and transparent environmental review process.
- Writing clear and effective comments on EISs with the goal of influencing federal decision-makers to mitigate at least 70 percent of the significant impacts identified by the EPA during the NEPA process.
- Ensuring that at least 90 percent of EPA projects subject to NEPA environmental assessment or EIS requirements (e.g., water treatment facility projects and other grants, new source NPDES permits and EPA facilities) are expected to result in no significant environmental impact.
- Promoting environmental justice considerations throughout the environmental decision-making process and encouraging public involvement early in the process to maximize transparency.
- Preparing environmental analyses (EISs or EAs*)* and posting them on the internet or making categorical exclusion determinations for EPA-issued National Pollutant Discharge Elimination System (NPDES) permits for new sources, for states/tribes without authorized NPDES programs; off-shore oil and gas sources, including permits for deep water ports, EPA laboratories and facilities; and Clean Water Act wastewater treatment plant grants.
- Preparing environmental analyses (EAs or EISs) and posting them on the internet or making categorical exclusion determinations for Special Appropriation grants for wastewater, drinking water supply and solid waste collection facilities; Border Environment Infrastructure Funds (for the US/Mexico Border Environment Cooperation Commission projects); and reviews conducted under "*EPA's Voluntary NEPA Compliance Policy*."
- Entering the results of their 309 reviews and NEPA compliance actions into the EIS Tracking Database maintained by headquarters OFA. Regions should report to the Office of Federal Activities quarterly on the status of their 309 reviews and NEPA compliance actions pursuant to the Government Performance Reporting Act reporting process.
- Assisting other federal agencies to improve the analysis of climate change issues under NEPA, including estimating greenhouse gas emissions associated with federal actions and consideration of mitigation measures, as well as fostering climate resiliency.

18. Criminal Enforcement Program

Description: The criminal enforcement program investigates and assists in the criminal prosecution of knowing violations of environmental laws as well as any associated violations

of the U.S. criminal code, such as wire fraud, smuggling, obstruction of justice, etc. The program works with other federal law enforcement agencies on cases of mutual interest, e.g., the Department of Homeland Security related to the illegal importation of banned pesticides. The program will continue to work with civil enforcement to look for criminal enforcement opportunities to advance National Enforcement Initiatives and instances of behavior on the part of regulated entities that represent inherently criminal conduct, such as falsifying data. The program will work with EPA civil enforcement and program offices in headquarters (HQ) and the regions to enhance the case screening process so that decisions to prosecute civilly or criminally are based on the best way to respond to the violation; the program will focus on securing the best results by providing clarity on when civil investigators should refer a matter to criminal enforcement and sharing criminal enforcement information with the civil enforcement program, where appropriate. The program will integrate environmental justice (EJ) concerns in assessments of criminal investigations and will use the EPA's screening tools, regional input and other relevant information. Cases that meet the threshold level for heightened analysis are considered to have potential EJ concerns for criminal enforcement purposes.

Activities:

EPA regions and OECA's Headquarters Civil Program coordinate with the Office of Criminal Enforcement, Forensics and Training to:

- Refer to the criminal enforcement program for consideration any matter that appears to be criminal in nature.
- Revise/update existing case screening policy memos to ensure that the criminal and civil enforcement programs are coordinating to ensure the optimal enforcement response to violations of federal environmental laws.
- Develop incentives and measures to ensure efficient sharing of information and resources between civil and criminal enforcement programs.
- Develop a shared civil/criminal case screening database, similar to the one developed in Region 1, for use in every region.
- Conduct case screening sessions to agree upon the appropriate enforcement response to a potential criminal offense.

The Office of Criminal Enforcement, Forensics and Training will:

- Develop/refine criteria for Tier 1 (TI) and Tier 2 (T2) cases as well as for opening lower Tier cases. Identify NON-T1/T2 cases that offer high deterrent value because of cumulative impacts of many similar smaller cases.
- Conduct semiannual case and docket reviews, by headquarters' Criminal Investigation Division, of SAC offices to advance and track high impact cases, including T1 and T2. Determine which cases, if any, should be closed (especially Tiers 3 and 4); reallocate resources to higher-impact cases.
- Develop and provide training for civil EPA counterparts to identify and share information regarding criminal conduct.
- Through NEIC, evaluate new and emerging technologies needed to implement enhanced targeting and compliance assurance approaches.
- Analyze emissions and compliance information to identify potential criminal violations by certain industrial sectors and individual facilities.

- Work with Department of Justice to: (1) explore innovative uses of criminal sentencing options, e.g., community service or environmental compliance plans; and (2) use information obtained pursuant to the Crimes Victim's Rights Act (CVRA) when developing environmental crimes case resolutions, e.g., restitution.
- Provide targeted training to state, tribal and law enforcement partners, particularly the International Association of Chiefs of Police, to enhance their abilities to safely spot, report and address environmental violations.
- Continue international enforcement efforts, e.g., working with INTERPOL to combat the illegal shipment of e-wastes.

Appendix 1: Projects Aligning with E-Enterprise Goals in which OECA Participates or Leads

This appendix highlights examples of projects, current as of April 2015, which align with E-Enterprise goals and in which OECA is participating or leading. Over the period of this NPM Guidance, EPA will complete or modify some of these activities, and develop and/or implement new projects. OECA encourages states and tribes to coordinate with EPA where they see the same or complementary priorities, processes or objectives. Advancing Next Generation Compliance complements E-Enterprise and is discussed in OECA's NPM Guidance. More information on E-Enterprise for the Environment is accessible at: http://www2.epa.gov/e-enterprise/about-e-enterprise-environment. Additional information is available at: http://www2.epa.gov/e-enterprise and http://www.exchangenetwork.net/e-enterprise/.

Project in Alignment with E-Enterprise	Sponsor or Initiators	Key EPA Offices	Shared Service Integration	EPA/State/Tribal Involvement
Scoping projects selected by the joint state-EPA E-Enterprise Leadership Council (EELC)				
Smart Tools for Inspectors	EELC, AR	OECA, OEI	Facility ID, Substance, CROMERR	States and EPA currently participating on scoping team.
Pesticides Label Matching	EELC, IN	OCSPP, OECA, EPA Regions 5 and 7	TBD	States and EPA currently participating on scoping team.
Ongoing projects with early achievements illustrating alignment with E-Enterprise Goals				
NPDES e-reporting Pilot with States	OECA	OECA, OEI	CROMERR and creation of a new shared service (new e-reporting tool)	Existing mechanism for state/EPA involvement. Pilot participants: Florida, South Dakota, Maine, New Hampshire, Puerto Rico, New Mexico, Pennsylvania, EPA Regions 1, 2 and 6.
Import-Export Hazardous Waste Rule with e-reporting	OSWER	OSWER, OECA	CROMERR	Primarily federal but states will benefit as a result of project implementation.
New Opportunity Evaluation				
Advanced Monitoring Integration Strategy	OAR, OECA	OAR, OECA, OW, ORD		Joint team evaluating opportunity

Aligned Projects Funded in FY 2015 Enacted				
NPDES Electronic Reporting Rule	OECA	OECA, OEI, OW	N/A	EPA has an internal workgroup under the regulation development process that includes the majority of the Regions and EPA programs. States have been extensively involved including an EPA-State Technical Workgroup that meets weekly to discuss various aspects of the proposed rule such as the data elements that will be implemented. Tribes have been consulted.
Smart Tools for RCRA Inspectors	OECA	OEI, OECA		This tool is intended for EPA RCRA Inspectors.

Appendix 2: FY 2016 Annual Commitment System (ACS) Measures

This appendix includes measures for FY 2016. Revisions from last year are underlined. When OECA identifies the National Enforcement Initiatives (NEIs) for FY 2017-2019 in the FY 2017 Addendum to the NPM Guidance, the EPA will also identify ACS measures for the new NEIs.

ENVIRONMENTAL PROTECTION AGENCY Office of Enforcement and Compliance Assurance FY 2016 NPM GUIDANCE MEASURES APPENDIX						
G/ O/S *	**ACS Code**	**Measure Text**	**Non-Commitment Indicator (Y/N)**	**State Performance Measure (Y/N)**	**Planning Target[15]**	**National Target (FY 2016 Pres. Bud)**
5	**PBS-ATX03**	Number of facilities evaluated for compliance within the national focus areas.	N	N	Y	N
5	**PBS-ATX04**	Number of addressing actions at facilities within the national focus areas.	N	N	Y	N
5	**PBS-NSR01**	Number of NSR/PSD investigations of cement plants.	N	N	Y	N
5	**PBS-NSR02**	Number of investigation completion reports or referrals to DOJ for cement plants.	N	N	Y	N
5	**PBS-NSR03**	Number of NSR/PSD investigations of glass manufacturing plants.	N	N	Y	N
5	**PBS-NSR04**	Number of completion reports or referrals to DOJ for glass manufacturing plants.	N	N	Y	N
5	**PBS-NSR05**	Number of NSR/PSD investigations of nitric and/or sulfuric acid plants.	N	N	Y	N

[15] Annual Commitment System (ACS) planning targets for FY 2016 are negotiated between the EPA regions and headquarters during 2015. For the measures which encompass state activities, the EPA regions coordinate with the affected states on the planning targets as applicable.

5	**PBS-NSR06**	Number of investigation completion reports or referrals to DOJ for nitric and/or sulfuric acid plants.	N	N	Y	N
5	**PBS-NSR07**	Number of NSR/PSD investigations of coal-fired electric utilities.	N	N	Y	N
5	**PBS-NSR08**	Number of completion reports or referrals to DOJ for coal-fired electric utilities.	N	N	Y	N
5	**PBS-NSR09**	Number of facilities reviewed for prospective projects that trigger NSR.	N	N	Y	N
5	**PBS-M105**	Number of Phase 1 municipal separate storm sewer system permit assessments conducted.	N	N	Y	N
5	**PBS-M106**	Number of civil judicial referrals and/or addressing actions for sanitary sewer systems (SSS) with total treatment capacity ≥10 mgd.	N	N	Y	N
5	**PBS-M107**	Number of civil judicial referrals and /or addressing actions for CSS communities serving populations ≥50,000.	N	N	Y	N
5	**PBS-M108**	Number of civil judicial referrals and/or addressing actions for Phase I and II MS4s.	N	N	Y	N
5	**PBS-CAF002**	Number of federal AFO/CAFO inspections.	N	N	Y	N
5	**PBS-CAF007**	Number of federal CAFO addressing actions.	N	N	Y	N
5	**PBS-CAF008**	Submit 1 progress report per federal fiscal year.	N	N	Y	N
5	**PBS-MNP05**	Number of targeted mines, mineral processing facilities, or both, inspected.	N	N	Y	N
5	**PBS-EE01**	Number of compliance evaluations/inspections conducted in the air and water programs at land-based natural gas extraction and production facilities (e.g., wells, compressor stations, gas plants), and at disposal sites (e.g., injection wells, lagoons, ponds, land application). Land impacts and	N	N	Y	N

		inspections conducted under other media programs may be included per discussion and agreement with the EEPI Strategy Implementation Team.				
5	**PBS-EE03**	Number of land-based natural gas extraction and production addressing actions.	N	N	Y	N
5	**SDWA02**	During FY 2016, the primacy agency must address with a formal enforcement action or return to compliance the number of priority systems equal to the number of its PWSs that have a score of 11 or higher on the July 2015 ETT report. State, territory and tribal breakouts shall be indicated in the comment field of the Annual Commitment System. Please note: A primacy agency's success at addressing violations will be tracked by means of the quarterly ETT reports. Numerical targets may be adjusted at mid-year. While it remains the ERP's goal that all of a priority system's violations will be returned to compliance, a primacy agency has met its commitment under the FY 2016 SDWA ACS measures with respect to a priority system if the score for that system has been brought below, and remains below, 11.	N	Y	Y	N
5	**SRF01**	Finalize all Round 3 SRF reports for state CAA, CWA and RCRA enforcement programs scheduled for calendar year 2015 no later than December 31, 2015 (first quarter of FY 2016). By September 30, 2016, complete draft reports for all Round 3 SRF reviews scheduled for calendar year 2016. (Final reports are to be completed by December 31, 2016 (first quarter of FY 2017).) Regions in FY 2013 developed a plan to complete all Round 3 state reviews by the end of calendar year 2017. OC and OWM will hold annual discussions with regions to establish whether any modifications to the schedules are necessary.	N	N	Y	N
5	**EJ01**	Percentage of non-exempt cases brought by the EPA in areas determined by the EPA to have potential EJ concerns. [Note: While we are tracking this measure, there is no specific target number or trend we expect to achieve. EJ is one of many factors the Agency considers in bringing an enforcement action.]	Y	N	N	N

5	**FED-FAC05**	Conduct ten (10) federal facility inspections. These inspections may be done in federal facility enforcement priority areas, national areas of focus, national enforcement initiatives, regional priority areas, priorities established in federal facility regional enforcement enhancement plans, or as otherwise deemed necessary by the region. These 10 inspection commitments can be achieved through any combination of single media or multimedia inspections. For any multimedia inspection conducted, it shall count as up to four inspections toward this goal if up to four of the individual inspections support priority areas as listed above. All of these inspections may simultaneously satisfy inspection commitments required in any National Enforcement Initiative or other core program area. FFEO will be as flexible as possible in assisting the regions in meeting this vital federal facility commitment.	N	N	100 federal facility inspections nationally	N
5	**CWA07**	By December 31, provide to OECA a specific NPDES Compliance Monitoring Strategy (CMS) plan for the current year for each authorized state in the region and a regional plan wherever EPA direct implementation occurs (e.g., non-authorized states, territories, Indian country, pretreatment, etc.). Each CMS plan should be developed in accordance with the guidelines in Part 1 of the 2014 revised NPDES CMS. Any proposed alternative CMS plan should be provided to OECA for consultation and review by August 15, unless the region and OECA agree upon a later date. By December 31, provide for each state and EPA direct implementation area, a numerical end of year report on EPA and state CMS plan outputs from the prior year, by category and subcategory, corresponding to each of the planned CMS activities. The ACS commitment for each region should reflect the total number of state and regional CMS plans and end of year reports to be submitted to OECA for the year (e.g., an annual ACS commitment of 12 for a region that will submit six state and regional CMS plans and six state and regional CMS end-of-year reports).	N	N	Y	N

5	**CAA04**	The number of compliance evaluations to be conducted by the regions at majors sources, 80% synthetic minors, and other sources (as appropriate). [Note: Region should break out evaluation projections by source classification and by compliance monitoring category (FCE, PCE, and Investigations). For the total number of evaluations to be conducted, the region should also identify how many of these evaluations are in Indian country.] Projected investigations under this commitment are those investigations initiated by the regions for the air enforcement program outside of the National Enforcement Initiatives, and identified by the air program (e.g., MACT, NSPS).	N	N	Y	N
5	**CAA06**	Ensure that delegated state, tribal and local agencies implement their compliance and enforcement programs in accordance with the CAA CMS and have negotiated facility-specific CMS plans in place. The regions are to provide the number of FCEs at majors and 80% synthetic minors to be conducted by individual state/local agencies to demonstrate program implementation consistent with CMS. However, if a delegated agency negotiates with a Region an alternative CMS plan or alternative activities (pursuant to the CAA CMS national dialogue), this commitment should reflect the alternative plan. [Note: Break out evaluation and activity projections (e.g., FCEs; PCEs included in alternative plan) by source classification. Please indicate when a commitment is pursuant to an approved alternative plan.] Prior to approving an alternative plan, regions should consult with the Office of Compliance (OC) and provide OC with information on how the state, tribal or local agency compliance monitoring air resources will be redirected and the rationale for making the change.	N	Y	Y	N
5	**RCRA01**	Project by state, and Indian Country where applicable, the number of operating non-governmental TSDFs, to be inspected by the region during the year. Regions must commit to inspect at least two (2) TSDFs in each state or Indian country unless OECA approves a deviation from this requirement, as indicated in the initial OECA opening bid. Financial responsibility is an important component of the RCRA core program and evaluating compliance with 40 CFR Parts 264/265 Subpart H and corrective action financial	N	N	Minimum of 100 TSDFs nationally	N

		responsibility should be included in the RCRA core program inspections. Regions must commit to inspect at least the same number of financial assurance instruments at RCRA operating facilities as the region inspects for operating CEIs. Once a region exceeds the number of CEIs and FA instrument reviews from the final agreed upon bid, any additional CEIs will not require a corresponding FA instrument review. The determination of which financial assurance instruments to review should take into account the potential risk posed by the facility, the type of financial assurance instrument provided by the facility, and whether the financial assurance instrument has been previously reviewed and is the same type of instrument (this does not apply to the financial test, which may be reviewed each year). The review of financial assurance instruments is for RCRA Subtitle C closure and post-closure and includes corrective action if there is a corrective action obligation at the facility under review				
5	**RCRA01.s**	Project by state the number of operating TSDFs to be inspected by the state during the year. Note: Only one inspection per facility counts towards this coverage measure. The RCRA CMS establishes minimum annual inspection expectations for TSDFs. At least 50 percent of the operating non-governmental TSDFs in the state must be inspected annually. The onsite inspections for RCRA01 and RCRA01.s should be CEIs. Completing the commitment includes evaluating compliance with the financial assurance requirements, 40 CFR Parts 264/265 Subpart H. Financial responsibility is an important component of the RCRA core program and should be included as part of the inspection of each TSDF (although the financial responsibility reviews do not have to occur at the same time nor be conducted by the same people who conduct the field inspections).	N	Y	Y	N
5	**RCRA02**	Project by state and Indian country, the number of LQGs, including those at federal facilities, to be inspected by the region during the year. Each region must commit to inspect at least six (6) LQGs in each state, and 20% of the region's LQGs universe in Indian country, unless OECA approves a deviation from this requirement. For example, deviations are	N	N	Minimum of 300 LQG inspections nationally and 20% of LQGs in Indian Country	N

		given for states with small universes where it doesn't make sense for a region to inspect 6 LQGs per year or 20% of the region's LQG universe in Indian country. Regions should select at least 2 of the region's total LQG inspections at facilities described in the high priority section as areas of emerging environmental concern. Regions may work with OECA to coordinate these inspections, including whether the inspection will be conducted at a TSDF or LQG. In the Comment Section, provide the number of federal facility LQG inspections.				
5	**RCRA02.s**	Project by state the number of LQGs to be inspected by the state during the year. At least 20 percent of the LQG universe should be covered by combined federal and state inspections unless an alternative plan is approved under the RCRA CMS. The region should identify in the "Comment" field of BAS any state that is following an approved Alternative Plan and a breakout of the inspection numbers in the plan.	N	Y	Y	N
5	**RCRA03**	Inspect each operating TSDF operated by states, local, or Tribal governments.	N	N	Y	N
5	**HQ-VOL**	Volume of Contaminated Media Addressed (VCMA). As part of the Goal 5 sub-objective, Support Cleaning up Our Communities, the following is the GPRA target: *By 2015, obtain commitments to clean up 1.5 billion cubic yards of contaminated soil and groundwater media as a result of concluded CERCLA and RCRA corrective action enforcement actions.* OECA has reported VCMA for contaminated soil and groundwater media as separate measures in its annual results since 2004. The GPRA target is a national target and regions are not required to post commitments in ACS.	N	N	200 million cubic yards	N
5	**TSCA 01OC**	Project the total number of FY 2016 TSCA inspections. In the comment field of the Annual Commitment System (ACS), the region shall break out the number of projected inspections by TSCA program area (LBP, PCBs, Asbestos, New and Existing Chemicals). *Note: The LBP component of this TSCA ACS commitment (TSCA 01OC) will serve as an*	N	N	Y	N

		OECA FY 2016 measure of compliance work being done to protect children's health.				
5	**TSCA 02OC**	Report other compliance monitoring activities at the end of the year; and break-out the description of other such activities by TSCA program area. (See the CMS for more details).	Y	N	N	N
5	**FIFRA-FED1**	Project regional (federal) FIFRA inspections. Each region should conduct a minimum of ten (10) FIFRA inspections. In the Comment Section, provide the number of federal facility inspections.	N	N	Minimum of 100 FIFRA federal inspections nationally	N
5	***NEW* FIFRA-FED 2**	For EPA regions with direct implementation responsibilities in Indian country and states without primacy, project the number of regional (federal) FIFRA inspections focused on the Worker Protection Standard (WPS).	N	N		N
5	**OSRE-01**	Reach a settlement or take an enforcement action by the start of remedial action at 99% of non-federal Superfund sites that have viable, liable parties.	N	N	99 percent	N
5	**OSRE-02**	Address all unaddressed costs in Statute of Limitations cases for sites with total past Superfund costs equal to or greater than $500,000 in value via settlement, referral to DOJ, filing a claim in bankruptcy, or where appropriate write-off.	N	N	100 percent of cases	N
5	**EPCRA 01**	Conduct at least four (4) EPCRA 313 data quality inspections.	N	N	Minimum of 40 nationally	N
5	**EPCRA 02**	Conduct at least twenty (20) EPCRA 313 non-reporter inspections (and/or other compliance monitoring activities as determined by the compliance monitoring national dialogue).	N	N	Minimum of 200 nationally	N

**Goal/Objective/Sub-Heading*

Appendix 3 - EXPLANATION OF CHANGES BETWEEN FY 2014-2015 AND FY 2016-2017 GUIDANCE

Office of Enforcement and Compliance Assurance

Change from FY 2015 Addendums and FY 2014 NPM Guidance		Reason for Change	Location of New/Modified Information
General	Addition: The **introduction** was expanded for FY 2016-2017 to summarize how early input from stakeholders influenced the draft NPM Guidance, reference regional Climate Change Adaptation Plans, highlight opportunities and guidelines for seeking flexibility when implementing OECA's NPM Guidance and related activities, and highlight OECA projects that are in alignment with EPA's E-Enterprise Goals.	The updated language takes into account early input and necessary updates for FY 2016-2017.	Pages 1-4 of draft FY 2016-2017 NPM Guidance.
National Areas of Focus	Addition: The **introduction to the National Areas of Focus** was expanded to briefly summarize the process and timing for selecting OECA's FY 2017-2019 National Enforcement Initiatives (NEIs).	The updated language shares information with stakeholders on the process/timing for selecting FY 2017-2019 NEIs.	Page 4
	Modification: The description of the priority area **Assuring Safe Drinking Water** was updated to specifically address some small systems that remain in persistent noncompliance despite primacy agency efforts.	The description was updated to note that EPA, states and tribes will work together to explore root causes of noncompliance and options for resolving them to ensure all available tools, resources and partners are engaged to help these small systems operate safely, comply with SDWA and become sustainable if possible.	Page 8
	Modification: The activities under **Implementing the Clean Water Act (CWA) Action Plan** were updated for FY 2016-2017 to take into account the NPDES Electronic Reporting Rule.	The activities were modified to take into account actively marketing NetDMR, Net and other e-reporting tools to the regulated community; training permittees; ensuring state and regional general permit requirements are entered into ICIS or state NPDES program data management system;	Pages 11-12

		reviewing state and regional general permit paper forms to evaluate consistency with Appendix A in the Proposed NPDES e-reporting rule.	
	Modification: State activities under **Implementing the Clean Water Act (CWA) Action Plan** were updated for FY 2016-2017 to further address e-reporting.	In FY 2016-2017, states should: work towards implementation of e-reporting; educate and train the regulated community; and develop e-reporting tools or use EPA tools (NetDMR; NeT).	Page 12
	Modification: OECA updated the description and activities section on **Advancing Next Generation Compliance** for FY 2016-2017.	OECA updated the activities for FY 2016-2017.	Pages 13-15
	Modification: OECA added a **State Review Framework** activity for regions for FY 2016-2017.	During FY 2016-2017, regions will implement any regional components to address the agreed-upon national focus issues under the "National Approach to Common State Enforcement Program Issues (Common Issues) project." OECA is coordinating with regions and ECOS on the common issues project.	Page 16
Program-Specific Guidance	Addition: A section on EPA's **Field Operations Group (FOG) Guidelines** was added for FY 2016-2017.	Regions and Headquarters intend to complete development and implementation of policies, procedures and systems that fully address EPA's ten Field Operations Group (FOG) Guidelines by the February 2016 deadline established by EPA's Deputy Administrator.	Pages 17-18
	Modification**:** The **Environmental Justice (EJ)** section was revised to reference that OECA leverages other initiatives and priorities that promote action in communities, such as Next Gen Compliance and the EPA's Cross-Agency Strategies, as appropriate. The language related to NEIs and Next Gen Compliance was updated for FY 2016-2017.	Regions are asked to consider EJ in the implementation of the NEIs. Also, where appropriate, when designing compliance and enforcement actions to gain the greatest possible environmental benefits in overburdened communities, regions should incorporate Next Gen Compliance principles, tools or approaches as appropriate.	Pages 18-19

	Modification: OECA's **Federal Facilities Enforcement Office (FFEO)** updated the description and regional activities within the FFEO section to reflect changes for FY 2016-2017.	FFEO updated the regional activities section to reflect changes in focus for FY 2016-2017 and to reference Regional Enforcement Plans.	Pages 20-21
	Modification: OECA updated regional activities in the **CWA NPDES** section.	Language on timing for submission of draft alternative Compliance Monitoring Strategy plans was included. The existing bullet on coordinating with the Center of Excellence for Biosolids was revised to recommend accessing biosolid program annual reports as needed.	Pages 23, 24
	Modification: In the **RCRA Subtitle C Hazardous Waste** Program section, OECA updated the regional focus areas.	OECA updated language on regional focus areas.	Page 30
	Modification**:** The description section for the **RCRA Underground Storage Tank (UST)** Subtitle I Program was updated for FY 2016-2017. The regional activity bullets were updated to address factors to consider when prioritizing inspections, timely and accurate reporting of data into RCRAInfo and ICIS, and encouraging states to optimize deterrence from the impact of enforcement by utilizing efficiencies within their authority including the use of delivery prohibition and addressing noncompliance on a corporate-wide basis statewide or other opportunities.	OECA updated the RCRA UST description/background section and a few regional activity bullets to appropriately address the focus for FY 2016-2017, taking into account early input from the program office.	Pages 31-32
	Modification: The description highlights that OECA has updated its Model 3008(h) administrative order on consent (AOC). A couple of regional activities for **RCRA Corrective Action** were updated for FY 2016-2017.	Regions were asked to leverage federal, state, tribal, local and other partnerships (e.g. EPA-FEMA MOU) to better coordinate resources; improve cleanups using greener and more resilient and sustainable practices; and revitalize sites through policy, guidance and, when appropriate, agreements and comfort	Pages 32-33

		letters. Implementation of Regional Climate Change Adaptation Plans were also referenced.	
	Modification: OECA updated the organization, heading and description/ background section for **TSCA Chemical Risk Reduction Programs;** the description indicates that regions should develop a plan for their overall TSCA inspections and other compliance activities based on the available resources and that prioritizes the problems to be addressed along with how the regions are providing oversight of state programs. If a region chooses not to develop a plan for its TSCA program, then the region shall use the distribution discussed in the NPM Guidance for TSCA resource allocation. This language is referenced via footnote in each TSCA section.	The revised language provides flexibility to a regional office to develop a plan for their TSCA program (inspections and other compliance activities) based on resources available in lieu of using the TSCA resource allocation approach outlined in the TSCA section of the NPM Guidance. This language is referenced via footnote in each TSCA section.	Page 34
	Modification: OECA updated and consolidated the **FIFRA** section of the FY 2016-2017 Guidance taking into account early input received from stakeholders. The updated FIFRA section discusses activities under the following 3 focus areas: Pesticide Product Integrity; Border Compliance; and Worker Protection Standards.	The updated activities in each FIFRA area take into account the early input received from stakeholders.	Pages 40-43
	Modification**:** A couple of regional activity bullets were updated in the **CERCLA** section.	Regions were asked to leverage federal, state, tribal or local and other partnerships (e.g. EPA-FEMA MOU) to better coordinate resources; improve cleanups using greener and more resilient and sustainable practices; and revitalize sites through policy, guidance, and, when appropriate, agreements and comfort letters. Implementation of Climate	Page 44

		Change Adaptation Plans were also referenced.	
Annual Commitment Measures	Modification**:** Updated language for FY 2016 was incorporated into the following ACS measures: **PBS EEO1, FED-FAC05, CWA 07 and CAA04.** For 4 other measures (SDWA02, SRF01, TSCA01 OC, OSRE-02), the fiscal year reference was updated to FY 2016 or a non-substantive edit was made relative to the existing measure.	Language was updated for FY 2016. All revisions are underlined in Appendix 1.	Appendix 2, pages 3, 4 and 5. PBS EE01 – page 3 FED-FAC05 – page 4 CWA07 – page 4 CAA04 - page 5
	Addition**:** A new ACS measure **FIFRA-Fed2** was included for FY 2016 to address regional inspections focused on the Worker Protection Standard (WPS).	A new ACS measure was included for FY 2016 to reflect the focus area of WPS. The ACS measure language reads as follows: For EPA regions with direct implementation responsibilities in Indian country and states without primacy, project the number of regional (federal) FIFRA inspections focused on the Worker Protection Standard (WPS).	Appendix 2, page 8.

Appendix 4 – OECA Key Contacts for each section of FY 2016-2017 NPM Guidance

Note: For the convenience of readers, more than one OECA contact is listed for most of the subject areas below.

Contact Name	Subject Area	Phone	Email
Scott Throwe Phil Brooks	Clean Air Act (CAA) National Enforcement Initiative (NEI): Cutting Toxic Air Pollution that Affects Communities' Health	202-564-7013 202-564-0652	throwe.scott@epa.gov brooks.phil@epa.gov
Ed Messina Phil Brooks Apple Chapman	CAA NEI: Reducing Widespread Air Pollution from the Largest Sources, Especially the Coal-fired Utility, Cement, Class, and Acid Sectors	202-564-2300 202-564-0652 202-564-5666	messina.ed@epa.gov brooks.phil@epa.gov chapman.apple@epa.gov
Rick Duffy Loren Denton Seth Heminway	Clean Water Act (CWA) NEI: Keeping Raw Sewage and Contaminated Storm water Out of Our Nation's Waters	202-564-5014 202-564-1148 202-564-7017	duffy.rick@epa.gov denton.loren@epa.gov heminway.seth@epa.gov
Mark Pollins Martha Segall Carol Galloway Kathy Greenwald	CWA NEI: Preventing Animal Waste from Contaminating Surface and Ground Waters	202-564-4001 202-564-0723 913-551-5092 202-564-3252	pollins.mark@epa.gov segall.martha@epa.gov galloway.carol@epa.gov greenwald.kathryn@epa.gov
Martha Segall Joyce Chandler Carol King	Assuring Safe Drinking Water	202-564-0723 202-564-7073 202-564-2412	segall.martha@epa.gov chandler.joyce@epa.gov king.carol@epa.gov
Van Housman	Reducing Pollution from Mineral Processing Operations NEI	202-564-0143	housman.van@epa.gov
Mamie Miller Andrew Stewart Rob Lischinsky	Assuring Energy Extraction Sector Compliance with Environmental Laws NEI	202-564-7011 202-564-1463 202-564-2628	miller.mamie@epa.gov stewart.andrew@epa.gov lischinsky.robert@epa.gov
Martha Segall Seth Heminway Joe Theis Mahri Monson	Implementing the Clean Water Act (CWA) Action Plan	202-564-0723 202-564-7017 202-564-4053 202-564-2657	segall.martha@epa.gov heminway.seth@epa.gov theis@joseph@epa.gov monson.mahri@epa.gov
David Hindin George Wyeth	Advancing Next Generation Compliance	202-564-1300 202-566-2203	hindin.david@epa.gov wyeth.george@epa.gov
Chris Knopes Mike Mason	Strengthening State Performance and Oversight	202-564-2337 202-564-0572	knopes.christopher@epa.gov mason.michael@epa.gov
Rick Duffy Tracy Back	Field Operations Guidance (FOG) Guidelines	202-564-5014 202-564-7076	duffy.rick@epa.gov back.tracy@epa.gov
Arati Tripathi	Environmental Justice	202-564-2044	tripathi.arati@epa.gov

Lance Elson Marie Muller	Federal Facilities	202-564-2577 202-564-0217	elson.lance@epa.gov muller.marie@epa.gov
Martha Segall Seth Heminway Rebecca Roose Joe Theis Mahri Monson	CWA National Pollutant Discharge Elimination System (NPDES) Program for Compliance Assurance and Enforcement	202-564-0723 202-564-7017 202-566-1387 202-564-4053 202-564-2657	segall.martha@epa.gov heminway.seth@epa.gov roose.rebecca@epa.gov theis.joseph@epa.gov monson.mahri@epa.gov
Joe Theis	CWA Section 404 – Discharge of Dredge and Fill Material	202-564-4053	theis.joseph@epa.gov
Martha Segall Joe Theis Dan Chadwick	CWA Section 311 – Oil Pollution Act	202-564-0723 202-564-4053 202-564-7054	segall.martha@epa.gov theis.joseph@epa.gov chadwick.dan@epa.gov
Loren Denton Martha Segall Dan Chadwick	SDWA Underground Injection Control (UIC) Program	202-564-1148 202-564-0723 202-564-7054	denton.loren@epa.gov segall.martha@epa.gov chadwick.dan@epa.gov
Julius Banks Rob Lischinsky	CAA Program for Compliance Assurance and Enforcement	202-564-0957 202-564-2628	banks.julius@epa.gov lischinsky.rob@epa.gov
Craig Haas Todd Stedeford Greg Sullivan Julius Banks Rob Lischinsky	CAA Section 112(r)	202-564-6447 202-564-2977 202-564-1298 202-564-0957 202-564-2628	haas.craig@epa.gov stedeford.todd@epa.gov sullivan.greg@epa.gov banks.julius@epa.gov lischinsky.rob@epa.gov
Diana Saenz Elizabeth Vizard	RCRA Subtitle C Hazardous Waste Program	202-564-4209 202-566-5940	saenz.diana@epa.gov vizard.elizabeth@epa.gov
Yolaanda Walker	RCRA Underground Storage Tank UST Subtitle I Program	202-564-4281	walker.yolaanda@epa.gov
Peter Neves Paul Borst	RCRA Corrective Action	202-564-6072 202-564-7066	neves.peter@epa.gov borst.paul@epa.gov
Todd Stedeford Greg Sullivan Elizabeth Vizard Everett Bishop Shirley Fan	TSCA[16] • Lead Risk Reduction Program • New and Existing Chemicals Program • PCB Program • Asbestos Program/AHERA	202-564-2977 202-564-1298 202-566-5940 202-564-7032 202-564-2425	stedeford.todd@epa.gov sullivan.greg@epa.gov vizard.elizabeth@epa.gov bishop.everett@epa.gov fan.shirley@epa.gov
Don Lott	• FIFRA	202-564-2652	lott.don@epa.gov

[16] The TSCA contacts can respond to questions on the TSCA subject areas. Everett Bishop is the Office of Compliance (OC) staff contact for PCB and asbestos program questions.

James Miles Elizabeth Vizard Helene Ambrosino		202-564-5161 202-566-5940 202-564-2627	miles.james@epa.gov vizard.elizabeth@epa.gov ambrosino.helene@epa.gov
Paul Borst	CERCLA	202-564-7066	borst.paul@epa.gov
Kathy Clark Greg Sullivan Todd Stedeford Elizabeth Vizard	EPCRA 313 Toxics Release Inventory	202-564-4164 202-564-1298 202-564-2977 202-564-5940	clark.kathy@epa.gov sullivan.greg@epa.gov stedeford.todd@epa.gov vizard.elizabeth@epa.gov
Craig Haas Greg Sullivan Todd Stedeford	EPCRA 304, 311/312 and CERCLA 103	202-564-6447 202-564-1298 202-564-2977	haas.craig@epa.gov sullivan.greg@epa.gov stedeford.todd@epa.gov
Kim DePaul Bob Heiss*	<u>Federal Activities</u> • NEPA compliance and Environmental Impact Statement reviews • Import/export of hazardous waste and international capacity building*	202-564-7128 202-564-4108	depaul.kimberley@epa.gov heiss.robert@epa.gov
Pat Straw Julie Lastra	Criminal Enforcement Program	202-564-2513 202-564-6510	straw.patricia@epa.gov lastra.julie@epa.gov
Jonathan Binder Fran Jonesi	OECA Tribal Issues	202-564-2516 202-564-7043	binder.jonathan@epa.gov jonesi.fran@epa.gov
Michele McKeever Maureen Lydon Kim Chavez	OECA's FY 2016-2017 National Program Manager (NPM) Guidance	202-564-3688 202-564-4046 202-564-4298	mckeever.michele@epa.gov lydon.maureen@epa.gov chavez.kimberly@epa.gov

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Evaluation Report

EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities

Report No. 10-P-0066

February 17, 2010



Report Contributors:

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Abbreviations

CBI	Confidential Business Information
EPA	U.S. Environmental Protection Agency
FY	Fiscal Year
NOC	Notice of Commencement
OECA	Office of Enforcement and Compliance Assurance
OECD	Organisation for Economic Cooperation and Development
OIG	Office of Inspector General
OPPT	Office of Pollution Prevention and Toxics
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
PMN	Premanufacture Notice
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act

Cover: From left to right: Toxic chemicals (photo courtesy New York State Department of Environmental Conservation); chemical testing (photo courtesy EPA); storage tanks at a chemical facility (photo courtesy U.S. Department of Homeland Security).

U.S. Environmental Protection Agency
Office of Inspector General

10-P-0066
February 17, 2010

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We conducted this evaluation to review the U.S. Environmental Protection Agency's (EPA's) implementation of the Toxic Substances Control Act (TSCA) by determining how well EPA's processes for oversight and regulation meet the objectives of TSCA, and whether the performance measures accurately reflect EPA's assurance that the objectives of TSCA are met.

Background

EPA is responsible for ensuring that new chemicals entering commerce do not pose unreasonable risk to human health and the environment. The Office of Pollution Prevention and Toxics (OPPT) is responsible for reviewing industry submissions and managing risks from new chemicals. The Office of Enforcement and Compliance Assurance (OECA) provides assistance and monitors compliance.

For further information, contact our Office of Congressional, Public Affairs and Management at (202) 566-2391.

To view the full report, click on the following link:
www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf

EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities

What We Found

EPA does not have integrated procedures and measures in place to ensure that new chemicals entering commerce do not pose an unreasonable risk to human health and the environment. We found that EPA's New Chemicals Program had limitations in three processes intended to identify and mitigate new risks – assessment, oversight, and transparency. The program is limited by an absence of test data and a reliance on modeling because TSCA does not require upfront testing as part of a Premanufacture Notice (PMN) submission. PMN submitters are required to submit health and safety data in their possession and a description of data known to or reasonably ascertainable by the submitter at the time of its submission. Nonetheless, the majority of PMN submissions do not include chemical toxicity or environmental fate data. Oversight of regulatory actions designed to reduce known risks is a low priority, and the resources allocated by EPA are not commensurate with the scope of monitoring and oversight work. In addition, EPA's procedures for handling confidential business information requests are predisposed to protect industry information rather than to provide public access to health and safety studies.

OPPT's and OECA's respective performance measures for managing risks from new chemicals do not accurately reflect program performance in preventing risk, nor do they assure compliance. In cases where full information does not exist or analyses are limited, OPPT reports the new chemicals as not having risk, while the limitations in the measure are not disclosed. OECA's performance measure is not outcome based; rather, the measure tracks program activities.

What We Recommend

We recommend that EPA better coordinate risk assessment and oversight activities by establishing a management plan that contains new goals and measures that demonstrate the results of OPPT and OECA actions. We recommend that the Office of Prevention, Pesticides, and Toxic Substances establish criteria for selecting chemicals or classes of chemicals for low-level exposure and cumulative risk assessments, and develop confidential business information classification criteria to improve EPA's transparency and information sharing. Finally, we recommend that OECA develop a management plan for Core TSCA enforcement that includes training, consistent enforcement strategies across regions for monitoring and inspection protocols, and a list of manufacturers and importers of chemicals for strategic targeting. The Agency agreed with our recommendations.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

February 17, 2010

MEMORANDUM

SUBJECT: EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities
Report No. 10-P-0066

FROM: Wade T. Najjum
Assistant Inspector General
Office of Program Evaluation

TO: Bob Perciasepe
Deputy Administrator

Steve Owens
Assistant Administrator for Prevention, Pesticides, and Toxic Substances

Cynthia Giles
Assistant Administrator for Enforcement and Compliance Assurance

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established resolution procedures.

The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time – is $786,181.

Action Required

In accordance with EPA Manual 2750, you are required to provide a written response to this report within 90 calendar days. You should include a corrective actions plan for agreed-upon actions,

including milestone dates. We have no objections to the further release of this report to the public. This report will be available at: http:www.epa.gov/oig.

If you or your staff have any questions regarding this report, please contact me at 202-566-0827 or najjum.wade@epa.gov, Jeffrey Harris at 202-566-0831 or harris.jeffrey@epa.gov, or Jill Ferguson at 202-566-2718 or ferguson.jill@epa.gov.

Table of Contents

Chapters

Appendices

Chapter 1
Introduction

Purpose

The objective of this evaluation was to assess the U.S. Environmental Protection Agency's (EPA's) implementation of the Toxic Substances Control Act (TSCA), with a focus on EPA's policies, procedures, and authority for managing risks to human health and the environment posed by new chemicals. Specifically, we sought to answer the following questions:

(1) How well do EPA processes for new chemical oversight and regulation meet the objectives of TSCA?
(2) Do the performance measures accurately reflect EPA's assurance that the objectives of TSCA are being achieved?

Background

In 1976, Congress passed the Toxic Substances Control Act to protect human health and the environment from risks associated with toxic chemicals.[1] The Act authorized EPA to collect information on, and to regulate the production and distribution of, chemicals. TSCA required EPA to (i) create an inventory of "existing chemicals" already in commerce, (ii) regulate unreasonable risk from "new chemicals" introduced into commerce subsequent to the Act, and (iii) make health and safety information available for examination while protecting manufacturers' confidential business information (CBI).

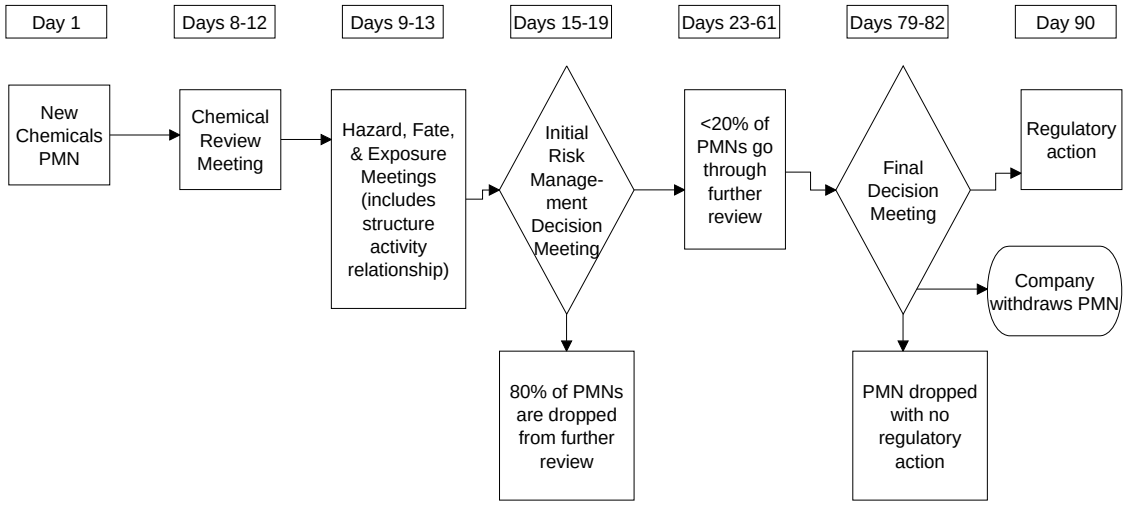
TSCA authorized EPA to identify and regulate unreasonable risks from new chemicals prior to manufacture or import. However, TSCA limits EPA's authority to require industry to conduct health and safety studies. Therefore, EPA's oversight is largely dependent on available data on comparable chemicals and any information provided by manufacturers and importers. To request additional information on chemical safety from industry, EPA must first make a determination that the chemical presents an unreasonable risk. In addition, EPA must ensure that the burden of EPA's request is commensurate with the potential harm from exposure to the new chemical. Although TSCA does not specifically authorize EPA to continually review the safety of a chemical once it enters commerce, Section 8(e) of TSCA requires producers and importers to maintain records and report to EPA any newly identified risks or harm from their chemicals – whether existing or new.

[1] TSCA excludes chemicals in pesticides, food, pharmaceuticals, tobacco, and firearms that are regulated by other statutes.

The New Chemicals Program

Manufacturers and importers must submit a Premanufacture Notice (PMN) to EPA at least 90 days prior to introducing a new chemical into commerce. EPA's multistep review process and tools to review PMNs are illustrated in Figure 1-1. Teams of EPA technical experts, including scientists, engineers, and toxicologists, use computer models to predict the potential toxic effects of a chemical based on available data. A PMN remains valid indefinitely once it has gone through the 90-day review period regardless of when (or whether) the chemical is manufactured or imported. Within 30 days of manufacture or import, a Notice of Commencement (NOC) must be submitted to EPA, at which time EPA adds the substance to the TSCA inventory.

Figure 1-1: New Chemicals Review Process

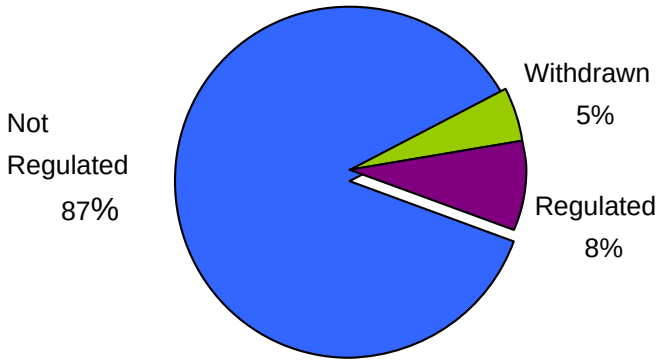


Source: EPA.

EPA can manage potential unreasonable risks found during the PMN review process through Consent Orders[2] and Significant New Use Rules (SNURs).[3] Between 1996 and 2008, EPA received approximately 1,500 PMNs annually, on average. As illustrated in Figure 1-2, on average, less than 10 percent were regulated.

[2] Through a Consent Order, EPA places certain conditions on the manufacture/import of the chemical, often including a requirement for more testing to be done on the chemical.
[3] A SNUR extends the requirements of a Consent Order to other manufacturers/importers, or puts restrictions on uses of the chemical other than those identified in the PMN. If EPA makes a determination that a chemical will cause harm to human health or environment, TSCA gives EPA authority to ban the chemical from manufacture or import.

Figure 1-2: Average Fate of PMNs Submitted to EPA



Source: EPA.

TSCA also implements the intent of Congress that health and safety studies for chemicals introduced into commerce be made available to the public. However, manufacturers and importers can request protection of CBI in health and safety studies submitted pursuant to PMN and Section 8(e) notice requirements.

Finally, TSCA directs that EPA collect a fee to defray the costs of assessing risks from new chemicals. The PMN fee is capped at $2,500 and $100 for large and small businesses, respectively. This fee cap has remained the same since TSCA was enacted in 1976. EPA began charging the fee in 1988.

EPA's Implementation and Oversight of TSCA

Two offices at EPA are primarily responsible for implementing TSCA: the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) and the Office of Enforcement and Compliance Assurance (OECA). Within OPPTS, the Office of Pollution Prevention and Toxics (OPPT) is responsible for reviewing submitter information and managing risks from new chemicals. As EPA's compliance and enforcement arm, OECA is responsible for providing assistance, monitoring, and enforcing compliance with TSCA by inspecting manufacturers and importers.

OPPT activities related to managing risk from new chemicals include:

- Developing guidance and tools for PMN submission review
- Reviewing PMNs and NOCs
- Maintaining the TSCA and CBI inventories, with periodic updates from information received under the Inventory Update Rule
- Restricting the manufacture of certain chemicals (based on results of PMN review) with Consent Orders and SNURs
- Reviewing risk information identified on Section 8(e) notices
- Making health and safety data available to the public

OECA activities related to Core TSCA[4] include providing compliance assistance and incentives as well as conducting inspections to ensure manufacturers and importers:

- submit required notices to EPA such as PMNs and NOCs,
- comply with terms of Consent Orders and SNURs,
- report any newly identified risk or harm as Section 8(e) notices,
- maintain all records of manufacturing, and adverse reactions to health or the environment by a chemical, as required by TSCA.

Noteworthy Achievements

EPA established an inventory of 62,000 existing chemicals when TSCA was enacted. Since then, EPA has added 23,000 new chemicals to the inventory. Through September 2008, EPA had regulated 1,432 chemicals by means of Consent Orders and issued a total of 1,415 SNURs. In addition, OPPT's New Chemicals Program developed and shared risk assessment models with industry.

Scope and Methodology

Our evaluation focused on EPA's strategy and processes for preventing risk from new chemicals under its Core TSCA responsibilities. Specifically, we evaluated how OPPT assesses and regulates risk from new chemicals through the PMN review process (TSCA Sections 5 and 8) and how OECA ensures compliance with Core TSCA submissions and manufacturing and importing restrictions (TSCA Sections 4, 5, 8, 12, and 13). We did not review EPA's management of risk from "existing chemicals"; however, incidental references to existing chemicals are included when relevant to the current discussion. We also reviewed EPA's policies and processes for making significant risk information from chemicals available to the public (TSCA Section 14). In addition, we reviewed the amount and history of the PMN submission fee (TSCA Section 26). We performed our evaluation between December 2008 and December 2009.

We conducted literature reviews, interviewed EPA staff and external experts, and analyzed EPA processes, measures, and data. We evaluated OPPT goals, measures, and data related to the prevention of unreasonable risk from new chemicals, as well as OECA goals, measures, and data for compliance assistance, inspections, and enforcement for regions and Headquarters. Appendix A includes a logic model we developed to identify shared or overlapping responsibilities of OPPT and OECA for managing risk from new chemicals. The logic model also shows how their activities, outputs, and outcomes contribute to the meeting of

[4] Core TSCA is the generic name for Title I that includes the major provisions of Sections 4, 5, 8, 12, and 13. TSCA consists of Title I: Control of Toxic Substance (also known as Core TSCA), and the subsequent amendments: Title II: Asbestos Hazard Emergency Response, Title III: Indoor Radon Abatement, and Title IV: Lead Exposure Reduction.

EPA's long-term goal of protecting human health and the environment from new chemical risks.

We conducted this review in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the review to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based upon our objectives.

Chapter 2
EPA Lacks a Coordinated Process for Ensuring Risk Mitigation

EPA is responsible for meeting TSCA's objective that new chemicals entering commerce do not pose an unreasonable risk to human health and the environment. However, EPA does not have integrated procedures and measures in place to ensure that it is achieving this objective. We found limitations in the three processes intended to identify and mitigate new risks – assessment, oversight, and transparency. EPA's New Chemicals Program is limited by the absence of test data and a reliance on modeling, because TSCA does not require upfront testing as part of a PMN submission. PMN submitters are required to submit health and safety data in their possession and a description of data known to or reasonably ascertainable by the submitter at the time of their submission. Nonetheless, the majority of PMN submissions do not include chemical toxicity or environmental fate data. Oversight of regulatory actions designed to reduce known risks is a low priority, and the resources allocated by EPA are not commensurate with the scope of monitoring and oversight work. Finally, EPA's procedures for handling CBI requests are predisposed to protect industry information rather than to provide public access to health and safety studies.

Limitations of Risk Assessment of New Chemicals

EPA's New Chemicals Program is limited by an absence of test data and the resulting reliance on existing information and models to overcome data gaps. To perform new chemical reviews, OPPT uses the information manufacturers submit on PMNs. According to OPPT managers, approximately 50 percent of the PMN submissions contain no test data, and close to 85 percent contain no toxicity data. In addition, only a few submissions contain environmental effects and fate data for the chemical. In the absence of test data, OPPT must rely upon expert analyses, comparisons with structurally similar chemicals, and models in order to perform its risk assessments. Specifically, reviewers utilize analog data on other PMN chemicals, Section 8(e) data, modeling tools, and/or regulatory options to support screening-level risk assessments.

External reviewers, including nongovernmental organizations, academics, and peers, have repeatedly expressed concerns that EPA's New Chemicals Review Process is limited because of its dependence on risk assessment models. As far back as 1994, a review by the Organisation for Economic Cooperation and Development (OECD) found that due to a paucity of experimental data, EPA has to rely on predictive methods that estimate the properties of a chemical.[5]

[5] Organisation for Economic Co-operation and Development, *US EPA/EC Joint Project on The Evaluation of (Quantitative) Structure Activity Relationships*, OCDE/GD(94)28, Environment Monograph No. 88, 1994.

According to the OECD report, the models in use by OPPT at the time of its review had good predictive capabilities for ecotoxicity, but had limited predictive capabilities for general systemic health effects.

More recently, Environmental Defense Fund scientists expressed concern that the models are not accurate in predicting risks from prolonged low-level exposure to chemicals. Currently, OPPT analyzes each new chemical in isolation without factoring in potential risks from multiple exposure pathways or from exposure to multiple chemicals. The National Research Council recently recommended that EPA revise its risk assessment process to assess cumulative exposure risks from multiple chemicals, because human health and environment are not exposed to one chemical at a time.[6] Additionally, pervasive CBI redactions inhibit independent peer reviews and oversight by independent and external knowledgeable parties.[7]

In order to complete PMN risk assessments, OPPT also refers to information on similar existing chemicals found in EPA's Integrated Risk Information System database. The database currently contains only 553 of the more than 80,000 chemicals in the TSCA inventory. At present, just 67 of those 553 substances have complete toxicological information.

The incomplete information available on existing chemicals further limits the amount of information upon which OPPT can assess the risk of new chemicals. Because OPPT depends on information reported by industry, it might miss chemical risks not self-disclosed by manufacturers. The models OPPT has developed are useful tools for estimating the risk of new chemicals, but are not as reliable as actual test data, particularly for some health threats.

If no potential risks are identified within the 90-day review period, the chemical may be manufactured after submitting a NOC. However, given the limitations of the review process, EPA's assurance that new chemicals or organisms introduced into commerce do not pose unreasonable risks to workers, consumers, or the environment is not supported by data or actual testing.

Limited Oversight of New and Existing Chemicals

Oversight of regulatory actions designed to reduce known chemical risks is a low priority. The resources allocated by EPA are not commensurate with the scope of monitoring and oversight work. One of OECA's responsibilities is to develop strategies, tools, and priorities to ensure compliance with Core TSCA regulations. We found that OECA's oversight of Core TSCA-regulated entities is inconsistent and presents a minimal presence. Further, OECA does not provide feedback to

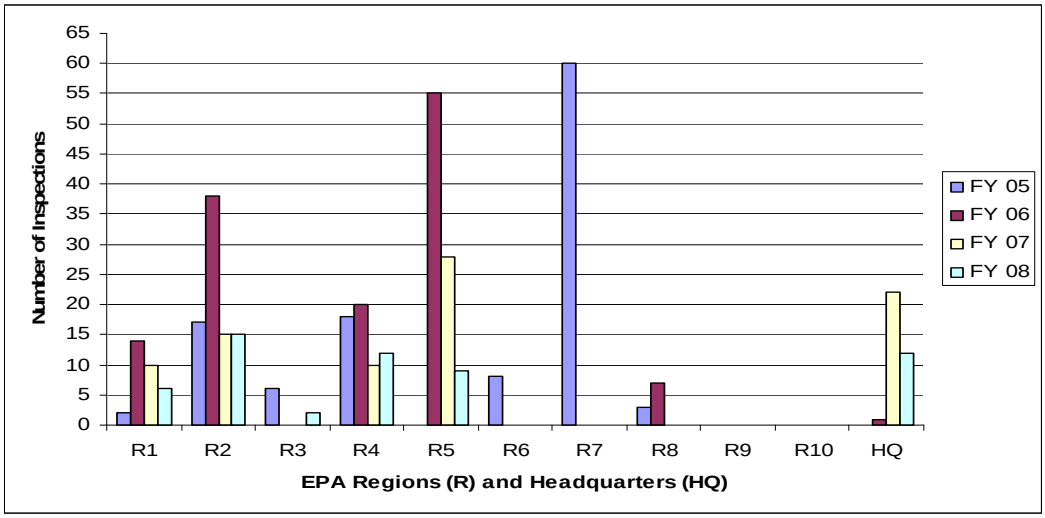
[6] Committee on the Health Risks of Phthalates, *Phthalates and Cumulative Risk Assessment: The Tasks Ahead,* National Research Council, 2008.
[7] Denison, Richard A., "Ten Essential Elements in TSCA Reform," *Environmental Law Review*, 2009.

OPPT regarding the results of its oversight activities, preventing an Agency assessment of how effectively EPA's New Chemicals Program is implemented.

Enforcement resources are not commensurate with the scope of work. The number of inspectors is declining and their allocation is not determined by potential risks. Over the course of the Core TSCA program, OECA has shifted responsibility for conducting inspections among regions; OECA headquarters; the Core TSCA Enforcement Center in Denver, Colorado; and combinations thereof. During the last resource shift in 2001, regions were offered the responsibility for ensuring compliance. Only Regions 2, 4, and 5 assumed responsibility for Core TSCA enforcement, while OECA Headquarters and the Core TSCA Enforcement Center assumed responsibility for the remaining seven regions. This dispersed responsibility has led to an inconsistent approach and process that hinders effective oversight.

EPA claims that deterrence is an essential element in its environmental compliance monitoring and enforcement program. However, only 56 Core TSCA inspections were conducted in Fiscal Year (FY) 2008 in a universe that is estimated to include hundreds of thousands of regulated entities. We found that there was minimal or no oversight in some regions (i.e., 3, 6, 8, 9, and 10). Figure 2-1 illustrates the trends in inspections from FY 2005 through FY 2008. According to Region 6 and 9 personnel, these two regions have a high concentration of chemical manufacturers and importers. Despite the large ports in Region 9 and numerous chemical manufacturers in Region 6, there are no TSCA inspectors to monitor compliance or coordinate with U.S. Customs and Border Protection inspections. Moreover, these regions are not informed of OECA inspections within their jurisdiction because OECA Headquarters staff does not coordinate inspections with these regions.

Figure 2-1: Number of Core TSCA Inspections by EPA Region and Headquarters, Fiscal Years 2005- 2008

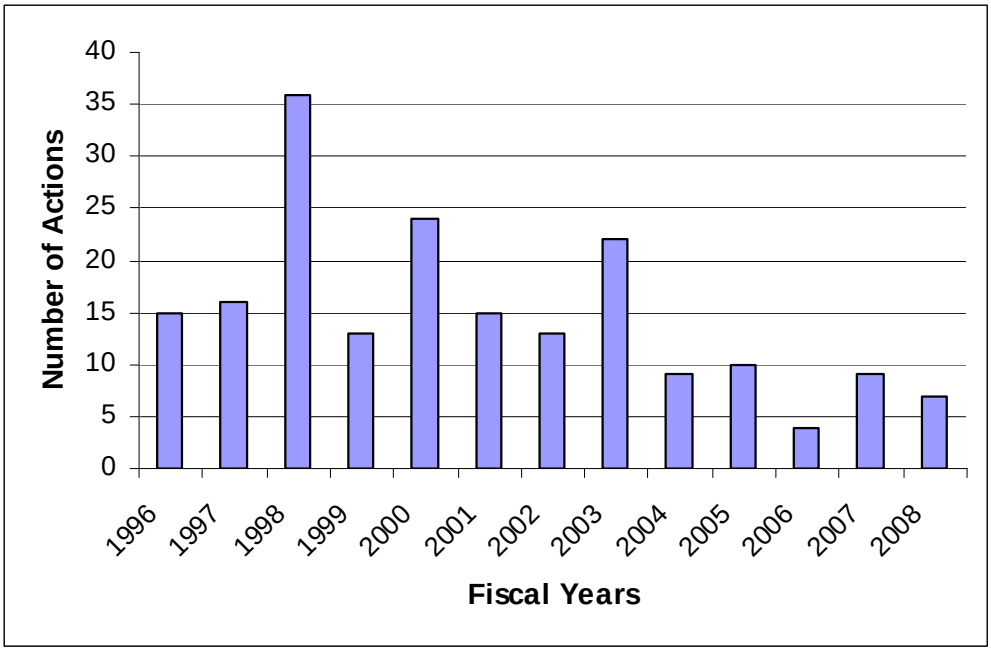


Source: OECA data.

OECA's allocation of inspection resources to Core TSCA enforcement reflects Core TSCA's low priority. Regions 2, 4, and 5 each have only one full-time equivalent employee conducting inspections. Until recently, OECA had tasked the oversight for the remaining regions to two inspectors in the Core TSCA Enforcement Center in Denver.[8] The Acting Branch Chief of OECA's Chemical Risk and Reporting Enforcement Branch explained that it is difficult to compete for EPA enforcement resources when other programs assess $10 million fines. OECA prioritizes EPA enforcement actions by outputs that will result in the highest fines rather than those that will reduce the most risk or exposure. Core TSCA's low fines make TSCA a low priority among the statutes EPA enforces. Additionally, Core TSCA enforcement actions have decreased in the past 5 years (FY 2004 to 2008), and the total number of Core TSCA inspections conducted declined from FY 2005 to 2008 nationwide, from 114 inspections to 56.

Figure 2-2 illustrates the variation and decline in Core TSCA enforcement actions. Between 1996 and 2008, a total of 193 Administrative Actions were completed for the Core TSCA violations identified. Regions 2, 4, and 5 (the three regions maintaining a Core TSCA enforcement presence) were responsible for over 50 percent of the penalties administered.

Figure 2-2: Core TSCA Enforcement Actions, Fiscal Years 1996-2008



Source: OECA data.

Finally, OECA's oversight of TSCA is hindered by an incomplete knowledge of the universe of manufactures and importers. With a lack of knowledge of the Core TSCA universe and low-level, geographically limited monitoring, OECA

[8] Core TSCA oversight responsibilities are being centralized in Headquarters and the inspections previously conducted by OECA staff in Denver will be conducted by OECA contractors out of Washington, DC.

cannot measure the impacts of its activities. OECA personnel we interviewed stated that the number of manufacturers and importers subject to Core TSCA regulations is large, but a complete list has not been identified as required.[9] Neither OECA nor the regional inspectors were able to provide us with the size of their regulated universe. However, both stated that the mix of the universe has changed and continues to change every year. They stated that the number of chemical manufacturers within the United States has decreased, while the number of importers has been increasing. This trend is a concern because inspectors believe that importers are at a higher risk of noncompliance.

Lack of Systematic Collaboration between OECA and OPPT

EPA implements TSCA through OPPT regulating risk from new chemicals entering commerce, and OECA monitoring industry for compliance with Core TSCA requirements and EPA regulatory actions. Although these activities are interconnected, EPA does not have an effective system in place requiring information sharing between the two activities. In addition, TSCA is not a shared priority between these two EPA programs. As a result, the two offices operate independently, each focusing its efforts only on the scope of work for which it is directly accountable.

OECA depends on timely and current information from OPPT to effectively execute its monitoring and oversight activities. Specifically, OECA needs information from OPPT databases on PMNs, NOCs, and Section 8(e) notices. In return, OPPT needs OECA to ascertain that manufacturers and importers submit PMNs and NOCs for each new chemical that enters commerce. In addition, OPPT depends on OECA inspections to (1) ensure that the manufacturers and importers submit all studies and information that identify new risks from chemicals, and (2) provide assurance that industry complies with Consent Orders and SNURs. However, in examining the TSCA implementation process in its entirety, we found a lack of systematic and timely communication between OPPT and OECA. Some examples include:

- According to EPA's regional inspectors, as of May 2009, their scheduled monthly conference calls with OPPT and OECA had not been held in 5 months.
- As of May 2009, OPPT had not provided regional inspectors with the current data that industry periodically submits to EPA in accordance with the 2006 TSCA Inventory Update.
- Inspectors reported that poor information sharing between OPPT, OECA, and regions was inhibiting the ability of inspectors to know their universe and select targets.
- Because of the minimal presence of OECA's Core TSCA activities, OPPT does not receive convincing feedback on industry's level of

[9] *OECA's Operations Manual for the Core TSCA Compliance and Enforcement Program*, February 2003.

compliance with their regulated actions, nor on whether industry is providing all required studies and risk information to OPPT.

The lack of collaboration between OECA and OPPT results in an uneven emphasis placed on the screening and regulation of new chemicals, with minimal follow-up and compliance assurance. The success of the New Chemicals Program depends on comprehensive screening, regulating when there is potential risk through regulatory actions (Consent Orders, SNURs, and/or bans), and support by vigilant and frequent monitoring of the regulated entities. However, EPA does not have effective guidance or a plan for shared priorities and accountabilities between OPPT and OECA.

Public Access to Health and Safety Data Not Assured

Another objective of TSCA is for chemical health and safety data to be made available to the public. However, we found that EPA's current process for handling CBI requests is weighted toward the protection of industry information rather than public access. Current CBI procedures, based on the TSCA statute, also do not allow EPA to discuss CBI with other countries such as Canada or the European Union unless companies provide permission to do so. TSCA provides protection for data that reveal the manufacturing processes of a chemical or mixture, and data that reveal the composition of a mixture. According to OPPT's Chief of TSCA Security Staff, companies are required to address a series of substantiation questions when requesting confidentiality for information submitted under TSCA. The CBI requests granted by EPA apply to information including the chemical manufacturer, chemical name, facility location, and quantity of chemical produced. When such basic information is assigned permanent CBI protection, the public cannot be fully informed about the health and safety data. The health and safety data are of limited value, for example, if the chemical the data pertain to is unknown. An increased disclosure of health and safety data would also provide academia and researchers information on risk data that could be used for further independent studies and external oversight.

The OPPT Chief of TSCA Security Staff estimated manufacturers and importers are sending a large percentage of submissions with requests for CBI protection (as high as 90 percent of PMNs and 50 percent of Section 8(e) notices). Despite the intention of TSCA to provide access to health and safety data, OPPT does not conduct any systematic verification or validation of the requests, instead deferring to the submitter's determination. EPA administratively tracks the presence or absence of CBI requests but does not comprehensively assess the merit of the claims. In some cases, the information claimed as CBI is publicly available through the manufacturer's advertising materials or even other EPA databases.

Furthermore, the current procedures for submitting PMNs and Section 8(e) notices allow manufacturers and importers to make the determination with regard to the length of time they would like CBI protection. Commonly, CBI

designations have no expiration date. Since there is no systematic verification or validation done for CBI requests, CBI protection on information in health and safety studies can potentially remain in effect indefinitely and, in some cases, incorrectly. For example, after a recent review of TSCA Inventory Update submissions (some dating back to 1998), EPA announced it will release information on 530 chemicals after finding that, without requests from submitters, it had needlessly provided confidential treatment for the chemical's health and safety data.

In addition to limiting public access, information sharing across EPA offices is often constrained by the TSCA CBI protections. Hard copies of CBI documents are housed at the CBI Center at EPA Headquarters. Some CBI information is available on OPPT's CBI Local Area Network, but it is only accessible to staff that deal directly with the PMN and Section 8(e) notice reviews. Sharing CBI with other EPA staff is a time- and labor-intensive process, because CBI must be handled in a secured manner in accordance with the TSCA CBI Protection Manual. Despite other national security clearance procedures, only individuals who have undergone CBI security training and have been granted clearance from OPPT may access CBI.

PMN Fees Do Not Defray EPA's Costs

TSCA authorizes EPA to charge a fee to businesses submitting a PMN application. The fee is intended to defray the cost of EPA's review under the New Chemicals Program. Currently, the fees collected from manufacturers and importers do not reflect actual costs. In 1988, the fee rule went into effect at $2,500 maximum, and it remains unchanged. For the past 5 years, fees collected by EPA for PMN reviews have amounted to approximately 11 percent of its costs (Table 2-1). Moreover, the monies collected are not directly used to fund EPA's review. Collected fees are deposited into the general Treasury and are not directed to the review program or even EPA.

Table 2-1: PMN Program Budget and Fees, Fiscal Years 2004-2008

	FY2004	FY2005	FY2006	FY2007	FY2008
PMN Budget	$12,166,700	$12,435,700	12,879,200	12,416,400	12,654,300
Fees Collected	$1,300,000	$1,390,000	$1,360,000	$1,290,000	$1,320,000
Percent Defrayed	10.7	11.2	10.6	10.4	10.4

Source: EPA.

Every year since FY 2001, EPA has sought permission to lift the maximum fee amount, but Congress has not approved an increase. The 2010 President's Budget proposes to eliminate the $2,500 cap on the fee, which EPA estimates would bring in an additional $4 million. An elimination of the fee cap would defray about 40 percent of the review cost. This proposal is consistent with government-

wide efforts to appropriately align program costs to those who benefit directly from such services. Of note is that EPA initially drafted a proposal to raise the cap to $12,500, not eliminate it completely. Also not mentioned in the published budget is the EPA proposal to establish a separate account within the Treasury for the PMN fees collected. This account would be accessible to the review program to defray review costs, and would be in line with the statute's intent.

Measures Do Not Reflect Performance

TSCA performance measures for prevention and compliance are deficient. OPPT's and OECA's respective performance measures for managing risks from new chemicals do not accurately reflect program performance in preventing risk or in assuring compliance. In cases where full information does not exist or analyses are limited, OPPT reports the new chemicals as not having risk, while the limitations in the measure are not disclosed. OECA's performance measure is not outcome based; rather, the measure tracks program activities.

Assurance of Protection from New Chemicals Overstated

Performance Measure: ***Percentage of new chemicals or organisms introduced into commerce that do not pose unreasonable risks to workers, consumers, or the environment.*** Target: 100 percent

EPA's New Chemicals Program seeks to prevent any new chemical from entering into commerce that poses an unreasonable risk. EPA's assessment of whether this objective has been met is based on self-disclosures from chemical manufactures and importers. OPPT's performance measure is calculated by comparing the risks identified on Section 8(e) notices received in the fiscal year to previously reviewed PMNs. The intent of the comparison is to measure present-day performance of the PMN review process. The question answered during the calculation of the measure is "what would the program conclude if it received the same chemical information [submitted and reviewed as a PMN] today?" If the risk identified in a Section 8(e) notice would not be correctly identified and mitigated by the review, then according to OPPT, it has failed to meet its target percentage. For FY 2005 and FY 2006, OPPT reported to Congress and the public that 100 percent of chemicals introduced into commerce did not pose any unreasonable risks. In FY 2007, it identified one failure resulting in a report of 96 percent success.

EPA receives approximately 300 Section 8(e) notices annually. Of those 300, approximately 30 are applicable to chemicals that had undergone the PMN review process. The applicable Section 8(e) notices may relate to chemicals that underwent PMN review as many as 20 years ago. Therefore, the notices do not necessarily relate to chemicals being introduced into commerce in the current year. While industry is required to submit these notices for any potentially unreasonable risks identified, industry is not required to conduct any regular

testing. Moreover, the measure does not include risks identified in scientific studies conducted by other organizations or through EPA's own data collection efforts; information from these sources is not required to be submitted through Section 8(e) notices.

Due to the allocation of limited resources to oversight activities, as discussed in the oversight limitations section of this report, EPA does not have assurance that industry submits all Section 8(e) notices for identified risks. One such example is the Agency's settlement with E. I. du Pont Nemours in 2005 resulting in a $10.5 million penalty – the largest EPA settlement under the TSCA statute. EPA's monitoring did not uncover the industry failure to inform EPA of newly identified risk. Rather, an attorney working on a class action suit on behalf of the citizens of Ohio and West Virginia brought this information to EPA in 2001. EPA issued a press release on July 8, 2004, and announced that OECA filed an administrative action against the company for two violations of TSCA Section 8(e). The press release stated, "The violations consist of multiple failures to report information to EPA about substantial risk of injury to human health or the environment from a chemical during a period beginning in June 1981 through March of 2001."

OECA inspectors emphasize assistance and oversight of smaller establishments, unlike DuPont, with the assumption that the larger companies are more likely to be cognizant of the regulations and more capable and inclined to comply.

Core TSCA OECA Performance Measures

In EPA's annual reports, OECA reported the number of inspections conducted, violations found, and fines issued for Core TSCA as results of performance rather than the amount of risk prevented or compliance assured. OECA does not report any other performance measure for Core TSCA.

OECA reports the number of inspections conducted as a measure of compliance success. This measurement method is insufficient for several reasons. First, it does not demonstrate that OECA's monitoring and enforcement activities are helping EPA prevent risk from toxic chemicals. Second, TSCA inspections are few in number compared with the estimated size of the universe of manufacturers and importers. Third, inspections are not strategically selected to cover a meaningful cross-section of the universe, and OECA has not provided a consistent targeting scheme to be used across regions.

Conclusions

EPA lacks a coordinated process for ensuring risk mitigation from new chemicals. OPPT and OECA need a coordinated, consistent, and strategically designed approach to Core TSCA implementation and enforcement. EPA cannot provide assurance that that all risks from new chemicals are regulated and that

the restrictions are followed by industry. While OPPT invests many resources in the review and regulation of new chemicals, OECA views TSCA as a low enforcement priority. Lack of consistency in procedures for information and priority sharing between OPPT, OECA, and regions has reduced effectiveness and efficiency by limiting access to necessary shared information. OECA has not instituted a nationwide strategy to maximize compliance assurance in a way that effectively uses its limited resources. Further, the lack of a collective EPA strategy for Core TSCA oversight and regulation can result in less effective risk mitigation and reduced public confidence.

Recommendations

We recommend that the Deputy Administrator:

2-1 Link the execution of OPPT's New Chemicals Program with OECA's Core TSCA program, establishing areas of mutual responsibility for managing new chemical risks.

2-2 Link the TSCA goals of OPPT and OECA and devise performance measures that ensure accountability of each office, while demonstrating EPA's overall assurance of meeting the objectives of TSCA.

2-3 Request statutory authority to increase PMN fees to recover PMN review costs with justification for lifting the fee cap without a new fee limit, or to establish a new fee limit to defray the review costs.

We recommend that the Assistant Administrator for Prevention, Pesticides, and Toxic Substances:

2-4 Establish criteria and procedures outlining what chemicals or classes of chemicals will undergo risk assessments for low-level and cumulative exposure. Periodically update and revise risk assessment tools and models with latest research and technology developments.

2-5 Develop a more detailed TSCA CBI classification guide that provides criteria for approving CBI coverage and establishes a time limit for all CBI requests to allow for eventual public access to health and safety data for chemicals.

We recommend that the Assistant Administrator for Enforcement and Compliance Assurance:

2-6 Develop a management plan for Core TSCA enforcement and compliance processes, including:
   a. Regularly scheduled Core TSCA education and training of OECA and OPPT personnel.

b. Consistent enforcement strategies across regions for monitoring and inspection protocols.
c. Periodic assessment and evaluations of techniques and strategies employed.

2-7 Ensure the planned enforcement strategies meet the objectives of TSCA while maximizing resources across regions and leveraging input from OPPT technical experts.

2-8 Develop a methodology to create and periodically update a list of known regulated entities. For unknown regulated entities or nonfilers, develop a profile of entities of interest for use by inspectors, as well as OPPT personnel.

Agency Comments and OIG Evaluation

The Agency concurred with our recommendations and agreed to implement them. It stated that TSCA authority is outdated and does not provide EPA with the tools to adequately protect human health and the environment. In September 2009, the Administrator announced a set of core principles to strengthen U.S. chemical management laws and in January 2010, listed, "assuring the safety of chemicals" as one of seven EPA priorities. The Agency commented that legislative reform of TSCA may take time and it will utilize its current authority to the fullest extent in the meantime.

Our recommendations are intended to result in more effective coordination of risk assessment, oversight, and enforcement activities for TSCA-regulated chemicals. In addition, the Agency's overall assurance of meeting the objective and intent of TSCA should be more accurately reflected in performance measures and public reports. The Agency has already started to take actions that will address our recommendations and there is potential to integrate new tools and authorities as they become available. The recommendations are open pending completion of corrective actions.

The Agency's complete response is included in Appendix B.

Status of Recommendations and Potential Monetary Benefits

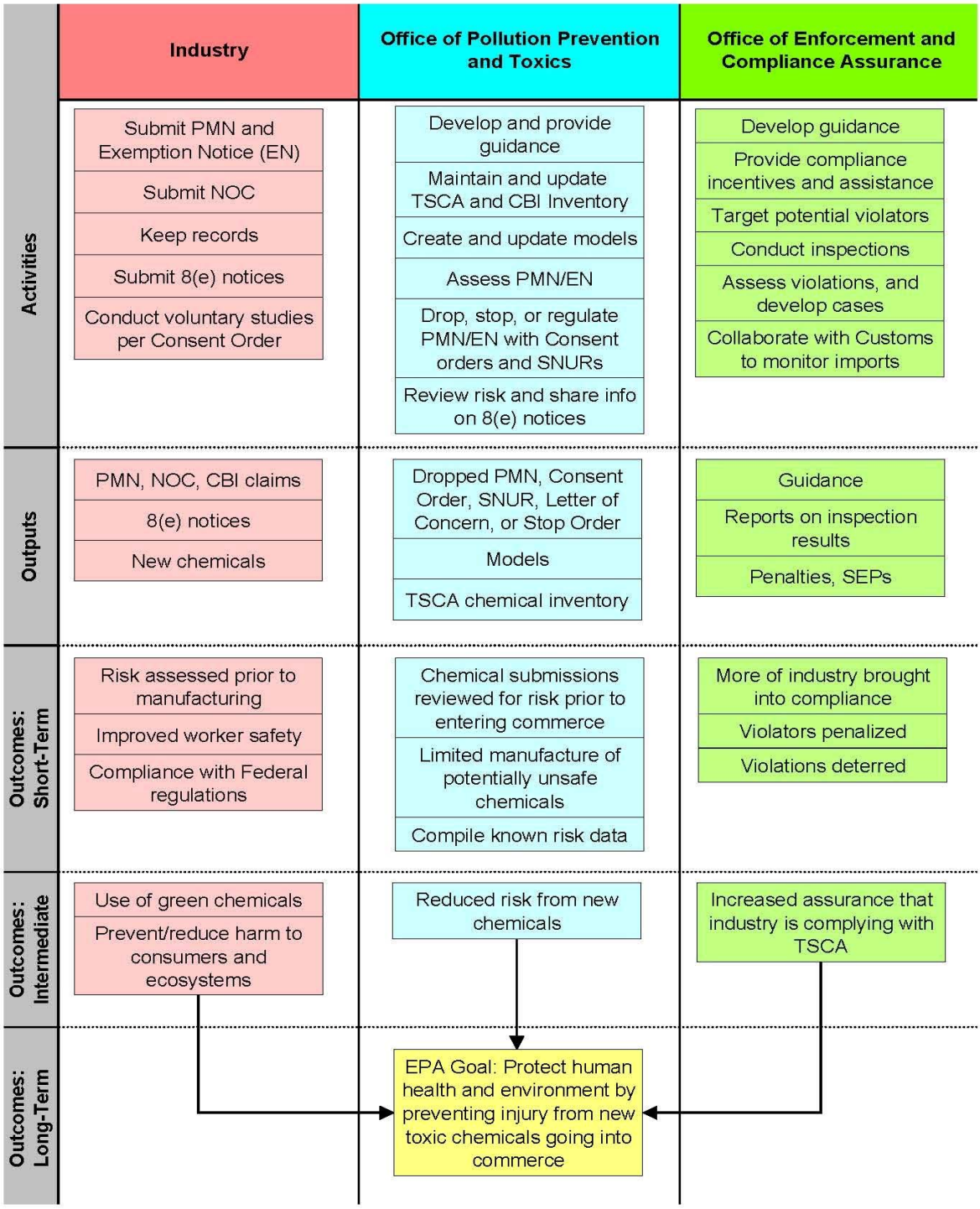
RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed To Amount
2-1	15	Link the execution of OPPT's New Chemicals Program with OECA's Core TSCA program, establishing areas of mutual responsibility for managing new chemical risks.	O	Deputy Administrator			
2-2	15	Link the TSCA goals of OPPT and OECA and devise performance measures that ensure accountability of each office, while demonstrating EPA's overall assurance of meeting the objectives of TSCA.	O	Deputy Administrator			
2-3	15	Request statutory authority to increase PMN fees to recover PMN review costs with justification for lifting the fee cap without a new fee limit, or to establish a new fee limit to defray the review costs.	O	Deputy Administrator			
2-4	15	Establish criteria and procedures outlining what chemicals or classes of chemicals will undergo risk assessments for low-level and cumulative exposure. Periodically update and revise risk assessment tools and models with latest research and technology developments.	O	Assistant Administrator for Prevention, Pesticides, and Toxic Substances			
2-5	15	Develop a more detailed TSCA CBI classification guide that provides criteria for approving CBI coverage and establishes a time limit for all CBI requests to allow for eventual public access to health and safety data for chemicals.	O	Assistant Administrator for Prevention, Pesticides, and Toxic Substances			
2-6	15	Develop a management plan for Core TSCA enforcement and compliance processes, including: a. Regularly scheduled Core TSCA education and training of OECA and OPPT personnel. b. Consistent enforcement strategies across regions for monitoring and inspection protocols. c. Periodic assessment and evaluations of techniques and strategies employed.	O	Assistant Administrator for Enforcement and Compliance Assurance			
2-7	16	Ensure the planned enforcement strategies meet the objectives of TSCA while maximizing resources across regions and leveraging input from OPPT technical experts.	O	Assistant Administrator for Enforcement and Compliance Assurance			
2-8	16	Develop a methodology to create and periodically update a list of known regulated entities. For unknown regulated entities or nonfilers, develop a profile of entities of interest for use by inspectors, as well as OPPT personnel.	O	Assistant Administrator for Enforcement and Compliance Assurance			

[1] O = recommendation is open with agreed-to corrective actions pending
C = recommendation is closed with all agreed-to actions completed
U = recommendation is undecided with resolution efforts in progress

Appendix A

New Chemicals Program Logic Model

This conceptual logic model for the New Chemicals Program illustrates the interrelated responsibilities among industry, OPPT, and OECA in meeting TSCA objectives. The logic model shows how the coordinated long-term outcomes of the three can contribute to the meeting of EPA's long-term goal.



Source: OIG analysis.

Appendix B

Agency Comments on Draft Report

(Received on January 15, 2010)

MEMORANDUM

SUBJECT: Draft Evaluation Report: EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities

FROM: Bob Perciaseppe
Deputy Administrator

TO: Jeffrey Harris
Director for Program Evaluation, Cross-Media Issues

Thank you for providing the opportunity to review the draft evaluation report: EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities. We appreciate and concur with OIG's recommendations. This memorandum includes the corrective actions the Agency commits to take in response to the recommendations, as well as planned completion dates for each action.

We note that OIG acknowledged in their report the limitations regarding the Agency's authority to regulate chemicals under the Toxic Substances Control Act (TSCA). It is true that TSCA authority is outdated and does not provide the tools to adequately protect human health and the environment as the American people expect, demand and deserve. As stated by Administrator Lisa Jackson in her testimony before the U.S. Senate Committee on Environment and Public Works about chemical management reform, the time has come to bring TSCA into the 21st century.

TSCA was signed into law in 1976 and was intended to provide protection of health and the environment against risks posed by chemicals in commerce. However, when TSCA was enacted, it authorized manufacture and use, without any evaluation, of all chemicals that were produced for commercial purposes in 1976 or earlier years. Thus, manufacturers of these "grandfathered" chemicals were not required to develop and produce data on toxicity and exposure that are needed to properly and fully assess potential risks. Further compounding this problem, the statute never provided adequate authority for EPA to evaluate existing chemicals as new concerns arose or as new scientific information became available.

TSCA does provide some authority to EPA to mandate industry to conduct testing, but even in these cases it has taken years to obtain data and information. As a result, there are large, troubling gaps in the available data and state of knowledge on many widely used chemicals in commerce. As OIG's report acknowledges, TSCA also does not place any legal obligation on producers to conduct testing on new chemicals being introduced into commerce. They are required only to supply existing data to EPA and are not required to provide all the data

necessary to fully assess a chemical's risks. The Agency should have the necessary tools to quickly and efficiently require testing, or obtain other information from manufacturers that is relevant to determining the safety of chemicals, without delays and obstacles currently in place, or excessive claims of confidential business information. All of this must happen with transparency and concern for the public's right to know.

In addition, we believe it is also important to evaluate TSCA enforcement with a clear understanding of the statutory and regulatory framework. Enforcement of Core TSCA is critical to ensuring environmental protection, but TSCA lacks the broad information-gathering and enforcement provisions equivalent to other major environmental protection statutes. For example, TSCA lacks the administrative authority to seek injunctive relief, issue administrative orders, collect samples, and quarantine and release chemical stocks, among other key authorities.

For these reasons and others, there is a compelling case that TSCA must be updated and strengthened. The following are the Administration's core principles to strengthen U.S. chemical management laws as announced by Administrator Jackson on September 29, 2009:

- Chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment.
- Manufacturers should provide EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment.
- Risk management decisions should take into account sensitive subpopulations, cost, availability of substitutes and other relevant considerations.
- Manufacturers and EPA should assess and act on priority chemicals, both existing and new, in a timely manner.
- Green chemistry should be encouraged and provisions assuring transparency and public access to information should be strengthened.
- EPA should be given a sustained source of funding for implementation.

Because legislative reform may take time, the Agency will utilize the current authority under TSCA to the fullest extent to protect the American people and the environment from dangerous chemicals. The recommendations contained in your report are consistent with the Agency's approach to effectively manage chemicals and we accept them. In accordance with EPA Manual 2750, below are responses for each recommendation contained in the OIG report.

Response to Specific Recommendations

The report recommends that the Deputy Administrator:

2-1 Link the execution of OPPT's New Chemicals Program with OECA's Core TSCA program, establishing areas of mutual responsibility for managing new chemical risks.

The Agency accepts this recommendation. OPPTS and OECA share responsibility for managing chemical risks and have already implemented several activities to ensure better communication and coordination. Specifically, senior managers of OPPT and OECA began discussions in the summer of 2009 regarding fostering better coordination across all TSCA enforcement and programmatic activities (including the New Chemicals Program). At the senior leader level, the two offices agreed to conduct formal quarterly meetings between the Assistant Administrators for OPPTS and OECA; the first two such meetings occurred in October and December 2009. The Assistant Administrators for OPPTS and OECA have continued to meet on several occasions to discuss TSCA enforcement matters.

Additionally, OPPTS and OECA conducted a national meeting in October with the Regions to discuss how to better coordinate our mutual responsibilities and to help identify priorities for 2011. Finally, OPPTS and OECA have also begun development of a document that enhances collaboration between the two offices and establishes clear areas of responsibility. The document is intended to provide structure for collaboration between the two offices to maximize the efforts to achieve the shared strategic goals of protecting public health and the environment by reducing risks. The target date for finalizing the document is June 30, 2010. Finally, at the staff level, greater collaboration between the offices is already taking place in the area of sharing information and developing focus areas. One example of this collaboration is an agreement to initiate a joint project in the 2nd quarter of FY 2010 to develop the criteria and supporting data needed to target for compliance inspection certain regulated facilities subject to New Chemical Significant New Use Rules (SNURs) and Low Volume Exemptions.

2-2 Link the TSCA goals of OPPT and OECA and devise performance measures that ensure accountability of each office, while demonstrating EPA's overall assurance of meeting the objectives of TSCA.

The Agency accepts this recommendation to devise related measures that ensure accountability yet reflect the separate functions of each office. As a first step, OPPTS and OECA will coordinate in the development of their respective National Program Managers (NPM) guidance. The NPM guidance establishes programmatic priorities and implementation strategies for the respective offices. An integral part of the NPM process is the development of the Annual Commitment System (ACS) accomplishments. The ACS is the central repository of Agency performance measurements. OPPTS and OECA will work to coordinate performance measures in the 2011 NPM and ACS processes. The draft NPM guidance is due to OCFO by February 12, 2010, the final guidance will be issued by OCFO on April 23, 2010 and full implementation will begin on October 1, 2010.

2-3 Request statutory authority to increase PMN fees to recover PMN review costs with justification for lifting the fee cap without a fee limit, or to establish a new fee limit to defray the review costs.

The Agency accepts this recommendation and has already taken steps to address the issue. In fact, the Agency has included in its President's Budget submissions since 1999 language to increase the PMN fees. Note that the U.S. Department of the Treasury collects the fees for the PMN program; they are not received by the Office of Prevention, Pesticides and Toxic Substances to recover PMN review costs. Moreover, as discussion of TSCA reform continues, we would like to highlight Administrator Jackson's core principal of giving EPA a sustained source of funding for implementation.

We recommend that the Assistant Administrator for Prevention, Pesticides and Toxic Substances (OPPTS):

2-4 Establish criteria and procedures outlining what chemicals or classes of chemicals will undergo risk assessments for low-level and cumulative exposure. Periodically update and revise risk assessment tools and models with latest research and technology developments.

OPPTS agrees with this recommendation, and recognizes the need to conduct cumulative risk assessments where appropriate. Such an assessment requires an understanding of the mode of action of the chemical or class of chemicals, and an understanding of common exposure pathways. Developing a better understanding of cumulative risk is a high priority of the Agency's science agenda. Under the authorities currently granted by TSCA, this level of understanding is not generally available for most PMNs in the New Chemicals Program. However, this information is available for some classes of chemicals in the Existing Chemicals Program; assessments of these chemical classes can inform the New Chemicals program when PMNs for similar chemicals are submitted. As stated in Administrator Jackson's principles for TSCA Reform, manufacturers should provide EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment.

To this end, OPPT is initiating cumulative assessments of eight phthalates as outlined in the Action Plan release on December 30, 2009. EPA intends to lay the groundwork to consider initiating rulemaking under TSCA Section 6(a) to regulate the eight phthalates in 2012. In preparation for the rulemaking, EPA intends, in cooperation with the U.S. Consumer Product Safety Commission (CPSC) and the U.S. Food and Drug Administration (FDA), to continue to work to fully assess the use, exposure and substitutes for these chemicals. In its further review, EPA plans to consider the future results of the cumulative assessment that will be developed by the CPSC. The cumulative assessment approach under development by CPSC, which may be completed in 2012, as well as the ongoing review of phthalates at the FDA and the assessment for EPA's IRIS program, are due to be completed in 2012.

In addition, with regard to the recommendation that the Office periodically update and revise risk assessment tools and models with latest research and technology developments, OPPTS agrees with this recommendation, and, in fact, does this on a routine basis. OPPT will report on progress on November 1, 2010.

2-5 Develop a more detailed CBI classification guide that provides criteria for approving CBI coverage and establishes a time limit for all CBI requests to allow for eventual public access to health and safety data for chemicals.

OPPTS accepts this recommendation. As stated in one of the Administration's core principles for TSCA reform, public access to information should be strengthened. The Agency is committed to transparency and believes that the public right to know about the hazards of chemicals is integral to sound chemical management practices. Since the summer of 2009, OPPTS has been making important strides in this area. In July 2009, OPPTS published notice that the Agency was shifting 530 chemicals from the non-public to the public portion of the TSCA Inventory. Another example is the new initiative to addess CBI claims in TSCA Notices of Substantial Risk (TSCA Section 8(e) filings). In early 2010 OPPTS will publish a Federal Register Notice that will inform chemical companies that they may not claim chemical identify as CBI in an 8(e) submission when the substance is listed on the public portion of the TSCA inventory. These efforts and others will be part of a multi-faceted approach, which will include periodic but systematic review of CBI claims made in TSCA filings classified as containing health and safety data.

It should be noted, the criteria for making CBI claims for TSCA are located generally at 40 CFR 2.208 and 2.306 but there are also TSCA rule specific regulations that provide criteria as well.

We recommend that the Assistant Administrator for Enforcement and Compliance Assurance (OECA):

2-6 Develop a management plan for Core TSCA enforcement and compliance processes including:

- **a. Regularly scheduled Core TSCA education and training of OECA and OPPT personnel.**
- **b. Consistent enforcement strategies across regions for monitoring and inspection protocols.**
- **c. Periodic assessment and evaluation of techniques and strategies employed.**

The Agency concurs with the recommendation that a plan be developed that includes training and education as well as the development of consistent national enforcement strategies and periodic assessment. We have made significant progress to address this recommendation. Specifically, OECA is working with OPPTS and the Regions to develop a TSCA Compliance Monitoring Strategy (CMS). The CMS is a plan to maximize available resources and develop consistent enforcement strategies across all of TSCA. A draft CMS document has been developed and is currently being reviewed by a Headquarters and Regional workgroup. Because the CMS covers all of TSCA and not

just the sections reviewed by the OIG, it is anticipated that drafting of the CMS will continue through the spring of 2010.

OECA is also currently revising the February 2003 Core TSCA Operations Manual and Inspection Manual to ensure the most current techniques and approaches are used to meet the objectives of TSCA. A regional workgroup is currently reviewing the first draft of both the operations and inspection manuals and comments are due to OECA by January 29, 2010.

Also, OECA will work with OPPTS to explore the development of a Core TSCA national meeting beginning in FY2011. The purpose of this meeting will be to provide training on current inspection and enforcement techniques as well as highlight best practices.

2-7 Ensure the planned enforcement strategies meet the objectives of TSCA while maximizing resources across regions and leveraging input from OPPT technical experts.

The Agency concurs with the recommendation that enforcement strategies align with the objectives of TSCA, that we maximize resources and leverage input from OPPT. OECA and OPPTS believe that quarterly meetings at the Assistant Administrator level, a coordinated NPM and ACS process, a CMS and revised operations and inspection manuals will address the concerns identified in this recommendation. Specific actions and dates are included in other responses to recommendations found in this document.

2-8 Develop a methodology to create and periodically update a list of known regulated entities. For unknown regulated entities or nonfilers, develop a profile of entities of interest for use by inspectors, as well as OPPT personnel.

The Agency concurs with the recommendation and agrees that enforcement could be enhanced with a targeted list of facilities. It is important to note that neither the TSCA statute nor the regulations require companies to notify EPA they are in the business of manufacturing, importing, or using chemicals. By introducing a new chemical into commerce, any facility could become newly regulated. As a consequence, OECA and OPPTS do not have complete and accurate information on the universe of regulated entities. However, OPPTS has recently made significant progress in integrating regulatory data systems and by early 2010 will integrate over 6,300 TSCA facility records with EPA's facility registry system (FRS). As more of the Agency's data systems become integrated, EPA's ability to define the universe will steadily improve. Finally, OPPTS and OECA will work together to identify a profile of potential targets within the universe of regulated entities in the revision to the Core TSCA Operations Manual.

Again, we appreciate the opportunity to review and comment on this draft report. Should you have any questions or concerns regarding this response, please contact Megan Carroll in OPPTS at 202-564-2814 or Rosemarie Kelley in OECA at 202-564-4014.

Appendix C

Distribution

Office of the Administrator
Deputy Administrator
Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances
Assistant Administrator, Office of Enforcement and Compliance Assurance
Agency Follow-up Official (the CFO)
Agency Follow-up Coordinator
General Counsel
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Audit Follow-up Coordinator, Office of the Administrator
Audit Follow-up Coordinator, Office of Prevention, Pesticides, and Toxic Substances
Audit Follow-up Coordinator, Office of Enforcement and Compliance Assurance
Acting Inspector General

Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)

Statistics for the New Chemicals Review Program under TSCA

Since the TSCA Inventory was established in 1979, EPA has reviewed more than 39,000 new chemical submissions (called Premanufacture Notices or PMNs) and an additional 15,000 PMN exemption notices. Here is a breakdown of the submissions and notices.

New Chemicals Program Activities through September 30, 2015

Type of Submission	Number Submitted Since 1979	FY 2015	FY 2014	FY 2013
Premanufacture Notices	39,962	589	657	637
Test Marketing Exemption Applications (TMEA)	883	15	4	24
Low Volume Exemptions (LVE)	12,919	399	434	399

Low Release/Low Exposure Exemption (LoRex)	104	2	6	7
Polymer Exemptions*				
Microbial Commercial Activity Notice (MCAN)	106	34	21	14
Significant New Use Notice (SNUN)	52	5	13	7
Total**	54,026	1,088	1,135	1,044
Notices of Commencement (NOC)***	13,933	267	395	403

Regulatory Action on PMNs	**Total Number Issued**	**FY 2015**	**FY 2014**	**FY 2013**
Section 5(e) Consent Orders	1,710	48	20	30
SNURs following section 5(e), Consent Orders - subset	(739)	(28)	(36)	(40)
SNURs following PMN review	1,457	131	95	157
PMNs withdrawn in face of action	2,068	53	52	66

* Since May 30, 1995, individual reporting for exempt polymers has not been required; reporting is now on a yearly basis on January 31 of the following year.
** Total includes Exemption modifications
***The number of NOCs received during the listed Fiscal Year

Approximately 10 percent of the 39,000 total PMN submissions have resulted in issuance of section 5(e) consent orders that impose various restrictions and testing requirements, and notices withdrawn in the face of regulation. For exemption notices, EPA can grant or deny the notice, with or without certain conditions of use specified in the notice, to which the submitter is legally bound.

Section 5(e) Consent Orders

More than 1,700 of all new chemicals submitted as PMNs have been subject to consent orders under TSCA section 5(e). Such "section 5(e) consent orders" serve to limit the production, processing, distribution in commerce, use, and disposal of new chemical substances that raise health or environmental concerns, pending receipt of required information.

Significant New Use Rules (SNURS)

A subset of 739 of the above-mentioned consent orders have associated with them a SNUR, issued by EPA under TSCA section 5(a)(2). In general, these SNURs mimic the Consent Order to bind all other manufacturers and processors to the terms and conditions contained in the Consent Order. For such chemical substances, persons are required to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the substance for the use designated as significant. The required SNUN provides EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit that activity before it occurs.

In addition to these 739 SNURs, an additional 1,457 new chemical substances were regulated by EPA with SNURs which require notice to EPA for potential new uses of the chemical (other than those reviewed as part of the PMN) that may pose unreasonable risks.

Withdrawals

In more than 2,000 cases, companies have withdrawn PMNs in the face of EPA concerns and likely regulatory requirements.

Contact Us to ask a question, provide feedback, or report a problem.

Reviewing New Chemicals under the Toxic Susbstances Control Act (TSCA) Home

Basic Information

EPA's Review Process

Filing a Premanufacture Notice with EPA

Regulatory Actions Under TSCA section 5

Premanufacture Notice Status

How to Make the Review Process More Efficient

Greg Schweer
Chief, New Chemicals Management Branch
Office of Pollution Prevention and Toxics

December 14, 2016

Benefits of a Robust PMN Submission

- A more robust PMN submission can result in a more efficient review by EPA.

- Having more information in the PMN submission will decrease the back-and-forth between EPA and the submitter, which takes time and resources.

- Risks that are identified can often be addressed by the submitter with more detailed information.

Chemical Identity

- Submit a correct CA Index name
- Check consistency of the chemical identity information provided in a submission, e.g., make sure that the chemical identity on PMN form page 4 matches the manufacturing diagram
- Provide information on polymers on PMN form page 5 (i.e., identities of reactants and residuals, lowest number average molecular weight, etc.).
- Provide as much structurally descriptive information as possible for UVCBs, e.g., describe the extent of the variable components
- Provide a generic name that that is "*only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible*" (40 CFR 720.85(a))
  - http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/policy.html

Clear Identification of Submitted Materials

- When submitting the PMN form, provide clear and descriptive names for attachments on page 12 of the PMN form (i.e., List of Attachments).
- For subsequent submissions of information, attach a table indicating all materials submitted. In this table, clearly indicate the test substance/chemical structure for any studies submitted (whether for the new chemical substance(NCS) or an analog).

Physical-Chemical Property Information

- Provide measured values for at least the basic physical/chemical properties of the NCS (water solubility, vapor pressure, melting point, octanol/water partition coefficient, boiling point).

- Provide particle size distribution analysis data if NCS is manufactured as a particulate.

Identification of Appropriate Analogs

- Identify an analog(s) for any endpoint – p/chem property, environmental fate, ecotoxicity, human health effects. Provide chemical name and CAS numbers.
- Provide justification for recommending that EPA consider the analog in its assessment.
- Provide the full studies on the endpoint(s) to better ensure consideration by EPA.
- Provide any QSAR Toxicity Analysis reports (e.g., DEREK)

More Detailed Information on Environmental Fate

- Provide full studies on Ready and/or Inherent Biodegradability and hydrolysis on the NCS or analog.
- Provide levels of residuals/starting materials in NCS to help interpret the results of fate studies.
- Provide detailed information on analytical methods used in the studies.
- Provide information on UV/Vis spectrum on the NCS or analog to help assess potential for photolysis.
- Provide information on chemical transformation during mfg, processing and use to help identify the form of the NCS released to the environment.

More Detailed Information on Worker Exposure

- Detailed descriptions of the manufacturing/processing/use operations and processes that identify:
  - What are the worker activities?
  - What is the frequency and duration of each worker activity?
  - How (dermal and/or inhalation) and during which activities is worker exposure expected?
  - If worker exposure is not expected, why not?
  - How many workers are exposed during these activities?

More Detailed Information on Worker Exposure

- Describe the specific type of personal protective equipment (PPE) that will be used at the manufacturing site and, to the extent known, at processing and use sites.
  - What kind of gloves (i.e., material composition, name/model number)?
  - What kind of protective clothing and goggles (i.e., name/model number)?
  - What kind of respirator (i.e., name/model number, cartridge type, assigned protection factor (APF))?

More Detailed Information on Worker Exposure

- If the neat NCS substance is a solid, will it be distributed to processors and users in a solid form or in a liquid or paste form?
  - Provide particle size distribution analysis data if substance is manufactured as a particulate.
- Include the Safety Data Sheet (SDS) or Materials Safety Data Sheet (MSDS).

More Detailed Information on Commercial and Consumer Exposure

- Description of the functional use of the NCS in products (e.g., OECD use codes).
- Information regarding quantity of the NCS in potential product or formulation (i.e., weight fraction, volume percent).
- Detailed description of the types of products or articles that will incorporate the NCS substance (e.g., household cleaners, plastic articles) including leaching rates where applicable.
- Description of how and where a potential product would be used (e.g., spray applied indoors, brushed on outdoor surface) including information regarding consumption rates, frequency and duration of use.

Environmental Releases from Manufacturing, Processing and Use Sites

- How often is the equipment cleaned (e.g., every day, after every batch, once a year)?
- What is used to clean the equipment (e.g. water, solvent, steam)?
- For all releases, provide estimates of the amount and the frequency of releases. Be sure to include detailed information on the basis for each estimate.
- How is waste (including cleaning and process waste) disposed (i.e., on-site waste water treatment, POTW, venting, incineration, landfill, etc.)

More Detailed Information on Transport and Disposal

- How is the NCS or the product containing the NCS transported from the manufacturing site(s) to the processing sites (e.g., totes, tank cars, drums)?
- How is the NCS or the product containing the NCS transported from the processing sites to further processing and/or use site(s)?
- Are the containers used to store / transport the NCS dedicated? Is the cleaning and disposal of the transport containers under your control (Y/N)?
- If the containers are cleaned or disposed of off-site, please provide available information including the cleaning methods, frequency of cleaning and estimated amount released per cleaning.

More Detailed Information on Transport and Disposal

- What are the NPDES permit numbers (i.e., non-storm water permit numbers) for the manufacturing site(s), known processing site(s), and known use site(s) or the NPDES permit numbers for the POTWs receiving wastewater from the facility(ies)?
  - What type of wastewater treatment technologies are used at the facilitiy(ies)?
  - Provide any removal efficiency information for your onsite treatment unit operations? Is the information estimated or measured?

More Detailed Information on Transport and Disposal

- What are the Clean Air Act operating permit numbers for the facilities with expected releases to air?
  - What type of air pollution control technologies are used at the facility(ies)?
  - Provide any removal efficiency information for your onsite treatment unit operations? Is the information estimated or measured?
  - Is the facility under a Leak Detection and Repair program (relates to the monitoring and management of fugitive releases). If “yes”, please describe the program.

Risk Management Considerations

- Consider using the “binding option” in the PMN form (EPA Form 7710-25):
  - Pollution control technology and efficiency
  - Physical form(s) of the PMN substance
  - PPE/engineering controls
  - Process description
  - Use information
- Ensure that the phone numbers and email addresses provided for the technical contact and authorized official are correct.
- Do not underestimate your maximum 12-month production volume estimate.

Risk Management Considerations

- Good practice to inform your EPA Program Manager (email, fax or phone message) that you have electronically submitted an amendment or document via CDX.

- When a suspension of more than 15 days appears to be needed, we encourage you to submit a written request for suspension thru CDX for the longer time period.

- Become familiar with the TSCA Section 5(e) Consent Order "Boilerplate" on EPA's website (https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-program-boilerplates).

ELECTRONIC CODE OF FEDERAL REGULATIONS

e-CFR data is current as of January 18, 2017

Title 40 → Chapter I → Subchapter A → Part 2 → Subpart B

Title 40: Protection of Environment
PART 2—PUBLIC INFORMATION

Subpart B—Confidentiality of Business Information

Contents

Back to Top

§2.201 Definitions.

For the purposes of this subpart:

(a) *Person* means an individual, partnership, corporation, association, or other public or private organization or legal entity, including Federal, State or local governmental bodies and agencies and their employees.

(b) *Business* means any person engaged in a business, trade, employment, calling or profession, whether or not all or any part of the net earnings derived from such engagement by such person inure (or may lawfully inure) to the benefit of any private shareholder or individual.

(c) *Business information* (sometimes referred to simply as *information*) means any information which pertains to the interests of any business, which was developed or acquired by that business, and (except where the context otherwise requires) which is possessed by EPA in recorded form.

(d) *Affected business* means, with reference to an item of business information, a business which has asserted (and not waived or withdrawn) a business confidentiality claim covering the information, or a business which could be expected to make such a claim if it were aware that disclosure of the information to the public was proposed.

(e) *Reasons of business confidentiality* include the concept of trade secrecy and other related legal concepts which give (or may give) a business the right to preserve the confidentiality of business information and to limit its use or disclosure by others in order that the business may obtain or retain business advantages it derives from its rights in the information. The definition is meant to encompass any concept which authorizes a Federal agency to withhold business information under 5 U.S.C. 552(b)(4), as well as any concept which requires EPA to withhold information from the public for the benefit of a business under 18 U.S.C. 1905 or any of the various statutes cited in §§2.301 through 2.309.

(f) [Reserved]

(g) Information which is *available to the public* is information in EPA's possession which EPA will furnish to any member of the public upon request and which EPA may make public, release or otherwise make available to any person whether or not its disclosure has been requested.

(h) *Business confidentiality claim* (or, simply, *claim*) means a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality, or a request for a determination that such information is entitled to such treatment.

(i) *Voluntarily submitted information* means business information in EPA's possession—

(1) The submission of which EPA had no statutory or contractual authority to require; and

(2) The submission of which was not prescribed by statute or regulation as a condition of obtaining some benefit (or avoiding some disadvantage) under a regulatory program of general applicability, including such regulatory programs as permit, licensing, registration, or certification programs, but excluding programs concerned solely or primarily with the award or administration by EPA of contracts or grants.

(j) *Recorded* means written or otherwise registered in some form for preserving information, including such forms as drawings, photographs, videotape, sound recordings, punched cards, and computer tape or disk.

(k) [Reserved]

(l) *Administrator, Regional Administrator, General Counsel, Regional Counsel,* and *Freedom of Information Officer* mean the EPA officers or employees occupying the positions so titled.

(m) *EPA office* means any organizational element of EPA, at any level or location. (The terms *EPA office* and *EPA legal office* are used in this subpart for the sake of brevity and ease of reference. When this subpart requires that an action be taken by an *EPA office* or by an *EPA legal office,* it is the responsibility of the officer or employee in charge of that office

to take the action or ensure that it is taken.)

(n) *EPA legal office* means the EPA General Counsel and any EPA office over which the General Counsel exercises supervisory authority, including the various Offices of Regional Counsel. (See paragraph (m) of this section.)

(o) A *working day* is any day on which Federal Government offices are open for normal business. Saturdays, Sundays, and official Federal holidays are not working days; all other days are.

Back to Top

§2.202 Applicability of subpart; priority where provisions conflict; records containing more than one kind of information.

(a) Sections 2.201 through 2.215 establish basic rules governing business confidentiality claims, the handling by EPA of business information which is or may be entitled to confidential treatment, and determinations by EPA of whether information is entitled to confidential treatment for reasons of business confidentiality.

(b) Various statutes (other than 5 U.S.C. 552) under which EPA operates contain special provisions concerning the entitlement to confidential treatment of information gathered under such statutes. Sections 2.301 through 2.311 prescribe rules for treatment of certain categories of business information obtained under the various statutory provisions. Paragraph (b) of each of those sections should be consulted to determine whether any of those sections applies to the particular information in question.

(c) The basic rules of §§2.201 through 2.215 govern except to the extent that they are modified or supplanted by the special rules of §§2.301 through 2.311. In the event of a conflict between the provisions of the basic rules and those of a special rule which is applicable to the particular information in question, the provision of the special rule shall govern.

(d) If two or more of the sections containing special rules apply to the particular information in question, and the applicable sections prescribe conflicting special rules for the treatment of the information, the rule which provides greater or wider availability to the public of the information shall govern.

(e) For most purposes, a document or other record may usefully be treated as a single unit of *information,* even though in fact the document or record is comprised of a collection of individual items of information. However, in applying the provisions of this subpart, it will often be necessary to separate the individual items of information into two or more categories, and to afford different treatment to the information in each such category. The need for differentiation of this type may arise, e.g., because a business confidentiality claim covers only a portion of a record, or because only a portion of the record is eligible for confidential treatment. EPA offices taking action under this subpart must be alert to this

problem.

(f) In taking actions under this subpart, EPA offices should consider whether it is possible to obtain the affected business's consent to disclosure of useful portions of records while protecting the information which is or may be entitled to confidentiality (e.g., by withholding such portions of a record as would identify a business, or by disclosing data in the form of industry-wide aggregates, multi-year averages or totals, or some similar form).

(g) This subpart does not apply to questions concerning entitlement to confidential treatment or information which concerns an individual solely in his personal, as opposed to business, capacity.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40000, Sept. 8, 1978; 50 FR 51661, Dec. 18, 1985]

Back to Top

§2.203 Notice to be included in EPA requests, demands, and forms; method of asserting business confidentiality claim; effect of failure to assert claim at time of submission.

(a) *Notice to be included in certain requests and demands for information, and in certain forms.* Whenever an EPA office makes a written request or demand that a business furnish information which, in the office's opinion, is likely to be regarded by the business as entitled to confidential treatment under this subpart, or whenever an EPA office prescribes a form for use by businesses in furnishing such information, the request, demand, or form shall include or enclose a notice which—

(1) States that the business may, if it desires, assert a business confidentiality claim covering part or all of the information, in the manner described by paragraph (b) of this section, and that information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in this subpart;

(2) States that if no such claim accompanies the information when it is received by EPA, it may be made available to the public by EPA without further notice to the business; and

(3) Furnishes a citation of the location of this subpart in the Code of Federal Regulations and the FEDERAL REGISTER.

(b) *Method and time of asserting business confidentiality claim.* A business which is submitting information to EPA may assert a business confidentiality claim covering the information by placing on (or attaching to) the information, at the time it is submitted to EPA, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as *trade secret, proprietary,* or *company confidential.* Allegedly confidential portions of otherwise non-confidential documents should be clearly identified by the business, and may be submitted separately to facilitate identification and

handling by EPA. If the business desires confidential treatment only until a certain date or until the occurrence of a certain event, the notice should so state.

(c) *Effect of failure to assert claim at time of submission of information.* If information was submitted by a business to EPA on or after October 1, 1976, in response to an EPA request or demand (or on an EPA-prescribed form) which contained the substance of the notice required by paragraph (a) of this section, and if no business confidentiality claim accompanied the information when it was received by EPA, the inquiry to the business normally required by §2.204(c)(2) need not be made. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files (see §2.204(c)(1)). However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information.

Back to Top

§2.204 Initial action by EPA office.

(a) *Situations requiring action.* This section prescribes procedures to be used by EPA offices in making initial determinations of whether business information is entitled to confidential treatment for reasons of business confidentiality. Action shall be taken under this section whenever an EPA office:

(1) Learns that it is responsible for responding to a request under 5 U.S.C. 552 for the release of business information; in such a case, the office shall issue an initial determination within the period specified in §2.112;

(2) Desires to determine whether business information in its possession is entitled to confidential treatment, even though no request for release of the information has been received; or

(3) Determines that it is likely that EPA eventually will be requested to disclose the information at some future date and thus will have to determine whether the information is entitled to confidential treatment. In such a case this section's procedures should be initiated at the earliest practicable time, in order to increase the time available for preparation and submission of comments and for issuance of determinations, and to make easier the task of meeting response deadlines if a request for release of the information is later received under 5 U.S.C. 552.

(b) *Previous confidentiality determination.* The EPA office shall first ascertain whether there has been a previous determination, issued by a Federal court or by an EPA legal office acting under this subpart, holding that the information in question is entitled to confidential treatment for reasons of business confidentiality.

(1) If such a determination holds that the information is entitled to confidential treatment, the EPA Office shall furnish

any person whose request for the information is pending under 5 U.S.C. 552 an initial determination (see §2.111 and §2.113) that the information has previously been determined to be entitled to confidential treatment, and that the request is therefore denied. The office shall furnish such person the appropriate case citation or EPA determination. If the EPA office believes that a previous determination which was issued by an EPA legal office may be improper or no longer valid, the office shall so inform the EPA legal office, which shall consider taking action under §2.205(h).

(2) With respect to all information not known to be covered by such a previous determination, the EPA office shall take action under paragraph (c) of this section.

(c) *Determining existence of business confidentiality claims.* (1) Whenever action under this paragraph is required by paragraph (b)(2) of this section, the EPA office shall examine the information and the office's records to determine which businesses, if any, are affected businesses (see §2.201(d)), and to determine which businesses if any, have asserted business confidentiality claims which remain applicable to the information. If any business is found to have asserted an applicable claim, the office shall take action under paragraph (d) of this section with respect to each such claim.

(2)(i) If the examination conducted under paragraph (c)(1) of this section discloses the existence of any business which, although it has not asserted a claim, might be expected to assert a claim if it knew EPA proposed to disclose the information, the EPA office shall contact a responsible official of each such business to learn whether the business asserts a claim covering the information. However, no such inquiry need be made to any business—

(A) Which failed to assert a claim covering the information when responding to an EPA request or demand, or supplying information on an EPA form, which contained the substance of the statements prescribed by §2.203(a);

(B) Which otherwise failed to assert a claim covering the information after being informed by EPA that such failure could result in disclosure of the information to the public; or

(C) Which has otherwise waived or withdrawn a claim covering the information.

(ii) If a request for release of the information under 5 U.S.C. 552 is pending at the time inquiry is made under this paragraph (c)(2), the inquiry shall be made by telephone or equally prompt means, and the responsible official contacted shall be informed that any claim the business wishes to assert must be brought to the EPA office's attention no later than the close of business on the third working day after such inquiry.

(iii) A record shall be kept of the results of any inquiry under this paragraph (c)(2). If any business makes a claim covering the information, the EPA office shall take further action under paragraph (d) of this section.

(3) If, after the examination under paragraph (c)(1) of this section, and after any inquiry made under paragraph (c)(2)

of this section, the EPA office knows of no claim covering the information and the time for response to any inquiry has passed, the information shall be treated for purposes of this subpart as not entitled to confidential treatment.

(d) *Preliminary determination.* Whenever action under this paragraph is required by paragraph (c)(1) or (2) of this section on any business's claim, the EPA Office shall make a determination with respect to each such claim. Each determination shall be made after consideration of the provisions of §2.203, the applicable substantive criteria in §2.208 or elsewhere in this subpart, and any previously-issued determinations under this subpart which are applicable.

(1) If, in connection with any business's claim, the office determines that the information may be entitled to confidential treatment, the office shall—

(i) Furnish the notice of opportunity to submit comments prescribed by paragraph (e) of this section to each business which is known to have asserted an applicable claim and which has not previously been furnished such notice with regard to the information in question;

(ii) Furnish, to any person whose request for release of the information is pending under 5 U.S.C. 552, a determination (in accordance with §2.113) that the information may be entitled to confidential treatment under this subpart and 5 U.S.C. 552(b)(4), that further inquiry by EPA pursuant to this subpart is required before a final determination on the request can be issued, that the person's request is therefore initially denied, and that after further inquiry a final determination will be issued by an EPA legal office; and

(iii) Refer the matter to the appropriate EPA legal office, furnishing the information required by paragraph (f) of this section after the time has elapsed for receipt of comments from the affected business.

(2) If, in connection with all applicable claims, the office determines that the information clearly is not entitled to confidential treatment, the office shall take the actions required by §2.205(f). However, if a business has previously been furnished notice under §2.205(f) with respect to the same information, no further notice need be furnished to that business. A copy of each notice furnished to a business under this paragraph (d)(2) and §2.205(f) shall be forwarded promptly to the appropriate EPA legal office.

(e) *Notice to affected businesses; opportunity to comment.* (1) Whenever required by paragraph (d)(1) of this section, the EPA office shall promptly furnish each business a written notice stating that EPA is determining under this subpart whether the information is entitled to confidential treatment, and affording the business an opportunity to comment. The notice shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the fact and date of receipt. The notice shall state the address of the office to which the business's comments shall be addressed (the EPA office furnishing the notice, unless the General Counsel has directed otherwise),

the time allowed for comments, and the method for requesting a time extension under §2.205(b)(2). The notice shall further state that EPA will construe a business's failure to furnish timely comments as a waiver of the business's claim.

(2) If action under this section is occasioned by a request for the information under 5 U.S.C. 552, the period for comments shall be 15 working days after the date of the business's receipt of the written notice. In other cases, the EPA office shall establish a reasonable period for comments (not less than 15 working days after the business's receipt of the written notice). The time period for comments shall be considered met if the business's comments are postmarked or hand delivered to the office designated in the notice by the date specified. In all cases, the notice shall call the business's attention to the provisions of §2.205(b).

(3) At or about the time the written notice is furnished, the EPA office shall orally inform a responsible representative of the business (by telephone or otherwise) that the business should expect to receive the written notice, and shall request the business to contact the EPA office if the written notice has not been received within a few days, so that EPA may furnish a duplicate notice.

(4) The written notice required by paragraph (e)(1) of this section shall invite the business's comments on the following points (subject to paragraph (e)(5) of this section):

(i) The portions of the information which are alleged to be entitled to confidential treatment;

(ii) The period of time for which confidential treatment is desired by the business (e.g., until a certain date, until the occurrence of a specified event, or permanently);

(iii) The purpose for which the information was furnished to EPA and the approximate date of submission, if known;

(iv) Whether a business confidentiality claim accompanied the information when it was received by EPA;

(v) Measures taken by the business to guard against undesired disclosure of the information to others;

(vi) The extent to which the information has been disclosed to others, and the precautions taken in connection therewith;

(vii) Pertinent confidentiality determinations, if any, by EPA or other Federal agencies, and a copy of any such determination, or reference to it, if available;

(viii) Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business' competitive position, and if so, what those harmful effects would be, why they should be viewed as

substantial, and an explanation of the causal relationship between disclosure and such harmful effects; and

(ix) Whether the business asserts that the information is voluntarily submitted information as defined in §2.201(i), and if so, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

(5) To the extent that the EPA office already possesses the relevant facts, the notice need not solicit responses to the matters addressed in paragraphs (e)(4) (i) through (ix) of this section, although the notice shall request confirmation of EPA's understanding of such facts where appropriate.

(6) The notice shall refer to §2.205(c) and shall include the statement prescribed by §2.203(a).

(f) *Materials to be furnished to EPA legal office.* When a matter is referred to an EPA legal office under paragraph (d)(1) of this section, the EPA office taking action under this section shall forward promptly to the EPA legal office the following items:

(1) A copy of the information in question, or (where the quantity or form of the information makes forwarding a copy of the information impractical) representative samples, a description of the information, or both;

(2) A description of the circumstances and date of EPA's acquisition of the information;

(3) The name, address, and telephone number of the EPA employee(s) most familiar with the information;

(4) The name, address and telephone number of each business which asserts an applicable business confidentiality claim;

(5) A copy of each applicable claim (or the record of the assertion of the claim), and a description of when and how each claim was asserted;

(6) Comments concerning each business's compliance or noncompliance with applicable requirements of §2.203;

(7) A copy of any request for release of the information pending under 5 U.S.C. 552;

(8) A copy of the business's comments on whether the information is entitled to confidential treatment;

(9) The office's comments concerning the appropriate substantive criteria under this subpart, and information the office possesses concerning the information's entitlement to confidential treatment; and

(10) Copies of other correspondence or memoranda which pertain to the matter.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40000, Sept. 8, 1978; 50 FR 51661, Dec. 18, 1985]

Back to Top

§2.205 Final confidentiality determination by EPA legal office.

(a) *Role of EPA legal office.* (1) The appropriate EPA legal office (see paragraph (i) of this section) is responsible for making the final administrative determination of whether or not business information covered by a business confidentiality claim is entitled to confidential treatment under this subpart.

(2) When a request for release of the information under 5 U.S.C. 552 is pending, the EPA legal office's determination shall serve as the final determination on appeal from an initial denial of the request.

(i) If the initial denial was issued under §2.204(b)(1), a final determination by the EPA legal office is necessary only if the requestor has actually filed an appeal.

(ii) If the initial denial was issued under §2.204(d)(1), however, the EPA legal office shall issue a final determination in every case, unless the request has been withdrawn. (Initial denials under §2.204(d)(1) are of a procedural nature, to allow further inquiry into the merits of the matter, and a requestor is entitled to a decision on the merits.) If an appeal from such a denial has not been received by the EPA Freedom of Information Officer on the tenth working day after issuance of the denial, the matter shall be handled as if an appeal had been received on that day, for purposes of establishing a schedule for issuance of an appeal decision under §2.117 of this part.

(b) *Comment period; extensions; untimeliness as waiver of claim.* (1) Each business which has been furnished the notice and opportunity to comment prescribed by §2.204(d)(1) and §2.204(e) shall furnish its comments to the office specified in the notice in time to be postmarked or hand delivered to that office not later than the date specified in the notice (or the date established in lieu thereof under this section).

(2) The period for submission of comments may be extended if, before the comments are due, a request for an extension of the comment period is made by the business and approved by the EPA legal office. Except in extraordinary circumstances, the EPA legal office will not approve such an extension without the consent of any person whose request for release of the information under 5 U.S.C. 552 is pending.

(3) The period for submission of comments by a business may be shortened in the manner described in paragraph (g) of this section.

(4) If a business's comments have not been received by the specified EPA office by the date they are due (including any approved extension), that office shall promptly inquire whether the business has complied with paragraph (b)(1) of this section. If the business has complied with paragraph (b)(1) but the comments have been lost in transmission, duplicate comments shall be requested.

(c) *Confidential treatment of comments from business.* If information submitted to EPA by a business as part of its comments under this section pertains to the business's claim, is not otherwise possessed by EPA, and is marked when received in accordance with §2.203(b), it will be regarded by EPA as entitled to confidential treatment and will not be disclosed by EPA without the business's consent, unless its disclosure is duly ordered by a Federal court, notwithstanding other provisions of this subpart to the contrary.

(d) *Types of final determinations; matters to be considered.* (1) If the EPA legal office finds that a business has failed to furnish comments under paragraph (b) of this section by the specified due date, it shall determine that the business has waived its claim. If, after application of the preceding sentence, no claim applies to the information, the office shall determine that the information is not entitled to confidential treatment under this subpart and, subject to §2.210, is available to the public.

(2) In all other cases, the EPA legal office shall consider each business's claim and comments, the various provisions of this subpart, any previously-issued determinations under this subpart which are pertinent, the materials furnished it under §2.204(f), and such other materials as it finds appropriate. With respect to each claim, the office shall determine whether or not the information is entitled to confidential treatment for the benefit of the business that asserted the claim, and the period of any such entitlement (e.g., until a certain date, until the occurrence of a specified event, or permanently), and shall take further action under paragraph (e) or (f) of this section, as appropriate.

(3) Whenever the claims of two or more businesses apply to the same information, the EPA legal office shall take action appropriate under the particular circumstances to protect the interests of all persons concerned (including any person whose request for the information is pending under 5 U.S.C. 552).

(e) *Determination that information is entitled to confidential treatment.* If the EPA legal office determines that the information is entitled to confidential treatment for the full period requested by the business which made the claim, EPA shall maintain the information in confidence for such period, subject to paragraph (h) of this section, §2.209, and the other provisions of this subpart which authorize disclosure in specified circumstances, and the office shall so inform the business. If any person's request for the release of the information is then pending under 5 U.S.C. 552, the EPA legal office shall issue a final determination denying that request.

(f) *Determination that information is not entitled to confidential treatment; notice; waiting period; release of information.*

(1) Notice of denial (or partial denial) of a business confidentiality claim, in the form prescribed by paragraph (f)(2) of this section, shall be furnished—

(i) By the EPA office taking action under §2.204, to each business on behalf of which a claim has been made, whenever §2.204(d)(2) requires such notice; and

(ii) By the EPA legal office taking action under this section, to each business which has asserted a claim applicable to the information and which has furnished timely comments under paragraph (b) of this section, whenever the EPA legal office determines that the information is not entitled to confidential treatment under this subpart for the benefit of the business, or determines that the period of any entitlement to confidential treatment is shorter than that requested by the business.

(2) The notice prescribed by paragraph (f)(1) of this section shall be written, and shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the fact of receipt and the date of receipt. The notice shall state the basis for the determination, that it constitutes final agency action concerning the business confidentiality claim, and that such final agency action may be subject to judicial review under Chapter 7 of Title 5, United States Code. With respect to EPA's implementation of the determination, the notice shall state that (subject to §2.210) EPA will make the information available to the public on the tenth working day after the date of the business's receipt of the written notice (or on such later date as is established in lieu thereof by the EPA legal office under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business's commencement of an action in a Federal court to obtain judicial review of the determination, and to obtain preliminary injunctive relief against disclosure. The notice shall further state that if such an action is timely commenced, EPA may nonetheless make the information available to the public (in the absence of an order by the court to the contrary), once the court has denied a motion for a preliminary injunction in the action or has otherwise upheld the EPA determination, or whenever it appears to the EPA legal office, after reasonable notice to the business, that the business is not taking appropriate measures to obtain a speedy resolution of the action. If the information has been found to be temporarily entitled to confidential treatment, the notice shall further state that the information will not be disclosed prior to the end of the period of such temporary entitlement to confidential treatment.

(3) The period established in a notice under paragraph (f)(2) of this section for commencement of an action to obtain judicial review may be extended if, before the expiration of such period, a request for an extension is made by the business and approved by the EPA legal office. Except in extraordinary circumstances, the EPA legal office will not approve such an extension without the consent of any person whose request for release of the information under 5 U.S.C. 552 is pending.

(4) After the expiration of any period of temporary entitlement to confidential treatment, a determination under this

paragraph (f) shall be implemented by the EPA legal office by making the information available to the public (in the absence of a court order prohibiting disclosure) whenever—

(i) The period provided for commencement by a business of an action to obtain judicial review of the determination has expired without notice to the EPA legal office of commencement of such an action;

(ii) The court, in a timely-commenced action, has denied the business' motion for a preliminary injunction, or has otherwise upheld the EPA determination; or

(iii) The EPA legal office, after reasonable notice has been provided to the business, finds that the business is not taking appropriate measures to obtain a speedy resolution of the timely-commenced action.

(5) Any person whose request for release of the information under 5 U.S.C. 552 is pending at the time notice is given under paragraph (f)(2) of this section shall be furnished a determination under 5 U.S.C. 552 stating the circumstances under which the information will be released.

(g) *Emergency situations.* If the General Counsel finds that disclosure of information covered by a claim would be helpful in alleviating a situation posing an imminent and substantial danger to public health or safety, he may prescribe and make known to interested persons such shorter comment period (paragraph (b) of this section), post-determination waiting period (paragraph (f) of this section), or both, as he finds necessary under the circumstances.

(h) *Modification of prior determinations.* A determination that information is entitled to confidential treatment for the benefit of a business, made under this subpart by an EPA legal office, shall continue in effect in accordance with its terms until an EPA legal office taking action under this section, or under §2.206 or §2.207, issues a final determination stating that the earlier determination no longer describes correctly the information's entitlement to confidential treatment because of change in the applicable law, newly-discovered or changed facts, or because the earlier determination was clearly erroneous. If an EPA legal office tentatively concludes that such an earlier determination is of questionable validity, it shall so inform the business, and shall afford the business an opportunity to furnish comments on pertinent issues in the manner described by §2.204(e) and paragraph (b) of this section. If, after consideration of any timely comments submitted by the business, the EPA legal office makes a revised final determination that the information is not entitled to confidential treatment, or that the period of entitlement to such treatment will end sooner than it would have ended under the earlier determination, the office will follow the procedure described in paragraph (f) of this section. Determinations under this section may be made only by, or with the concurrence of, the General Counsel.

(i) *Delegation and redelegation of authority.* Unless the General Counsel otherwise directs, or this subpart otherwise specifically provides, determinations and actions required by this subpart to be made or taken by an EPA legal office shall

be made or taken by the appropriate Regional counsel whenever the EPA office taking action under §2.204 or §2.206(b) is under the supervision of a Regional Administrator, and by the General Counsel in all other cases. The General Counsel may redelegate any or all of his authority under this subpart to any attorney employed by EPA on a full-time basis under the General Counsel's supervision. A Regional Counsel may redelegate any or all of his authority under this subpart to any attorney employed by EPA on a full-time basis under the Regional counsel's supervision.

[41 FR 36902, Sept. 1, 1976, as amended at 50 FR 51661, Dec. 18, 1985]

Back to Top

§2.206 Advance confidentiality determinations.

(a) An advance determination under this section may be issued by an EPA legal office if—

(1) EPA has requested or demanded that a business furnish business information to EPA;

(2) The business asserts that the information, if submitted, would constitute voluntarily submitted information under §2.201(i);

(3) The business will voluntarily submit the information for use by EPA only if EPA first determines that the information is entitled to confidential treatment under this subpart; and

(4) The EPA office which desires submission of the information has requested that the EPA legal office issue a determination under this section.

(b) The EPA office requesting an advance determination under this section shall—

(1) Arrange to have the business furnish directly to the EPA legal office a copy of the information (or, where feasible, a description of the nature of the information sufficient to allow a determination to be made), as well as the business's comments concerning the matters addressed in §2.204(e)(4), excluding, however, matters addressed in §2.204 (e)(4)(iii) and (e)(4)(iv); and

(2) Furnish to the EPA legal office the materials referred to in §2.204(f) (3), (7), (8), and (9).

(c) In making a determination under this section, the EPA legal office shall first determine whether or not the information would constitute voluntarily submitted information under §2.201(i). If the information would constitute voluntarily submitted information, the legal office shall further determine whether the information is entitled to confidential treatment.

(d) If the EPA legal office determines that the information would not constitute voluntarily submitted information, or determines that it would constitute voluntarily submitted information but would not be entitled to confidential treatment, it shall so inform the business and the EPA office which requested the determination, stating the basis of the determination, and shall return to the business all copies of the information which it may have received from the business (except that if a request under 5 U.S.C. 552 for release of the information is received while the EPA legal office is in possession of the information, the legal office shall retain a copy of the information, but shall not disclose it unless ordered by a Federal court to do so). The legal office shall not disclose the information to any other EPA office or employee and shall not use the information for any purpose except the determination under this section, unless otherwise directed by a Federal court.

(e) If the EPA legal office determines that the information would constitute voluntarily submitted information and that it is entitled to confidential treatment, it shall so inform the EPA office which requested the determination and the business which submitted it, and shall forward the information to the EPA office which requested the determination.

Back to Top

§2.207 Class determinations.

(a) The General Counsel may make and issue a class determination under this section if he finds that—

(1) EPA possesses, or is obtaining, related items of business information;

(2) One or more characteristics common to all such items of information will necessarily result in identical treatment for each such item under one or more of the provisions in this subpart, and that it is therefore proper to treat all such items as a class for one or more purposes under this subpart; and

(3) A class determination would serve a useful purpose.

(b) A class determination shall clearly identify the class of information to which it pertains.

(c) A class determination may state that all of the information in the class—

(1) Is, or is not, voluntarily submitted information under §2.201(i);

(2) Is, or is not, governed by a particular section of this subpart, or by a particular set of substantive criteria under this subpart;

(3) Fails to satisfy one or more of the applicable substantive criteria, and is therefore ineligible for confidential

treatment;

(4) Satisfies one or more of the applicable substantive criteria; or

(5) Satisfies one or more of the applicable substantive criteria during a certain period, but will be ineligible for confidential treatment thereafter.

(d) The purpose of a class determination is simply to make known the Agency's position regarding the manner in which information within the class will be treated under one or more of the provisions of this subpart. Accordingly, the notice of opportunity to submit comments referred to in §2.204(d)(1)(ii) and §2.205(b), and the list of materials required to be furnished to the EPA legal office under §2.204(d)(1)(iii), may be modified to reflect the fact that the class determination has made unnecessary the submission of materials pertinent to one or more issues. Moreover, in appropriate cases, action based on the class determination may be taken under §2.204(b)(1), §2.204(d), §2.205(d), or §2.206. However, the existence of a class determination shall not, of itself, affect any right a business may have to receive any notice under §2.204(d)(2) or §2.205(f).

Back to Top

§2.208 Substantive criteria for use in confidentiality determinations.

Determinations issued under §§2.204 through 2.207 shall hold that business information is entitled to confidential treatment for the benefit of a particular business if—

(a) The business has asserted a business confidentiality claim which has not expired by its terms, nor been waived nor withdrawn;

(b) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures;

(c) The information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding);

(d) No statute specifically requires disclosure of the information; and

(e) Either—

(1) The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position; or

(2) The information is voluntarily submitted information (see §2.201(i)), and its disclosure would be likely to impair the Government's ability to obtain necessary information in the future.

Back to Top

§2.209 Disclosure in special circumstances.

(a) *General.* Information which, under this subpart, is not available to the public may nonetheless be disclosed to the persons, and in the circumstances, described by paragraphs (b) through (g) of this section. (This section shall not be construed to restrict the disclosure of information which has been determined to be available to the public. However, business information for which a claim of confidentiality has been asserted shall be treated as being entitled to confidential treatment until there has been a determination in accordance with the procedures of this subpart that the information is not entitled to confidential treatment.)

(b) *Disclosure to Congress or the Comptroller General.* (1) Upon receipt of a written request by the Speaker of the House, President of the Senate, chairman of a committee or subcommittee, or the Comptroller General, as appropriate, EPA will disclose business information to either House of Congress, to a committee or subcommittee of Congress, or to the Comptroller General, unless a statute forbids such disclosure.

(2) If the request is for business information claimed as confidential or determined to be confidential, the EPA office processing the request shall provide notice to each affected business of the type of information disclosed and to whom it is disclosed. Notice shall be given at least ten days prior to disclosure, except where it is not possible to provide notice ten days in advance of any date established by the requesting body for responding to the request. Where ten days advance notice cannot be given, as much advance notice as possible shall be provided. Where notice cannot be given before the date established by the requesting body for responding to the request, notice shall be given as promptly after disclosure as possible. Such notice may be given by notice published in the FEDERAL REGISTER or by letter sent by certified mail, return receipt requested, or telegram. However, if the requesting body asks in writing that no notice under this subsection be given, EPA will give no notice.

(3) At the time EPA discloses the business information, EPA will inform the requesting body of any unresolved business confidentiality claim known to cover the information and of any determination under this subpart that the information is entitled to confidential treatment.

(c) *Disclosure to other Federal agencies.* EPA may disclose business information to another Federal agency if—

(1) EPA receives a written request for disclosures of the information from a duly authorized officer or employee of the other agency or on the initiative of EPA when such disclosure is necessary to enable the other agency to carry out a function on behalf of EPA;

(2) The request, if any, sets forth the official purpose for which the information is needed;

(3) When the information has been claimed as confidential or has been determined to be confidential, the responsible EPA office provides notice to each affected business of the type of information to be disclosed and to whom it is to be disclosed. At the discretion of the office, such notice may be given by notice published in the FEDERAL REGISTER at least 10 days prior to disclosure, or by letter sent by certified mail return receipt requested or telegram either of which must be received by the affected business at least 10 days prior to disclosure. However, no notice shall be required when EPA furnishes business information to another Federal agency to perform a function on behalf of EPA, including but not limited to—

(i) Disclosure to the Department of Justice for purposes of investigation or prosecution of civil or criminal violations of Federal law related to EPA activities;

(ii) Disclosure to the Department of Justice for purposes of representing EPA in any matter; or

(iii) Disclosure to any Federal agency for purposes of performing an EPA statutory function under an interagency agreement.

(4) EPA notifies the other agency of any unresolved business confidentiality claim covering the information and of any determination under this subpart that the information is entitled to confidential treatment, and that further disclosure of the information may be a violation of 18 U.S.C. 1905; and

(5) The other agency agrees in writing not to disclose further any information designated as confidential unless—

(i) The other agency has statutory authority both to compel production of the information and to make the proposed disclosure, and the other agency has, prior to disclosure of the information to anyone other than its officers and employees, furnished to each affected business at least the same notice to which the affected business would be entitled under this subpart;

(ii) The other agency has obtained the consent of each affected business to the proposed disclosure; or

(iii) The other agency has obtained a written statement from the EPA General Counsel or an EPA Regional Counsel that disclosure of the information would be proper under this subpart.

(d) *Court-ordered disclosure.* EPA may disclose any business information in any manner and to the extent ordered by a Federal court. Where possible, and when not in violation of a specific directive from the court, the EPA office disclosing information claimed as confidential or determined to be confidential shall provide as much advance notice as possible to each affected business of the type of information to be disclosed and to whom it is to be disclosed, unless the affected business has actual notice of the court order. At the discretion of the office, subject to any restrictions by the court, such notice may be given by notice in the FEDERAL REGISTER, letter sent by certified mail return receipt requested, or telegram.

(e) *Disclosure within EPA.* An EPA office, officer, or employee may disclose any business information to another EPA office, officer, or employee with an official need for the information.

(f) *Disclosure with consent of business.* EPA may disclose any business information to any person if EPA has obtained the prior consent of each affected business to such disclosure.

(g) *Record of disclosures to be maintained.* Each EPA office which discloses information to Congress, a committee or subcommittee of Congress, the Comptroller General, or another Federal agency under the authority of paragraph (b) or (c) of this section, shall maintain a record of the fact of such disclosure for a period of not less than 36 months after such disclosure. Such a record, which may be in the form of a log, shall show the name of the affected businesses, the date of disclosure, the person or body to whom disclosure was made, and a description of the information disclosed.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40000, Sept. 8, 1978; 50 FR 51661, Dec. 18, 1985]

Back to Top

§2.210 Nondisclosure for reasons other than business confidentiality or where disclosure is prohibited by other statute.

(a) Information which is not entitled to confidential treatment under this subpart shall be made available to the public (using the procedures set forth in §§2.204 and 2.205) if its release is requested under 5 U.S.C. 552, unless EPA determines (under subpart A of this part) that, for reasons other than reasons of business confidentiality, the information is exempt from mandatory disclosure and cannot or should not be made available to the public. Any such determination under subpart A shall be coordinated with actions taken under this subpart for the purpose of avoiding delay in responding to requests under 5 U.S.C. 552.

(b) Notwithstanding any other provision of this subpart, if any statute not cited in this subpart appears to require EPA to give confidential treatment to any business information for reasons of business confidentiality, the matter shall be referred promptly to an EPA legal office for resolution. Pending resolution, such information shall be treated as if it were entitled to confidential treatment.

Back to Top

§2.211 Safeguarding of business information; penalty for wrongful disclosure.

(a) No EPA officer or employee may disclose, or use for his or her private gain or advantage, any business information which came into his or her possession, or to which he or she gained access, by virtue of his or her official position or employment, except as authorized by this subpart.

(b) Each EPA officer or employee who has custody or possession of business information shall take appropriate measures to properly safeguard such information and to protect against its improper disclosure.

(c) Violation of paragraph (a) or (b) of this section shall constitute grounds for dismissal, suspension, fine, or other adverse personnel action. Willful violation of paragraph (a) of this section may result in criminal prosecution under 18 U.S.C. 1905 or other applicable statute.

(d) Each contractor or subcontractor with the United States Government, and each employee of such contractor or subcontractor, who is furnished business information by EPA under §2.301(h), §2.302(h), §2.304(h), §2.305(h), §2.306(j), §2.307(h), §2.308(i), or §2.310(h) shall use or disclose that information only as permitted by the contract or subcontract under which the information was furnished. Contractors or subcontractors shall take steps to properly safeguard business information including following any security procedures for handling and safeguarding business information which are contained in any manuals, procedures, regulations, or guidelines provided by EPA. Any violation of this paragraph shall constitute grounds for suspension or debarment of the contractor or subcontractor in question. A willful violation of this paragraph may result in criminal prosecution.

[41 FR 36902, Sept. 1, 1976, as amended at 50 FR 51662, Dec. 18, 1985; 58 FR 461, Jan. 5, 1993]

Back to Top

§2.212 Establishment of control offices for categories of business information.

(a) The Administrator, by order, may establish one or more mutually exclusive categories of business information, and may designate for each such category an EPA office (hereinafter referred to as a *control office*) which shall have responsibility for taking actions (other than actions required to be taken by an EPA legal office) with respect to all information within such category.

(b) If a control office has been assigned responsibility for a category of business information, no other EPA office, officer, or employee may make available to the public (or otherwise disclose to persons other than EPA officers and

employees) any information in that category without first obtaining the concurrence of the control office. Requests under 5 U.S.C. 552 for release of such information shall be referred to the control office.

(c) A control office shall take the actions and make the determinations required by §2.204 with respect to all information in any category for which the control office has been assigned responsibility.

(d) A control office shall maintain a record of the following, with respect to items of business information in categories for which it has been assigned responsibility:

(1) Business confidentiality claims;

(2) Comments submitted in support of claims;

(3) Waivers and withdrawals of claims;

(4) Actions and determinations by EPA under this subpart;

(5) Actions by Federal courts; and

(6) Related information concerning business confidentiality.

Back to Top

§2.213 Designation by business of addressee for notices and inquiries.

(a) A business which wishes to designate a person or office as the proper addressee of communications from EPA to the business under this subpart may do so by furnishing in writing to the Headquarters Freedom of Information Operations (1105), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, the following information: The name and address of the business making the designation; the name, address, and telephone number of the designated person or office; and a request that EPA inquiries and communications (oral and written) under this subpart, including inquiries and notices which require reply within deadlines if the business is to avoid waiver of its rights under this subpart, be furnished to the designee pursuant to this section. Only one person or office may serve at any one time as a business's designee under this subpart.

(b) If a business has named a designee under this section, the following EPA inquiries and notices to the business shall be addressed to the designee:

(1) Inquiries concerning a business's desire to assert a business confidentiality claim, under §2.204(c)(2)(i)(A);

(2) Notices affording opportunity to substantiate confidentiality claims, under §2.204(d)(1) and §2.204(e);

(3) Inquires concerning comments, under §2.205(b)(4);

(4) Notices of denial of confidential treatment and proposed disclosure of information, under §2.205(f);

(5) Notices concerning shortened comment and/or waiting periods under §2.205(g);

(6) Notices concerning modifications or overrulings of prior determinations, under §2.205(h);

(7) Notices to affected businesses under §§2.301(g) and 2.301(h) and analogous provisions in §§2.302, 2.303, 2.304, 2.305, 2.306, 2.307, and 2.308; and

(8) Notices to affected businesses under §2.209.

(c) The Freedom of Information Officer shall, as quickly as possible, notify all EPA offices that may possess information submitted by the business to EPA, the Regional Freedom of Information Offices, the Office of General Counsel, and the offices of Regional Counsel of any designation received under this section. Businesses making designations under this section should bear in mind that several working days may be required for dissemination of this information within EPA and that some EPA offices may not receive notice of such designations.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40001, Sept. 8, 1978]

Back to Top

§2.214 Defense of Freedom of Information Act suits; participation by affected business.

(a) In making final confidentiality determinations under this subpart, the EPA legal office relies to a large extent upon the information furnished by the affected business to substantiate its claim of confidentiality. The EPA legal office may be unable to verify the accuracy of much of the information submitted by the affected business.

(b) If the EPA legal office makes a final confidentiality determination under this subpart that certain business information is entitled to confidential treatment, and EPA is sued by a requester under the Freedom of Information Act for disclosure of that information, EPA will:

(1) Notify each affected business of the suit within 10 days after service of the complaint upon EPA;

(2) Where necessary to preparation of EPA's defense, call upon each affected business to furnish assistance; and

(3) Not oppose a motion by any affected business to intervene as a party to the suit under rule 24(b) of the Federal Rules of Civil Procedure.

(c) EPA will defend its final confidentiality determination, but EPA expects the affected business to cooperate to the fullest extent possible in this defense.

[43 FR 40001, Sept. 8, 1978]

Back to Top

§2.215 Confidentiality agreements.

(a) No EPA officer, employee, contractor, or subcontractor shall enter into any agreement with any affected business to keep business information confidential unless such agreement is consistent with this subpart. No EPA officer, employee, contractor, or subcontractor shall promise any affected business that business information will be kept confidential unless the promise is consistent with this subpart.

(b) If an EPA office has requested information from a State, local, or Federal agency and the agency refuses to furnish the information to EPA because the information is or may constitute confidential business information, the EPA office may enter into an agreement with the agency to keep the information confidential, notwithstanding the provisions of this subpart. However, no such agreement shall be made unless the General Counsel determines that the agreement is necessary and proper.

(c) To determine that an agreement proposed under paragraph (b) of this section is necessary, the General Counsel must find:

(1) The EPA office requesting the information needs the information to perform its functions;

(2) The agency will not furnish the information to EPA without an agreement by EPA to keep the information confidential; and

(3) Either:

(i) EPA has no statutory power to compel submission of the information directly from the affected business, or

(ii) While EPA has statutory power to compel submission of the information directly from the affected business,

compelling submission of the information directly from the business would—

(A) Require time in excess of that available to the EPA office to perform its necessary work with the information,

(B) Duplicate information already collected by the other agency and overly burden the affected business, or

(C) Overly burden the resources of EPA.

(d) To determine that an agreement proposed under paragraph (b) of this section is proper, the General Counsel must find that the agreement states—

(1) The purpose for which the information is required by EPA;

(2) The conditions under which the agency will furnish the information to EPA;

(3) The information subject to the agreement;

(4) That the agreement does not cover information acquired by EPA from another source;

(5) The manner in which EPA will treat the information; and

(6) That EPA will treat the information in accordance with the agreement subject to an order of a Federal court to disclose the information.

(e) EPA will treat any information acquired pursuant to an agreement under paragraph (b) of this section in accordance with the procedures of this subpart except where the agreement specifies otherwise.

[43 FR 40001, Sept. 8, 1978]

Back to Top

§§2.216-2.300 [Reserved]

Back to Top

§2.301 Special rules governing certain information obtained under the Clean Air Act.

(a) *Definitions.* For the purpose of this section:

(1) *Act* means the Clean Air Act, as amended, 42 U.S.C. 7401 *et seq.*

(2)(i) *Emission data* means, with reference to any source of emission of any substance into the air—

(A) Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source (or of any pollutant resulting from any emission by the source), or any combination of the foregoing;

(B) Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of the emissions which, under an applicable standard or limitation, the source was authorized to emit (including, to the extent necessary for such purposes, a description of the manner or rate of operation of the source); and

(C) A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

(ii) Notwithstanding paragraph (a)(2)(i) of this section, the following information shall be considered to be *emission data* only to the extent necessary to allow EPA to disclose publicly that a source is (or is not) in compliance with an applicable standard or limitation, or to allow EPA to demonstrate the feasibility, practicability, or attainability (or lack thereof) of an existing or proposed standard or limitation:

(A) Information concerning research, or the results of research, on any project, method, device or installation (or any component thereof) which was produced, developed, installed, and used only for research purposes; and

(B) Information concerning any product, method, device, or installation (or any component thereof) designed and intended to be marketed or used commercially but not yet so marketed or used.

(3) *Standard or limitation* means any emission standard or limitation established or publicly proposed pursuant to the Act or pursuant to any regulation under the Act.

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(5) *Manufacturer* has the meaning given it in section 216(1) of the Act, 42 U.S.C. 7550(1).

(b) *Applicability.* (1) This section applies to business information which was—

(i) Provided or obtained under section 114 of the Act, 42 U.S.C. 7414, by the owner or operator of any stationary source, for the purpose (A) of developing or assisting in the development of any implementation plan under section 110 or 111(d) of the Act, 42 U.S.C. 7410, 7411(d), any standard of performance under section 111 of the Act, 42 U.S.C. 7411, or any emission standard under section 112 of the Act, 42 U.S.C. 7412, (B) of determining whether any person is in violation of any such standard or any requirement of such a plan, or (C) of carrying out any provision of the Act (except a provision of Part II of the Act with respect to a manufacturer of new motor vehicles or new motor vehicle engines);

(ii) Provided or obtained under section 208 of the Act, 42 U.S.C. 7542, for the purpose of enabling the Administrator to determine whether a manufacturer has acted or is acting in compliance with the Act and regulations under the Act, or provided or obtained under section 206(c) of the Act, 42 U.S.C. 7525(c); or

(iii) Provided in response to a subpoena for the production of papers, books, or documents issued under the authority of section 307(a) of the Act, 42 U.S.C. 7607(a).

(2) Information will be considered to have been provided or obtained under section 114 of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 114, or if its submission could have been required under section 114, regardless of whether section 114 was cited as the authority for any request for the information, whether an order to provide the information was issued under section 113(a) of the Act, 42 U.S.C. 7413(a), whether an action was brought under section 113(b) of the Act, 42 U.S.C. 7413(b), or whether the information was provided directly to EPA or through some third person.

(3) Information will be considered to have been provided or obtained under section 208 of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 208, or if its submission could have been required under section 208, regardless of whether section 208 was cited as the authority for any request for the information, whether an action was brought under section 204 of the Act, 42 U.S.C. 7523, or whether the information was provided directly to EPA or through some third person.

(4) Information will be considered to have been provided or obtained under section 206(c) of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 206(c), or if its submission could have been required under section 206(c) regardless of whether section 206(c) was cited as authority for any request for the information, whether an action was brought under section 204 of the Act, 42 U.S.C. 7523, or whether the information was provided directly to EPA or through some third person.

(5) Information will be considered to have been provided or obtained under section 307(a) of the Act if it was provided in response to a subpoena issued under section 307(a), or if its production could have been required by subpoena under section 307(a), regardless of whether section 307(a) was cited as the authority for any request for the information, whether

a subpoena was issued by EPA, whether a court issued an order under section 307(a), or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules that apply without change.* Except as otherwise provided in paragraph (d) of this section, §§2.201 through 2.207, §2.209, and §§2.211 through 2.215 apply without change to information to which this section applies.

(d) *Data submitted under 40 CFR part 98.* (1) Sections 2.201 through 2.215 do not apply to data submitted under 40 CFR part 98 that EPA has determined, pursuant to sections 114(c) and 307(d) of the Clean Air Act, to be either of the following:

(i) Emission data.

(ii) Data not otherwise entitled to confidential treatment pursuant to section 114(c) of the Clean Air Act.

(2) Except as otherwise provided in paragraphs (d)(2) and (d)(4) of this section, §§2.201 through 2.215 do not apply to data submitted under 40 CFR part 98 data that EPA has determined, pursuant to sections 114(c) and 307(d) of the Clean Air Act, to be entitled to confidential treatment. EPA shall treat that information as confidential in accordance with the provisions of §2.211, subject to paragraph (d)(4) of this section and §2.209.

(3) Upon receiving a request under 5 U.S.C. 552 for data submitted under 40 CFR part 98 that EPA has determined, pursuant to sections 114(c) and 307(d) of the Clean Air Act, to be entitled to confidential treatment, the EPA office shall furnish the requestor a notice that the information has been determined to be entitled to confidential treatment and that the request is therefore denied. The notice shall include or cite to the appropriate EPA determination.

(4) Modification of prior confidentiality determination. A determination made pursuant to sections 114(c) and 307(d) of the Clean Air Act that information submitted under 40 CFR part 98 is entitled to confidential treatment shall continue in effect unless, subsequent to the confidentiality determination, EPA takes one of the following actions:

(i) EPA determines, pursuant to sections 114(c) and 307(d) of the Clean Air Act, that the information is emission data or data not otherwise entitled to confidential treatment under section 114(c) of the Clean Air Act.

(ii) The Office of General Counsel issues a final determination, based on the criteria in §2.208, stating that the information is no longer entitled to confidential treatment because of change in the applicable law or newly-discovered or changed facts. Prior to making such final determination, EPA shall afford the business an opportunity to submit comments on pertinent issues in the manner described by §§2.204(e) and 2.205(b). If, after consideration of any timely comments submitted by the business, the Office of General Counsel makes a revised final determination that the information is not entitled to confidential treatment under section 114(c) of the Clean Air Act, EPA will notify the business in accordance with

the procedures described in §2.205(f)(2).

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies to information to which this section applies, except that information which is emission data, a standard or limitation, or is collected pursuant to section 211(b)(2)(A) of the Act is not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(f) *Availability of information not entitled to confidential treatment.* Section 2.210 does not apply to information to which this section applies. Emission data, standards or limitations, and any other information provided under section 114 or 208 of the Act which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public notwithstanding any other provision of this part. Emission data and standards or limitations provided in response to a subpoena issued under section 307(a) of the Act shall be available to the public notwithstanding any other provision of this part. Information (other than emission data and standards or limitations) provided in response to a subpoena issued under section 307(a) of the Act, which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public, unless EPA determines that the information is exempt from mandatory disclosure under 5 U.S.C. 552(b) for reasons other than reasons of business confidentiality and cannot or should not be made available to the public.

(g) *Disclosure of information relevant to a proceeding.* (1) Under sections 114, 208 and 307 of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2) In connection with any proceeding other than a proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, information to which this section applies which may be entitled to confidential treatment may be made available to the public under this paragraph (g)(2). No information shall be made available to the public under this paragraph (g)(2) until any affected business has been informed that EPA is considering making the information available to the public under this paragraph (g)(2) in connection with an identified proceeding, and has afforded the business a reasonable period for comment (such notice and opportunity to comment may be afforded in connection with the notice prescribed by §2.204(d)(1) and §2.204(e)). Information may be made available to the public under this paragraph (g)(2) only if, after consideration of any timely comments submitted by the business, the General Counsel determines that the information is relevant to the subject of the proceeding and the EPA office conducting the proceeding determines that the public interest would be served by making the information available to the public. Any affected business shall be given at least 5 days' notice by the General Counsel prior to making the information available to the public.

(3) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory

hearing, information to which this section applies which may be entitled to confidential treatment may be made available to the public, or to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(3). An EPA office proposing disclosure of information under this paragraph (g)(3), shall so notify the presiding officer in writing. Upon receipt of such a notification, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(3) has been proposed, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed under this paragraph (g)(3) only if, after consideration of any timely comments submitted by the business, the EPA office determines in writing that, for reasons directly associated with the conduct of the proceeding, the contemplated disclosure would serve the public interest, and the presiding officer determines in writing that the information is relevant to a matter in controversy in the proceeding. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to the public or to one or more of the parties of record to the proceeding.

(4) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, information to which this section applies may be made available to one or more parties of record to the proceeding, upon request of a party, under this paragraph (g)(4). A party of record seeking disclosure of information shall direct his request to the presiding officer. Upon receipt of such a request, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(4) has been requested, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed to a party of record under this paragraph (g)(4) only if, after consideration of any timely comments submitted by the business, the presiding officer determines in writing that (i) the party of record has satisfactorily shown that with respect to a significant matter which is in controversy in the proceeding, the party's ability to participate effectively in the proceeding will be significantly impaired unless the information is disclosed to him, and (ii) any harm to an affected business that would result from the disclosure is likely to be outweighed by the benefit to the proceeding and to the public interest that would result from the disclosure. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information to confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to one or more of the parties of record to the proceeding.

(h) *Disclosure to authorized representatives.* (1) Under sections 114, 208 and 307(a) of the Act, EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h) (2) or (3) of this section.

(2)(i) A person under contract or subcontract to the United States government to perform work in support of EPA in connection with the Act or regulations which implement the Act may be considered an authorized representative of the United States for purposes of this paragraph (h). For purposes of this section, the term “contract” includes grants and cooperative agreements under the Environmental Programs Assistance Act of 1984 (Pub. L. 98-313), and the term “contractor” includes grantees and cooperators under the Environmental Programs Assistance Act of 1984. Subject to the limitations in this paragraph (h)(2), information to which this section applies may be disclosed:

(A) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor or subcontractor may carry out the work required by the contract or subcontract; or

(B) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary in order that the contractor or subcontractor may carry out the work required by the contract or subcontract.

(ii) No information shall be disclosed under this paragraph (h)(2), unless this contract or subcontract in question provides:

(A) That the contractor or subcontractor and the contractor's or subcontractor's employees shall use the information only for the purpose of carrying out the work required by the contract or subcontract, shall refrain from disclosing the information to anyone other than EPA without the prior written approval of each affected business or of an EPA legal office and shall return to EPA all copies of the information (and any abstracts or extracts therefrom) upon request by the EPA program office, whenever the information is no longer required by the contractor or subcontractor for the performance of the work required under the contract or subcontract, or upon completion of the contract or subcontract (where the information was provided to the contractor or subcontractor by an agency other than EPA, the contractor may disclose or return the information to that agency);

(B) That the contractor or subcontractor shall obtain a written agreement to honor such terms of the contract or subcontract from each of the contractor's or subcontractor's employees who will have access to the information, before such employee is allowed such access; and

(C) That the contractor or subcontractor acknowledges and agrees that the contract or subcontract provisions concerning the use and disclosure of business information are included for the benefit of, and shall be enforceable by, both the United States government and any affected business having an interest in information concerning it supplied to the contractor or subcontractor by the United States government under the contract or subcontract.

(iii) No information shall be disclosed under this paragraph (h)(2) until each affected business has been furnished notice of the contemplated disclosure by the EPA program office and has been afforded a period found reasonable by that office (not less than 5 working days) to submit its comments. Such notice shall include a description of the information to be disclosed, the identity of the contractor or subcontractor, the contract or subcontract number, if any, and the purposes to be served by the disclosure.

(iv) The EPA program office shall prepare a record of each disclosure under this paragraph (h)(2), showing the contractor or subcontractor, the contract or subcontract number, the information disclosed, the date(s) of disclosure, and each affected business. The EPA program office shall maintain the record of disclosure and the determination of necessity prepared under paragraph (h)(2)(i) of this section for a period of not less than 36 months after the date of the disclosure.

(3) A State or local governmental agency which has duties or responsibilities under the Act, or under regulations which implement the Act, may be considered an authorized representative of the United States for purposes of this paragraph (h). Information to which this section applies may be furnished to such an agency at the agency's written request, but only if—

(i) The agency has first furnished to the EPA office having custody of the information a written opinion from the agency's chief legal officer or counsel stating that under applicable State or local law the agency has the authority to compel a business which possesses such information to disclose it to the agency, or

(ii) Each affected business is informed of those disclosures under this paragraph (h)(3) which pertain to it, and the agency has shown to the satisfaction of an EPA legal office that the agency's use and disclosure of such information will be governed by State or local law and procedures which will provide adequate protection to the interests of affected businesses.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40002, Sept. 8, 1978; 43 FR 42251, Sept. 20, 1978; 50 FR 51662, Dec. 18, 1985; 58 FR 461, Jan. 5, 1993; 58 FR 5061, Jan. 19, 1993; 58 FR 7189, Feb. 5, 1993; 76 FR 30817, May 26, 2011; 76 FR 64015, Oct. 17, 2011]

Back to Top

§2.302 Special rules governing certain information obtained under the Clean Water Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Clean Water Act, as amended, 33 U.S.C. 1251 *et seq.*

(2)(i) *Effluent data* means, with reference to any source of discharge of any pollutant (as that term is defined in section 502(6) of the Act, 33 U.S.C. 1362 (6))—

(A) Information necessary to determine the identity, amount, frequency, concentration, temperature, or other characteristics (to the extent related to water quality) of any pollutant which has been discharged by the source (or of any pollutant resulting from any discharge from the source), or any combination of the foregoing;

(B) Information necessary to determine the identity, amount, frequency, concentration, temperature, or other characteristics (to the extent related to water quality) of the pollutants which, under an applicable standard or limitation, the source was authorized to discharge (including, to the extent necessary for such purpose, a description of the manner or rate of operation of the source); and

(C) A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

(ii) Notwithstanding paragraph (a)(2)(i) of this section, the following information shall be considered to be *effluent data* only to the extent necessary to allow EPA to disclose publicly that a source is (or is not) in compliance with an applicable standard or limitation, or to allow EPA to demonstrate the feasibility, practicability, or attainability (or lack thereof) of an existing or proposed standard or limitation:

(A) Information concerning research, or the results of research, on any product, method, device, or installation (or any component thereof) which was produced, developed, installed, and used only for research purposes; and

(B) Information concerning any product, method, device, or installation (or any component thereof) designed and intended to be marketed or used commercially but not yet so marketed or used.

(3) *Standard or limitation* means any prohibition, any effluent limitation, or any toxic, pre-treatment or new source performance standard established or publicly proposed pursuant to the Act or pursuant to regulations under the Act, including limitations or prohibitions in a permit issued or proposed by EPA or by a State under section 402 of the Act, 33 U.S.C. 1342.

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this part.

(b) *Applicability.* (1) This section applies only to business information—

(i) Provided to or obtained by EPA under section 308 of the Act, 33 U.S.C. 1318, by or from the owner or operator of any point source, for the purpose of carrying out the objective of the Act (including but not limited to developing or assisting in the development of any standard or limitation under the Act, or determining whether any person is in violation of any such standard or limitation); or

(ii) Provided to or obtained by EPA under section 509(a) of the Act, 33 U.S.C. 1369(a).

(2) Information will be considered to have been provided or obtained under section 308 of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 308, or if its submission could have been required under section 308, regardless of whether section 308 was cited as the authority for any request for the information, whether an order to provide the information was issued under section 309(a)(3) of the Act, 33 U.S.C. 1319(a)(3), whether a civil action was brought under section 309(b) of the Act, 33 U.S.C. 1319(b), and whether the information was provided directly to EPA or through some third person.

(3) Information will be considered to have been provided or obtained under section 509(a) of the Act if it was provided in response to a subpoena issued under section 509(a), or if its production could have been required by subpoena under section 509(a), regardless of whether section 509(a) was cited as the authority for any request for the information, whether a subpoena was issued by EPA, whether a court issued an order under section 307(a), or whether the information was provided directly to EPA or through some third person.

(4) This section specifically does not apply to information obtained under section 310(d) or 312(g)(3) of the Act, 33 U.S.C. 1320(d), 1322(g)(3).

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207, 2.209, 2.211 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies to information to which this section applies, except that information which is effluent data or a standard or limitation is not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(f) *Availability of information not entitled to confidential treatment.* Section 2.210 does not apply to information to which this section applies. Effluent data, standards or limitations, and any other information provided or obtained under section 308 of the Act which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public notwithstanding any other provision of this part. Effluent data and standards or limitations provided in response to a subpoena issued under section 509(a) of the Act shall be available to the public notwithstanding any other provision of this

part. Information (other than effluent data and standards or limitations) provided in response to a subpoena issued under section 509(a) of the Act, which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public, unless EPA determines that the information is exempt from mandatory disclosure under 5 U.S.C. 552(b) for reasons other than reasons of business confidentiality and cannot or should not be made available to the public.

(g) *Disclosure of information relevant to a proceeding.* (1) Under sections 308 and 509(a) of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information to which this section applies because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2)-(4) The provisions of §2.301(g) (2), (3), and (4) are incorporated by reference as paragraphs (g) (2), (3), and (4), respectively of this section.

(h) *Disclosure to authorized representatives.* (1) Under sections 308 and 509(a) of the Act, EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2)-(3) The provisions of §2.301(h) (2) and (3) are incorporated by reference as paragraphs (h) (2) and (3), respectively, of this section.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40003, Sept. 8, 1978]

Back to Top

§2.303 Special rules governing certain information obtained under the Noise Control Act of 1972.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Noise Control Act of 1972, 42 U.S.C. 4901 *et seq.*

(2) *Manufacturer* has the meaning given it in 42 U.S.C. 4902(6).

(3) *Product* has the meaning given it in 42 U.S.C. 4902(3).

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(b) *Applicability.* This section applies only to information provided to or obtained by EPA under section 13 of the Act, 42 U.S.C. 4912, by or from any manufacturer of any product to which regulations under section 6 or 8 of the Act (42 U.S.C. 4905, 4907) apply. Information will be deemed to have been provided or obtained under section 13 of the Act, if it was provided in response to a request by EPA made for the purpose of enabling EPA to determine whether the manufacturer has acted or is acting in compliance with the Act, or if its submission could have been required under section 13 of the Act, regardless of whether section 13 was cited as authority for the request, whether an order to provide such information was issued under section 11(d) of the Act, 42 U.S.C. 4910(d), and whether the information was provided directly to EPA by the manufacturer or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and 2.209 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(f) [Reserved]

(g) *Disclosure of information relevant to a proceeding.* (1) Under section 13 of the Act, any information to which this section applies may be released by EPA because of its relevance to a matter in controversy in a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2)-(4) The provisions of §2.301(g) (2), (3), and (4) are incorporated by reference as paragraphs (g) (2), (3), and (4), respectively, of this section.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40003, Sept. 8, 1978]

Back to Top

§2.304 Special rules governing certain information obtained under the Safe Drinking Water Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Safe Drinking Water Act, 42 U.S.C. 300f *et seq.*

(2) *Contaminant* means any physical, chemical, biological, or radiological substance or matter in water.

(3) *Proceeding* means any rulemaking, adjudication, or licensing process conducted by EPA under the Act or under regulations which implement the Act, except for any determination under this part.

(b) *Applicability.* (1) This section applies only to information—

(i) Which was provided to or obtained by EPA pursuant to a requirement of a regulation which was issued by EPA under the Act for the purpose of—

(A) Assisting the Administrator in establishing regulations under the Act;

(B) Determining whether the person providing the information has acted or is acting in compliance with the Act; or

(C) Administering any program of financial assistance under the Act; and

(ii) Which was provided by a person—

(A) Who is a supplier of water, as defined in section 1401(5) of the Act, 42 U.S.C. 300f(5);

(B) Who is or may be subject to a primary drinking water regulation under section 1412 of the Act, 42 U.S.C. 300g-1;

(C) Who is or may be subject to an applicable underground injection control program, as defined in section 1422(d) of the Act, 42 U.S.C.300h-1(d);

(D) Who is or may be subject to the permit requirements of section 1424(b) of the Act, 42 U.S.C. 300h-3(b);

(E) Who is or may be subject to an order issued under section 1441(c) of the Act, 42 U.S.C. 300j(c); or

(F) Who is a grantee, as defined in section 1445(e) of the Act, 42 U.S.C. 300j-4(e).

(2) This section applies to any information which is described by paragraph (b)(1) of this section if it was provided in response to a request by EPA or its authorized representative (or by a State agency administering any program under the Act) made for any purpose stated in paragraph (b)(1) of this section, or if its submission could have been required under section 1445 of the Act, 42 U.S.C. 300j-4, regardless of whether such section was cited in any request for the information, or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207, 2.209, and 2.211 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies to information to which this section applies, except that information which deals with the existence, absence, or level of contaminants in drinking water is not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(f) *Nondisclosure for reasons other than business confidentiality or where disclosure is prohibited by other statute.* Section 2.210 applies to information to which this section applies, except that information which deals with the existence, absence, or level of contaminants in drinking water shall be available to the public notwithstanding any other provision of this part.

(g) *Disclosure of information relevant to a proceeding.* (1) Under section 1445(d) of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information to which this section applies because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2)-(4) The provisions of §2.301(g) (2), (3), (4) are incorporated by reference as paragraphs (g) (2), (3), and (4), respectively, of this section.

(h) *Disclosure to authorized representatives.* (1) Under section 1445(d) of the Act, EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2)-(3) The provisions of §2.301(h) (2) and (3) are incorporated by reference as paragraphs (h) (2) and (3), respectively, of this section.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40003, Sept. 8, 1978]

Back to Top

§2.305 Special rules governing certain information obtained under the Solid Waste Disposal Act, as amended.

(a) *Definitions.* For purposes of this section:

(1) *Act* means the Solid Waste Disposal Act, as amended, including amendments made by the Resource

Conservation and Recovery Act of 1976, as amended, 42 U.S.C. 6901 *et seq.*

(2) *Person* has the meaning given it in section 1004(15) of the Act, 42 U.S.C. 6903(15).

(3) *Hazardous waste* has the meaning given it in section 1004(5) of the Act, 42 U.S.C. 6903(5).

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act including the issuance of administrative orders and the approval or disapproval of plans (e.g. closure plans) submitted by persons subject to regulation under the Act, but not including determinations under this subpart.

(b) *Applicability.* This section applies to information provided to or obtained by EPA under section 3001(b)(3)(B), 3007, or 9005 of the Act, 42 U.S.C 6921(b)(3)(B), 6927, or 6995. Information will be considered to have been provided or obtained under sections 3001(b)(3)(B), 3007, or 9005 of the Act if it was provided in response to a request from EDA made for any of the purposes stated in the Act or if its submission could have been required under those provisions of the Act regardless of whether a specific section was cited as the authority for any request for the information or whether the information was provide directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and 2.209 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(f) [Reserved]

(g) *Disclosure of information relevant in a proceeding.* (1) Under sections 3007(b) and 9005(b) of the Act (42 U.S.C. 6927(b) and 6995(b)), any information to which this section applies may be disclosed by EPA because of the relevance of the information in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (g).

(2)-(4) The provisions of §2.301(g) (2), (3), and (4) are incorporated by reference as paragraphs (g) (2), (3), and (4), respectively, of this section.

(h) *Disclosure to authorized representatives.* (1) Under sections 3001(b)(3)(B), 3007(b), and 9005(b) of the Act (42 U.S.C. 6921(b)(3)(B), 6927(b), and 6995(b)), EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2)-(3) The provisions of §2.301(h) (2) and (3) are incorporated by reference as paragraphs (h) (2) and (3), respectively, of this section.

(4) At the time any information is furnished to a contractor, subcontractor, or State or local government agency under this paragraph (h), the EPA office furnishing the information to the contractor, subcontractor, or State or local government agency shall notify the contractor, subcontractor, or State or local government agency that the information may be entitled to confidential treatment and that any knowing and willful disclosure of the information may subject the contractor, subcontractor, or State or local government agency and its employees to penalties in section 3001(b)(3)(B), 3007(b)(2), or 9005(b)(1) of the Act (42 U.S.C. 6921(b)(3)(B), 6927(b), or 6995(b)).

[43 FR 40003, Sept. 8, 1978, as amended at 50 FR 51662, Dec. 18, 1985]

Back to Top

§2.306 Special rules governing certain information obtained under the Toxic Substances Control Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

(2) *Chemical substance* has the meaning given it in section 3(2) of the Act, 15 U.S.C. 2602(2).

(3)(i) *Health and safety data* means the information described in paragraphs (a)(3)(i) (A), (B), and (C) of this section with respect to any chemical substance or mixture offered for commercial distribution (including for test marketing purposes and for use in research and development), any chemical substance included on the inventory of chemical substances under section 8 of the Act (15 U.S.C. 2607), or any chemical substance or mixture for which testing is required under section 4 of the Act (15 U.S.C. 2603) or for which notification is required under section 5 of the Act (15 U.S.C. 2604).

(A) Any study of any effect of a chemical substance or mixture on health, on the environment, or on both, including underlying data and epidemiological studies; studies of occupational exposure to a chemical substance or mixture; and

toxicological, clinical, and ecological studies of a chemical substance or mixture;

(B) Any test performed under the Act; and

(C) Any data reported to, or otherwise obtained by, EPA from a study described in paragraph (a)(3)(i)(A) of this section or a test described in paragraph (a)(3)(i)(B) of this section.

(ii) Notwithstanding paragraph (a)(3)(i) of this section, no information shall be considered to be *health and safety data* if disclosure of the information would—

(A) In the case of a chemical substance or mixture, disclose processes used in the manufacturing or processing the chemical substance or mixture or,

(B) In the case of a mixture, disclose the portion of the mixture comprised by any of the chemical substances in the mixture.

(4) [Reserved]

(5) *Mixture* has the meaning given it in section 3(8) of the Act, 15 U.S.C. 2602(8).

(6) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(b) *Applicability.* This section applies to all information submitted to EPA for the purpose of satisfying some requirement or condition of the Act or of regulations which implement the Act, including information originally submitted to EPA for some other purpose and either relied upon to avoid some requirement or condition of the Act or incorporated into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. Information will be considered to have been provided under the Act if the information could have been obtained under authority of the Act, whether the Act was cited as authority or not, and whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.203, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that the provisions of paragraph (e)(3) of this section regarding the time allowed for seeking judicial review shall be reflected in any notice furnished to a business under §2.204(d)(2).

(e) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) Notwithstanding §2.205(i), the General Counsel (or his designee), rather than the regional counsel, shall make the determinations and take the actions required by §2.205;

(2) In addition to the statement prescribed by the second sentence of §2.205(f)(2), the notice of denial of a business confidentiality claim shall state that under section 20(a) of the Act, 15 U.S.C. 2619, the business may commence an action in an appropriate Federal district court to prevent disclosure.

(3) The following sentence is substituted for the third sentence of §2.205(f)(2): “With respect to EPA's implementation of the determination, the notice shall state that (subject to §2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the date of the business' receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business' commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against disclosure.”; and

(4) Notwithstanding §2.205(g), the 31 calendar day period prescribed by §2.205(f)(2), as modified by paragraph (e)(3) of this section, shall not be shortened without the consent of the business.

(f) [Reserved]

(g) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies, except that health and safety data are not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(h) *Disclosure in special circumstances.* Section 2.209 applies to information to which this section applies, except that the following two additional provisions apply to §2.209(c):

(1) The official purpose for which the information is needed must be in connection with the agency's duties under any law for protection of health or the environment or for specific law enforcement purposes; and

(2) EPA notifies the other agency that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the officers and employees of the other agency to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(i) *Disclosure of information relevant in a proceeding.* (1) Under section 14(a)(4) of the Act (15 U.S.C. 2613(a)(4)), any

information to which this section applies may be disclosed by EPA when the information is relevant in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. However, any such disclosure shall be made in a manner that preserves the confidentiality of the information to the extent practicable without impairing the proceeding. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (i).

(2)-(4) The provisions of §2.301(g) (2), (3), and (4) are incorporated by reference as paragraphs (i) (2), (3), and (4), respectively, of this section.

(j) *Disclosure of information to contractors and subcontractors.* (1) Under section 14(a)(2) of the Act (15 U.S.C. 2613(a)(2)), any information to which this section applies may be disclosed by EPA to a contractor or subcontractor of the United States performing work under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Subject to the limitations in this paragraph (j), information to which this section applies may be disclosed:

(i) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract; or

(ii) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract.

(2)-(4) The provisions of §2.301(h)(2) (ii), (iii), and (iv) are incorporated by reference as paragraphs (j) (2), (3), and (4), respectively, of this section.

(5) At the time any information is furnished to a contractor or subcontractor under this paragraph (j), the EPA office furnishing the information to the contractor or subcontractor shall notify the contractor or subcontractor that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the contractor or subcontractor and its employees to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(k) *Disclosure of information when necessary to protect health or the environment against an unreasonable risk of injury.* (1) Under section 14(a)(3) of the Act (15 U.S.C 2613(a)(3)), any information to which this section applies may be disclosed by EPA when disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment. However, any disclosure shall be made in a manner that preserves the confidentiality of the

information to the extent not inconsistent with protecting health or the environment against the unreasonable risk of injury. Disclosure of information to which this section applies because of the need to protect health or the environment against an unreasonable risk of injury shall be made only in accordance with this paragraph (k).

(2) If any EPA office determines that there is an unreasonable risk of injury to health or the environment and that to protect health or the environment against the unreasonable risk of injury it is necessary to disclose information to which this section applies that otherwise might be entitled to confidential treatment under this subpart, the EPA office shall notify the General Counsel in writing of the nature of the unreasonable risk of injury, the extent of the disclosure proposed, how the proposed disclosure will serve to protect health or the environment against the unreasonable risk of injury, and the proposed date of disclosure. Such notification shall be made as soon as practicable after discovery of the unreasonable risk of injury. If the EPA office determines that the risk of injury is so imminent that it is impracticable to furnish written notification to the General Counsel, the EPA office shall notify the General Counsel orally.

(3) Upon receipt of notification under paragraph (k)(2) of this section, the General Counsel shall make a determination in writing whether disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury. The General Counsel shall also determine the extent of disclosure necessary to protect against the unreasonable risk of injury as well as when the disclosure must be made to protect against the unreasonable risk of injury.

(4) If the General Counsel determines that disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury, the General Counsel shall furnish notice to each affected business of the contemplated disclosure and of the General Counsel's determination. Such notice shall be made in writing by certified mail, return receipt requested, at least 15 days before the disclosure is to be made. The notice shall state the date upon which disclosure will be made. However, if the General Counsel determines that the risk of injury is so imminent that it is impracticable to furnish such notice 15 days before the proposed date of disclosure, the General Counsel may provide notice by means that will provide receipt of the notice by the affected business at least 24 hours before the disclosure is to be made. This may be done by telegram, telephone, or other reasonably rapid means.

[43 FR 40003, Sept. 8, 1978, as amended at 44 FR 17674, Mar. 23, 1979; 58 FR 462, Jan. 5, 1993]

Back to Top

§2.307 Special rules governing certain information obtained under the Federal Insecticide, Fungicide and Rodenticide Act.

(a) *Definitions.* For the purposes of this section;

(1) *Act* means the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.,* and its predecessor, 7 U.S.C. 135 *et seq.*

(2) *Applicant* means any person who has submitted to EPA (or to a predecessor agency with responsibility for administering the Act) a registration statement or application for registration under the Act of a pesticide or of an establishment.

(3) *Registrant* means any person who has obtained registration under the Act of a pesticide or of an establishment.

(b) *Applicability.* This section applies to all information submitted to EPA by an applicant or registrant for the purpose of satisfying some requirement or condition of the Act or of regulations which implement the Act, including information originally submitted to EPA for some other purpose but incorporated by the applicant or registrant into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. This section does not apply to information supplied to EPA by a petitioner in support of a petition for a tolerance under 21 U.S.C. 346a(d), unless the information is also described by the first sentence of this paragraph.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.203, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that the provisions of paragraph (e) of this section regarding the time allowed for seeking judicial review shall be reflected in any notice furnished to a business under §2.204(d)(2).

(e) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) Notwithstanding §2.205(i), the General Counsel (or his designee), rather than the Regional Counsel, shall make the determinations and take the actions required by §2.205;

(2) In addition to the statement prescribed by the second sentence of §2.205(f)(2), the notice of denial of a business confidentiality claim shall state that under section 10(c) of the Act, 7 U.S.C. 136h(c), the business may commence an action in an appropriate Federal district court for a declaratory judgment;

(3) The following sentence is substituted for the third sentence of §2.205(f)(2): “With respect to EPA's implementation of the determination, the notice shall state that (subject to §2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the date of the business's receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the

business's commencement of an action in a Federal court to obtain judicial review of the determination or to obtain a declaratory judgment under section 10(c) of the Act and to obtain preliminary injunctive relief against disclosure."; and

(4) Notwithstanding §2.205(g), the 31 calendar day period prescribed by §2.205(f)(2), as modified by paragraph (e)(3) of this section, shall not be shortened without the consent of the business.

(f) [Reserved]

(g) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(h) *Disclosure in special circumstances.* (1) Section 2.209 applies without change to information to which this section applies. In addition, under section 12(a)(2)(D) of the Act, 7 U.S.C. 136j(a)(2)(D), EPA possesses authority to disclose any information to which this section applies to physicians, pharmacists, and other qualified persons needing such information for the performance of their duties, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority under section 12(a)(2)(D) of the Act may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2) Information to which this section applies may be disclosed (notwithstanding the fact that it might otherwise be entitled to confidential treatment under this subpart) to physicians, pharmacists, hospitals, veterinarians, law enforcement personnel, or governmental agencies with responsibilities for protection of public health, and to employees of any such persons or agencies, or to other qualified persons, when and to the extent that disclosure is necessary in order to treat illness or injury or to prevent imminent harm to persons, property, or the environment, in the opinion of the Administrator or his designee.

(3) Information to which this section applies may be disclosed (notwithstanding the fact that it otherwise might be entitled to confidential treatment under this subpart) to a person under contract to EPA to perform work for EPA in connection with the Act or regulations which implement the Act, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor may carry out the work required by the contract. Any such disclosure to a contractor shall be made only in accordance with the procedure and requirements of §2.301(h)(2) (ii) through (iv).

(4) Information to which this section applies, and which relates to formulas of products, may be disclosed at any public hearing or in findings of fact issued by the Administrator, to the extent and in the manner authorized by the Administrator or his designee.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40005, Sept. 8, 1978]

Back to Top

§2.308 Special rules governing certain information obtained under the Federal Food, Drug and Cosmetic Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*

(2) *Petition* means a petition for the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, pursuant to section 408(d) of the Act, 21 U.S.C. 346a(d).

(3) *Petitioner* means a person who has submitted a petition to EPA (or to a predecessor agency).

(b) *Applicability.* (1) This section applies only to business information submitted to EPA (or to an advisory committee established under the Act) by a petitioner, solely in support of a petition which has not been acted on by the publication by EPA of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, as provided in section 408(d) (2) or (3) of the Act, 21 U.S.C. 346a(d) (2) or (3).

(2) Section 2.307, rather than this section, applies to information described by the first sentence of §2.307(b) (material incorporated into submissions in order to satisfy the requirements of the Federal Insecticide, Fungicide and Rodenticide Act, as amended), even though such information was originally submitted by a petitioner in support of a petition.

(3) This section does not apply to information gathered by EPA under a proceeding initiated by EPA to establish a tolerance under section 408(e) of the Act, 21 U.S.C. 346a(e).

(c) *Basic rules which apply without change.* Sections 2.201, 2.202, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Effect of submission of information without claim.* Section 2.203 (a) and (b) apply without change to information to which this section applies. Section 2.203(c), however, does not apply to information to which this section applies. A petitioner's failure to assert a claim when initially submitting a petition shall not constitute a waiver of any claim the petitioner may have.

(e) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that—

(1) Unless the EPA office has on file a written waiver of a petitioner's claim, a petitioner shall be regarded as an

affected business, a petition shall be treated as if it were covered by a business confidentiality claim, and an EPA office acting under §2.204(d) shall determine that the information in the petition is or may be entitled to confidential treatment and shall take action in accordance with §2.204(d)(1);

(2) In addition to other required provisions of any notice furnished to a petitioner under §2.204(e), such notice shall state that—

(i) Section 408(f) of the Act, 21 U.S.C. 346a(f), affords absolute confidentiality to information to which this section applies, but after publication by EPA of a regulation establishing a tolerance (or exempting the pesticide chemical from the necessity of a tolerance) neither the Act nor this section affords any protection to the information;

(ii) Information submitted in support of a petition which is also incorporated into a submission in order to satisfy a requirement or condition of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.,* is regarded by EPA as being governed, with respect to business confidentiality, by §2.307 rather than by this section;

(iii) Although it appears that this section may apply to the information at this time, EPA is presently engaged in determining whether for any reason the information is entitled to confidential treatment or will be entitled to such treatment if and when this section no longer applies to the information; and

(iv) Information determined by EPA to be covered by this section will not be disclosed for as long as this section continues to apply, but will be made available to the public thereafter (subject to §2.210) unless the business furnishes timely comments in response to the notice.

(f) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) Notwithstanding §2.205(i), the General Counsel or his designee, rather than the Regional counsel, shall in all cases make the determinations and take the actions required by §2.205;

(2) In addition to the circumstances mentioned in §2.205(f)(1), notice in the form prescribed by §2.205(f)(2) shall be furnished to each affected business whenever information is found to be entitled to confidential treatment under section 408(f) of the Act but not otherwise entitled to confidential treatment. With respect to such cases, the following sentences shall be substituted for the third sentence of §2.205(f)(2): “With respect to EPA's implementation of the determination, the notice shall state that (subject to §2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the business's receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business's commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against

disclosure; provided, that the information will not be made available to the public for so long as it is entitled to confidential treatment under section 408(f) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(f).”; and

(3) Notwithstanding §2.205(g), the 31 calendar day period prescribed by §2.205(f)(2), as modified by paragraph (f)(2) of this section, shall not be shortened without the consent of the business.

(g) [Reserved]

(h) *Substantive criteria for use in confidentiality determinations.* Section 2.208 does not apply to information to which this section applies. Such information shall be determined to be entitled to confidential treatment for so long as this section continues to apply to it.

(i) *Disclosure in special circumstances.* (1) Section 2.209 applies to information to which this section applies. In addition, under Section 408(f) of the Act, 21 U.S.C. 346a(f), EPA is authorized to disclose the information to other persons. Such authority under section 408(f) of the Act may be exercised only in accordance with paragraph (i)(2) or (i)(3) of this section.

(2) Information to which this section applies may be disclosed (notwithstanding the fact that it otherwise might be entitled to confidential treatment under this subpart) to a person under contract to EPA to perform work for EPA in connection with the Act, with the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, or regulations which implement either such Act, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor may carry out the work required by the contract. Any such disclosure to a contractor shall be made only in accordance with the procedures and requirements of §2.301(h)(2) (ii) through (iv).

(3) Information to which this section applies may be disclosed by EPA to an advisory committee in accordance with section 408(d) of the Act, 21 U.S.C. 346a(d).

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40005, Sept. 8, 1978]

Back to Top

§2.309 Special rules governing certain information obtained under the Marine Protection, Research and Sanctuaries Act of 1972.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Marine Protection, Research and Sanctuaries Act of 1972, 33 U.S.C. 1401 *et seq.*

(2) *Permit* means any permit applied for or granted under the Act.

(3) *Application* means an application for a permit.

(b) *Applicability.* This section applies to all information provided to or obtained by EPA as a part of any application or in connection with any permit.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and 2.209 through 2.215 apply without change to information to which this section applies.

(d) *Substantive criteria for use in confidentiality determinations.* Section 2.208 does not apply to information to which this section applies. Pursuant to section 104(f) of the Act, 33 U.S.C. 1414(f), no information to which this section applies is eligible for confidential treatment.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40005, Sept. 8, 1978]

Back to Top

§2.310 Special rules governing certain information obtained under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(a) *Definitions.* For purposes of this section:

(1) *Act* means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, including amendments made by the Superfund Amendments and Reauthorization Act of 1986, 42 U.S.C. 9601, *et seq.*

(2) *Person* has the meaning given it in section 101(21) of the Act, 42 U.S.C. 9601(21).

(3) *Facility* has the meaning given it in section 101(9) of the Act, 42 U.S.C. 9601(9).

(4) *Hazardous substance* has the meaning given it in section 101(14) of the Act, 42 U.S.C. 9601(14).

(5) *Release* has the meaning given it in section 101(22) of the Act, 42 U.S.C. 9601(22).

(6) *Proceeding* means any rulemaking or adjudication conducted by EPA under the Act or under regulations which implement the Act (including the issuance of administrative orders under section 106 of the Act and cost recovery pre-litigation settlement negotiations under sections 107 or 122 of the Act), any cost recovery litigation under section 107 of the Act, or any administrative determination made under section 104 of the Act, but not including determinations under this

subpart.

(b) *Applicability.* This section applies only to information provided to or obtained by EPA under section 104 of the Act, 42 U.S.C. 9604, by or from any person who stores, treats, or disposes of hazardous wastes; or where necessary to ascertain facts not available at the facility where such hazardous substances are located, by or from any person who generates, transports, or otherwise handles or has handled hazardous substances, or by or from any person who performs or supports removal or remedial actions pursuant to section 104(a) of the Act. Information will be considered to have been provided or obtained under section 104 of the Act if it was provided in response to a request from EPA or a representative of EPA made for any of the purposes stated in section 104, if it was provided pursuant to the terms of a contract, grant or other agreement to perform work pursuant to section 104, or if its submission could have been required under section 104, regardless of whether section 104 was cited as authority for any request for the information or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and §§2.209 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(f) [Reserved]

(g)(1) Under section 104(e)(7)(A) of the Act (42 U.S.C. 9604(e)(7)(A)) any information to which this section applies may be disclosed by EPA because of the relevance of the information in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of §2.301(g)(2) are to be used as paragraph (g)(2) of this section.

(3) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, except with respect to litigation conducted by a Federal court, information to which this section applies which may be entitled to confidential treatment may be made available to the public, or to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(3). An EPA office proposing disclosure of information under this paragraph (g)(3) shall so notify the presiding officer in writing. Upon receipt of such a notification, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(3) has been proposed, and shall afford each such

business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed under this paragraph (g)(3) only if, after consideration of any timely comments submitted by the business, the EPA office determines in writing that, for reasons directly associated with the conduct of the proceeding, the contemplated disclosure would serve the public interest, and the presiding officer determines in writing that the information is relevant to a matter in controversy in the proceeding. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to the public or to one or more of the parties of record to the proceeding.

(4) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, except with respect to litigation conducted by a Federal court, information to which this section applies which may be entitled to confidential treatment may be made available to one or more parties of record to the proceeding, upon request of a party, under this paragraph (g)(4). A party of record seeking disclosure of information shall direct his request to the presiding officer. Upon receipt of such a request, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(4) has been requested, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed to a party of record under this paragraph (g)(4) only if, after consideration of any timely comments submitted by the business, the presiding officer determines in writing that:

(i) The party of record has satisfactorily shown that with respect to a significant matter which is in controversy in the proceeding, the party's ability to participate effectively in the proceeding will be significantly impaired unless the information is disclosed to him; and

(ii) Any harm to an affected business that would result from the disclosure is likely to be outweighed by the benefit to the proceeding and the public interest that would result from the disclosure.

The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to one or more of the parties of record to the proceeding.

(5) In connection with cost recovery pre-litigation settlement negotiations under sections 107 or 122 of the Act (42 U.S.C. 9607, 9622), any information to which this section applies that may be entitled to confidential treatment may be

made available to potentially responsible parties pursuant to a contractual agreement to protect the information.

(6) In connection with any cost recovery proceeding under section 107 of the Act involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, any information to which this section applies that may be entitled to confidential treatment may be made available to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(6). Such disclosure must be made pursuant to a stipulation and protective order signed by all parties to whom disclosure is made and by the presiding officer.

(h) *Disclosure to authorized representatives.* (1) Under section 104(e)(7) of the Act (42 U.S.C. 9604(e)(7)), EPA possesses authority to disclose to any authorized representative of the Untied States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2) The provisions of §2.301(h)(2) are to be used as paragraph (h)(2) of this section.

(3) The provisions of §2.301(h)(3) are to be used as paragraph (h)(3) of this section.

(4) At the time any information is furnished to a contractor, subcontractor, or State or local government under this paragraph (h), the EPA office furnishing the information to the contractor, subcontractor, or State or local government agency shall notify the contractor, subcontractor, or State or local government agency that the information may be entitled to confidential treatment and that any knowing and willful disclosure of the information may subject the contractor, subcontractor, or State or local government agency and its employees to penalties in section 104(e)(7)(B) of the Act (42 U.S.C. 9604(e)(7)(B)).

[50 FR 51663, Dec. 18, 1985, as amended at 58 FR 462, Jan. 5, 1993]

Back to Top

§2.311 Special rules governing certain information obtained under the Motor Vehicle Information and Cost Savings Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Motor Vehicle Information and Cost Savings Act, as amended, 15 U.S.C. 1901 *et seq.*

(2) *Average fuel economy* has the meaning given it in section 501(4) of the Act, 15 U.S.C. 2001(4).

(3) *Fuel economy* has the meaning given it in section 501(6) of the Act, 15 U.S.C. 2001(6).

(4) *Fuel economy data* means any measurement or calculation of fuel economy for any model type and average fuel economy of a manufacturer under section 503(d) of the Act, 15 U.S.C. 2003(d).

(5) *Manufacturer* has the meaning given it in section 501(9) of the Act, 15 U.S.C. 2001(9).

(6) *Model type* has the meaning given it in section 501(11) of the Act, 15 U.S.C. 2001(11).

(b) *Applicability.* This section applies only to information provided to or obtained by EPA under Title V, Part A of the Act, 15 U.S.C. 2001 through 2012. Information will be considered to have been provided or obtained under Title V, Part A of the Act if it was provided in response to a request from EPA made for any purpose stated in Title V, Part A, or if its submission could have been required under Title V Part A, regardless of whether Title V Part A was cited as the authority for any request for information or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and §§2.209 through 2.215 apply without change to information to which this section applies.

(d) [Reserved]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies, except that information this is fuel economy data is not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(f) [Reserved]

(g) *Disclosure of information relevant to a proceeding.* (1) Under section 505(d)(1) of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding under Title V, Part A of the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information to which this section applies because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of §2.301(g)(2) are to be used as paragraph (g)(2) of this section.

(3) The provisions of §2.301(g)(3) are to be used as paragraph (g)(3) of this section.

(4) The provisions of §2.301(g)(4) are to be used as paragraph (g)(3) of this section.

[50 FR 51663, Dec. 18, 1985]

Back to Top

Need assistance?

regulatory requirements to nine states in multiple different circuits, and if denied could impact the 13 states within the ozone transport region established in CAA section 184. This proposed action also discusses at length prior EPA action and analyses concerning the transport of pollutants between the different states under CAA section 110. For these reasons, the Administrator determines that, when finalized, this action is of nationwide scope and effect for purposes of section 307(b)(1). Thus, pursuant to CAA section 307(b) any petitions for review of any final action regarding this document would be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date any final action is published in the **Federal Register**.

VI. Statutory Authority

42 U.S.C. 7401 *et seq.*

Dated: January 11, 2017.

Gina McCarthy,

Administrator.

[FR Doc. 2017–01097 Filed 1–18–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2017–0026; FRL–9958–34]

Statutory Requirements for Substantiation of Confidential Business Information (CBI) Claims Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In June 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA). EPA is announcing an interpretation of TSCA section 14 concerning confidential business information (CBI) claims for information submitted to EPA. EPA interprets the revised TSCA section 14(c)(3) as requiring substantiation of non-exempt CBI claims at the time the information claimed as CBI is submitted to EPA.

FOR FURTHER INFORMATION CONTACT:

For general information contact: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

For technical information contact: Scott M. Sherlock, Attorney Advisor, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8257; email address: *sherlock.scott@epa.gov.*

DATES: This action is effective on March 20, 2017.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This announcement is directed to the public in general. It may, however, be of particular interest to you if you manufacture (defined by statute to include import) and/or process chemicals covered by TSCA (15 U.S.C. 2601 *et seq.*). This may include businesses identified by the North American Industrial Classification System (NAICS) codes 325 and 32411. Because this action is directed to the general public and other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2017–0026. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

2. *Other related information.* For information about EPA's programs to evaluate new and existing chemicals and their potential risks and the amended TSCA, go to *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act.*

II. What action is the Agency taking?

The amended TSCA provides new requirements relating to the assertion, substantiation and review of CBI claims. EPA is interpreting the revised TSCA section 14(c)(3) as requiring substantiation of all CBI claims at the time the information claimed as CBI is submitted to EPA, except for claims for information subject to TSCA section 14(c)(2).

This action facilitates the Agency's implementation of TSCA section 14(g) to review all CBI claims for chemical identity, with limited exceptions, as well as to review a representative sample of at least 25% of other non-exempt claims.

III. What is the Agency's authority for taking this action?

EPA has determined that TSCA section 14(c)(3), 15 U.S.C. 2613(c)(3), requires an affected business to substantiate all TSCA CBI claims, except for information subject to TSCA section 14(c)(2), at the time the affected business submits the claimed information to EPA.

TSCA section 14(c)(1)(a) requires an affected business to assert a claim for protection from disclosure concurrent with submission of the information in accordance with existing or future rules. TSCA section 14(c)(3) in turn requires an affected business submitting a claim to protect information from disclosure to substantiate the claim, also in accordance with existing or future rules. The language of TSCA section 14(c)(3) is as follows:

> ''(3) Substantiation requirements. Except as provided in paragraph (2), a person asserting a claim to protect information from disclosure under this section shall substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section.''

EPA interprets TSCA section 14(c)(3) to require substantiation for all TSCA CBI claims, except for information

within TSCA section 14(c)(2). That is the clear import of the language, ''a person asserting a claim to protect information from disclosure under this section shall substantiate the claim . . .'' While the final clause requires that submissions be in accordance with EPA rules, EPA interprets this provision as addressing the form and manner of a submission, not as making the substantiation requirement conditional upon a future EPA rulemaking. In the future, EPA may promulgate regulations governing the form and manner of substantiating CBI claims for those submissions addressed by this action. Nonetheless, EPA considers the statutory substantiation requirement to be in place as of the effective date of this action.

EPA's interpretation is supported by legislative history for the recent amendments to TSCA. Both the Senate and House intended to require substantiation of CBI claims. See S. Rpt. 114–67 (observing, on page 5, that ''section 14 [of pre-amendment TSCA] and EPA's implementation of it has been criticized for failing to require . . . . up-front substantiation of confidentiality claims,'' and, on page 22, stating that, under the Senate bill, ''all new claims for protection of information not presumed to be protected from disclosure must be substantiated by the claimant''); H. Rpt. 114–176 at 29 (a confidentiality claim must ''include . . . . a justification for each claim of confidentiality''); Senate Environment and Public Works Committee summary: ''Reforming the Toxic Substances Control Act'' at 3 (*http://www.epw.senate.gov/public/_cache/files/aa2ac4d1-15bb-4e71-9588-909d49bdcff2/tsca-reform-marketing-packet-5.19-final.pdf*). (''The legislation promotes additional transparency by requiring up-front substantiation of claims to protect confidential commercial information. . . .'') EPA's interpretation also is supported by TSCA section 14(i)(2), which provides that, ''nothing in this chapter'' prevents EPA from requiring substantiation before the effective date of rules that may be promulgated after June 22, 2016, the date on which the amendments to TSCA were enacted.

It might be maintained that TSCA section 14(c)(3) does not impose a substantiation requirement, but merely authorizes EPA to promulgate rules requiring substantiation. Alternatively, it might be maintained that the section does impose a substantiation requirement, but that the requirement must be effectuated through EPA rulemaking.

The first reading does not effectuate the legislative intent to require substantiation. In addition, the provision is not worded as a mere grant of authority. Numerous other provisions of TSCA—both of the pre-amended statute and of the Lautenberg amendments—demonstrate that Congress used more straightforward language when it intended simply to grant EPA rulemaking or other authority (*e.g.,* TSCA section 14(f)(1) (''The Administrator may require any person . . . to reassert and substantiate or re-substantiate'' an existing claim under certain circumstances); TSCA section 4(a)(2) (''The Administrator may, by rule, order, or consent agreement . . . . require the development of new information''). Finally, TSCA section 14(c)(1) already authorizes EPA to promulgate rules governing the assertion of CBI claims. This paragraph provides authority for EPA to promulgate rules requiring substantiation, and EPA in fact promulgated a number of rules requiring substantiation under similarly worded authority in pre-amendment TSCA section 14(c)(1). See, *e.g.,* 40 CFR 711.30(b)(1), requiring up-front substantiation for chemical identity claims for Chemical Data Reporting under part 711. To interpret TSCA section 14(c)(3) as merely providing authority to require substantiation, where that authority already exists in TSCA section 14(c)(1), would arguably give TSCA section 14(c)(3) no effect at all.

The second reading amounts to a revision of the legislative text. TSCA section 14(c)(3) does not require EPA to undertake rulemaking; it merely acknowledges that EPA ''may'' do so. Unless this ''may'' were read as ''shall'', EPA would be under no obligation to promulgate the rules required to carry out the objective of requiring substantiation. Here again, numerous other provisions of TSCA demonstrate that Congress used clear language—and included deadlines—when it intended to require EPA to promulgate regulations (*e.g.,* TSCA section 6(b)(1)(A)(''Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a risk-based screening process. . . .'').

Having determined that TSCA section 14(c)(3) requires substantiation of all non-exempt TSCA CBI claims, EPA believes the provision is best interpreted as requiring substantiation *concurrent with the submission.* This is the natural reading of the requirement that ''a person asserting a claim . . . . shall substantiate the claim.'' By analogy, TSCA section 14(c)(5)—another requirement newly added by the Lautenberg amendments—provides that a claimant ''shall certify that the statement required to assert a [confidentiality] claim . . . . and any information required to substantiate a claim . . . . are true and correct.'' While this provision does not explicitly state that the certification must accompany the submission, it is reasonable to conclude that Congress intended that result. Moreover, a requirement to substantiate CBI claims at some unspecified time would not create any meaningful self-executing requirement, because there would be no point in time at which an affected business could be found not to have complied.

Reading the law as requiring substantiation concurrent with the CBI claim also comports with the legislative history. In addition to the history cited earlier in this document, the Senate Report, on p. 5, noted stakeholder concerns that, under pre-amendment TSCA, the lack of a requirement for up-front substantiation resulted in ''an over-abundance of CBI claims, some of which may not be legitimate.'' Interpreting TSCA section 14(c)(3) as requiring substantiation of a CBI claim concurrent with the claim's submission best effectuates the expressed intent of Congress.

This interpretation is consistent with the requirement in TSCA section 14(g)(1) that EPA review most confidentiality claims for chemical identity and at least 25% of claims for other types of non-exempt information within 90 days after the receipt of the claim. An approach under which substantiations were submitted at some point after assertion of CBI claims would significantly reduce (and has already significantly reduced) the short period for such CBI reviews. To date, for each review, the Agency must contact each affected business, request the submission of a substantiation, and allow a period of time for the affected business to submit the substantiation. Since timely substantiation provides critical information for completing CBI reviews, it is reasonable to conclude that Congress intended for claims to be substantiated at the time the CBI claim is asserted.

When the amendments to TSCA became law on June 22, 2016, EPA published initial Questions and Answers (Q and A's) in an effort to respond to the inquiries and requests concerning EPA's views on the new law. EPA needed to issue guidance to the public as quickly as possible on a broad range of matters under the amendments, since the amendments became effective

upon signature. In the Q and A's on TSCA section 14, EPA stated that the Agency was using existing authorities to obtain CBI substantiations and that the Agency may revise CBI substantiation requirements for specific types of information submissions by subsequent rulemaking. Since the time the Q and A's were developed, EPA has heard the views of a number of stakeholders and has had the opportunity to more fully review the statute and legislative history and to evaluate the operational considerations associated with the interpretation of TSCA section 14(c)(3).

Operationally, given the large volume of CBI claims, including those that the Agency has already received and those that the Agency expects to receive in the future, it is administratively efficient to interpret the statute as requiring up-front substantiation, which necessarily saves the Agency the time and resources that would otherwise be spent in attempting to contact the affected business. Up-front substantiation will also significantly enhance EPA's ability to meet the review deadlines in TSCA section 14(g). Further, requiring substantiation concurrent with submission will mitigate any need for an affected business to request an extension to substantiate a CBI claim. Additionally, requiring the affected business to provide justification at the time of submission may help limit unwarranted claims of CBI. Based on this further review, for the reasons stated above, EPA has concluded that the provision is best read as creating a requirement to substantiate non-exempt TSCA CBI claims concurrent with their submission.

IV. Implementation

Existing EPA confidentiality rules at 40 CFR part 2, section 2.204(e), provide substantiation questions that the Agency may specifically request answers to, pursuant to the procedures in those regulations. While those specific questions are not dictated by the self-executing substantiation requirement in TSCA section 14(c)(3), EPA suggests that companies look to those questions for guidance as to how to fulfill the TSCA section 14(c)(3) substantiation requirement for information that is not currently subject to an existing regulatory up-front substantiation requirement. The answers to those questions typically form the basis of EPA final confidentiality determinations, and substantiations that do not address those questions might not provide sufficient information to uphold a determination, pursuant to TSCA section 14(g)(1), that information claimed as CBI is eligible for confidential protection. For information that is currently subject to a regulatory up-front substantiation requirement (for example, chemical identity CBI claims in the Chemical Data Reporting rule, under 40 CFR 711.30), the terms of that requirement, including the substantiation questions required, will continue to govern the substantiation.

EPA has revised its Web pages on CBI to assist compliance with this interpretation of TSCA section 14. The Web pages list the substantiation questions from 40 CFR 2.204(e) and provide information on substantiation exemptions and on how the substantiations should be directed to the Agency.

Because EPA is providing this interpretation of TSCA section 14(c)(3) for the first time in this document, the Agency is setting different procedures for those who have submitted or will submit information claimed as CBI under TSCA before the effective date of this action, *i.e.,* March 20, 2017, and those who submit information claimed as CBI afterwards.

A. TSCA Submissions Filed on or After March 20, 2017

Those submissions containing information claimed as CBI filed on or after the effective-date of this action (*i.e.,* March 20, 2017) must provide a substantiation for all information claimed as confidential, other than information exempt from substantiation pursuant to TSCA section 14(c)(2). Any non-exempt CBI claim that is submitted without a substantiation will be considered deficient, and EPA will send a notice of deficiency to the affected business. The notice will inform the affected business that it must submit its substantiation within 30 calendar days in order to remedy its deficient CBI claim. The notice letter will also inform the affected business that if a timely substantiation has not been received by EPA within 30 days of receipt of the letter, then any CBI claims not substantiated will be considered withdrawn, and the information may be made public with no further notice to the affected business.

B. TSCA Submissions Filed Between June 22, 2016 and March 20, 2017

Those submissions containing information claimed as CBI filed between June 22, 2016 and March 20, 2017, must provide a substantiation for all information claimed as confidential, other than information exempt from substantiation pursuant to TSCA section 14(c)(2). The Agency is giving submitters until September 18, 2017 to provide substantiations and direct them to the Agency. If a substantiation has already been provided to EPA with the submission or in response to a substantiation request, no additional substantiation need be filed for the same information. Be aware, however, that if some non-exempt information claimed as confidential in a particular submission has already been substantiated and some has not, the unsubstantiated information claimed as CBI in the submission must still be substantiated by September 18, 2017. The CBI claims, and the substantiations, may then be reviewed consistent with the provisions of TSCA, its implementing regulations and in accordance with the Agency procedures set forth in 40 CFR part 2. Once September 18, 2017 has passed, if no substantiation has been received for a claim, then EPA will provide the affected business 30 days' notice and a final opportunity to substantiate. The notice will inform the affected business that any CBI claims not substantiated at the end of the 30 days will be considered withdrawn, and the information may be made public with no further notice to the affected business.

EPA's electronic reporting systems for TSCA submissions have been modified to require substantiations for non-exempt CBI claims in submissions filed on or after March 20, 2017. Any new paper TSCA submissions that are directed to the Agency after that date must include substantiations for all non-exempt CBI claims at the time of submission.

For electronic submissions made using EPA's Central Data Exchange (CDX) during the period from June 22, 2016 to March 20, 2017 that were not substantiated, affected businesses must provide substantiation for CBI claims using the amendment processes for the particular submission type. Information on electronic reporting, including how to make amendments, can be found at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information.*

For any paper TSCA submissions that were submitted to the Agency during the period from June 22, 2016 to March 20, 2017, the affected business must submit substantiations for any non-exempt CBI claims that have not yet been substantiated. Submit these substantiations to: TSCA Confidential Business Information Center (7407M), WJC East; Room 6428; Attn: TSCA CBI Substantiations. U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460–0001.

Courier Deliveries should be directed to:

U.S. EPA, Office of Pollution Prevention and Toxics, Confidential Business Information Center (CBIC), Attn: TSCA CBI Substantiations. 1201 Constitution Avenue NW., WJC East; Room 6428 Washington, DC 20004–3302, (202) 564–8930.

More information on how to substantiate CBI claims for paper submissions can be found at *https://www.epa.gov/tsca-cbi/.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: January 13, 2017.

James J. Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2017–01235 Filed 1–18–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2013–0024; FRL–9958–64–OAR]

California State Nonroad Engine Pollution Control Standards; In-Use Diesel-Fueled Transport Refrigeration Units (TRUs) and TRU Generator Sets and Facilities Where TRUs Operate; Notice of Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of decision.

SUMMARY: The Environmental Protection Agency (''EPA'') is granting the California Air Resources Board (''CARB'') request for authorization of amendments to its Airborne Toxic Control Measure for In-Use Diesel-Fueled Transport Refrigeration Units (''TRU'') and TRU Generator Sets and Facilities Where TRUs Operate (together ''2011 TRU Amendments''). EPA's decision also confirms that certain of the 2011 TRU amendments are within the scope of prior EPA authorizations. The 2011 TRU Amendments primarily provide owners of TRU engines with certain flexibilities; clarify recordkeeping requirements for certain types of TRU engines; establish requirements for businesses that arrange, hire, contract, or dispatch the transport of goods in TRU-equipped trucks, trailers, or containers; and address other issues that arose during the initial implementation of the regulation. This decision is issued under the authority of the Clean Air Act (''CAA'' or ''Act'').

DATES: Petitions for review must be filed by March 20, 2017.

ADDRESSES: EPA has established a docket for this Notice of Decision under Docket ID EPA–HQ–OAR–2015–0224. All documents relied upon in making this decision, including those submitted to EPA by CARB, are contained in the public docket. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air and Radiation Docket in the EPA Headquarters Library, EPA West Building, Room 3334, located at 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m.; Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744. The Air and Radiation Docket and Information Center's Web site is *http://www.epa.gov/oar/docket.html.* The email address for the Air and Radiation Docket is: *a-and-r-Docket@epa.gov,* the telephone number is (202) 566–1742, and the fax number is (202) 566–9744. An electronic version of the public docket is available through the federal government's electronic public docket and comment system. You may access EPA dockets at *http://www.regulations.gov.* After opening the *www.regulations.gov* Web site, enter EPA–HQ–OAR–2015–0224 in the ''Enter Keyword or ID'' fill-in box to view documents in the record. Although a part of the official docket, the public docket does not include Confidential Business Information (''CBI'') or other information whose disclosure is restricted by statute.

EPA's Office of Transportation and Air Quality (''OTAQ'') maintains a Web page that contains general information on its review of California waiver and authorization requests. Included on that page are links to prior waiver **Federal Register** notices, some of which are cited in today's notice; the page can be accessed at *http://www.epa.gov/otaq/cafr.htm.*

FOR FURTHER INFORMATION CONTACT: David Dickinson, Attorney-Advisor, Transportation and Climate Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., (6405J), Washington, DC 20460. Telephone: (202) 343–9256. Fax: (202) 343–2804. Email: *dickinson.david@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

EPA granted an authorization for California's initial set of TRU regulations on January 9, 2009.[1] EPA also granted a within-the-scope authorization for amendments to the TRU regulations, adopted in 2010, on June 28, 2013.[2] The TRU regulations establish in-use performance standards for diesel-fueled TRUs and TRU generator sets which operate in California, and facilities where TRUs operate. The TRU regulations are contained in an Airborne Toxic Control Measure (''ATCM'') adopted by CARB to reduce the general public's exposure to diesel particulate matter (''PM''), other toxic airborne contaminants and air pollutants generated by TRUs and reduce near source risk at facilities where TRUs congregate. TRUs are refrigeration systems powered by internal combustion engines which control the environment of temperature-sensitive products that are transported in semi-trailer vans, truck vans, ''reefer'' railcars or shipping containers. The engines in TRUs do not propel the vehicle, but are used strictly to power the refrigeration system. These TRU engines are nonroad engines and vary in horsepower (''hp'') generally from 7 hp to 36 hp.

By letter dated March 2, 2015, CARB submitted a request to EPA for authorization of amendments to its TRU regulations [3] pursuant to section 209(e) of the CAA.[4] The 2011 TRU Amendments were adopted by CARB on October 21, 2011, and became operative state law on October 15, 2012.[5] The 2011 TRU Amendments provide owners of 2001 through 2003 model year (MY) TRU engines that complied with applicable Low-Emission TRU (''LETRU'') in-use performance standards by specified compliance deadlines a one- or two-year extension from the more stringent Ultra-Low Emission (''ULETRU'') in-use performance standards. The amendments also clarify manual recordkeeping requirements for electric standby-equipped TRUs and ultimately require automated electronic tracking system requirements for such TRUs and establish requirements for businesses that arrange, hire, contract, or dispatch the transport of goods in TRU-equipped trucks, trailers or containers. A more

[1] 74 FR 3030 (January 16, 2009).

[2] 78 FR 38970 (June 28, 2013).

[3] 13 California Code of Regulations (CCR), sections 2111, 2112, Appendix A therein, 2139, 2147, 2440, 2441, 2442, 2443.1, 2443.2, 2443.3, 2444.1, 2444.2, 2445.1, 2445.2, 2447, 2474 and 2448.

[4] ''Clean Air Act § 209(e)(2) Authorization Support Document submitted by the California Air Resources Board, March 2, 2015,'' at EPA–HQ–OAR–2015–0224–0002 (Authorization Support Document).

[5] *Id.,* Attachment 13.

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2017–0002; FRL–9958–33]

Risk Evaluation Scoping Efforts Under TSCA for Ten Chemical Substances; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA will hold a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of risk evaluations under development for the ten chemical substances designated on December 19, 2016 for risk evaluations pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. In particular, EPA is providing the public an opportunity to identify information specifically related to the conditions of use for the ten chemical substances (*i.e.,* the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of). EPA plans to use this information as it develops the scoping documents for the TSCA risk evaluations of the ten chemical substances; these scoping documents must be issued within six months of the **Federal Register** notice that designated the chemical substances for a TSCA risk evaluation (*i.e.,* for these ten chemical substances, the scoping documents must be issued by June 19, 2017).

DATES: *Meeting Date.* The meeting will be held on February 14, 2017 from 9:00 a.m. to 3:00 p.m.

To request accommodation of a disability, please contact the meeting logistics person listed under **FOR FURTHER INFORMATON CONTACT**, preferably by February 3, 2017, to give EPA as much time as possible to process your request.

Meeting Registration. You may register online (preferred) or in person at the meeting. To register online, for the meeting, go to: *https://tscachemicaluse.eventbrite.com.* Advance registration for the meeting must be completed no later than February 10, 2017. On-site registration will be permitted, but seating and speaking priority will be given to those who pre-register by the deadline.

Comments. EPA will hear oral comments at the meeting, and will accept written comments and materials submitted to the dockets on or before March 1, 2017. For further information about participation and submitting materials, see Unit IV. under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: *Meeting.* The meeting will be held at the Ronald Reagan Building and International Trade Center, in the Polaris Room, located at 1300 Pennsylvania Avenue Northwest, Washington, DC 20004. The meeting will also be available by remote access for registered participants.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Sheila Canavan, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 566–1978; email address: *Canavan.sheila@epa.gov.*

For meeting logistics or registration contact: Klara Zimmerman; telephone number: (301) 634–1722; email address: *Klara_Zimmerman@abtassoc.com.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use or dispose of any of the ten chemical substances identified for risk evaluation in the **Federal Register** notice published on December 19, 2016, entitled ''Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act'' (81 FR 91927). This action may be of particular interest to entities that are regulated under TSCA (*e.g.,* entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110, among others). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. How can I get copies of this document and other related information?

The docket for this meeting, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0002, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. Background

EPA is required to conduct chemical risk evaluations under section 6(b) the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. (15 U.S.C. 2605(b)(4)). Pursuant to TSCA section 6(b)(2)(A), EPA identified ten chemical substances for initial risk evaluations under TSCA in the **Federal Register** notice of December 19, 2016, entitled ''Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act'' (81 FR 91927) (FRL–9956–47).

The first step in the risk evaluation process, as outlined in TSCA, is to issue a scoping document for each chemical substance within six months of its designation in the **Federal Register**. TSCA section 6(b)(4)(B) also directs EPA to establish, by a rulemaking promulgated within one year of enactment, a process for conducting risk evaluations, which includes the process for issuing scoping documents. The Agency expects to propose such a procedural rule shortly, which will be applicable to risk evaluations once finalized. However, TSCA directed EPA to concurrently ensure that risk evaluations were being conducted on ten chemical substances by December 19, 2016. As a result, EPA must publish scoping documents for these initial ten chemical substances by June 19, 2017, which is before the procedural rule is expected to be finalized. Accordingly, EPA's scoping efforts for these ten substances will be based directly on the terms of TSCA section 6(b)(4)(D), and not the pending procedural rulemaking. Each completed scoping document will describe the scope of information about the chemical substance that the Agency expects to consider in the risk evaluation, including its conditions of use, hazards, and exposures, including to potentially exposed or susceptible subpopulations.

At the public meeting, EPA will provide an overview briefing to describe the information the Agency has

obtained thus far relating to the conditions of use for the ten chemical substances. To assist EPA in this scoping process, EPA is providing the public with an opportunity to identify information specifically related to the conditions of use (*i.e.,* the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of). EPA plans to use this information as it develops scoping documents for the TSCA risk evaluations for the ten chemical substances.

In view of the statutory deadline to complete these ten risk evaluations, it will be difficult, and may not be possible, for EPA to adjust the scope of the evaluations following release of the scoping document under TSCA section 6(b)(4)(D). In addition, EPA notes that the scoping document is a foundation for determining the scope of preemption arising after final risk evaluations (TSCA section 18(a)(1)(B)). Thus, EPA requests that members of the public provide any available information relating to the scope of the risk evaluations at the February meeting or to the docket by March 1, 2017. EPA will likely not be able to accommodate information as to scope received after that time.

III. Meeting

A. Remote Access

The meeting will be accessible remotely for registered participants. Registered participants will receive information on how to connect remotely to the meeting prior to its start.

B. Public Participation at the Meeting

Anyone may register to attend the meeting as observers and may also register to provide oral comments on the day of the meeting. A registered speaker is encouraged to focus on issues directly relevant to the meeting's subject matter. Each speaker is allowed no more than 5 minutes to provide oral comments. To accommodate as many registered speakers as possible, speakers may present oral comments only, without visual aids or written material.

C. Submitting Written Materials

Anyone may submit written materials to the dockets described in Unit IV.C.

IV. How can I request to participate in this meeting?

A. Registration

To attend the meeting in person or to receive remote access, you must register no later than February 10, 2017, using one of the methods described under **ADDRESSES**. While on-site registration will be available, seating will be on a first-come, first-served basis, with priority given to early registrants, until room capacity is reached. The Agency anticipates that approximately 125 people will be able to attend the meeting in person. For registrants not able to attend in person, the meeting will also provide remote access capabilities; registered participants will be provided information on how to connect to the meeting prior to its start.

B. Required Registration Information

Members of the public may register to attend as observers or speak if planning to offer oral comments during the scheduled public comment period. To register for the meeting online, you must provide your full name, organization or affiliation, and contact information to the on-line signup or to the meeting registration contact person listed under **FOR FURTHER INFORMATION CONTACT**. Do not submit any information in your request that is considered Confidential Business Information (CBI). Requests to participate in the meeting, identified by docket ID No. EPA–HQ–OPPT–2017–0002, must be received on or before February 10, 2017.

C. Risk Evaluation Dockets for the Ten Chemical Substances

You may also elect to provide information to EPA's dockets for the ten chemical substances for which risk evaluations have begun. EPA has established separate dockets for each of the ten chemical substances for risk evaluation to facilitate receipt of information which may be useful to the Agency's risk evaluations. As noted above, EPA is asking the public for assistance in identifying information specifically related to the conditions of use (*i.e.,* intended, known or reasonably foreseen uses) that would assist the Agency in identifying potential exposure scenarios (pathways, routes and populations). EPA is requesting that any such information by submitted by March 1, 2017.

1,4-Dioxane. Docket ID No.: EPA–HQ–OPPT–2016–0723.

1-Bromopropane. Docket ID No.: EPA–HQ–OPPT–2016–0741.

Asbestos. Docket ID No.: EPA–HQ–OPPT–2016–0736.

Carbon Tetrachloride. Docket ID No.: EPA–HQ–OPPT–2016–0733.

Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD). Docket ID No.: EPA–HQ–OPPT–2016–0735.

Methylene Chloride. Docket ID No.: EPA–HQ–OPPT–2016–0742.

N-Methylpyrrolidone (NMP). Docket ID No.: EPA–HQ–OPPT–2016–0743.

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone). Docket ID No.: EPA–HQ–OPPT–2016–0725.

Trichloroethylene (TCE). Docket ID No.: EPA–HQ–OPPT–2016–0737.

Tetrachloroethylene (also known as Perchloroethylene). Docket ID No.: EPA–HQ–OPPT–2016–0732.

Information can be submitted by one of the following methods:

Online using the Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting information or comments. Once submitted, this information cannot be edited or withdrawn. EPA may publish any information received to its public docket. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written statement or information. The written information should include discussion of all points you wish to make. Learn more about CBI or multimedia submissions, and general guidance on making effective comments or providing useful information by visiting EPA's Web site at *https://www.epa.gov/dockets/commenting-epa-dockets.*

Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460–0001.

Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow instructions at *http://www.epa.gov/dockets/contacts.html.*

Authority: 15 U.S.C. 2605.

Dated: January 12, 2017.

James J. Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2017–01236 Filed 1–18–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2016–0686; FRL–9958–49–OW]

Request for Nominations for Peer Reviewers and for Public Comment on Peer Review Materials To Inform the Derivation of a Water Concentration Value for Lead in Drinking Water

AGENCY: Environmental Protection Agency (EPA).

potentially affected public entities and Indian Tribes.

(f) The Director may extend the compliance dates in paragraphs (a), (b), and (d) of this section for individual communities if the Director determines the community needs additional time to comply in order to avoid undue economic hardship. Where the Director extends the compliance date of any of these requirements for a community, the Director shall notify the Regional Administrator of the extension and the reason for the extension. The Director shall post on its Web site a notice that includes the name of the community and the new compliance date(s). The notice shall remain on the Director's Web site until the new compliance date.

■ 5. Amend § 122.42 by adding paragraph (f) to read as follows:

§ 122.42 Additional conditions applicable to specified categories of NPDES permits (applicable to State NPDES programs, see § 123.25).

* * * * *

(f) *Public Notification requirements for CSO discharges to the Great Lakes Basin.* Any permit issued for combined sewer overflow (CSO) discharges to the Great Lakes Basin must:

(1) Require implementation of the public notification requirements in § 122.38(a);

(2) Specify the information that must be included on outfall signage, which, at a minimum, must include those elements in § 122.38(a)(1)(i);

(3) Specify outfalls and public access areas where signs are required pursuant to § 122.38(a)(1)(i);

(4) Specify the timing and minimum information required for providing initial and supplemental notification to:

(i) Local public health department and other potentially affected entities under § 122.38(a)(2); and

(ii) The public under § 122.38(a)(3).

(5) Specify the location of CSO discharges that must be monitored for volume and discharge duration and the location of CSO discharges where CSO volume and duration may be estimated;

(6) Require submittal of an annual notice in accordance with § 122.38(b);

(7) Specify protocols for making the annual notice under § 122.38(b) available to the public; and

(8) Require all CSO discharges be electronically reported in a discharge monitoring report or a sewer overflow event report pursuant to 40 CFR 122.41(l)(6) or (7).

* * * * *

PART 123—STATE PROGRAM REQUIREMENTS

■ 6. The authority for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

■ 7. Amend § 123.25 by revising paragraph (a)(46) and adding paragraph (a)(47) to read as follows:

§ 123.25 Requirements for permitting.

(a) * * *

(46) For states that wish to receive electronic documents, 40 CFR part 3—(Electronic Reporting); and

(47) For a Great Lakes State, § 122.38.

* * * * *

[FR Doc. 2016–31745 Filed 1–12–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA–HQ–OPPT–2016–0426; FRL–9956–28]

RIN 2070–AK24

TSCA Inventory Notification (Active-Inactive) Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The recent amendments to the Toxic Substances Control Act (TSCA) require EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either ''active'' or ''inactive'' in U.S. commerce. To accomplish that, EPA is proposing to require a retrospective electronic notification of chemical substances on the TSCA Inventory that were manufactured (including imported) for non-exempt commercial purposes during the ten-year time period ending on June 21, 2016. EPA would also accept such notices for chemical substances that were processed. EPA would use these notifications to distinguish active substances from inactive substances. EPA would include the active and inactive designations on the TSCA Inventory and as part of its regular publications of the Inventory. EPA is also proposing to establish procedures for forward-looking electronic notification of chemical substances on the TSCA Inventory that are designated as inactive, if and when the manufacturing or processing of such chemical substances for non-exempt commercial purposes is expected to resume. Upon receipt of a valid notice, EPA would change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active. EPA is proposing the procedures regarding the manner in which such retrospective and forward-looking activity notifications must be submitted, the details of the notification requirements, exemptions from such requirements, and procedures for handling claims of confidentiality.

DATES: Comments must be received on or before March 14, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0426, by one of the following methods.

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Myrta R. Christian, Chemistry, Economics, and Sustainable Strategies Division (Mailcode 7401M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8498; email address: *christian.myrta@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you domestically manufactured, imported, or processed chemical substances listed on the TSCA Chemical Substance Inventory for nonexempt commercial purposes during the ten-year time period ending on June 21,

2016. You may also be affected by this action if you intend to domestically manufacture, import, or process chemical substances listed on the TSCA Chemical Substance Inventory in the future. The following list of North American Industrial Classification System (NAICS) codes are not intended to be exhaustive, but rather provides a guide to help readers determine whether this action may apply to them:

- Chemical manufacturing or processing (NAICS code 325).
- Petroleum and Coal Products Manufacturing (NAICS code 324).

In addition, the discussion in Unit III.A. describes in more detail which chemical substances would and would not be subject to reporting under this proposed action. You may also consult 40 CFR 710.3 and 710.4, as well as the proposed regulatory text in this document, for further information on the applicability of exemptions to this proposed rule. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

EPA is proposing this rule under TSCA section 8(b), 15 U.S.C. 2607(b). As described in more detail in Unit II.A., TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Public Law 114–182. The Government Paperwork Elimination Act (GPEA), 44 U.S.C. 3504, provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

Note that TSCA's statutory definition of ''manufacture'' includes importing. Accordingly, the regulatory definition of ''manufacture'' for this rule includes importation. All references to manufacturing in this notice should be understood to also encompass importing. Where EPA's intent is to specifically refer to domestic manufacturing or importing (both activities constitute ''manufacture''), this notice will do so expressly.

C. What action is the Agency taking?

Pursuant to TSCA section 8(b)(4)(A), EPA is proposing procedural, retrospective notification requirements for persons who manufactured chemical substances on the TSCA Inventory as described in Unit III.A. Persons who manufactured these chemical substances for nonexempt commercial purposes during the ten-year time period ending on June 21, 2016, would be required to notify the Agency of certain information described in Unit III.C., including chemical identity and the date range when manufacture occurred in that ten-year time period. EPA would use the chemical identity information obtained from this retrospective reporting to designate as active those chemical substances on the TSCA Inventory for which notices were received. If no notice is received during this retrospective reporting for a chemical substance subject to designation on the TSCA Inventory, then that substance would be designated as inactive. EPA would require date range information in order to obtain confirmation that the chemical substance in question had indeed been manufactured or processed between June 21, 2006 and June 21, 2016.

Pursuant to TSCA section 8(b)(5)(B), EPA is also proposing procedural, forward-looking notification requirements for persons who intend to manufacture or process inactive chemical substances on the TSCA Inventory. After EPA's first publication of the TSCA Inventory that includes active and inactive designations determined by the retrospective reporting, persons who intend to manufacture or process for nonexempt commercial purposes those chemical substances designated as inactive on the TSCA Inventory would be required to notify the Agency of certain information described in Unit III.C. Such notification must occur before the actual date of manufacturing or processing. EPA is proposing that notification, which shall include chemical identity and the actual date of manufacturing or processing, occur no more than 30 days before the actual date of manufacturing or processing.

Included in this proposed rule are electronic reporting requirements described in Unit III.D. that are similar to those established in 2013 for reporting other kinds of information to EPA under TSCA sections 4, 5, 8(a), and 8(d). See 78 FR 72818, December 4, 2013 (FRL 9394–6). The Agency is proposing to require submitters to use EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal, for reporting information under this proposed rule. The information would be submitted to the Agency under TSCA section 8(b), but the practical rationales for requiring submissions to proceed through CDX, cited in 2013, are also pertinent here by analogy.

Also included in this proposal are amendments to 40 CFR part 710, which conform the definitions applicable to these reporting requirements with those that apply to Chemical Data Reporting rule requirements (definitions found at 40 CFR 704.3 and 711.3) and the submission of Premanufacture Notifications (definitions found at 40 CFR 720.3). EPA believes that basing Section 8(b) reporting on definitions that are already familiar to the public from CDR and PMN reporting would reduce the potential for confusion and reduce the burden of rule familiarization. EPA is not proposing to modify the 40 CFR part 710 definitions in any manner that either is not conforming to Part 704, 710, or 720, or is a purely technical correction (*e.g.,* eliminating references to the Canal Zone from the definition of ''State''). Any other changes to the definitions in 40 CFR part 710 are beyond the scope of this proposal.

Included in this proposed rule are procedures for persons who co-manufacture or co-process a reportable chemical substance. These procedures would allow the submission of a single commercial activity notification in single instances of co-manufacturing or co-processing of a particular volume of a chemical substance. These proposed procedures are similar to Chemical Data Reporting rule requirements (40 CFR 711.22) when two or more persons are involved in a particular manufacture or import transaction. EPA believes that allowing a single notification for co-manufacturers and co-processors would serve to provide the Agency with the information necessary to designate a chemical substance as active on the TSCA Inventory while reducing duplicative reporting.

Also included in this proposed rule are requirements for filing a joint submission when specific chemical identity information is claimed confidential by a supplier. If an importer cannot provide the specific chemical identity of a reportable substance to EPA because the information is claimed confidential by a supplier, and therefore is unknown to the importer, the importer would be required to ask the supplier to provide the confidential chemical identity information directly to the Agency in a joint submission. If a domestic manufacturer or processor cannot provide the specific chemical identity of a reportable substance to EPA because the chemical identity of a reactant is claimed confidential by a supplier, and therefore is unknown to the domestic manufacturer or processor, the manufacturer or processor would be required to ask the supplier to provide the confidential chemical identity information directly to the Agency in a joint submission. EPA would only accept joint submissions that are submitted electronically using CDX.

This requirement is similar to Chemical Data Reporting rule requirements (40 CFR 711.15) and would allow EPA to obtain the information necessary to identify the specific chemical identity of a reportable substance and designate it as active on the TSCA Inventory.

D. Why is the Agency taking this action?

TSCA section 8(b)(4)(A) requires EPA to issue a final retrospective reporting rule by June 22, 2017. These proposed reporting requirements would enable EPA to fulfill a statutory obligation to designate chemical substances on the TSCA Inventory as active or inactive in U.S. commerce. This proposed rule is not intended to indicate conclusions about the risks of chemical substances on the TSCA Inventory. Nonetheless, the designation of a chemical substance as active or inactive would be relevant to the Agency's prioritization of chemical substances in U.S. commerce under TSCA section 6(b).

Furthermore, TSCA section 8(b)(5) establishes a forward-looking notification requirement that goes into effect as soon as EPA designates inactive substances. EPA is proposing to establish the procedural framework whereby manufacturers and processors would discharge their notice obligations under this section of TSCA.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of establishing the proposed reporting requirements for manufacturers and processors. This analysis, which is available in the docket, is discussed in Unit VI. and is briefly summarized here (Ref. 1).

During the retrospective (or ''start-up'') period, between approximately June 2017 and June 2018, typical costs per firm are estimated at $1,346 per submission (with an estimated seven chemicals per submission), with possible additional costs at $40.22 per CDX registration in the event that the submitter is not currently registered in CDX. Among manufacturers, an estimated 6,169 firms would undertake rule familiarization with 4,692 completing compliance determination, form completion, and recordkeeping. For manufacturers, the total burden during start-up is estimated at 86,783 hours with an associated total cost of $6.68 million. For processors, the estimate of the universe of potentially affected firms is 161,550 who might initiate rule familiarization. For processors initiating rule familiarization, the cost would be 4 hours per firm (about $300 per firm). EPA believes that it is unlikely that 100% of processors will initiate rule familiarization and that the percentage will be less. EPA estimates that only 100 processors will complete compliance determination, form completion, and recordkeeping. For the 100 processors who complete a submission with one chemical, the burden during start-up is estimated at 692 hours with an associated cost of $0.05 million. Lastly, for 469 new CDX registrations (for individuals lacking previous experience with electronic reporting to EPA), burden during start-up is estimated at 249 hours with an associated cost of $0.02 million.

The rule has minimal burden and cost implications related to ongoing reporting after the start-up year. The forward-looking (or ''Ongoing'') reporting after June 2018 involves compliance determination, form completion, and recordkeeping for twenty manufacturers and/or processors per year. Burden and cost are estimated to total 142 burden hours per year with an associated cost of $10,790 per year.

Agency activities due to the rule include CDX and Chemical Information Submission System (CISS) capacity expansions, time to manage commercial activity notices, and increased costs incurred when making revisions to the TSCA Inventory. Associated costs are estimated at $3.84 million during start-up, and $0.20 million annually thereafter.

Combining Industry and Agency cost estimates, and annualizing over a 10-year period, the total cost of the rule is estimated at $7.22 million per year using a 3% discount rate, and at $8.77 million per year using a 7% discount rate.

F. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a CD–ROM or other electronic media that you mail to EPA, mark the outside of the media as CBI and then identify electronically within the media the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked would not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Background

A. Overview of Applicable Authority

EPA is required under TSCA section 8(b), 15 U.S.C. 2607(b), to compile and keep current a list of chemical substances manufactured or processed in the United States. In 1977, EPA promulgated a rule under TSCA section 8(a), 15 U.S.C. 2607(a), to provide the information necessary for EPA to compile a list of chemical substances that had been in commerce since January of 1975 (Ref. 2). This list is known as the TSCA Chemical Substance Inventory (or simply the ''TSCA Inventory''). Since compiling the initial TSCA Inventory, EPA regularly adds new chemical substances that have completed new chemical review requirements pursuant to TSCA section 5(a), 15 U.S.C. 2604(a), and that have been manufactured or processed for nonexempt commercial purposes. EPA maintains the TSCA Inventory as the authoritative list of all the chemical substances reported to the Agency for inclusion on the TSCA Inventory.

1. Retrospective reporting under TSCA section 8(b)(4)(A). TSCA section 8(b)(4)(A) requires EPA to promulgate a rule that requires manufacturers to notify the Agency, by not later than 180 days after the date on which the final rule is published in the **Federal Register**, of each chemical substance on the TSCA Inventory that was manufactured for nonexempt commercial purpose during the 10-year period ending on June 21, 2016. If EPA receives a valid notice for a chemical substance on the TSCA Inventory, EPA must designate that chemical substance as an active substance. If EPA receives no valid notice for a chemical substance on the TSCA Inventory (and that is subject to designation), EPA must designate that chemical substance as an inactive substance.

2. Forward-looking reporting under TSCA section 8(b)(5)(B). TSCA section 8(b)(5)(B) requires persons who intend to manufacture or process chemical substances for nonexempt commercial purposes in the future that are designated on the TSCA Inventory as inactive to notify EPA prior to the date that these chemicals are to be manufactured or processed. Upon receiving a valid notice, EPA must change the designation of the chemical substance from inactive to active.

3. Processors. TSCA section 8(b)(4)(A) indicates that the Administrator may require processors to report similarly to

manufacturers under the rule. This proposed rule would not require processors to report during the retrospective reporting period. However, once EPA has designated a chemical substance as an inactive substance, the processing of that chemical substance for a non-exempt commercial purpose would be unlawful, unless the processor first submits a notice as required by TSCA section 8(b)(5)(B). Therefore, this proposed rule would allow processors to report during the retrospective reporting period, extended to not later than 360 days after the date on which the final rule is published in the **Federal Register** (which will be 180 days after EPA's publication of the first version of the TSCA Inventory with preliminary commercial activity designations). Processors could report any chemical substance that they had processed for a nonexempt commercial purpose during the 10-year period ending on June 21, 2016. The extended submission period for processors would allow processors time to evaluate whether they wish to voluntarily report chemical substances that have not been reported by manufacturers or importers and that are preliminarily designated as inactive on EPA's publication of the first version of the revised TSCA Inventory. (These designations would be merely preliminary so there would not yet be an obligation to report under TSCA Section 8(b)(5)(B).) If EPA receives no notice on a chemical substance that is subject to designation, EPA then must designate that preliminarily inactive substance as actually inactive. Hence, persons who processed a chemical substance between June 2006 and June 2016 may wish to report under TSCA section 8(b)(4)(A) in order to avoid a subsequent obligation to curtail processing on the day that EPA designates the substance as inactive, under TSCA section 8(b)(5)(B). Processing could resume as soon as the notice under TSCA section 8(b)(5)(B) is submitted, but processors may nonetheless find it less disruptive to ensure that the chemical substance is earlier reported as active under TSCA section 8(b)(5)(A).

4. General provisions. General provisions for TSCA section 8(b) rules appear in 40 CFR part 710. These provisions include definitions that apply to reporting under this proposed rule and also describe the scope of the Inventory. For example, 40 CFR 710.1 describes requirements for EPA to compile and keep current the TSCA Inventory of chemical substances manufactured or processed for commercial purposes, including the periodic updates to the Inventory to include new chemical substances reported under TSCA section 5(a) and commercialized for nonexempt purposes. In addition, the definitions in TSCA section 3 apply to this rulemaking.

5. Electronic reporting under the Government Paperwork Elimination Act (GPEA). GPEA, 44 U.S.C. 3504, provides that, when practicable, Federal organizations should use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3), provides that any requirement in title 40 of the CFR to submit a notice directly to the Agency can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form (Ref. 3). For more information about CROMERR, go to *http://www.epa.gov/cromerr*.

III. Summary of Proposed Rule

EPA is proposing reporting and procedural requirements for manufacturers and processors of chemical substances pursuant to TSCA section 8(b).

A. What chemical substances would be reportable under this rule?

1. Reportable chemical substances. As a general matter, the retrospective reporting requirement of this proposed rule would apply to chemical substances listed on the TSCA Inventory that were manufactured for a nonexempt commercial purposes during the 10-year period ending on June 21, 2016. This lookback period is set by statute. TSCA also establishes forward-looking reporting requirements, at section 8(b)(5)(B), with respect to chemical substances listed on the TSCA Inventory that EPA designates as inactive. The TSCA Inventory is available at *https://www.epa.gov/tsca-inventory*.

2. Exemptions from reporting. i. Statutory background. This proposed rule provides exemptions from reporting based on sections 8(b)(4) and (5) and the general objectives that EPA can infer from that text. Unlike the reporting that informed the initial compilation of the TSCA Inventory (which arose under TSCA section 8(a)), the reporting requirements described in this proposed rule arise directly under TSCA section 8(b). EPA must finalize the retrospective reporting requirements by June 22, 2017, and all mandatory reporting under TSCA section 8(b)(4) must be completed by not later than 180 days thereafter. TSCA section 8(b)(4) and 8(b)(5) reporting requirements apply to ''each chemical substance,'' found on the TSCA Inventory, subject to the provision that reporting obligations shall only be triggered by manufacturing or processing for a ''nonexempt commercial purpose.'' The retrospective reporting requirements under TSCA section 8(b)(4) are expressed as being ''subject to the limitations'' of TSCA section 8(a)(5)(A). TSCA section 8(a)(5)(A), in turn, specifies that ''to the extent feasible,'' EPA shall: (1) Avoid requiring reporting that is ''unnecessary or duplicative;'' (2) ''minimize the cost of compliance'' to small manufacturers and processors; and (3) apply reporting obligations to the persons likely to have information relevant for effective implementation.

Furthermore, as EPA interprets its statutory authority, the reporting is intended to support two key objectives. First, to enable EPA to determine which reportable chemical substances are active in U.S. commerce. EPA will accomplish this based on notices received. Reportable chemical substances for which no notices are received would be considered inactive in U.S. commerce. See TSCA section 8(b)(4)(A)(iii). Second, with respect to chemical substances identified as being active in commerce that are listed on the confidential portion of the TSCA Inventory, to require that persons manufacturing or processing such chemical substances request that existing claims for protection against disclosure of the specific chemical identity be maintained. See TSCA sections 8(b)(4)(B)(ii), 8(b)(4)(C), 8(b)(5).

ii. Excluded chemical substances. If a chemical substance is not listed on the TSCA Inventory, then by the terms of TSCA sections 8(b)(4) and (5), it is not subject to reporting under this proposed rule. For example, chemical substances that are manufactured under a TSCA section 5(h) exemption are not added to the TSCA Inventory. Accordingly, this proposed rule would not require that reporting occur with respect to such substances. This is reflected in the proposed definitions at 40 CFR 710.23, which are drafted in such a manner that if a chemical substance was not on the TSCA Inventory as of June 22, 2016, it would not be subject to reporting.

Naturally occurring chemical substances also are proposed to be excluded from reporting under this proposed rule, so long as the manufacturing and processing of such substances meets the criteria set forth in 40 CFR 710.27(b). When EPA required

manufacturers and processors to submit notices in support of the original compilation of the TSCA Inventory in 1977, EPA made clear that reporting on naturally occurring chemical substances would not be necessary, as these substances would automatically be included in the Inventory as a category: ''Naturally Occurring Chemical Substances,'' 42 FR 64578 (1977). EPA proposes to simply designate the whole category of Naturally Occurring Chemical Substances as active substances, by rule, without the need for reporting to differentiate among such substances.

Finally, this proposed rule would not require manufacturers to report chemical substances that are on both the non-confidential portion of the TSCA Inventory and the interim list of active substances described in TSCA section 8(b)(6). Such reporting would be unnecessary, since EPA already has reporting data to establish that the chemical substance was in active commerce at some time between June 21, 2006 and June 21, 2016. Furthermore, for such substances, there are no existing claims for protection against disclosure of the specific identity of the chemical substance for any party to elect to maintain or not maintain. With respect to chemical substances on the confidential portion of the TSCA Inventory, however, such reporting still serves a statutory function under TSCA sections 8(b)(4)(B)(ii) and 8(b)(4)(C), even where there is already adequate evidence, prior to reporting, that the substance was in active commerce during the lookback period.

Regarding the composition of the interim list of active substances, TSCA section 8(b)(6) requires EPA to compile an interim list of active substances reported under 40 CFR part 711 for the purposes of TSCA section 6(b), before promulgation of the rule. The definition of the interim list is somewhat ambiguous, since it refers to the ''reporting period that most closely preceded June 22, 2016.'' The term ''reporting period'' is not defined under 40 CFR part 711. In light of the definitional ambiguity of TSCA section 8(b)(6) and EPA's weighing of the statutory objectives noted previously, EPA has construed the ''interim list of active substances'' to include 2012 CDR data, which avoids delay of this proposed rule, but would allow for the 2016 CDR data to give rise to a reporting exemption as soon as they are publicly released in final form. Under the proposal, manufacturers and processors of chemical substances on the non-confidential portion of the Inventory would be exempt from reporting if the manufacture of that chemical substance was already reported (by any party) in response to 2012 or 2016 CDR.

iii. Manufacturing or processing for an exempt commercial purpose. TSCA section 8(b) directs EPA to limit reporting obligations to manufacturing and processing for ''nonexempt commercial purpose.'' This phrase had a commonly-accepted usage at the time that TSCA was amended, in 2016. See, for example, ''Certain New Chemicals; Receipt and Status Information'' (referencing TSCA section 5 requirements as applying to manufacture for ''nonexempt commercial purpose'') (Ref. 4), and ''2016 Chemical Data Reporting Frequent Questions'' (associating ''nonexempt commercial purpose'' with exemptions codified at 40 CFR 720.30 and 40 CFR 711.10(a)) (Ref. 5). Since reporting under TSCA section 8(b) is a form of existing chemical reporting, EPA construes the phrase ''nonexempt commercial purpose'' consistent with the manner in which the 40 CFR 720.30 exemptions from pre-manufacture reporting requirements were adapted for use in the CDR at 40 CFR 711.10. Thus, for example, the manufacturing or processing of chemical substances solely in small quantities for research and development would not trigger reporting obligations under this proposed rule. Similarly, the manufacturing or processing of impurities, or byproducts that have no subsequent commercial purpose, would not trigger reporting obligations under this proposed rule. Finally, since the CDR integrates reporting exemptions for persons who import chemical substances solely as part of articles with reporting exemptions for nonexempt commercial purposes (see 40 CFR 711.10), EPA construes the TSCA 8(b) reference to ''nonexempt commercial purpose'' as also encompassing this article exemption. Further supporting this interpretation, EPA believes it would be incongruous to establish a more comprehensive reporting obligation for the import of inactive existing chemical substances under TSCA section 8(b)(5) (*i.e.,* including import as part of an article), than would be applicable to the import of new chemical substances under TSCA section 5 (*i.e.,* excluding import as part of an article).

3. Chemical substances added to the Inventory on or after June 22, 2016. In this proposed rule, chemical substances added to the Inventory on or after June 22, 2016 would be designated as active, without the need for any reporting to establish that the chemical substance is active and without the need for any statement by manufacturers or processors indicating whether such persons wish to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance. Reporting under TSCA section 8(b)(4) is based on manufacturing or processing, for non-exempt commercial purposes, that occurred between June 21, 2006 and June 21, 2016. TSCA section 8(b)(4)(A)(iii) directs EPA to classify a chemical substance as inactive if no notice of manufacturing or processing is received by EPA. A substance added to the Inventory on or after June 22, 2016, however, would be added so recently that it has no manufacturing or processing overlapping with the lookback period. It would be illogical to designate a very recent addition to the Inventory as inactive, on the grounds that the chemical substance was too recently added to the Inventory to be captured in the retrospective reporting of current manufacturing and processing. Furthermore, if a chemical substance was added to the Inventory on or after June 22, 2016, then any claim for the protection against disclosure of the specific chemical identity of such a substance would be a new claim rather than the maintenance of an existing claim for protection of the information. For the reasons presented previously, EPA construes TSCA section 8(b)(4) reporting requirements to be limited to chemical substances that were added to the Inventory prior to June 22, 2016.

B. When would reporting be required?

1. Retrospective reporting period for manufacturers. This proposed rule would require manufacturers to report to the Agency not later than 180 days after the final rule is published in the **Federal Register**. The 180-day time period for this retrospective reporting for manufacturers is the maximum time allowed under TSCA section 8(b)(4)(A). Following this retrospective reporting for manufacturers, EPA would include the active and inactive designations, determined by the notices received, on the TSCA Inventory.

2. Retrospective reporting period for processors. This proposed rule would allow processors to report to the Agency not later than 360 days after the final rule is published in the **Federal Register**. The 360-day time period for this retrospective reporting for processors would allow processors to search EPA's publication of a first draft of the TSCA Inventory with active designations and draft inactive designations, based on retrospective reporting by manufacturers, and to report only those chemical substances

not already reported. This first draft of the TSCA Inventory with active designations and draft inactive designations would not have the legal effect of actually designating any chemical substance as inactive. Processors would have the option to simply not report under TSCA section 8(b)(4) and continue processing until such time when EPA has actually designated a chemical substance as inactive. At such time, any further processing of the chemical substance, without prior notification to EPA, would be prohibited by section 8(b)(5). Prior notification would allow EPA to add the chemical substance to the TSCA Inventory as an active substance.

3. Forward-looking reporting. After EPA completes its review of the notices submitted under TSCA section 8(b)(4)(A), it must designate as inactive any chemical substance (subject to designation) for which no notice was received. TSCA section 8(b)(5)(B) provides that, once a chemical substance has been designated as inactive, any person who intends to manufacture or process that inactive substance for a nonexempt commercial purpose must first notify the Agency before the date on which the inactive substance is manufactured or processed. EPA proposes to furthermore limit the submission period for such notices, so that they may not be submitted more than 30 days before the actual date of manufacturing or processing.

The 30-day time period for forward-looking reporting is based on EPA's experience with Premanufacture Notices (PMNs). Although persons often form the intent to commercially manufacture or process chemical substances several months ahead of time, EPA's experience with processing PMNs is that business decisions, technical difficulties, and other unforeseen circumstances may delay a company's plans to commercialize. EPA believes that a commercial activity notice reflects a more tentative or provisional intent to manufacture or process if it is submitted more than 30 days prior to the actual date of manufacturing or processing of the chemical substance. As such, it is less reliable as evidence that placement as active Inventory is warranted. Reassigning chemical substances from inactive to active status, based on relatively unreliable indicia of intent to manufacture, could affect the reliability of the Inventory designations. Therefore, this proposed rule would require that forward-looking reporting of chemical substances designated as inactive on the TSCA Inventory occur not earlier than 30 days before companies intend to manufacturing or processing for nonexempt commercial purposes.

C. What information would be reported?

1. Retrospective reporting period for manufacturers. This proposed rule would require that manufacturers reporting for the retrospective reporting period provide certain information including chemical identity, type of commercial activity (*i.e.,* whether it is domestic manufacture and/or import), date range of manufacture for nonexempt commercial purpose during the 10-year reporting period ending on June 21, 2016, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity, if applicable.

2. Retrospective reporting period for processors. This proposed rule would allow processors to report for the retrospective reporting period, provided that the processor reports timely and consistent with the pertinent reporting requirements, including providing certain information such as chemical identity, date range of processing for nonexempt commercial purpose during the 10-year reporting period ending on June 21, 2016, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity, if applicable.

3. Forward-looking reporting. TSCA section 8(b)(5) requires that manufacturers and processors of inactive substances notify EPA before the date on which they manufacture or process an inactive substance for non-exempt commercial purposes. This proposed rule stipulates that they would do so in the following manner: By reporting certain information including chemical identity, type of commercial activity (*i.e.,* whether it is domestic manufacture, import, and/or processing), actual date of manufacturing or processing for nonexempt commercial purpose, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity, if applicable.

4. Reporting forms. EPA developed two versions of a Notice of Activity (NOA) reporting form for submitting the information described in this proposed rule for the two reporting scenarios, retrospective and forward-looking (Ref. 6). NOA Form A (EPA Form No. TBD–1) would be used by manufacturers for the retrospective reporting period. It would also be used by processors who report for the retrospective reporting period. NOA Form B (EPA Form No. TBD–2) would be used by manufacturers and processors for forward-looking reporting. The new NOA forms are based on EPA's Notice of Commencement (NOC) form (Ref. 7), since much of the information submitted in an NOC form is the same or similar to the information proposed in the NOA.

Any person required to report under this proposed rule would provide the information identified in the relevant version of the NOA forms to the extent it is known to or reasonably ascertainable by them. Drafts of the two versions of the proposed NOA reporting forms are available in the docket for public review (Ref. 6).

As noted previously, these forms require very basic explanatory information about the type of commercial activity at issue (domestic manufacture, import, or processing) as well as the date range over which the activity occurred or the date when the activity is intended to resume. The collection of this explanatory information is intended to reduce the likelihood of receiving erroneous notices (*e.g.,* notices regarding commercial activity outside the lookback period), to support EPA's capacity to inquire into the accuracy of activity notices, and thus to increase the reliability of commercial activity designations on the TSCA Inventory.

D. How would information be submitted to EPA?

In 2013, EPA finalized a rule to require electronic reporting of certain information submitted to the Agency under TSCA sections 4, 5, 8(a) and 8(d) (Ref. 8). The final rule followed two previous rules requiring similar electronic reporting of information submitted to the Agency for TSCA Chemical Data Reporting and Pre-Manufacture Notifications. This proposed rule would require electronic reporting similar to the requirements established in 2013 for submitting certain other information under TSCA (see 711.35 and 720.40). This proposed rule would require submitters to use EPA's CDX, the Agency's electronic reporting portal, and EPA's Chemical Information Submission System (CISS), a web-based reporting tool, for all reporting under this proposed rule in accordance with section 3.2000 of 40 CFR part 3 (CROMERR) (Ref. 3).

This proposed rule would require persons submitting notices of activity to EPA under TSCA section 8(b) to follow these same electronic reporting procedures used for other TSCA submissions, *i.e.,* to register with EPA's CDX and use CISS to prepare a data file for submission. Registration in CDX

enables CDX to authenticate identity and verify authorization. To register, the CDX registrant (also referred to as ''Electronic Signature Holder'' or ''Public/Private Key Holder'') agrees to the Terms and Conditions, provides information about the submitter and organization, and selects a user name and password. Users who have previously registered with CDX for other submissions would be able to add the ''Submission for Chemical Safety and Pesticide Program'' service to their current registration in CDX and use the CISS web-based reporting tool.

EPA developed the Chemical Information Submission System (CISS) for use in submitting data electronically under TSCA sections 4, 5, 8(a), and 8(d) to the Agency. The tool is available for use with Windows, Macs, Linux, and UNIX based computers and uses ''Extensible Markup Language'' (XML) specifications for efficient data transmission across the Internet. CISS works with CDX to secure online communication and provides user-friendly navigation. The NOA forms described in this proposed rule will be included in an e-NOA software module in CISS. Once a user completes entry of the relevant data fields and metadata information in the appropriate NOA form, the CISS reporting tool validates the submission by performing a basic error check. CISS also allows the user to choose ''Preview,'' ''Save,'' or ''Submit.'' When ''Submit'' is selected, the user is asked to provide the user name and password that was created during the CDX registration process. CISS then submits the data via CDX. Upon successful receipt of the submission by EPA, the status of the submissions will be flagged as ''Submitted.'' The user can also login to the application and download their Copy of Record.

EPA believes that electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency. It also allows submitters to share a draft submission within their organization and more easily save a copy for their records or future use. The resource and time requirements to review, process, store, and retrieve data by the Agency would also be reduced.

Any person submitting a reporting form could claim any part or all of the form as confidential. Except as otherwise provided in this proposed rule, any information that is claimed as confidential would be disclosed by EPA only to the extent and by the means of the procedures set forth in 40 CFR part 2.

E. How would CBI claims and requests be handled?

Notices pursuant to this rulemaking may contain two different types of CBI assertions: Claims for protection of information other than specific chemical identify, and requests to maintain existing claims for protection of specific chemical identify.

1. *Information other than specific chemical identity.* For all new claims for protection (*i.e.,* for all CBI assertions under this rule other than requests to maintain existing claims for protection of specific chemical identity), TSCA section 14(c)(1)(B) and 14(c)(5) require that persons claiming CBI must provide a specific, certification statement regarding the basis for the CBI claims. In addition, this proposed rule would require that all such claims be substantiated at the time of submission, except for claims for information exempted from substantiation under section 14(c)(2). In view of the rapid EPA review of claims required by section 14(g)(1), and in order to reduce the likelihood of unwarranted claims, EPA believes that a concurrent substantiation is required. EPA will review a representative subset of these claims as specified by section 14(g)(1).

2. *Requests to maintain existing CBI claims for chemical identity.* Requests to maintain existing CBI claims for specific chemical identity on Form A are governed in part by TSCA sections 8(b)(4)(C–E). TSCA section 8(b)(4)(C), in particular, requires EPA to issue a rule to establish a review plan for these requests. That review plan must specify a time when the Form A CBI requests for specific chemical identity are to be substantiated. EPA will be conducting a separate rulemaking to establish this review plan. Therefore, this proposal does not include mandatory substantiation requirements for Form A CBI requests for chemical identity. Mandatory substantiation requirements will be part of the review plan promulgated under section 8(b)(4)(C). However, the Agency proposes to allow companies to submit early substantiation at the same time that their Form A is filed, if they so choose. As long as the period between the date these earlier substantiations are received and the due date to be established in the review plan (yet to be proposed) is not more than five years, these early substantiations would exempt the company from the requirement to submit additional substantiation for their Form A under the terms of the review plan. See section 8(b)(4)(D)(i). EPA will review requests to maintain CBI claims for specific chemical identity in accordance with the 8(b)(4)(D) review plan in the timeframe mandated by section 8(b)(4)(E).

Any manufacturer or processor submitting an active chemical notification under TSCA section 8(b)(4)(A) may seek to maintain an existing CBI claim for specific chemical identity, regardless of whether that person asserted the original claim that caused the specific chemical identity to be treated as confidential. EPA believes this is the correct interpretation of ''a manufacturer or processor . . . that seeks to maintain an existing claim for protection of against disclosure'' of specific chemical identity. A number of manufacturers and processors may legitimately benefit from the confidential status of a specific chemical identity, and the initial claimant may no longer exist. EPA does not believe that Congress intended for specific confidential chemical identities to be disclosed without providing the opportunity for manufacturers and processors to make a request that the identities should remain confidential simply because the original claimants no longer manufacture the chemical substances.

Pursuant to TSCA section 8(b)(4)(B)(iv), EPA would move an active chemical substance from the confidential portion of the Inventory to the non-confidential portion if no manufacturer or processor submitting an active chemical notification under TSCA section 8(b)(4)(A) requests to maintain the existing CBI claim for the specific identity of that chemical substance. See proposed 710.37(a).

Requests to maintain existing CBI claims for specific chemical identity on Form B are governed by TSCA section 8(b)(5)(B), which provides that the request to maintain the claim must be substantiated not later than 30 days after submitting Form B. See section 8(b)(5)(B)(ii)(II). Proposed substantiation requirements for Form B CBI claims for chemical identity are found in section 710.37(a)(1)(ii).

Although TSCA section 8(b)(5) provides that substantiation for requests to maintain existing CBI claims for specific chemical identity must be provided not later than 30 days after submitting a Form B, persons submitting a Form B may find it more efficient to simply provide the substantiation for a CBI claim for specific chemical identity at the time of filing. Section 8(b)(5)(iii)(II) provides that the Agency shall ''promptly'' review CBI claims for specific chemical identity in Form B. The Agency intends to review these claims within 90 days of receipt of the substantiation.

IV. Request for Comments

EPA is seeking public comment on all aspects of this proposed rule, including specific issues throughout this document, as well as other issues discussed in this Unit.

A. Considerations for the Agency's Economic Impact Analysis

EPA has evaluated the potential costs for manufacturers and processors of chemical substances reportable under this proposed rule (Ref. 1). EPA is specifically seeking additional information and data that the Agency could consider in developing the final economic analysis. In particular, EPA is seeking data that could facilitate the Agency's further evaluation of the potentially affected industry and firms, including data related to potential impacts for those small businesses that would be subject to reporting.

B. Electronic Reporting

Requiring electronic reporting under this proposed rule that is similar to those established in 2013 for other TSCA reporting, EPA expects to save time, improve data quality, and provide efficiencies for both submitters and the Agency. EPA is specifically interested in comments related to the adoption of the existing mechanisms and procedures for use in transmitting the notices proposed in this rule, including comments related to the extent to which potential reporting entities are already familiar with these mechanisms and procedures because of their existing use for other TSCA reporting. EPA is also interested in feedback on how electronic reporting affects potential reporting entities in terms of reporting time, reporting efficiency, and potential burden associated with training to use the electronic systems (*i.e.,* CDX and CISS).

V. References

The following is a listing of the documents that are specifically referenced in this proposed rule. The docket includes these references and other information considered by EPA. For assistance in locating these other documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. 2016. EPA. Burden and Cost Report for the Proposed Rule: TSCA Inventory Notification Requirements (RIN 2070–AK24, December 21, 2016).
2. 1977. EPA. Inventory Reporting Requirements; Final Rule. **Federal Register** (42 FR 64572, December 23, 1977) (FRL 817–1).
3. 2005. EPA. Cross-Media Electronic Reporting Rule (CROMERR); Final Rule. **Federal Register** (70 FR 59848, October 13, 2005) (FRL 7977–1).
4. 2010. EPA. Certain New Chemicals; Receipt and Status Information; Notice. **Federal Register** (75 FR 71688, November 24, 2010) (FRL 8852–1).
5. 2016. EPA. 2016 Chemical Data Reporting Frequent Questions. *https://www.epa.gov/chemical-data-reporting/2016-chemical-data-reporting-frequent-questions*.
6. 2016. EPA. Notice of Activity Form A and Form B; Draft.
7. 2009. EPA. Notice of Commencement Form; Final.
8. 2013. EPA. Electronic Reporting Under the Toxic Substances Control Act; Final Rule. **Federal Register** (78 FR 72818, December 4, 2013) (FRL 9394–6).
9. 2016. EPA. Information Collection Request for the TSCA section 8(b) Proposed Reporting Requirements for TSCA Inventory Notification Active-Inactive (EPA ICR No. 2517.01).
10. 2016. EPA. Small Entity Analysis Report for the Proposed Rule: TSCA Inventory Notification Requirements (December 16, 2016).

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

The information collection activities associated with this proposed rule have been submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq.* Specifically, EPA has prepared an Information Collection Request (ICR) to estimate the potential burden and costs associated with the proposed requirements (Ref. 9). The ICR, which is available in the docket, has been assigned the EPA ICR No. 2517.01 (OMB Control No. 2070-[new]). You can find a copy of the ICR in the docket for this proposed rule (Ref. 9), and it is briefly summarized here.

Start-Up Year Burden/Cost (Retrospective). Covers respondents/affected entities, *i.e.,* persons who manufacture chemical substances.

Respondents' obligation to respond: Mandatory.

Estimated number of respondents: 4,692.

Frequency of response: Once and on-occasion.

Estimated burden: 86,783 hours. The term ''burden'' is defined at 5 CFR 1320.3(b).

Estimated cost: $6.68 million.

Note that an additional number of respondents (*i.e.,* processors), as high as 161,550, are each assumed to undergo four hours of rule familiarization (about $300 per firm), but would likely not be required to submit information. This is based on an assumption that 100 percent of processor firms would undertake rule familiarization. However, EPA believes that it is unlikely that 100% of processors would initiate rule familiarization and that the actual percentage would be lower. Although this count, and the associated burden and costs, are not included in the estimates, the estimated burden and costs account for the bulk of total start-up costs (88%). In addition, the estimated burden and costs includes 469 CDX registrations in addition to NOA submissions.

Ongoing Annual Burden/Cost (Forward-looking): Covers respondents/affected entities, *i.e.,* persons who manufacture or process chemical substances.

Respondents' obligation to respond: Mandatory.

Estimated number of respondents: 20.

Frequency of response: On-occasion.

Total estimated burden: 142 hours.

Total estimated cost: $10,790.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and included on any related collection instrument (*e.g.,* the form).

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov*, Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 13, 2017. EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

EPA certifies under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule would not have a significant economic impact on a substantial number of small entities if the rule has a very small level of impact on the small entities subject to the rule.

The small entities subject to the requirements of this action are manufacturers, and processors of chemical substances. As the most burdensome conditions are incurred during the start-up year for manufacturers, these reporters are the subject of the quantitative analysis with other reporters and other years assessed by inference. The detailed analysis is available in the docket (Ref. 10).

The quantitative analysis addresses the ''most affected'' subset of entities who are expected to incur the highest typical burden under the proposed rule as entities manufacturing (or importing) chemicals that must submit NOAs involving an average of seven chemicals per entity in the start-up year. These small entities most directly regulated by this rule are small businesses in NAICS 325: Chemical Manufacturing, and 324: Petroleum and Coal Products Manufacturing reporting during the start-up year. EPA has determined that all of the small entities (comprising about 96% of the total number of entities) within the scope of the quantitative analysis would experience an impact of less than 1% of revenues. This analysis follows EPA guidance on Regulatory Flexibility Act (RFA) and Small Business Regulatory Enforcement Fairness Act (SBREFA) analyses. Per this guidance document, the preferred measure of economic impacts is the ''sales test:'' Annualized compliance costs as a percentage of sales (or revenue or receipts when sales data are not readily available). This measure is termed ''cost impact percentage'' in the small entity analysis.

Additional groups of small entities may be affected by the rule and are expected to incur similar or lesser impacts, by inference. First, processors submitting NOAs during the start-up year are expected to incur a smaller unit burden with one chemical per NOA, and therefore experience similar or lesser impacts than manufacturers. Secondly, all reporters in future years, with lower counts and relatively smaller unit burdens, would therefore incur much lower impact than entities during the start-up year, Therefore, inferences drawn regarding small entity impacts on the most affected group may be extended to characterize the impacts on processors during the start-up year and all entities for future years.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action is not expected to impose enforceable duty on any state, local or tribal governments, and the requirements imposed on the private sector are not expected to result in annual expenditures of $100 million or more for the private sector. As such, EPA has determined that the requirements of UMRA sections 202, 203, 204, or 205 do not apply to this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications because it would not have any effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications because it is not expected to have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000).

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action would not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 710

Environmental protection, Chemicals, Reporting and Recordkeeping, TSCA Inventory.

Dated: December 23, 2016.

James J. Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 710—[AMENDED]

■ 1. The authority citation for part 710 would continue to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 2. Redesignate §§ 710.1 through 710.4 as subpart A under the following subpart A heading:

PART 710—COMPILATION OF THE TSCA CHEMICAL SUBSTANCE INVENTORY

Subpart A—General Provisions

Sec.

Subpart B—Commercial Activity Notification

* * * * *

■ 3. Revise § 710.1 paragraph (b) to read as follows:

Subpart A—General Provisions

§ 710.1 Scope and compliance.

* * * * *

(b) This part applies to the activities associated with the compilation of the TSCA Chemical Substance Inventory (TSCA Inventory) and the designation of chemical substances on the TSCA Inventory as active or inactive in U.S. commerce.

* * * * *

■ 4. Revise § 710.3 paragraph (d) to read as follows:

§ 710.3 Definitions.

* * * * *

(d) The following definitions also apply to this part:

Act means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

Administrator means the Administrator of the U.S. Environmental Protection Agency, any employee or authorized representative of the Agency to whom the Administrator may either herein or by order delegate his/her authority to carry out his/her functions, or any other person who will by operation of law be authorized to carry out such functions.

Article means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 710.4(d)(5); except that fluids and particles are not considered articles regardless of shape or design.

Byproduct means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

CASRN means Chemical Abstracts Service Registry Number.

Chemical substance means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical; except that ''chemical substance'' does *not* include: (1) Any mixture; (2) any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide; (3) tobacco or any tobacco product, but not including any derivative products; (4) any source material, special nuclear material, or byproduct material; (5) any pistol, firearm, revolver, shells, and cartridges; and (6) any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

Commerce means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State or (2) which affects trade, traffic, transportation, or commerce between a place in a State and any place outside of such State.

Customs territory of the United States means the 50 States, Puerto Rico, and the District of Columbia.

Distribute in commerce and *distribution in commerce* means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold after its introduction into commerce.

Domestic means within the geographical boundaries of the 50 United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

EPA means the U.S. Environmental Protection Agency.

Importer means any person who imports any chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. ''Importer'' includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate, (1) the consignee, (2) the importer of record, (3) the actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20, or (4) the transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR 144.

Impurity means a chemical substance which is unintentionally present with another chemical substance.

Intermediate means any chemical substance that is consumed, in whole or in part, in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rate(s) of such chemical reaction(s).

Inventory means the TSCA Chemical Substance Inventory, which is EPA's comprehensive list of confidential and non-confidential chemical substances manufactured or processed in the United States for non-exempt commercial purpose that EPA compiled and keeps current under section 8(b) of the Act.

Manufacture means to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. When a chemical substance, manufactured other than by import, is: (1) Produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production.

Manufacture for commercial purposes means: (1) To manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage, and includes, among other things, the ''manufacture'' of any amount of a chemical substance or mixture (i) for commercial distribution, including for test marketing, or (ii) for use by the manufacturer, including use for product research and development or as an intermediate. (2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes.

Manufacturer means a person who manufactures a chemical substance.

Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that

''mixture'' does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

New chemical substance means any chemical substance which is not included on the Inventory.

Person includes any individual, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal Government.

Process means to process for commercial purposes. Process includes the preparation of a chemical substance or mixture, after its manufacture, (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.

Process for commercial purposes means the preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes.

Processor means any person who processes a chemical substance or mixture.

Site means a contiguous property unit. Property divided only by a public right-of-way will be considered one site. More than one manufacturing plant may be located on a single site. (1) For chemical substances manufactured under contract, *i.e.,* by a toll manufacturer, the site is the location where the chemical substance is physically manufactured. (2) The site for an importer who imports a chemical substance described in § 710.25 is the U.S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance. The import site, in some cases, may be the organization's headquarters in the United States. If there is no such operating unit or headquarters in the United States, the site address for the importer is the U.S. address of an agent acting on behalf of the importer who is authorized to accept service of process for the importer.

Small quantities solely for research and development (or ''small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product'') means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

State means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

Technically qualified individual means a person (1) who because of his/her education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under his/her supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in this paragraph may be delegated to another individual, or other individuals, as long as each meets the criteria in paragraph (1) of this definition.

Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

United States, when used in the geographic sense, means all of the States, territories, and possessions of the United States.

■ 5. Add a new subpart B to read as follows:

Subpart B—Commercial Activity Notification

§ 710.23 Definitions.

The following definitions also apply to subpart B of this part.

Active substance means any interim active substance, any naturally occurring chemical substance as defined by § 710.27(b), any substance added to the TSCA Inventory on or after June 22, 2016, and any chemical substance subject to commercial activity designation that the Administrator designated as active based on the receipt of a notice under this subpart.

Central Data Exchange or CDX means EPA's centralized electronic document reporting portal, or its successors.

Chemical substance subject to commercial activity designation means a chemical substance that requires a designation as either an active or an inactive substance. A chemical substance is subject to commercial activity designation if it was added to the TSCA Inventory before June 22, 2016, it is not an interim active substance, it is not a naturally occurring chemical substance as defined by § 710.27(b), and it has not yet been designated by the Administrator as either an active or an inactive substance.

Chemical Information Submission System or CISS means EPA's web-based reporting tool for preparing and submitting a Notice of Activity.

e-NOA means EPA's software module within CISS for generating and completing Notice of Activity forms A and B.

Existing claim for protection of specific chemical identity against disclosure is a claim to continue protection of specific chemical identity of a chemical substance that is listed on the confidential portion of the TSCA Inventory.

Inactive substance means any chemical substance subject to commercial activity designation, that the Administrator designates as inactive based on the lack of receipt of a notice under this subpart.

Interim active substance means any chemical substance that was reported, pursuant to 40 CFR part 711, as having been manufactured in either 2010 or 2011. After such time when EPA has made public a compiled list of chemical

substances that were reported, pursuant to 40 CFR part 711, as having been manufactured in either 2012, 2013, 2014, or 2015, the term shall also include any such additional chemical substances that were there reported as having been manufactured in those additional years.

Known to or reasonably ascertainable by means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

Lookback period means the period beginning on June 21, 2006 and ending on June 21, 2016.

Reportable chemical substance means a chemical substance that is listed on the TSCA Inventory and that is either: (1) A chemical substance subject to commercial activity designation for which notification is required or allowed under § 710.25(a) and § 710.25(b), (2) an interim active substance for which notification is required under § 710.25(a), or (3) an inactive substance for which notification is required under § 710.25(c).

Submission period means the applicable period for submitting a Notice of Activity under § 710.25.

§ 710.25 Persons subject to the notification requirement.

The following persons are subject to the requirements of this subpart.

(a) *Who must submit the Notice of Activity Form A?* Any person who manufactured a chemical substance subject to commercial activity designation or who manufactured an interim active substance that is on the confidential portion of the TSCA Inventory, at any time during the lookback period, except as provided in § 710.27, must submit a Notice of Activity Form A as specified under § 710.29 and § 710.30.

(b) *Who else may submit the Notice of Activity Form A?* Any person who processed a chemical substance subject to commercial activity designation, at any time during the lookback period, except as provided in § 710.27, may submit a Notice of Activity Form A as specified under § 710.29 and § 710.30.

(c) *Who must submit the Notice of Activity Form B?* Any person who intends to manufacture or process an inactive chemical substance, except as provided in § 710.27, after the effective date of the Administrator's designation of such chemical substance as an inactive substance, must submit a Notice of Activity Form B as specified under § 710.29 and § 710.30.

§ 710.27 Activities for which notification is not required.

(a) *In general.* The following activities do not trigger notification requirements under this subpart:

(1) The manufacturing or processing of a chemical substance solely in small quantities for research and development.

(2) The import of a chemical substance as part of an article.

(3) The manufacturing or processing of a chemical substance as described in § 720.30(g) or (h).

(b) *Manufacturing or processing naturally occurring chemical substances.* The following activities do not trigger notification requirements under this subpart:

(1) The manufacture of a naturally occurring chemical substance, as described in § 710.4(b). Some chemical substances can be manufactured both as described in § 710.4(b) and by means other than those described in § 710.4(b). If a person manufactures a chemical substance by means other than those described in § 710.4(b), this exemption is inapplicable, regardless of whether the chemical substance also could have been produced as described in § 710.4(b). This exemption does not cover the manufacture of a chemical substance from a naturally occurring chemical substance.

(2) The processing of a naturally occurring chemical substance only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water.

§ 710.29 Information required in the notification.

(a) *Reporting information to EPA.* Any person who reports information to EPA, including post-notification substantiation of confidentiality claims under § 710.37(b), must do so using the e-NOA software module, the CISS reporting tool, and the CDX electronic reporting portal provided by EPA at the addresses set forth in § 710.39. For notices of activity under § 710.25(a) and § 710.25(b), the submission must include all information described in paragraph (b) of this section. For a Notice of Activity under § 710.25(c), the submission must include all information described in paragraph (c) of this section. A person must submit a separate form for each chemical substance that the person is required to report. CDX, CISS, and e-NOA allow a person to report multiple chemical substances in one session that will be transmitted to EPA on separate forms. Using e-NOA and registering in CDX are described in instructions available from EPA at the Web sites set forth in § 710.39.

(b) *Information to be reported on the Notice of Activity Form A.* Any person submitting a Notice of Activity Form A under § 710.25(a) or § 710.25(b) must submit the information described in this paragraph for each reportable chemical substance during the submission period specified in § 710.30(a). A person submitting information under § 710.25(a) or § 710.25(b) must report information to the extent that such information is known to or reasonably ascertainable by that person. A notice must be submitted for each chemical substance for which the person is required to report. A person reporting information under § 710.25(a) or § 710.25(b) must report the following:

(1) Information specified in § 710.29(d).

(2) The type of commercial activity for each reportable chemical substance: Whether the chemical substance was domestically manufactured in the United States, imported into the United States, or both domestically manufactured in the United States and imported into the United States during the lookback period.

(3) The first date and the last date that each reportable chemical substance was domestically manufactured in the United States, imported into the United States, or both domestically manufactured in the United States and imported into the United States during the lookback period.

(c) *Information to be reported on a Notice of Activity Form B.* Any person submitting a Notice of Activity Form B under § 710.25(c) must provide the information described in this paragraph for each inactive chemical substance intended to be manufactured or processed at the time specified in § 710.30(b). A person submitting information under § 710.25(c) must report information to the extent that such information is known to or reasonably ascertainable by that person. A notice must be submitted for each chemical substance that the person intends to manufacture or process. A person submitting a notice of activity under § 710.25(c) must report the following:

(1) Information specified in § 710.29(d).

(2) The type of intended commercial activity for the inactive substance: Whether the inactive substance is intended to be domestically manufactured in the United States, imported into the United States, processed in the United States, or a particular combination of these.

(3) The actual date by which the inactive substance is to be domestically manufactured in the United States, imported into the United States, or processed in the United States.

(d) *Information to be reported on either the Notice of Activity Form A or Form B.*

(1) *Company.* The name of the submitting company.

(2) *Authorized official.* The name and address of the authorized official for the submitting company.

(3) *Technical contact.* The name and telephone number of a person who will serve as technical contact for the submitting company and who will be able to answer questions about the information submitted by the company to EPA.

(4) *Chemical-specific information.* The correct CA Index name as used to list the chemical substance on the Inventory and the correct corresponding CASRN must be submitted for each reportable chemical substance. Persons who wish to report chemical substances listed on the confidential portion of the TSCA Inventory must report the chemical substances using a TSCA Accession Number and generic name.

(i) If an importer submitting a notice cannot provide the information specified in § 710.29(d)(4) because it is unknown to the importer and claimed as confidential by the supplier of the chemical substance or mixture, the importer must ask the supplier to provide the specific chemical identity information directly to EPA in a joint submission using the same e-NOA software module used for commercial activity reporting. Such request must include instructions for submitting chemical identity information electronically, using e-NOA, CISS, and CDX (see § 710.39), and for clearly referencing the importer's submission. Contact information for the supplier, a trade name or other name for the chemical substance or mixture, and a copy of the request to the supplier must be included with the importer's submission with respect to the chemical substance.

(ii) If a manufacturer or processor submitting a notice cannot provide the information specified in § 710.29(d)(4) because the reportable chemical substance is manufactured or processed using a reactant having a specific chemical identity that is unknown to the manufacturer or processor and claimed as confidential by its supplier, the manufacturer or processor must ask the supplier of the confidential reactant to provide the specific chemical identity of the confidential reactant directly to EPA in a joint submission using the same e-NOA software module used for commercial activity reporting. Such request must include instructions for submitting chemical identity information electronically using e-NOA, CISS, and CDX (see § 710.39), and for clearly referencing the manufacturer's or processor's submission. Contact information for the supplier, a trade name or other name for the chemical substance, and a copy of the request to the supplier must be included with the manufacturer's or processor's submission with respect to the chemical substance.

(iii) EPA will only accept joint submissions that are submitted electronically using e-NOA, CISS, and CDX (see § 710.39) and that clearly reference the primary submission to which they refer.

(5) *Certification statement.* The authorized official must certify that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on the form are true and correct using the certification statement in this paragraph.

(i) The certification must be signed and dated by the authorized official for the submitting company.

(ii) The following is the required certification language:

''I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of my knowledge is, true, accurate, and complete. I am aware there are significant penalties for submitting incomplete, false and/or misleading information, including the possibility of fine and imprisonment for knowing violations.''

§ 710.30 When to submit notifications.

(a*) When must a Notice of Activity Form A be submitted?* The Notice of Activity Form A required to be submitted under § 710.25(a) must be submitted during the applicable submission period.

(1) *Manufacturers.* The submission period for manufacturers under § 710.25(a) begins on [date on which the final rule is published in the **Federal Register**] and ends on [180 days after the date on which the final rule is published in the **Federal Register**].

(2) *Processors.* The submission period for processors under § 710.25(b) begins on [date on which the final rule is published in the **Federal Register**] and ends on [360 days after the date on which the final rule is published in the **Federal Register**].

(b) *When must a Notice of Activity Form B be submitted?* The Notice of Activity Form B required to be submitted under § 710.25(c) must be submitted before a person manufactures or processes the inactive substance, but not more than 30 days prior to the actual date of manufacturing or processing.

§ 710.33 Co-manufacturers and co-processors.

(a) *Notice of Activity submitted by co-manufacturers.* When, in a single instance of manufacturing or importing a particular volume of a chemical substance during the lookback period, two or more persons qualify as the manufacturer or importer of that volume, they may determine among themselves who should make the required submission under § 710.25(a). If no notice is submitted as required under this subpart, EPA will hold each such person liable for failure to submit a notice.

(b) *Notice of activity by prospective co-manufacturers or co-processors.* If two or more persons intend to manufacture, import, or process a particular volume of an inactive substance, such that multiple persons would qualify as the manufacturer, importer, or processor of that volume, they may determine among themselves who will submit the required notice under § 710.25(c). If no notice is submitted as required under this subpart, all of the persons remain subject to the reporting requirements, and EPA will hold each such person liable for a failure to submit a notice prior to the date of manufacturing, importing, or processing.

§ 710.35 Recordkeeping requirements.

Each person who is subject to the notification requirements of this part must retain records that document any information reported to EPA. Records relevant to a notice of activity under § 710.25(a) and § 710.25(b) must be retained for a period of 5 years beginning on the last day of the submission period. Records relevant to a notice of activity under § 710.25(c) must be retained for a period of 5 years beginning on the day that the notice was submitted.

§ 710.37 Confidentiality claims.

(a) *Chemical identity.* Any persons submitting information under this part may request to maintain an existing claim of confidentiality for the specific chemical identity of a reportable chemical substance only if the identity of the chemical substance is listed on the confidential portion of the TSCA

Inventory as of the time the notice is submitted for that chemical substance under this part. Any such requests to maintain an existing claim of confidentiality must be made at the time the information is submitted. If no person submitting the information specified in § 710.29(d)(4) for a particular chemical substance requests that the claim be maintained, EPA will treat the specific chemical identity of that chemical substance as not subject to a confidentiality claim and will move the chemical substance to the public portion of the TSCA Inventory. Except as set forth in this subsection, information claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 2. The following steps must be taken to maintain an existing claim of confidentiality for the specific chemical identity of a reportable chemical substance.

(1) *Substantiation of requests.*

(i) *Notice of Activity Form A.* A person requesting to maintain an existing claim of confidentiality for specific chemical identity may submit with the notice detailed written answers to the questions in paragraph (1)(iii) of this section, signed and dated by an authorized official. If these early answers are received less than five years before the date on which substantiation is due pursuant to TSCA Section 8(b)(4)(D)(i) the early answers will be deemed to be substantiations made under TSCA Section (8)(b)(4)(D)(i) and the person will be exempt from further substantiation requirements under Section (8)(b)(4)(D)(i). Early answers that do not include the answers to questions in paragraph (1)(iii) of this section will not be deemed to be substantiations made under the TSCA section (8)(b)(4)(D)(i) requirement.

(ii) *Notice of Activity Form B.* A person requesting to maintain an existing claim of confidentiality for specific chemical identity must submit detailed written answers to the questions in paragraph (1)(iii) of this section within 30 days of submitting the notice, signed and dated by an authorized official. If this information is not submitted within 30 days of submitting the notice, EPA will consider the specific chemical identity as not subject to a confidentiality claim and may make the information public without further notice.

(iii) *Substantiation questions.*

(A) What harmful effects to your competitive position, if any, or to your supplier's competitive position, do you think would result from the identity of the chemical substance being disclosed in connection with reporting under this part? How could a competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the harmful effects?

(B) How long should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential?

(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured for a commercial purpose by anyone?

(E) Is the fact that the chemical substance is being manufactured for a commercial purpose available to the public, for example in technical journals, libraries, or State, local, or Federal agency public files?

(F) What measures have been taken to prevent undesired disclosure of the fact that the chemical substance is being manufactured for a commercial purpose?

(G) To what extent has the fact that this chemical substance is manufactured for commercial purposes been revealed to others? What precautions have been taken regarding these disclosures? Have there been public disclosures or disclosures to competitors?

(H) Does this particular chemical substance leave the site of manufacture in any form, *e.g.,* as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?

(I) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?

(J) For what purpose do you manufacture the chemical substance?

(K) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, please attach copies of such determinations.

(2) *Identification of claims.* If any of the information contained in the answers to the questions listed in paragraph (a)(1)(iii) of this section is asserted to be confidential, the submitter must clearly identify the information that is claimed as confidential by marking the specific information on each page with a label such as ''confidential business information,'' ''proprietary,'' or ''trade secret.''

(b) *Information other than specific chemical identity.* Any persons submitting information under this part may assert a claim of confidentiality for information other than specific chemical identity. Any such confidentiality claims must be made at the time the information is submitted. Confidentiality claims will apply only to the information submitted with the claim. Confidentiality claims cannot be made when a response field on a reporting form is left blank or designated as not known or reasonably ascertainable. Except as set forth in this section, information claimed as confidential in accordance with this subsection will be treated and disclosed in accordance with 40 CFR part 2. The following steps must be taken to assert a claim of confidentiality for information other than specific chemical identity. If no claim is asserted at the time the information is submitted, or if the following steps are not taken, EPA will consider the information as not subject to a confidentiality claim and may make the information public without further notice.

(1) *Substantiation of claims.* A person asserting a claim of confidentiality for information other than specific chemical identity must submit detailed written answers to the following questions at the time of submission, signed and dated by an authorized official.

(i) For what period of time do you request that the information be maintained as confidential, *e.g.,* until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.

(ii) Information submitted to the EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?

(iii) What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information be considered confidential?

(iv) Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? If so, specify which.

(v) Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?

(vi) Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.

(vii) For each item or category of information claimed as confidential, *explain with specificity* why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

(viii) Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, please explain whether the information is the kind that would customarily not be released to the public.

(ix) Whether you assert the information as voluntary or involuntary, please address why disclosure of the information would tend to lessen the availability to the EPA of similar information in the future.

(x) If you believe any information to be (a) trade secret(s), please so state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).

(xi) Explain any other issue you deem relevant.

(2) *Identification of claims.* If any of the information contained in the answers to the questions listed in paragraph (b)(1) of this section is asserted to be confidential, the submitter must clearly identify the information that is claimed as confidential by marking the specific information on each page with a label such as ''confidential business information,'' ''proprietary,'' or ''trade secret.''

(3) *Certification statement for claims.* In submitting a claim of confidentiality, a person must certify the truth of the following four statements concerning all information which is claimed as confidential:

(i) My company has taken reasonable measures to protect the confidentiality of the information.

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law.

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

§ 710.39 Electronic filing.

(a) EPA will accept information submitted under this subpart only if submitted in accordance with this section. All information must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, Notices of Activity and any associated information must be generated and completed using the e-NOA software module.

(b) Obtain instructions for registering in CDX as follows:

(1) *Web site.* The CDX Registration User Guide is available at *https://www.epa.gov/sites/production/files/documents/cdx_registration_guide_v0_02.pdf*. To register in CDX, go to *https://cdx.epa.gov* and follow the appropriate links.

(2) *Telephone.* Contact the EPA CDX Help Desk at 1–888–890–1995.

(3) *Email.* Email the EPA CDX Help Desk at *HelpDesk@epacdx.net*.

(c) Obtain instructions for using the e-NOA software module as follows:

(1) *Web site.* Go to the EPA New Chemicals under the Toxic Substances Control Act Web site at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn* and follow the appropriate links.

(2) *Telephone.* Contact the EPA TSCA Hotline at 1–202–554–1404.

(3) *Email.* Email the EPA TSCA Hotline at *TSCA-Hotline@epa.gov*.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[IB Docket No. 98–96; FCC 16–179]

1998 Biennial Regulatory Review—Review of Accounts Settlement in the Maritime Mobile and Maritime Mobile-Satellite Radio Services

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, the Federal Communications Commission (Commission) proposes to withdraw as an accounting authority and transition its functions and duties to private accounting authorities. The Commission seeks comment on a transition plan and a timetable to implement an orderly transition to the privatization of the accounts-settlement function.

DATES: Comments due on or before March 14, 2017, and reply comments due on or before April 13, 2017.

ADDRESSES: You may submit comments, identified by IB Docket 98–96, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://www.fcc.gov/cgb/ecfs.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.
- *Email: ecfs@fcc.gov.* Include IB Docket No. 98–96 in the subject line of the message.
- *Mail:* Commercial overnight mail (other than U.S. Postal Service Express Mail, and Priority Mail, must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street SW., Washington, DC 20554.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Dana Shaffer, Office of Managing Director at (202) 418–0832.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Further Notice of Proposed Rulemaking (*Second FNPRM*), FCC 16–179, IB Docket No. 98–96, adopted on December 22, 2016, and released on December 30, 2016. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW., Room CY–A257, Portals II, Washington, DC 20554, and may also be purchased from the Commission's copy contractor, BCPI, Inc., Portals II, 445 12th Street SW., Room CY–B402, Washington, DC 20554. Customers may contact BCPI, Inc. via their Web site, *http://www.bcpi.com,* or call 1–800–378–3160. This document is available in alternative formats (computer diskette, large print, audio record, and braille).

Federal Register

Tuesday,
April 11, 2000

Part VII

Environmental Protection Agency

Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6576–3]

Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations

AGENCY: Environmental Protection Agency (EPA, or Agency).

ACTION: Final Policy Statement.

SUMMARY: EPA today issues its revised final policy on ''Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations,'' commonly referred to as the ''Audit Policy.'' The purpose of this Policy is to enhance protection of human health and the environment by encouraging regulated entities to voluntarily discover, promptly disclose and expeditiously correct violations of Federal environmental requirements. Incentives that EPA makes available for those who meet the terms of the Audit Policy include the elimination or substantial reduction of the gravity component of civil penalties and a determination not to recommend criminal prosecution of the disclosing entity. The Policy also restates EPA's long-standing practice of not requesting copies of regulated entities' voluntary audit reports to trigger Federal enforcement investigations. Today's revised Audit Policy replaces the 1995 Audit Policy (60 FR 66706), which was issued on December 22, 1995, and took effect on January 22, 1996. Today's revisions maintain the basic structure and terms of the 1995 Audit Policy while clarifying some of its language, broadening its availability, and conforming the provisions of the Policy to actual Agency practice. The revisions being released today lengthen the prompt disclosure period to 21 days, clarify that the independent discovery condition does not automatically preclude penalty mitigation for multi-facility entities, and clarify how the prompt disclosure and repeat violation conditions apply to newly acquired companies. The revised Policy was developed in close consultation with the U.S. Department of Justice (DOJ), States, public interest groups and the regulated community. The revisions also reflect EPA's experience implementing the Policy over the past five years.

DATES: This revised Policy is effective May 11, 2000.

FOR FURTHER INFORMATION CONTACT: Catherine Malinin Dunn (202) 564–2629 or Leslie Jones (202) 564–5123. Documentation relating to the development of this Policy is contained in the environmental auditing public docket (#C–94–01). An index to the docket may be obtained by contacting the Enforcement and Compliance Docket and Information Center (ECDIC) by telephone at (202) 564–2614 or (202) 564–2119, by fax at (202) 501–1011, or by email at docket.oeca@epa.gov. ECDIC office hours are 8:00 am to 4:00 pm Monday through Friday except for Federal holidays. An index to the docket is available on the Internet at www.epa.gov/oeca/polguid/enfdock.html. Additional guidance regarding interpretation and application of the Policy is also available on the Internet at www.epa.gov/oeca/ore/apolguid.html.

SUPPLEMENTARY INFORMATION: This Notice is organized as follows:

I. Explanation of Policy

A. Introduction

On December 22, 1995, EPA issued its final policy on ''Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations'' (60 FR 66706) (Audit Policy, or Policy). The purpose of the Policy is to enhance protection of human health and the environment by encouraging regulated entities to voluntarily discover, disclose, correct and prevent violations of Federal environmental law. Benefits available to entities that make disclosures under the terms of the Policy include reductions in the amount of civil penalties and a determination not to recommend criminal prosecution of disclosing entities.

Today, EPA issues revisions to the 1995 Audit Policy. The revised Policy reflects EPA's continuing commitment to encouraging voluntary self-policing while preserving fair and effective enforcement. It lengthens the prompt disclosure period to 21 days, clarifies that the independent discovery condition does not automatically preclude Audit Policy credit in the multi-facility context, and clarifies how the prompt disclosure and repeat violations conditions apply in the acquisitions context. The revised final Policy takes effect May 11, 2000.

B. Background and History

The Audit Policy provides incentives for regulated entities to detect, promptly disclose, and expeditiously correct violations of Federal environmental requirements. The Policy contains nine conditions, and entities that meet all of them are eligible for 100% mitigation of any gravity-based penalties that otherwise could be assessed. (''Gravity-based'' refers to that portion of the penalty over and above the portion that represents the entity's economic gain from noncompliance, known as the ''economic benefit.'') Regulated entities that do not meet the first condition—systematic discovery of violations—but meet the other eight conditions are eligible for 75% mitigation of any gravity-based civil penalties. On the criminal side, EPA will generally elect not to recommend criminal prosecution

by DOJ or any other prosecuting authority for a disclosing entity that meets at least conditions two through nine—regardless of whether it meets the systematic discovery requirement—as long as its self-policing, discovery and disclosure were conducted in good faith and the entity adopts a systematic approach to preventing recurrence of the violation.

The Policy includes important safeguards to deter violations and protect public health and the environment. For example, the Policy requires entities to act to prevent recurrence of violations and to remedy any environmental harm that may have occurred. Repeat violations, those that result in actual harm to the environment, and those that may present an imminent and substantial endangerment are not eligible for relief under this Policy. Companies will not be allowed to gain an economic advantage over their competitors by delaying their investment in compliance. And entities remain criminally liable for violations that result from conscious disregard of or willful blindness to their obligations under the law, and individuals remain liable for their criminal misconduct.

When EPA issued the 1995 Audit Policy, the Agency committed to evaluate the Policy after three years. The Agency initiated this evaluation in the Spring of 1998 and published its preliminary results in the **Federal Register** on May 17, 1999 (64 FR 26745). The evaluation consisted of the following components:

- An internal survey of EPA staff who process disclosures and handle enforcement cases under the 1995 Audit Policy;
- A survey of regulated entities that used the 1995 Policy to disclose violations;
- A series of meetings and conference calls with representatives from industry, environmental organizations, and States;
- Focused stakeholder discussions on the Audit Policy at two public conferences co-sponsored by EPA's Office of Enforcement and Compliance Assurance (OECA) and the Vice President's National Partnership for Reinventing Government, entitled ''Protecting Public Health and the Environment through Innovative Approaches to Compliance'';
- A **Federal Register** notice on March 2, 1999, soliciting comments on how EPA can further protect and improve public health and the environment through new compliance and enforcement approaches (64 FR 10144); and
- An analysis of data on Audit Policy usage to date and discussions amongst EPA officials who handle Audit Policy disclosures.

The same May 17, 1999, **Federal Register** notice that published the evaluation's preliminary results also proposed revisions to the 1995 Policy and requested public comment. During the 60-day public comment period, the Agency received 29 comment letters, copies of which are available through the Enforcement and Compliance Docket and Information Center. (See contact information at the beginning of this notice.) Analysis of these comment letters together with additional data on Audit Policy usage has constituted the final stage of the Audit Policy evaluation. EPA has prepared a detailed response to the comments received; a copy of that document will also be available through the Docket and Information Center as well on the Internet at www.epa.gov/oeca/ore/apolguid.html.

Overall, the Audit Policy evaluation revealed very positive results. The Policy has encouraged voluntary self-policing while preserving fair and effective enforcement. Thus, the revisions issued today do not signal any intention to shift course regarding the Agency's position on self-policing and voluntary disclosures but instead represent an attempt to fine-tune a Policy that is already working well.

Use of the Audit Policy has been widespread. As of October 1, 1999, approximately 670 organizations had disclosed actual or potential violations at more than 2700 facilities. The number of disclosures has increased each of the four years the Policy has been in effect.

Results of the Audit Policy User's Survey revealed very high satisfaction rates among users, with 88% of respondents stating that they would use the Policy again and 84% stating that they would recommend the Policy to clients and/or their counterparts. No respondents stated an unwillingness to use the Policy again or to recommend its use to others.

The Audit Policy and related documents, including Agency interpretive guidance and general interest newsletters, are available on the Internet at www.epa.gov/oeca/ore/apolguid. Additional guidance for implementing the Policy in the context of criminal violations can be found at www.epa.gov/oeca/oceft/audpol2.html.

In addition to the Audit Policy, the Agency's revised Small Business Compliance Policy (''Small Business Policy'') is also available for small entities that employ 100 or fewer individuals. The Small Business Policy provides penalty mitigation, subject to certain conditions, for small businesses that make a good faith effort to comply with environmental requirements by discovering, disclosing and correcting violations. EPA has revised the Small Business Policy at the same time it revised the Audit Policy. The revised Small Business Policy will be available on the Internet at www.epa.gov/oeca/smbusi.html.

C. Purpose

The revised Policy being announced today is designed to encourage greater compliance with Federal laws and regulations that protect human health and the environment. It promotes a higher standard of self-policing by waiving gravity-based penalties for violations that are promptly disclosed and corrected, and which were discovered systematically—that is, through voluntary audits or compliance management systems. To provide an incentive for entities to disclose and correct violations regardless of how they were detected, the Policy reduces gravity-based penalties by 75% for violations that are voluntarily discovered and promptly disclosed and corrected, even if not discovered systematically.

EPA's enforcement program provides a strong incentive for compliance by imposing stiff sanctions for noncompliance. Enforcement has contributed to the dramatic expansion of environmental auditing as measured in numerous recent surveys. For example, in a 1995 survey by Price Waterhouse LLP, more than 90% of corporate respondents who conduct audits identified one of the reasons for doing so as the desire to find and correct violations before government inspectors discover them. (A copy of the survey is contained in the Docket as document VIII–A–76.)

At the same time, because government resources are limited, universal compliance cannot be achieved without active efforts by the regulated community to police themselves. More than half of the respondents to the same 1995 Price Waterhouse survey said that they would expand environmental auditing in exchange for reduced penalties for violations discovered and corrected. While many companies already audit or have compliance management programs in place, EPA believes that the incentives offered in this Policy will improve the frequency and quality of these self-policing efforts.

D. Incentives for Self-Policing

Section C of the Audit Policy identifies the major incentives that EPA

provides to encourage self-policing, self-disclosure, and prompt self-correction. For entities that meet the conditions of the Policy, the available incentives include waiving or reducing gravity-based civil penalties, declining to recommend criminal prosecution for regulated entities that self-police, and refraining from routine requests for audits. (As noted in Section C of the Policy, EPA has refrained from making routine requests for audit reports since issuance of its 1986 policy on environmental auditing.)

1. Eliminating Gravity-Based Penalties

In general, civil penalties that EPA assesses are comprised of two elements: the economic benefit component and the gravity-based component. The economic benefit component reflects the economic gain derived from a violator's illegal competitive advantage. Gravity-based penalties are that portion of the penalty over and above the economic benefit. They reflect the egregiousness of the violator's behavior and constitute the punitive portion of the penalty. For further discussion of these issues, see ''Calculation of the Economic Benefit of Noncompliance in EPA's Civil Penalty Enforcement Cases,'' 64 FR 32948 (June 18, 1999) and ''A Framework for Statute-Specific Approaches to Penalty Assessments,'' #GM–22 (1984), U.S. EPA General Enforcement Policy Compendium.

Under the Audit Policy, EPA will not seek gravity-based penalties for disclosing entities that meet all nine Policy conditions, including systematic discovery. (''Systematic discovery'' means the detection of a potential violation through an environmental audit or a compliance management system that reflects the entity's due diligence in preventing, detecting and correcting violations.) EPA has elected to waive gravity-based penalties for violations discovered systematically, recognizing that environmental auditing and compliance management systems play a critical role in protecting human health and the environment by identifying, correcting and ultimately preventing violations.

However, EPA reserves the right to collect any economic benefit that may have been realized as a result of noncompliance, even where the entity meets all other Policy conditions. Where the Agency determines that the economic benefit is insignificant, the Agency also may waive this component of the penalty.

EPA's decision to retain its discretion to recover economic benefit is based on two reasons. First, facing the risk that the Agency will recoup economic benefit provides an incentive for regulated entities to comply on time. Taxpayers whose payments are late expect to pay interest or a penalty; the same principle should apply to corporations and other regulated entities that have delayed their investment in compliance. Second, collecting economic benefit is fair because it protects law-abiding companies from being undercut by their noncomplying competitors, thereby preserving a level playing field.

2. 75% Reduction of Gravity-based Penalties

Gravity-based penalties will be reduced by 75% where the disclosing entity does not detect the violation through systematic discovery but otherwise meets all other Policy conditions. The Policy appropriately limits the complete waiver of gravity-based civil penalties to companies that conduct environmental auditing or have in place a compliance management system. However, to encourage disclosure and correction of violations even in the absence of systematic discovery, EPA will reduce gravity-based penalties by 75% for entities that meet conditions D(2) through D(9) of the Policy. EPA expects that a disclosure under this provision will encourage the entity to work with the Agency to resolve environmental problems and begin to develop an effective auditing program or compliance management system.

3. No Recommendations for Criminal Prosecution

In accordance with EPA's Investigative Discretion Memo dated January 12, 1994, EPA generally does not focus its criminal enforcement resources on entities that voluntarily discover, promptly disclose and expeditiously correct violations, unless there is potentially culpable behavior that merits criminal investigation. When a disclosure that meets the terms and conditions of this Policy results in a criminal investigation, EPA will generally not recommend criminal prosecution for the disclosing entity, although the Agency may recommend prosecution for culpable individuals and other entities. The 1994 Investigative Discretion Memo is available on the Internet at http://www.epa.gov/oeca/ore/ aed/comp/acomp/a11.html.

The ''no recommendation for criminal prosecution'' incentive is available for entities that meet conditions D(2) through D(9) of the Policy. Condition D(1) ''systematic discovery'' is not required to be eligible for this incentive, although the entity must be acting in good faith and must adopt a systematic approach to preventing recurring violations. Important limitations to the incentive apply. It will not be available, for example, where corporate officials are consciously involved in or willfully blind to violations, or conceal or condone noncompliance. Since the regulated entity must satisfy conditions D(2) through D(9) of the Policy, violations that cause serious harm or which may pose imminent and substantial endangerment to human health or the environment are not eligible. Finally, EPA reserves the right to recommend prosecution for the criminal conduct of any culpable individual or subsidiary organization.

While EPA may decide not to recommend criminal prosecution for disclosing entities, ultimate prosecutorial discretion resides with the U.S. Department of Justice, which will be guided by its own policy on voluntary disclosures (''Factors in Decisions on Criminal Prosecutions for Environmental Violations in the Context of Significant Voluntary Compliance or Disclosure Efforts by the Violator,'' July 1, 1991) and by its 1999 Guidance on Federal Prosecutions of Corporations. In addition, where a disclosing entity has met the conditions for avoiding a recommendation for criminal prosecution under this Policy, it will also be eligible for either 75% or 100% mitigation of gravity-based civil penalties, depending on whether the systematic discovery condition was met.

4. No Routine Requests for Audit Reports

EPA reaffirms its Policy, in effect since 1986, to refrain from routine requests for audit reports. That is, EPA has not and will not routinely request copies of audit reports to trigger enforcement investigations. Implementation of the 1995 Policy has produced no evidence that the Agency has deviated, or should deviate, from this Policy. In general, an audit that results in expeditious correction will reduce liability, not expand it. However, if the Agency has independent evidence of a violation, it may seek the information it needs to establish the extent and nature of the violation and the degree of culpability.

For discussion of the circumstances in which EPA might request an audit report to determine Policy eligibility, see the explanatory text on cooperation, section I.E.9.

E. Conditions

Section D describes the nine conditions that a regulated entity must

meet in order for the Agency to decline to seek (or to reduce) gravity-based penalties under the Policy. As explained in section I.D.1 above, regulated entities that meet all nine conditions will not face gravity-based civil penalties. If the regulated entity meets all of the conditions except for D(1)—systematic discovery—EPA will reduce gravity-based penalties by 75%. In general, EPA will not recommend criminal prosecution for disclosing entities that meet at least conditions D(2) through D(9).

1. Systematic Discovery of the Violation Through an Environmental Audit or a Compliance Management System

Under Section D(1), the violation must have been discovered through either (a) an environmental audit, or (b) a compliance management system that reflects due diligence in preventing, detecting and correcting violations. Both ''environmental audit'' and ''compliance management system'' are defined in Section B of the Policy.

The revised Policy uses the term ''compliance management system'' instead of ''due diligence,'' which was used in the 1995 Policy. This change in nomenclature is intended solely to conform the Policy language to terminology more commonly in use by industry and by regulators to refer to a systematic management plan or systematic efforts to achieve and maintain compliance. No substantive difference is intended by substituting the term ''compliance management system'' for ''due diligence,'' as the Policy clearly indicates that the compliance management system must reflect the regulated entity's due diligence in preventing, detecting and correcting violations.

Compliance management programs that train and motivate employees to prevent, detect and correct violations on a daily basis are a valuable complement to periodic auditing. Where the violation is discovered through a compliance management system and not through an audit, the disclosing entity should be prepared to document how its program reflects the due diligence criteria defined in Section B of the Policy statement. These criteria, which are adapted from existing codes of practice—such as Chapter Eight of the U.S. Sentencing Guidelines for organizational defendants, effective since 1991—are flexible enough to accommodate different types and sizes of businesses and other regulated entities. The Agency recognizes that a variety of compliance management programs are feasible, and it will determine whether basic due diligence criteria have been met in deciding whether to grant Audit Policy credit.

As a condition of penalty mitigation, EPA may require that a description of the regulated entity's compliance management system be made publicly available. The Agency believes that the availability of such information will allow the public to judge the adequacy of compliance management systems, lead to enhanced compliance, and foster greater public trust in the integrity of compliance management systems.

2. Voluntary Discovery

Under Section D(2), the violation must have been identified voluntarily, and not through a monitoring, sampling, or auditing procedure that is required by statute, regulation, permit, judicial or administrative order, or consent agreement. The Policy provides three specific examples of discovery that would not be voluntary, and therefore would not be eligible for penalty mitigation: emissions violations detected through a required continuous emissions monitor, violations of NPDES discharge limits found through prescribed monitoring, and violations discovered through a compliance audit required to be performed by the terms of a consent order or settlement agreement. The exclusion does not apply to violations that are discovered pursuant to audits that are conducted as part of a comprehensive environmental management system (EMS) required under a settlement agreement. In general, EPA supports the implementation of EMSs that promote compliance, prevent pollution and improve overall environmental performance. Precluding the availability of the Audit Policy for discoveries made through a comprehensive EMS that has been implemented pursuant to a settlement agreement might discourage entities from agreeing to implement such a system.

In some instances, certain Clean Air Act violations discovered, disclosed and corrected by a company prior to issuance of a Title V permit are eligible for penalty mitigation under the Policy. For further guidance in this area, see ''Reduced Penalties for Disclosures of Certain Clean Air Act Violations,'' Memorandum from Eric Schaeffer, Director of the EPA Office of Regulatory Enforcement, dated September 30, 1999. This document is available on the Internet at www.epa.gov/oeca/ore/apolguid.html.

The voluntary requirement applies to discovery only, not reporting. That is, any violation that is voluntarily discovered is generally eligible for Audit Policy credit, regardless of whether reporting of the violation was required after it was found.

3. Prompt Disclosure

Section D(3) requires that the entity disclose the violation in writing to EPA within 21 calendar days after discovery. If the 21st day after discovery falls on a weekend or Federal holiday, the disclosure period will be extended to the first business day following the 21st day after discovery. If a statute or regulation requires the entity to report the violation in fewer than 21 days, disclosure must be made within the time limit established by law. (For example, unpermitted releases of hazardous substances must be reported immediately under 42 U.S.C. 9603.) Disclosures under this Policy should be made to the appropriate EPA Regional office or, where multiple Regions are involved, to EPA Headquarters. The Agency will work closely with States as needed to ensure fair and efficient implementation of the Policy. For additional guidance on making disclosures, contact the Audit Policy National Coordinator at EPA Headquarters at 202–564–5123.

The 21-day disclosure period begins when the entity discovers that a violation has, or may have, occurred. The trigger for discovery is when any officer, director, employee or agent of the facility has an objectively reasonable basis for believing that a violation has, or may have, occurred. The ''objectively reasonable basis'' standard is measured against what a prudent person, having the same information as was available to the individual in question, would have believed. It is not measured against what the individual in question thought was reasonable at the time the situation was encountered. If an entity has some doubt as to the existence of a violation, the recommended course is for the entity to proceed with the disclosure and allow the regulatory authorities to make a definitive determination. Contract personnel who provide on-site services at the facility may be treated as employees or agents for purposes of the Policy.

If the 21-day period has not yet expired and an entity suspects that it will be unable to meet the deadline, the entity should contact the appropriate EPA office in advance to develop disclosure terms acceptable to EPA. For situations in which the 21-day period already has expired, the Agency may accept a late disclosure in the exceptional case, such as where there are complex circumstances, including where EPA determines the violation could not be identified and disclosed within 21 calendar days after discovery.

EPA also may extend the disclosure period when multiple facilities or acquisitions are involved.

In the multi-facility context, EPA will ordinarily extend the 21-day period to allow reasonable time for completion and review of multi-facility audits where: (a) EPA and the entity agree on the timing and scope of the audits prior to their commencement; and (b) the facilities to be audited are identified in advance. In the acquisitions context, EPA will consider extending the prompt disclosure period on a case-by-case basis. The 21-day disclosure period will begin on the date of discovery by the acquiring entity, but in no case will the period begin earlier than the date of acquisition.

In summary, Section D(3) recognizes that it is critical for EPA to receive timely reporting of violations in order to have clear notice of the violations and the opportunity to respond if necessary. Prompt disclosure is also evidence of the regulated entity's good faith in wanting to achieve or return to compliance as soon as possible. The integrity of Federal environmental law depends upon timely and accurate reporting. The public relies on timely and accurate reports from the regulated community, not only to measure compliance but to evaluate health or environmental risk and gauge progress in reducing pollutant loadings. EPA expects the Policy to encourage the kind of vigorous self-policing that will serve these objectives and does not intend that it justify delayed reporting. When violations of reporting requirements are voluntarily discovered, they must be promptly reported. When a failure to report results in imminent and substantial endangerment or serious harm to the environment, Audit Policy credit is precluded under condition D(8).

4. Discovery and Disclosure Independent of Government or Third Party Plaintiff

Under Section D(4), the entity must discover the violation independently. That is, the violation must be discovered and identified before EPA or another government agency likely would have identified the problem either through its own investigative work or from information received through a third party. This condition requires regulated entities to take the initiative to find violations on their own and disclose them promptly instead of waiting for an indication of a pending enforcement action or third-party complaint.

Section D(4)(a) lists the circumstances under which discovery and disclosure will not be considered independent. For example, a disclosure will not be independent where EPA is already investigating the facility in question. However, under subsection (a), where the entity does not know that EPA has commenced a civil investigation and proceeds in good faith to make a disclosure under the Audit Policy, EPA may, in its discretion, provide penalty mitigation under the Audit Policy. The subsection (a) exception applies only to civil investigations; it does not apply in the criminal context. Other examples of situations in which a discovery is not considered independent are where a citizens' group has provided notice of its intent to sue, where a third party has already filed a complaint, where a whistleblower has reported the potential violation to government authorities, or where discovery of the violation by the government was imminent. Condition D(4)(c)—the filing of a complaint by a third party—covers formal judicial and administrative complaints as well as informal complaints, such as a letter from a citizens' group alerting EPA to a potential environmental violation.

Regulated entities that own or operate multiple facilities are subject to section D(4)(b) in addition to D(4)(a). EPA encourages multi-facility auditing and does not intend for the ''independent discovery'' condition to preclude availability of the Audit Policy when multiple facilities are involved. Thus, if a regulated entity owns or operates multiple facilities, the fact that one of its facilities is the subject of an investigation, inspection, information request or third-party complaint does not automatically preclude the Agency from granting Audit Policy credit for disclosures of violations self-discovered at the other facilities, assuming all other Audit Policy conditions are met. However, just as in the single-facility context, where a facility is already the subject of a government inspection, investigation or information request (including a broad information request that covers multiple facilities), it will generally not be eligible for Audit Policy credit. The Audit Policy is designed to encourage regulated entities to disclose violations before any of their facilities are under investigation, not after EPA discovers violations at one facility. Nevertheless, the Agency retains its full discretion under the Audit Policy to grant penalty waivers or reductions for good-faith disclosures made in the multi-facility context. EPA has worked closely with a number of entities that have received Audit Policy credit for multi-facility disclosures, and entities contemplating multi-facility auditing are encouraged to contact the Agency with any questions concerning Audit Policy availability.

5. Correction and Remediation

Under Section D(5), the entity must remedy any harm caused by the violation and expeditiously certify in writing to appropriate Federal, State, and local authorities that it has corrected the violation. Correction and remediation in this context include responding to spills and carrying out any removal or remedial actions required by law. The certification requirement enables EPA to ensure that the regulated entity will be publicly accountable for its commitments through binding written agreements, orders or consent decrees where necessary.

Under the Policy, the entity must correct the violation within 60 calendar days from the date of discovery, or as expeditiously as possible. EPA recognizes that some violations can and should be corrected immediately, while others may take longer than 60 days to correct. For example, more time may be required if capital expenditures are involved or if technological issues are a factor. If more than 60 days will be required, the disclosing entity must so notify the Agency in writing prior to the conclusion of the 60-day period. In all cases, the regulated entity will be expected to do its utmost to achieve or return to compliance as expeditiously as possible.

If correction of the violation depends upon issuance of a permit that has been applied for but not issued by Federal or State authorities, the Agency will, where appropriate, make reasonable efforts to secure timely review of the permit.

6. Prevent Recurrence

Under Section D(6), the regulated entity must agree to take steps to prevent a recurrence of the violation after it has been disclosed. Preventive steps may include, but are not limited to, improvements to the entity's environmental auditing efforts or compliance management system.

7. No Repeat Violations

Condition D(7) bars repeat offenders from receiving Audit Policy credit. Under the repeat violations exclusion, the same or a closely-related violation must not have occurred at the same facility within the past 3 years. The 3-year period begins to run when the government or a third party has given the violator notice of a specific violation, without regard to when the original violation cited in the notice

actually occurred. Examples of notice include a complaint, consent order, notice of violation, receipt of an inspection report, citizen suit, or receipt of penalty mitigation through a compliance assistance or incentive project.

When the facility is part of a multi-facility organization, Audit Policy relief is not available if the same or a closely-related violation occurred as part of a pattern of violations at one or more of these facilities within the past 5 years. If a facility has been newly acquired, the existence of a violation prior to acquisition does not trigger the repeat violations exclusion.

The term ''violation'' includes any violation subject to a Federal, State or local civil judicial or administrative order, consent agreement, conviction or plea agreement. Recognizing that minor violations sometimes are settled without a formal action in court, the term also covers any act or omission for which the regulated entity has received a penalty reduction in the past. This condition covers situations in which the regulated entity has had clear notice of its noncompliance and an opportunity to correct the problem.

The repeat violation exclusion benefits both the public and law-abiding entities by ensuring that penalties are not waived for those entities that have previously been notified of violations and fail to prevent repeat violations. The 3-year and 5-year ''bright lines'' in the exclusion are designed to provide regulated entities with clear notice about when the Policy will be available.

8. Other Violations Excluded

Section D(8) provides that Policy benefits are not available for certain types of violations. Subsection D(8)(a) excludes violations that result in serious actual harm to the environment or which may have presented an imminent and substantial endangerment to public health or the environment. When events of such a consequential nature occur, violators are ineligible for penalty relief and other incentives under the Audit Policy. However, this condition does not bar an entity from qualifying for Audit Policy relief solely because the violation involves release of a pollutant to the environment, as such releases do not necessarily result in serious actual harm or an imminent and substantial endangerment. To date, EPA has not invoked the serious actual harm or the imminent and substantial endangerment clauses to deny Audit Policy credit for any disclosure.

Subsection D(8)(b) excludes violations of the specific terms of any order, consent agreement, or plea agreement. Once a consent agreement has been negotiated, there is little incentive to comply if there are no sanctions for violating its specific requirements. The exclusion in this section also applies to violations of the terms of any response, removal or remedial action covered by a written agreement.

9. Cooperation

Under Section D(9), the regulated entity must cooperate as required by EPA and provide the Agency with the information it needs to determine Policy applicability. The entity must not hide, destroy or tamper with possible evidence following discovery of potential environmental violations. In order for the Agency to apply the Policy fairly, it must have sufficient information to determine whether its conditions are satisfied in each individual case. In general, EPA requests audit reports to determine the applicability of this Policy only where the information contained in the audit report is not readily available elsewhere and where EPA decides that the information is necessary to determine whether the terms and conditions of the Policy have been met. In the rare instance where an EPA Regional office seeks to obtain an audit report because it is otherwise unable to determine whether Policy conditions have been met, the Regional office will notify the Office of Regulatory Enforcement at EPA headquarters.

Entities that disclose potential criminal violations may expect a more thorough review by the Agency. In criminal cases, entities will be expected to provide, at a minimum, the following: access to all requested documents; access to all employees of the disclosing entity; assistance in investigating the violation, any noncompliance problems related to the disclosure, and any environmental consequences related to the violations; access to all information relevant to the violations disclosed, including that portion of the environmental audit report or documentation from the compliance management system that revealed the violation; and access to the individuals who conducted the audit or review.

F. Opposition to Audit Privilege and Immunity

The Agency believes that the Audit Policy provides effective incentives for self-policing without impairing law enforcement, putting the environment at risk or hiding environmental compliance information from the public. Although EPA encourages environmental auditing, it must do so without compromising the integrity and enforceability of environmental laws. It is important to distinguish between EPA's Audit Policy and the audit privilege and immunity laws that exist in some States. The Agency remains firmly opposed to statutory and regulatory audit privileges and immunity. Privilege laws shield evidence of wrongdoing and prevent States from investigating even the most serious environmental violations. Immunity laws prevent States from obtaining penalties that are appropriate to the seriousness of the violation, as they are required to do under Federal law. Audit privilege and immunity laws are unnecessary, undermine law enforcement, impair protection of human health and the environment, and interfere with the public's right to know of potential and existing environmental hazards.

Statutory audit privilege and immunity run counter to encouraging the kind of openness that builds trust between regulators, the regulated community and the public. For example, privileged information on compliance contained in an audit report may include information on the cause of violations, the extent of environmental harm, and what is necessary to correct the violations and prevent their recurrence. Privileged information is unavailable to law enforcers and to members of the public who have suffered harm as a result of environmental violations. The Agency opposes statutory immunity because it diminishes law enforcement's ability to discourage wrongful behavior and interferes with a regulator's ability to punish individuals who disregard the law and place others in danger. The Agency believes that its Audit Policy provides adequate incentives for self-policing but without secrecy and without abdicating its discretion to act in cases of serious environmental violations.

Privilege, by definition, invites secrecy, instead of the openness needed to build public trust in industry's ability to self-police. American law reflects the high value that the public places on fair access to the facts. The Supreme Court, for example, has said of privileges that, '' [w]hatever their origins, these exceptions to the demand for every man's evidence are not lightly created nor expansively construed, for they are in derogation of the search for truth.'' *United States* v. *Nixon*, 418 U.S. 683, 710 (1974). Federal courts have unanimously refused to recognize a privilege for environmental audits in the context of government investigations. See, *e.g., United States* v. *Dexter Corp.,* 132 F.R.D. 8, 10 (D.Conn. 1990)

(application of a privilege ''would effectively impede [EPA's] ability to enforce the Clean Water Act, and would be contrary to stated public policy.'') Cf. In re Grand Jury Proceedings, 861 F. Supp. 386 (D. Md. 1994) (company must comply with a subpoena under Food, Drug and Cosmetics Act for self-evaluative documents).

G. Effect on States

The revised final Policy reflects EPA's desire to provide fair and effective incentives for self-policing that have practical value to States. To that end, the Agency has consulted closely with State officials in developing this Policy. As a result, EPA believes its revised final Policy is grounded in commonsense principles that should prove useful in the development and implementation of State programs and policies.

EPA recognizes that States are partners in implementing the enforcement and compliance assurance program. When consistent with EPA's policies on protecting confidential and sensitive information, the Agency will share with State agencies information on disclosures of violations of Federally-authorized, approved or delegated programs. In addition, for States that have adopted their own audit policies in Federally-authorized, approved or delegated programs, EPA will generally defer to State penalty mitigation for self-disclosures as long as the State policy meets minimum requirements for Federal delegation. Whenever a State provides a penalty waiver or mitigation for a violation of a requirement contained in a Federally-authorized, approved or delegated program to an entity that discloses those violations in conformity with a State audit policy, the State should notify the EPA Region in which it is located. This notification will ensure that Federal and State enforcement responses are coordinated properly.

For further information about minimum delegation requirements and the effect of State audit privilege and immunity laws on enforcement authority, see ''Statement of Principles: Effect of State Audit/Immunity Privilege Laws on Enforcement Authority for Federal Programs,'' Memorandum from Steven A. Herman et al, dated February 14, 1997, to be posted on the Internet under www.epa.gov/oeca/oppa.

As always, States are encouraged to experiment with different approaches to assuring compliance as long as such approaches do not jeopardize public health or the environment, or make it profitable not to comply with Federal environmental requirements. The Agency remains opposed to State legislation that does not include these basic protections, and reserves its right to bring independent action against regulated entities for violations of Federal law that threaten human health or the environment, reflect criminal conduct or repeated noncompliance, or allow one company to profit at the expense of its law-abiding competitors.

H. Scope of Policy

EPA has developed this Policy to guide settlement actions. It is the Agency's practice to make public all compliance agreements reached under this Policy in order to provide the regulated community with fair notice of decisions and to provide affected communities and the public with information regarding Agency action. Some in the regulated community have suggested that the Agency should convert the Policy into a regulation because they feel doing so would ensure greater consistency and predictability. Following its three-year evaluation of the Policy, however, the Agency believes that there is ample evidence that the Policy has worked well and that there is no need for a formal rulemaking. Furthermore, as the Agency seeks to respond to lessons learned from its increasing experience handling self-disclosures, a policy is much easier to amend than a regulation. Nothing in today's release of the revised final Policy is intended to change the status of the Policy as guidance.

I. Implementation of Policy

1. Civil Violations

Pursuant to the Audit Policy, disclosures of civil environmental violations should be made to the EPA Region in which the entity or facility is located or, where the violations to be disclosed involve more than one EPA Region, to EPA Headquarters. The Regional or Headquarters offices decide whether application of the Audit Policy in a specific case is appropriate. Obviously, once a matter has been referred for civil judicial prosecution, DOJ becomes involved as well. Where there is evidence of a potential criminal violation, the civil offices coordinate with criminal enforcement offices at EPA and DOJ.

To resolve issues of national significance and ensure that the Policy is applied fairly and consistently across EPA Regions and at Headquarters, the Agency in 1995 created the Audit Policy Quick Response Team (QRT). The QRT is comprised of representatives from the Regions, Headquarters, and DOJ. It meets on a regular basis to address issues of interpretation and to coordinate self-disclosure initiatives. In addition, in 1999 EPA established a National Coordinator position to handle Audit Policy issues and implementation. The National Coordinator chairs the QRT and, along with the Regional Audit Policy coordinators, serves as a point of contact on Audit Policy issues in the civil context.

2. Criminal Violations

Criminal disclosures are handled by the Voluntary Disclosure Board (VDB), which was established by EPA in 1997. The VDB ensures consistent application of the Audit Policy in the criminal context by centralizing Policy interpretation and application within the Agency.

Disclosures of potential criminal violations may be made directly to the VDB, to an EPA regional criminal investigation division or to DOJ. In all cases, the VDB coordinates with the investigative team and the appropriate prosecuting authority. During the course of the investigation, the VDB routinely monitors the progress of the investigation as necessary to ensure that sufficient facts have been established to determine whether to recommend that relief under the Policy be granted.

At the conclusion of the criminal investigation, the Board makes a recommendation to the Director of EPA's Office of Criminal Enforcement, Forensics, and Training, who serves as the Deciding Official. Upon receiving the Board's recommendation, the Deciding Official makes his or her final recommendation to the appropriate United States Attorney's Office and/or DOJ. The recommendation of the Deciding Official, however, is only that—a recommendation. The United States Attorney's Office and/or DOJ retain full authority to exercise prosecutorial discretion.

3. Release of Information to the Public

Upon formal settlement, EPA places copies of settlements in the Audit Policy Docket. EPA also makes other documents related to self-disclosures publicly available, unless the disclosing entity claims them as Confidential Business Information (and that claim is validated by U.S. EPA), unless another exemption under the Freedom of Information Act is asserted and/or applies, or the Privacy Act or any other law would preclude such release. Presumptively releasable documents include compliance agreements reached under the Policy (see Section H) and descriptions of compliance management systems submitted under Section D(1).

Any material claimed to be Confidential Business Information will be treated in accordance with EPA regulations at 40 CFR Part 2. In determining what documents to release, EPA is guided by the Memorandum from Assistant Administrator Steven A. Herman entitled ''Confidentiality of Information Received Under Agency's Self-Disclosure Policy,'' available on the Internet at www.epa.gov/oeca/sahmemo.html.

II. Statement of Policy—Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations

A. Purpose

This Policy is designed to enhance protection of human health and the environment by encouraging regulated entities to voluntarily discover, disclose, correct and prevent violations of Federal environmental requirements.

B. Definitions

For purposes of this Policy, the following definitions apply:

''Environmental Audit'' is a systematic, documented, periodic and objective review by regulated entities of facility operations and practices related to meeting environmental requirements.

''Compliance Management System'' encompasses the regulated entity's documented systematic efforts, appropriate to the size and nature of its business, to prevent, detect and correct violations through all of the following:

(a) Compliance policies, standards and procedures that identify how employees and agents are to meet the requirements of laws, regulations, permits, enforceable agreements and other sources of authority for environmental requirements;

(b) Assignment of overall responsibility for overseeing compliance with policies, standards, and procedures, and assignment of specific responsibility for assuring compliance at each facility or operation;

(c) Mechanisms for systematically assuring that compliance policies, standards and procedures are being carried out, including monitoring and auditing systems reasonably designed to detect and correct violations, periodic evaluation of the overall performance of the compliance management system, and a means for employees or agents to report violations of environmental requirements without fear of retaliation;

(d) Efforts to communicate effectively the regulated entity's standards and procedures to all employees and other agents;

(e) Appropriate incentives to managers and employees to perform in accordance with the compliance policies, standards and procedures, including consistent enforcement through appropriate disciplinary mechanisms; and

(f) Procedures for the prompt and appropriate correction of any violations, and any necessary modifications to the regulated entity's compliance management system to prevent future violations.

''Environmental audit report'' means the documented analysis, conclusions, and recommendations resulting from an environmental audit, but does not include data obtained in, or testimonial evidence concerning, the environmental audit.

''Gravity-based penalties'' are that portion of a penalty over and above the economic benefit, *i.e.,* the punitive portion of the penalty, rather than that portion representing a defendant's economic gain from noncompliance.

''Regulated entity'' means any entity, including a Federal, State or municipal agency or facility, regulated under Federal environmental laws.

C. Incentives for Self-Policing

1. No Gravity-Based Penalties

If a regulated entity establishes that it satisfies all of the conditions of Section D of this Policy, EPA will not seek gravity-based penalties for violations of Federal environmental requirements discovered and disclosed by the entity.

2. Reduction of Gravity-Based Penalties by 75%

If a regulated entity establishes that it satisfies all of the conditions of Section D of this Policy except for D(1)—systematic discovery—EPA will reduce by 75% gravity-based penalties for violations of Federal environmental requirements discovered and disclosed by the entity.

3. No Recommendation for Criminal Prosecution

(a) If a regulated entity establishes that it satisfies at least conditions D(2) through D(9) of this Policy, EPA will not recommend to the U.S. Department of Justice or other prosecuting authority that criminal charges be brought against the disclosing entity, as long as EPA determines that the violation is not part of a pattern or practice that demonstrates or involves:

(i) A prevalent management philosophy or practice that conceals or condones environmental violations; or

(ii) High-level corporate officials' or managers' conscious involvement in, or willful blindness to, violations of Federal environmental law;

(b) Whether or not EPA recommends the regulated entity for criminal prosecution under this section, the Agency may recommend for prosecution the criminal acts of individual managers or employees under existing policies guiding the exercise of enforcement discretion.

4. No Routine Request for Environmental Audit Reports

EPA will neither request nor use an environmental audit report to initiate a civil or criminal investigation of an entity. For example, EPA will not request an environmental audit report in routine inspections. If the Agency has independent reason to believe that a violation has occurred, however, EPA may seek any information relevant to identifying violations or determining liability or extent of harm.

D. Conditions

1. Systematic Discovery

The violation was discovered through:

(a) An environmental audit; or

(b) A compliance management system reflecting the regulated entity's due diligence in preventing, detecting, and correcting violations. The regulated entity must provide accurate and complete documentation to the Agency as to how its compliance management system meets the criteria for due diligence outlined in Section B and how the regulated entity discovered the violation through its compliance management system. EPA may require the regulated entity to make publicly available a description of its compliance management system.

2. Voluntary Discovery

The violation was discovered voluntarily and not through a legally mandated monitoring or sampling requirement prescribed by statute, regulation, permit, judicial or administrative order, or consent agreement. For example, the Policy does not apply to:

(a) Emissions violations detected through a continuous emissions monitor (or alternative monitor established in a permit) where any such monitoring is required;

(b) Violations of National Pollutant Discharge Elimination System (NPDES) discharge limits detected through required sampling or monitoring; or

(c) Violations discovered through a compliance audit required to be performed by the terms of a consent order or settlement agreement, unless the audit is a component of agreement terms to implement a comprehensive environmental management system.

3. Prompt Disclosure

The regulated entity fully discloses the specific violation in writing to EPA within 21 days (or within such shorter time as may be required by law) after the entity discovered that the violation has, or may have, occurred. The time at which the entity discovers that a violation has, or may have, occurred begins when any officer, director, employee or agent of the facility has an objectively reasonable basis for believing that a violation has, or may have, occurred.

4. Discovery and Disclosure Independent of Government or Third-Party Plaintiff

(a) The regulated entity discovers and discloses the potential violation to EPA prior to:

(i) The commencement of a Federal, State or local agency inspection or investigation, or the issuance by such agency of an information request to the regulated entity (where EPA determines that the facility did not know that it was under civil investigation, and EPA determines that the entity is otherwise acting in good faith, the Agency may exercise its discretion to reduce or waive civil penalties in accordance with this Policy);

(ii) Notice of a citizen suit;

(iii) The filing of a complaint by a third party;

(iv) The reporting of the violation to EPA (or other government agency) by a ''whistleblower'' employee, rather than by one authorized to speak on behalf of the regulated entity; or

(v) imminent discovery of the violation by a regulatory agency.

(b) For entities that own or operate multiple facilities, the fact that one facility is already the subject of an investigation, inspection, information request or third-party complaint does not preclude the Agency from exercising its discretion to make the Audit Policy available for violations self-discovered at other facilities owned or operated by the same regulated entity.

5. Correction and Remediation

The regulated entity corrects the violation within 60 calendar days from the date of discovery, certifies in writing that the violation has been corrected, and takes appropriate measures as determined by EPA to remedy any environmental or human harm due to the violation. EPA retains the authority to order an entity to correct a violation within a specific time period shorter than 60 days whenever correction in such shorter period of time is feasible and necessary to protect public health and the environment adequately. If more than 60 days will be needed to correct the violation, the regulated entity must so notify EPA in writing before the 60-day period has passed. Where appropriate, to satisfy conditions D(5) and D(6), EPA may require a regulated entity to enter into a publicly available written agreement, administrative consent order or judicial consent decree as a condition of obtaining relief under the Audit Policy, particularly where compliance or remedial measures are complex or a lengthy schedule for attaining and maintaining compliance or remediating harm is required.

6. Prevent Recurrence

The regulated entity agrees in writing to take steps to prevent a recurrence of the violation. Such steps may include improvements to its environmental auditing or compliance management system.

7. No Repeat Violations

The specific violation (or a closely related violation) has not occurred previously within the past three years at the same facility, and has not occurred within the past five years as part of a pattern at multiple facilities owned or operated by the same entity. For the purposes of this section, a violation is:

(a) Any violation of Federal, State or local environmental law identified in a judicial or administrative order, consent agreement or order, complaint, or notice of violation, conviction or plea agreement; or

(b) Any act or omission for which the regulated entity has previously received penalty mitigation from EPA or a State or local agency.

8. Other Violations Excluded

The violation is not one which (a) resulted in serious actual harm, or may have presented an imminent and substantial endangerment, to human health or the environment, or (b) violates the specific terms of any judicial or administrative order, or consent agreement.

9. Cooperation

The regulated entity cooperates as requested by EPA and provides such information as is necessary and requested by EPA to determine applicability of this Policy.

E. Economic Benefit

EPA retains its full discretion to recover any economic benefit gained as a result of noncompliance to preserve a ''level playing field'' in which violators do not gain a competitive advantage over regulated entities that do comply. EPA may forgive the entire penalty for violations that meet conditions D(1) through D(9) and, in the Agency's opinion, do not merit any penalty due to the insignificant amount of any economic benefit.

F. Effect on State Law, Regulation or Policy

EPA will work closely with States to encourage their adoption and implementation of policies that reflect the incentives and conditions outlined in this Policy. EPA remains firmly opposed to statutory environmental audit privileges that shield evidence of environmental violations and undermine the public's right to know, as well as to blanket immunities, particularly immunities for violations that reflect criminal conduct, present serious threats or actual harm to health and the environment, allow noncomplying companies to gain an economic advantage over their competitors, or reflect a repeated failure to comply with Federal law. EPA will work with States to address any provisions of State audit privilege or immunity laws that are inconsistent with this Policy and that may prevent a timely and appropriate response to significant environmental violations. The Agency reserves its right to take necessary actions to protect public health or the environment by enforcing against any violations of Federal law.

G. Applicability

(1) This Policy applies to settlement of claims for civil penalties for any violations under all of the Federal environmental statutes that EPA administers, and supersedes any inconsistent provisions in media-specific penalty or enforcement policies and EPA's 1995 Policy on ''Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations.''

(2) To the extent that existing EPA enforcement policies are not inconsistent, they will continue to apply in conjunction with this Policy. However, a regulated entity that has received penalty mitigation for satisfying specific conditions under this Policy may not receive additional penalty mitigation for satisfying the same or similar conditions under other policies for the same violation, nor will this Policy apply to any violation that has received penalty mitigation under other policies. Where an entity has failed to meet any of conditions D(2) through D(9) and is therefore not eligible for penalty relief under this Policy, it may still be eligible for penalty

relief under other EPA media-specific enforcement policies in recognition of good faith efforts, even where, for example, the violation may have presented an imminent and substantial endangerment or resulted in serious actual harm.

(3) This Policy sets forth factors for consideration that will guide the Agency in the exercise of its enforcement discretion. It states the Agency's views as to the proper allocation of its enforcement resources. The Policy is not final agency action and is intended as guidance. This Policy is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States. As with the 1995 Audit Policy, EPA may decide to follow guidance provided in this document or to act at variance with it based on its analysis of the specific facts presented. This Policy may be revised without public notice to reflect changes in EPA's approach to providing incentives for self-policing by regulated entities, or to clarify and update text.

(4) This Policy should be used whenever applicable in settlement negotiations for both administrative and civil judicial enforcement actions. It is not intended for use in pleading, at hearing or at trial. The Policy may be applied at EPA's discretion to the settlement of administrative and judicial enforcement actions instituted prior to, but not yet resolved, as of the effective date of this Policy.

(5) For purposes of this Policy, violations discovered pursuant to an environmental audit or compliance management system may be considered voluntary even if required under an Agency ''partnership'' program in which the entity participates, such as regulatory flexibility pilot projects like Project XL. EPA will consider application of the Audit Policy to such partnership program projects on a project-by-project basis.

(6) EPA has issued interpretive guidance addressing several applicability issues pertaining to the Audit Policy. Entities considering whether to take advantage of the Audit Policy should review that guidance to see if it addresses any relevant questions. The guidance can be found on the Internet at www.epa.gov/oeca/ore/apolguid.html.

H. Public Accountability

EPA will make publicly available the terms and conditions of any compliance agreement reached under this Policy, including the nature of the violation, the remedy, and the schedule for returning to compliance.

I. Effective Date

This revised Policy is effective May 11, 2000.

Dated: March 30, 2000.

Steven A. Herman,

Assistant Administrator for Enforcement and Compliance Assurance.

[FR Doc. 00–8954 Filed 4–10–00; 8:45 am]

BILLING CODE 6560–50–P

Water Act and 40 CFR part 143, subpart B; and

(5) The signature, date, name and position of the signatory; and if the signatory is an authorized representative of a responsible corporate officer, a general partner or proprietor, the name and position of the responsible corporate officer, a general partner or proprietor.

(f) Manufacturers or importers that self-certify products must maintain, at a primary place of business within the United States, certificates of conformity and sufficient documentation to confirm that products meet the lead free requirements of this subpart. Sufficient documentation may include: Detailed schematic drawings of the products indicating dimensions, calculations of the weighted average lead content of the product, lead content of materials used in manufacture and other documentation used in verifying the lead content of a plumbing device. This documentation and certificates of conformity must be provided upon request to the Administrator as specified in § 143.20(b).

(g) The certificate of conformity and documentation must be completed prior to a product's introduction into commerce.

§ 143.20 Compliance provisions.

(a) Noncompliance with the Safe Drinking Water Act or this subpart may be subject to enforcement. Enforcement actions may include seeking injunctive relief, civil or criminal penalties.

(b) The Administrator may, on a case-by-case basis, request any information deemed necessary to determine whether a person has acted or is acting in compliance with section 1417 of the Safe Drinking Water Act and this subpart. Such information requested must be provided to the Administrator at a time and in a format as may be reasonably determined by the Administrator.

[FR Doc. 2017–00743 Filed 1–13–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA–HQ–OPPT–2016–0636; FRL–9957–74]

RIN 2070–AK23

Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: As required under section 6(b)(1) of the Toxic Substances Control Act (TSCA), EPA is proposing to establish a risk-based screening process and criteria that EPA will use to identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time. The proposed rule describes the processes for identifying potential candidates for prioritization, selecting a candidate, screening that candidate against certain criteria, formally initiating the prioritization process, providing opportunities for public comment, and proposing and finalizing designations of priority. Prioritization is the initial step in a new process of existing chemical substance review and risk management activity established under recent amendments to TSCA.

DATES: Comments must be received on or before March 20, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0636, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Ryan Schmit, Immediate Office, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–0610; email address: *schmit.ryan@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This proposed rule does not propose to establish any requirements on persons or entities outside of the Agency. This action may, however, be of interest to entities that are or may manufacture or import a chemical substance regulated under TSCA (*e.g.,* entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What action is the agency taking?

EPA is proposing to establish the internal processes and criteria by which EPA will identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time.

C. Why is the agency taking this action?

This rulemaking is required by TSCA section 6(b)(1)(A). Prioritization of chemical substances for further evaluation will ensure that the Agency's limited resources are conserved for those chemical substances most likely to present risks, thereby furthering EPA's overall mission to protect health and the environment.

D. What is the agency's authority for taking this action?

EPA is proposing this rule pursuant to the authority in TSCA section 6(b), 15 U.S.C. 2605(b). See also the discussion in Units II.A and B.

E. What are the estimated incremental impacts of this action?

This is a proposed rule that would establish the processes by which EPA intends to designate chemical substances as either High or Low-Priority Substances for risk evaluation. It would not establish any requirements on persons or entities outside of the Agency. EPA did not, therefore, estimate potential incremental impacts from this action.

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that

you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. Recent Amendments to TSCA

On June 22, 2016, the President signed into law the ''Frank R. Lautenberg Chemical Safety for the 21st Century Act'' (Pub. L. 114–182), which imposed sweeping reforms to TSCA. The bill received broad bipartisan support in the U.S. House of Representatives and Senate, and its passage was heralded as the most significant update to an environmental law in over 20 years. The amendments give EPA improved authority to take actions to protect people and the environment from the effects of dangerous chemical substances. Additional information on the new law is available on EPA's Web site at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act.*

When TSCA was originally enacted in 1976, it established an EPA-administered health and safety review process for new chemical substances prior to allowing their entry into the marketplace. However, tens of thousands of chemical substances in existence at that time were ''grandfathered in'' with no requirement for EPA to ever evaluate their risks to health or the environment. The absence of a review requirement or deadlines for action, coupled with a burdensome statutory standard for taking risk management action on existing chemical substances, resulted in very few chemical substances ever being assessed for safety by EPA, and even fewer subject to restrictions to address identified risks.

One of the key features of the new law is the requirement that EPA now systematically prioritize and assess existing chemical substances, and manage identified risks. Through a combination of new authorities, a risk-based safety standard, mandatory deadlines for action, and minimum throughput requirements, TSCA effectively creates a ''pipeline'' by which EPA will conduct existing chemical substances review and management. This new pipeline—from prioritization to risk evaluation to risk management (when warranted)—is intended to drive steady forward progress on the backlog of existing chemical substances left largely unaddressed by the original law. Prioritization is the initial step in this process.

B. Statutory Requirements for Prioritization

TSCA section 6(b)(1) requires EPA to establish, by rule, the process and criteria for prioritizing chemical substances for risk evaluation. Specifically, the law requires EPA to establish ''a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time.'' TSCA sections 6(b)(1) through (3) provide further specificity on both the process and criteria, including preferences for certain chemical substances that EPA must apply, the procedural steps, definitions of High-Priority Substances and Low-Priority Substances, and screening criteria that EPA must consider in designating a chemical substance as either High-Priority Substances or Low-Priority Substances. The statutory requirements related to prioritization are described in further detail in this unit.

1. *Prioritization Steps.* Based on TSCA sections 6(b)(1) through (3), EPA is proposing to include four steps or phases in prioritization: (1) Pre-Prioritization, (2) Initiation, (3) Proposed Designation, and (4) Final Designation. During the Pre-Prioritization phase, EPA is proposing to apply the statutory preferences in TSCA section 6(b)(2), along with other criteria, to narrow the pool of potential candidates, and identify a single chemical substance (or category of chemical substances) to screen against the statutory criteria in TSCA section 6(b)(1)(A). Aside from the statutory preferences listed, the law does not direct or limit EPA in how it is to ultimately select a chemical substance on which to initiate prioritization, requiring only that the process be ''risk-based.'' At the Initiation step, EPA must announce a candidate chemical substance and give the public a 90-day comment period to submit relevant information. 15 U.S.C. 2605(b)(1)(C)(i). At the Proposed Designation step, EPA must propose to designate a chemical substance as either a High-Priority Substance or a Low-Priority Substance, publish the proposed designation and the information, analysis, and basis used to make the designation, and take public comment a second time for 90 days. 15 U.S.C. 2605(b)(1)(C)(ii). At Final Designation, EPA must either finalize a High-Priority Substance designation and initiate a risk evaluation, or finalize a Low-Priority Substance designation in which case it will not conduct a risk evaluation on the chemical substance unless and until information leads EPA to revisit that priority designation. 15 U.S.C. 2605(b)(3)(A) and (B).

2. *Screening criteria and statutory preferences.* The statute defines a High-Priority Substance as one that the Administrator concludes, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by the Administrator. 15 U.S.C. 2605(b)(1)(B)(i). Conversely, the law specifies that a Low-Priority Substance is one that the Administrator concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for designating a chemical substance a High-Priority Substance. 15 U.S.C. 2605(b)(1)(B)(ii).

In designating the priority of a chemical substance, EPA must screen a candidate chemical substance against certain criteria specified in TSCA section 6(b)(1)(A). These include the hazard and exposure potential of the chemical substance (*e.g.,* persistence and bioaccumulation, potentially exposed or susceptible subpopulations, and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed. EPA interprets ''significant changes in'' conditions of use to have relevance primarily in the context of revising a priority designation. With respect to an initial prioritization decision, any changes in use that have occurred in the past would already be captured by the concept of ''conditions of use,'' as defined in TSCA section 3.

The results of this screen will help inform EPA's proposed priority designation. However, given that the statutory deadlines are triggered at the initiation of prioritization, and that EPA will want to have a good understanding of the chemical substance before triggering those deadlines, EPA will consider these screening criteria earlier in the process. As discussed in more detail in Unit III., EPA is therefore proposing to include the screening review in the rule as part of the pre-prioritization phase.

In designating High-Priority Substances, EPA is to give preference to chemical substances that are listed in the 2014 Update of the TSCA Work Plan for Chemical Assessments (Ref. 1) that: (1) Have persistence and bioaccumulation scores of 3; and (2) are known human carcinogens and have high acute and chronic toxicity. 15 U.S.C. 2605(b)(2)(D). The law further requires that 50% of all ongoing risk evaluations be drawn from the 2014 Update to the TSCA Work Plan for Chemical Assessments, meaning that, at least at the outset of the program, EPA will need to draw at least 50% of High-Priority Substance designations from the same list. 15 U.S.C. 2605(b)(2)(B).

3. *Metals and metal compounds.* When prioritizing metals or metal compounds, EPA must use the March 2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 2) (or a successor document that addresses appropriate considerations for conducting a risk assessment on a metal or metal compound and is peer reviewed by the Science Advisory Board). 15 U.S.C. 2605(b)(2)(E). However, during the prioritization process, EPA will not be conducting chemical risk assessments; and, consequently, much of this guidance will not be directly relevant. EPA interprets this provision to ensure that the analysis and considerations during the prioritization process take into account the special attributes and behaviors of metals and metal compounds that are relevant to judgments of risk. For example, this might include consideration of the document's Key Principles that differentiate inorganic metals and metal compounds from organic and organometallic compounds, and their unique attributes, properties, issues, and processes. Because EPA will not conduct risk assessments on metals or metal compounds for purposes of prioritization, EPA will not refer to sections that provide guidance on how to incorporate the Key Principles into risk assessments.

4. *Timeframe.* TSCA requires that the prioritization process last between nine and twelve months. 15 U.S.C. 2605(b)(1)(C). This timeframe takes on particular significance, given that the statute does not authorize EPA to ''pause'' or delay the prioritization once it has been initiated, and that a final High-Priority Substance designation results in the chemical substance moving immediately into a risk evaluation process that must be generally completed within three years. 15 U.S.C. 2605(b)(4)(G).

5. *Opportunities for public participation.* As already mentioned, TSCA requires EPA to provide two 90-day public comment periods during prioritization—one following initiation, and a second following a proposed designation. 15 U.S.C. 2605(b)(1)(C)(i) and (ii). TSCA further requires that EPA include a process for extending the comment deadline for up to three months in order to receive or evaluate information coming from a TSCA section 4 test order. 15 U.S.C. 2605(b)(1)(C)(iii). These public comment periods, coupled with the nine month minimum timeframe for prioritization, ensure that the public will be on notice of EPA's intention to further evaluate a chemical's risks and will have opportunity to engage early in the process before the risk evaluation has started.

6. *Default to High-Priority Substance Designation.* If, after prioritization has been initiated, the public has been given an opportunity to submit relevant information, and EPA has extended the comment period pursuant to TSCA section 6(b)(1)(C)(iii) in order to receive or evaluate additional information, EPA determines that the available information is insufficient to enable the designation of the chemical substance as a Low-Priority Substance, the statute requires EPA to propose a High-Priority Substance designation. 15 U.S.C. 2605(b)(1)(C)(iii). Based in part on this provision, and as discussed further in Unit III, EPA is proposing to require a default-to-high in all cases in which insufficient information exists to designate the chemical as a Low-Priority Substance at both the proposed and final designation.

7. *Initial ten chemicals for risk evaluation.* TSCA requires EPA to, within six months of enactment, ensure that risk evaluations are being conducted on ten chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments, and to publish a list of those chemical substances during that same period. 15 U.S.C. 2605(b)(2)(A). The initial ten chemical substances are not subject to the prioritization process or the procedures in this rule. However, completion of these risk evaluations triggers the ongoing designation requirement discussed in Unit II.B.8.

8. *Ongoing designations.* Upon completion of a risk evaluation (other than those requested by a manufacturer pursuant to TSCA section 6(b)(4)(C)(ii)), EPA must designate at least one additional High-Priority Substance to take its place. 15 U.S.C. 2605(b)(2)(C). Because designation as a High-Priority Substance results in the chemical substance moving immediately to risk evaluation, this provision prevents the number of existing chemical substances undergoing risk evaluation from ever decreasing over time. In addition, EPA must designate at least twenty chemical substances as High-Priority Substances by three and one half years after enactment, effectively doubling the number of chemical substances in the review pipeline. 15 U.S.C. 2605(b)(2)(B). The statute also requires that at least twenty chemical substances be designated as Low-Priority Substances by three and one half years after enactment, but without a comparable requirement to continue designating additional Low-Priority Substances after that. 15 U.S.C. 2605(b)(2)(B), (b)(3)(C). Although EPA must continue to prioritize and evaluate chemical substances ''at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines,'' this provision does not modify the minimum throughput or other ongoing designation requirements for High-Priority Substances. 15 U.S.C. 2605(b)(2)(C). It does, however, suggest that EPA must have adequate resources should EPA plan to designate more than twenty chemical substances as High-Priority Substances at any given time.

9. *Revision of designation.* TSCA allows the Administrator to revise the designation of a Low-Priority Substance to a High-Priority Substance ''based on information made available to the Administrator.'' 15 U.S.C. 2605(b)(3)(B). This provision does not restrict the basis for a revision to the discovery or receipt of new information. For example, EPA could also justify a revision based on information that was available but was not considered at the time of the original prioritization decision, or information that was considered but which EPA now views differently as a result of changes in scientific understanding (*e.g.,* changes in scientific understanding of how a chemical can enter or interact with the human body).

10. *Other relevant statutory requirements.* TSCA imposes new

requirements on EPA in a number of different areas that EPA is not proposing to incorporate or otherwise address in this proposed rule. For example, amendments to TSCA section 4 require EPA to ''. . . reduce and replace, to the extent practicable, [. . .] the use of vertebrate animals in the testing of chemical substances . . .'' and to develop a strategic plan to promote such alternative test methods. 15 U.S.C. 2603(h). Likewise, TSCA section 26 requires, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, that EPA use certain scientific standards and base those decisions on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). While these requirements are relevant to the prioritization of chemical substances, EPA is not obliged to include them in this proposed rule. By their express terms, these statutory requirements apply to EPA's decisions under TSCA section 6, without the need for regulatory action. Moreover, in contrast to TSCA section 6, Congress has not directed EPA to implement these other requirements ''by rule;'' it is well-established that where Congress has declined to require rulemaking, the implementing agency has complete discretion to determine the appropriate method by which to implement those provisions. *E.g., United States* v. *Storer Broadcasting Co.,* 351 U.S. 192 (1956).

A number of stakeholders raised questions as to whether EPA should define a number of important terms in this rule (*e.g.,* ''best available science'', ''weight-of-the-evidence'', ''sufficiency of information'', ''unreasonable risk'', and ''reasonably available information''). Many of the terms used in the proposed rule are not novel concepts and are already in use, and their meaning is discussed extensively in existing Agency guidance. For example, extensive descriptions for the phrases ''best available science'', ''weight-of-the-evidence'', and ''sufficiency of information'' can be found in EPA's Risk Characterization Handbook (Ref. 3), and in other existing Agency guidance.

EPA believes further defining these and other terms in the proposed rule is unnecessary and ultimately problematic. These terms have and will continue to evolve with changing scientific methods and innovation. Codifying specific definitions for these phrases in this rule may inhibit the flexibility and responsiveness of the Agency to quickly adapt to and implement changing science. The Agency intends to use existing guidance definitions and to update definitions and guidance as necessary.

While EPA is seeking public comment on all aspects of this proposed rule, the Agency is specifically requesting public input on this issue. The Agency welcomes public comments regarding the pros and cons of codifying these or other definitions and/or approaches for these or any other terms. EPA encourages commenters to suggest alternative definitions the Agency should consider for codification in this procedural rule. Please explain your views as clearly as possible, providing specific examples to illustrate your concerns and suggest alternate wording, where applicable.

C. Prioritization Under the 2012 TSCA Work Plan Methodology

Prioritization of chemical substances for review is not a novel concept for the Agency. In 2012, EPA released the TSCA Work Plan Chemicals: Methods Document in which EPA described the process the Agency intended to use to identify potential candidate chemical substances for near-term review and assessment under TSCA (Ref. 4). EPA also published an initial list of TSCA Work Plan chemicals identified for further assessment under TSCA as part of its chemical safety program in 2012 (Ref. 5), and an updated list of chemical substances for further assessment in 2014 (Ref. 1). The process for identifying these chemical substances was based on a combination of hazard, exposure, and persistence and bioaccumulation characteristics.

Congress expressly recognized the validity of EPA's existing prioritization methodology for the TSCA Work Plan. For example, the law requires that EPA give certain preferences to chemical substances listed on the 2014 Update to the TSCA Work Plan. 15 U.S.C. 2605(b)(2)(D). Moreover, the law requires that at least 50 percent of all ongoing risk evaluations be drawn from the 2014 Update to the TSCA Work Plan. 15 U.S.C. 2605(b)(2)(B). The statutory screening criteria in TSCA section 6(b)(1)(A) also significantly overlaps with the considerations in the Work Plan methodology (*e.g.,* persistence, bioaccumulation, toxicity, carcinogenicity, etc.).

However, there are a number of key differences between EPA's TSCA Work Plan process and the prioritization process that TSCA now requires. First, the Work Plan process involved culling through thousands of chemical substances to create a list that EPA could, over time and without prescribed deadlines, focus its limited resources on. The TSCA Work Plan did not require EPA to assess listed chemical substances, and included no deadlines for completing risk assessments or addressing identified risks. Prioritization under this proposed rule will involve a similar culling, but upon designating a chemical substance as a High-Priority Substance, the Agency must start a risk evaluation, and generally complete that evaluation within a specified amount of time. If EPA determines in the risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must also initiate a risk management rulemaking subject to statutory deadlines. 15 U.S.C. 2605(c). As such, EPA will need to be judicious in selecting the chemical substances that go into prioritization.

Further, while chemical substances listed on the TSCA Work Plan were likely to be well-characterized for hazard and have at least some information indicating potential exposure, Work Plan chemical substance assessments have generally focused on specific chemical uses. Given the statutory deadlines, EPA generally intends to ensure it has a more complete set of data upfront that would allow EPA to evaluate a chemical substance under all conditions of use (a broader scope) within the statutory deadlines. For chemical substances with insufficient information to conduct a risk evaluation, EPA generally expects to pursue a significant amount of data gathering before initiating prioritization.

Finally, the TSCA Work Plan process focused solely on identifying potential high risk chemical substances for further review. Because the statute also requires the identification of Low-Priority Substances—those chemical substances that EPA has determined, based on sufficient evidence, do not warrant further review at the time—EPA will need to undertake new and different analyses than it has done to date under the TSCA Work Plan.

While EPA has drawn from the TSCA Work Plan methodology and EPA's experience in implementing that process in developing this proposed rule, EPA is proposing to tailor the process for prioritization to the specific requirements in the new statute.

D. Stakeholder Involvement

On August 10, 2016, EPA held a one day public meeting to hear from stakeholders to better understand their viewpoints on the development of the prioritization rule. The meeting began with a presentation from EPA on how the Agency has prioritized chemicals for further review under the TSCA Work Plan methodology. The remainder of the day was reserved for public comment. Commenters had approximately four

minutes to present their comments orally and there was a total of 28 oral comments on the prioritization rule. Further information is available on EPA's Web site at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/meetings-and-webinars-amended-toxic-substances-control.*

Stakeholders were also able to provide written comments. EPA received 50 written comments on the prioritization rule, although many of those who presented orally also submitted written versions as well. These comments and a transcript of the meeting are accessible in the meeting's docket, identified by Docket ID No. EPA–HQ–OPPT–2016–0399, available online at *https://www.regulations.gov/.*

The commenters included representatives from industry, environmental groups, academics, private citizens, trade associations, and health care representatives, and provided a diversity of perspectives. Overall, there was a general expression of support for the new law and EPA's inclusive approach to implementation to date. Most groups agreed that the prioritization rule had the potential to increase transparency in EPA's chemical substance review and management process, and urged the Agency to work towards this goal.

A number of commenters suggested codifying specific details in the rule, such as a system for scoring and ranking chemical substances; a listing of the specific hazard and exposure information upon which EPA will base prioritization decisions; and definitions of terms referenced in the statute like ''weight of evidence'' and ''best available science.'' Others encouraged EPA to keep the rules focused on a framework for general process, to retain Agency discretion where appropriate, and to reserve specific scientific considerations for Agency guidance.

EPA considered all of these comments in the development of this proposed rule, and welcomes additional feedback from stakeholders on the Agency's proposed process for chemical substance prioritization as presented in this document.

III. Summary of Proposed Rule

This proposed rule incorporates all of the elements required by statute, but also supplements those requirements with additional criteria the Agency expects to consider, some clarifications for greater transparency, and additional procedural steps to ensure effective implementation. Specific components of the approach are discussed in this unit. EPA requests comments on all aspects of this proposed rulemaking.

A. Policy Objective

The prioritization process under TSCA is the principal gateway to risk evaluation. EPA is ultimately making a judgment as to whether or not a particular chemical substance warrants further assessment. As a general matter, the overall objective of the process should be to guide the Agency towards identifying the High-Priority Substances that have the greatest hazard and exposure potential first. EPA may also consider the relative hazard and exposure of a potential candidate's likely substitute(s) in order to avoid moving the market to a chemical substance of equal or greater risks. However, the prioritization process is not intended to be an exact scoring or ranking exercise and EPA is not proposing such a system in this rule. The precise order in which EPA identifies High-Priority Substances (all of which must meet the same statutory standard) should not be allowed to slow the Agency's progress towards fully evaluating the risks from those chemical substances. Further, the level of analysis necessary to support an exact ranking system is not appropriate at the prioritization stage, where the sole outcome is a decision on whether EPA will further evaluate the chemical substance. EPA intends to conserve its resources and the Agency's deeper analytic efforts for the actual risk evaluation. This policy objective is stated directly in the proposed rule.

Low-Priority Substance designations serve some of the same policy objectives. Although the statute does not require EPA to designate more than twenty Low-Priority Substances, doing so ensures that chemical substances with clearly low hazard and exposure potential are taken out of consideration for further assessment, thereby conserving resources for the chemical substances with the greatest potential risks. There is also value in identifying Low-Priority Substances as part of this process, as it gives the public notice of chemical substances for which potential risks are likely low or nonexistent, and industry some insight into which chemical substances are likely not to be regulated under TSCA.

B. Scope of Designations

EPA will designate the priority of a ''chemical substance,'' as a whole, under this established process, and will not limit its designation to a specific use or subset of uses of a chemical substance. EPA is proposing this in response to clear statutory directives: The relevant provisions of TSCA section 6 repeatedly refer to both the designation and evaluation of ''chemical substances'' under the ''conditions of use.'' ''Conditions of use'' are broadly defined as ''the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.'' 15 U.S.C. 2602.

Although some commenters at the public meeting suggested that the prioritization process should allow EPA to designate a specific use of a chemical substance as a High-Priority Substance or a Low-Priority Substance, EPA does not interpret the statute to support such an interpretation. To the contrary, the addition of the phrase ''conditions of use'' (emphasis added) was intended to move the Agency away from its past practice of assessing only narrow uses of a chemical substance, towards a comprehensive approach to chemical substance management. While EPA clearly retains some discretion in determining those conditions of use, as a matter of law, EPA considers that it would be an abuse of that discretion to simply disregard known, intended, or reasonably foreseen uses in its analyses.

C. Timeframe

As discussed in Unit II., TSCA section 6(b)(1)(C) requires that the prioritization process last between nine and twelve months. EPA is proposing in this rule that initiation of the prioritization begins upon publication of a notice in the **Federal Register** that identifies a chemical substance for prioritization and provides the results of the screening review. The process is complete upon publication of a notice in the **Federal Register** announcing a final priority designation. Accordingly, the proposed rule specifies that the process—from initiation to final designation—shall last between 9 and 12 months.

This timeframe serves dual purposes. The minimum 9-month timeframe ensures that the general public; potentially-affected industries; state, tribal and local governments; environmental and health non-governmental organizations; and others have ample notice of upcoming federal action on a given chemical substance, and opportunity to engage with EPA early in the process. The 12-month maximum timeframe, coupled with the default-to-high provision discussed later, keeps the existing chemical substances review pipeline in a forward motion, and prevents EPA from getting mired in analysis before ever reaching the risk evaluation step.

D. Categories of Chemical Substances

TSCA section 26 provides EPA with authority to take action on categories of chemical substances. 15 U.S.C. 2625(c). ''Category of Chemical Substances'' is defined at 15 U.S.C. 2625(c)(2)(A). Although the proposed rule most often references ''chemical substances,'' EPA is also proposing to include a clear statement in the regulation that nothing in the proposed rule shall be construed as a limitation on EPA's authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can prioritize and evaluate categories of chemical substances.

E. Chemicals Subject to Prioritization

Generally, all chemical substances listed on the TSCA Inventory are subject to prioritization. TSCA contemplates that, over time, all chemical substances on the TSCA Inventory will be prioritized into either High- or Low-Priority Substances, and that all High-Priority Substances will be evaluated. EPA notes that chemical substances newly added to the TSCA Inventory following EPA's completion of pre-manufacture review under section 5 of TSCA (15 U.S.C. 2604) are also candidates for prioritization, although EPA expects that such chemical substances are not likely to be High-Priority candidates in light of the risk-related determination that the Agency must make pursuant to TSCA section 5(a)(3).

TSCA further requires EPA to go through a separate process of determining which chemical substances on the TSCA Inventory are still actively being manufactured, and EPA has initiated a separate rulemaking for that purpose (RIN 2070–AK24). This distinction will inform EPA's exposure judgments during the prioritization process. However, there is nothing in TSCA that prohibits EPA from initiating the prioritization process on an ''inactive'' chemical substance and ultimately designating that chemical substance as either a High-Priority Substances (*e.g.,* if exposures of concern arise from ongoing uses) or Low-Priority Substance.

F. Pre-Prioritization Considerations

As discussed earlier, TSCA requires that EPA establish a process, including criteria for designating a chemical substance as either a High-Priority Substances or Low-Priority Substance. 15 U.S.C. 2605(b)(1). Aside from the statutory preferences for chemical substances on the 2014 Update to the TSCA Work Plan (Ref. 1), the statute leaves EPA with broad discretion to choose which chemical substance to put into that process. Accordingly, this proposed rule includes a discussion of the criteria EPA expects to use to cull through the chemical substances on the TSCA Inventory. These include criteria that will be used to identify potential candidates for High-Priority Substances or Low-Priority Substances, and that describe how the extent of available information on potential candidates will affect whether they are selected for prioritization.

For example, in identifying potential candidates for High-Priority Substance designations, EPA is proposing to seek to identify chemical substances where available information suggests that the chemical substance may present a hazard and that exposure is present under ''one or more conditions of use,'' but where an ''unreasonable risk'' determination cannot be made without a more extensive or complete assessment in a risk evaluation. EPA interprets the statutory definition of a High-Priority Substance (''. . . may present an unreasonable risk [. . .] because of a potential hazard and a potential route of exposure . . .'') to set a fairly low bar, and EPA expects that a large number of chemical substances will meet this definition. Although EPA will prioritize a ''chemical substance'' as a whole, EPA may base its identification of a potential candidate as a High-Priority Substance, and ultimately the proposed designation, on a single condition of use, provided the hazard and exposure associated with that single use support such a designation. This proposal is based on the statutory definition of a High-Priority Substance, which is clear that the standard for the chemical as a whole can be met based on a single condition of use (''. . . because of *a* potential hazard and *a* potential route of exposure . . .'').

Conversely, in identifying potential candidates for Low-Priority Substance designation, EPA is proposing that it will seek to identify chemical substances where the information indicates that hazard and exposure potential for ''all conditions of use'' are so low that EPA can confidently set that chemical substance aside without doing further evaluation. By comparison, then, TSCA's definition of Low-Priority Substance (''. . . based on sufficient information, such *substance* does not meet the standard for [. . .] a high-priority substance . . .'') is fairly rigorous, and effectively requires EPA to determine that under no condition of use does the chemical meet the High-Priority Substance standard. Consequently, EPA expects it will be more difficult to support such designations. Unlike High-Priority Substances, EPA will not be able to designate a chemical substance as a Low-Priority Substance without first looking at all of the conditions of use. While not determinative, EPA believes that its Safer Chemicals Ingredients List (SCIL) (Ref. 6) will be a good starting point for identifying potential candidates for Low-Priority Substance designations.

EPA is also proposing to include the following list of additional exposure and hazard considerations that can be used to narrow the field of potential candidates: (1) Persistent, bioaccumulative, and toxic; (2) Used in children's products; (3) Used in consumer products; (4) Detected in human and/or ecological biomonitoring programs; (5) Potentially of concern for children's health; (6) High acute and chronic toxicity; (7) Probable or known carcinogen; (8) Neurotoxicity; or (9) Other emerging exposure and hazard concerns to human health or the environment, as determined by the Agency. These criteria are drawn from EPA's 2012 TSCA Work Plan methodology (Ref. 4), which, as discussed earlier, was the process EPA had been using to prioritize chemical substances for assessment under TSCA. EPA will evaluate one or more of these nine considerations, and chemical substances that meet one or more of these criteria may be identified as potential candidates for High-Priority Substance designations. For example, if a chemical substance is highly toxic and used in consumer products, EPA may wish to consider that chemical substance as a potential High-Priority Substance candidate. EPA may also choose to identify potential candidates based on other criteria that suggest the chemical substance may otherwise present a human health or environmental concern, as contemplated in the ''catch-all'' provision (9). The fact that a chemical substance meets one of these criteria is not determinative of an outcome, including whether or not EPA will select the chemical substance to go into the prioritization process and/or the priority designation that the chemical substance will ultimately receive. Conversely, chemical substances that meet none of these criteria may be good potential candidates for Low-Priority Substance designation. The considerations are intended to serve as a general guide for the Agency, based on EPA's current understanding of important considerations regarding

potential chemical risk. It should also be noted that while these considerations are drawn from EPA's 2012 Work Plan methodology (Ref. 4), EPA will apply them differently for prioritization. In the TSCA Work Plan context, only chemical substances that met these initial criteria were eligible for listing on Work Plan. For purposes of prioritization under TSCA, the considerations do not determine eligibility, but rather are designed to help EPA to narrow its focus.

G. Information Availability

Another key consideration in the pre-prioritization phase is the existence and availability of risk-related information on a candidate or potential candidate chemical substance. Because EPA must complete its prioritization process within 12 months once prioritization has been initiated for a chemical substance, immediately initiate a risk evaluation for High-Priority Substance, and complete the risk evaluation within three years of initiation, EPA cannot assume that it will be able to require the generation of critical information during these time frames. Furthermore, the statute does not grant EPA the discretion to significantly delay either of these processes, pending development of information. Consequently, prior to initiating the prioritization process for a chemical substance, EPA will generally review the available hazard and exposure-related information, and evaluate whether that information would be sufficient to allow EPA to complete both prioritization and risk evaluation processes. As part of such an evaluation, EPA expects to consider the quality, objectivity, utility, and integrity of the available information. To the extent the information is not currently available or is insufficient, EPA will determine whether or not information can be developed and collected, reviewed and incorporated into analyses and decisions in a timely manner. The proposed rule makes it clear that sufficiency of available information is likely to be a crucial factor in the selection of the chemical substances that EPA chooses to put into the prioritization process.

As noted, if information gaps are identified *during* the prioritization or risk evaluation processes, EPA expects that it could be difficult to require the development of necessary chemical substance information, and receive, evaluate, and incorporate that information into analyses and decisions within the statutory timeframes. Tests necessary for risk evaluation, for example, could take months or years to develop and execute, plus additional time for EPA to issue the order or rule, and to collect, review and incorporate the new information. To avoid such a scenario, EPA believes that it will need to do a significant amount of upfront data gathering and review. This approach ensures that EPA stays on track to meet relevant statutory deadlines—particularly those for risk evaluation.

The proposed rule makes clear that EPA generally expects to use this new authority, as appropriate and necessary, to gather the requisite information prior to initiating prioritization. This could include, as appropriate, TSCA information collection, testing, and subpoena authorities, including those under TSCA sections 4, 8, and 11(c), to develop needed information.

Given the importance of ensuring that sufficient information is available to conduct the prioritization and risk evaluation processes, EPA is proposing to include this consideration during the earliest stage in the process: During the identification of potential candidates. However, this criterion remains relevant even after EPA has selected a candidate and screened that chemical substance against the statutory criteria in TSCA section 6(b)(1)(A). Thus, if at any time prior to the publication of a notice in the **Federal Register** initiating prioritization, EPA determines that more information will be necessary to support a prioritization designation or a subsequent risk evaluation, EPA can choose not to initiate prioritization for that chemical substance pending development of additional information.

H. Selection and Screening of a Candidate Chemical Substance

As noted in Unit II., TSCA requires that EPA give preference to chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that (1) have a Persistence and Bioaccumulation Score of 3; and (2) are known human carcinogens and have high acute and chronic toxicity. TSCA section 6(b)(2)(B) further requires that 50 percent of all ongoing risk evaluations be drawn from the 2014 Update to the TSCA Work Plan for Chemical Assessments, meaning that EPA will need to draw at least 50 percent of High-Priority Substance candidates from the same list. By operation of the statute, TSCA requires that all TSCA Work Plan chemical substances eventually be prioritized. However, it is premature to presume that those chemical substances will necessarily be prioritized as High-Priority Substances, or that EPA would find unreasonable risk.

Aside from these statutory preferences, however, TSCA does not limit how EPA must ultimately select a candidate chemical substance to put into the prioritization process. EPA is proposing that it will select a candidate—for either High-Priority Substances or Low-Priority Substance—based on the policy objectives described in Unit III.A. and the pre-prioritization considerations described in Unit III. F. and G. The development of the proposed rule, including these policy objectives, considerations and criteria, was informed by EPA's experience implementing the 2012 TSCA Work Plan methodology, which has been the Agency's primary tool for identifying candidate chemical substances for further assessment under TSCA. In addition, EPA fully recognizes the important role that stakeholders can play in helping the Agency to identify candidates for prioritization or to better understand the unique uses or characteristics of a particular chemical. EPA continues to welcome this type of engagement and dialogue early in the process, including during the pre-prioritization phase. While the proposed rule provides multiple opportunities for public feedback *during* the prioritization process, EPA is requesting comment on whether and how EPA should solicit additional input at the pre-prioritization phase. Further, given EPA's objective to avoid simply moving the market to substitute chemical substances of equal or greater risks, EPA requests comment on whether and how information on the availability of chemical substitutes should be taken into account during this phase of the prioritization process.

Once a single candidate chemical substance (or category of chemical substances) is selected, EPA will screen the selected candidate against the specific criteria and considerations in TSCA section 6(b)(1)(A). Those criteria and considerations are: (1) The chemical substance's hazard and exposure potential; (2) the chemical substance's persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the chemical substance near significant sources of drinking water; (5) the chemical substance's conditions of use or significant changes in conditions of use; and (6) the chemical substance's production volume or significant changes in production volume. Because TSCA does not prohibit EPA from expanding the statutory screening criteria, the proposed rule also provides an additional criterion: (7) Any other risk-based criteria relevant to the

designation of the chemical substance's priority, in EPA's discretion. This final criterion allows the screening review to adapt with future changes in our understanding of science and chemical risks. In addition, EPA fully recognizes the important role that stakeholders can play in helping the Agency to identify candidates for prioritization or to better understand the unique uses or characteristics of a particular chemical. EPA continues to welcome this type of engagement and dialogue early in the process, including during the pre-prioritization phase. While the proposed rule provides multiple opportunities for public feedback during the prioritization process, EPA is requesting comment on whether and how EPA should solicit additional input at the pre-prioritization phase.

The screening review is not a risk evaluation, but rather a review of available information on the chemical substance that relates to the screening criteria. EPA expects to evaluate all relevant sources of information while conducting the screening review, including, as appropriate, the hazard and exposure sources listed in Appendices A and B of the 2012 TSCA Work Plan methodology (Ref. 4). Ultimately, the screening review and other considerations during the pre-prioritization phase are meant to inform EPA's decisions on (1) whether to initiate the prioritization process on a particular chemical substance, and (2) once initiated, the proposed designation of that chemical substance as either a High-Priority Substances or Low-Priority Substance.

I. Initiation of Prioritization

The prioritization process officially begins, for purposes of triggering the nine to twelve month statutory timeframe, when EPA publishes a notice in the **Federal Register** identifying a chemical substance for prioritization. The proposed rule also specifies that EPA will publish the results of the screening review in the **Federal Register**, describing the information, analysis and basis used to conduct that review and providing in the docket copies of relevant information not otherwise protected as confidential business information under TSCA section 14. Publication of the notice in the **Federal Register** also initiates a 90-day public comment period. For each chemical substance, EPA will open a docket to facilitate receipt of public comments and access to publicly available information throughout this process. Interested persons can submit information regarding the results of the screening review or any other information relevant to the chemical substance. Of particular interest to EPA will be information related to ''conditions of use'' that are missing from the screening results. EPA will consider all relevant information received during this comment period. Consistent with TSCA section 6(b)(1)(C)(iii), the proposed rule further allows EPA to extend this initial public comment period for up to 3 months to receive and/or evaluate information developed from a test order, commensurate with EPA's need for additional time to receive and/or evaluate this information. As a practical matter, EPA is unlikely to often extend this initial public comment, given EPA's intention to ensure that all or most of the necessary information is available before initiating the prioritization process. Further, a three month window would not often provide a sufficient time to gather, let alone consider, new test data for the prioritization process. This is generally expected to be the case even with the authority to more quickly collect such information under the new test order authority in TSCA section 4.

J. Proposed Priority Designation

Based on the results of the screening review, relevant information received from the public in the initial comment period, and other information as appropriate, EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance, as those terms are defined in TSCA. In making this proposed designation, as directed by the statute, EPA will not consider costs or other non-risk factors.

This proposed rule provides that EPA will publish the proposed designation in the **Federal Register**, along with an identification of the information, analysis and basis used to support a proposed designation, in a form and manner that EPA deems appropriate, and provide a second comment period of 90 days, during which time the public may submit comments on EPA's proposed designation. EPA proposes to use the same docket for this step of the process. Because the supporting documentation for a proposed High-Priority Substance designation is likely to foreshadow what will go into a scoping document for risk evaluation, EPA will be particularly interested in early comments on the accuracy of scope-related information such as the chemical's ''conditions of use.''

In the event of insufficient information at the proposed designation step, EPA is proposing to designate a chemical substance as a High-Priority Substance. EPA expects this situation to occur infrequently based on its application of the criteria and considerations during the pre-prioritization phase. However, if for some reason the information available to EPA is insufficient to support a proposed designation of the chemical substance as a Low-Priority Substance, including after any extension of the initial public comment period, consistent with the statute, the proposed rule requires EPA to propose to designate the chemical substance as a High-Priority Substance. The statute requires that the prioritization process lead to one of two outcomes by the end of the 12-month deadline: A High-Priority Substance designation or a Low-Priority Substance designation. 15 U.S.C. 2605(b)(1)(B). There is no third option to allow EPA to either require the development of additional information or otherwise toll this deadline. Further, the statute specifically requires that a Low-Priority Substance designation be based on ''information sufficient to establish'' that a chemical substance meets the definition. 15 U.S.C. 2605(b)(1)(B)(ii). There is no comparable statutory requirement for High-Priority Substance designations. 15 U.S.C. 2605(b)(1)(B)(i). It is also relevant that the effect of designating a chemical as High-Priority Substance is that EPA further evaluates the chemical substance; by contrast, a Low-Priority Substance designation is a final Agency determination that no further evaluation is warranted—a determination that constitutes final agency action, subject to judicial review. 15 U.S.C. 2618(a)(1)(C)(i).

The logical implication of this statutory structure is that scientific uncertainty in this process (including as a result of insufficient information) is to weigh in favor of a High-Priority Substance designation, as it is merely an interim step that ensures that the chemical will be further evaluated. EPA's proposal would also ensure that this process would not create any incentives for parties to withhold readily available information, or inadvertently discourage the voluntary generation of data, as could occur were EPA to establish, for example, a default designation to Low-Priority. As a practical matter, however, EPA expects this situation to occur infrequently, based on its proposed criteria and considerations that will generally ensure that sufficient information is available to conduct a risk evaluation before initiating prioritization. Priority designations, whether they were based on sufficient information or a lack of sufficient information, are neither an

affirmation of risk nor safety. EPA therefore recognizes that all priority designations will need to be carefully communicated to the public.

For proposed designations as Low-Priority Substances, EPA is proposing to require that all comments that could be raised on the issues in the proposed designation must be presented during the comment period. Any issues not raised will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding. This is a well-established principle of administrative law and practice, *e.g., Nuclear Energy Institute* v. *EPA,* 373 F.3d 1251, 1290–1291 (D.C. Cir. 2004), and the need for such a provision is reinforced by the statutory deadlines under which EPA must operate here. EPA is restricting this to Low-Priority Substance designations, as it is the last opportunity for public input before EPA's action becomes final, and thus it is imperative that any issues are shared during this public comment period. By contrast, designation of a chemical substance as a High-Priority Substance is not final agency action. The statute mandates additional opportunities for public input during the risk evaluation process, and EPA does not consider it appropriate to restrict the public's ability to comment during these subsequent processes based on this early phase proceeding.

K. Final Priority Designation

After considering any additional information collected during the proposed designation step, as appropriate, the last step in the prioritization process is for EPA to finalize its designation of a chemical substance as either a High-Priority Substance or a Low-Priority Substance. The proposed rule specifies that EPA will publish the priority designation in the **Federal Register**, and will use the same docket. Again, TSCA prohibits costs or other non-risk factors from being considered in this designation. And, as with the proposed designation step, if information available to EPA remains insufficient to support the final designation of the chemical substance as a Low-Priority Substance, EPA will finalize the designation as a High-Priority Substance. Although final High-Priority designations based on insufficient information are unlikely for all the reasons described in Unit III.J., such a designation would require EPA to conduct a risk evaluation on that substance, and to support the risk evaluation with adequate information. EPA would need to develop or require development of the necessary information and complete the risk evaluation within the 3-year statutory deadline.

L. Repopulation of High-Priority Substances

TSCA requires EPA to finalize a designation for at least one new High-Priority Substance upon completion of a risk evaluation for another chemical substance, other than a risk evaluation that was requested by a manufacturer. Because the timing for the completion of risk evaluation and/or the prioritization process will be difficult to predict, EPA intends to satisfy this 1-off-1-on replacement obligation as follows: In the notice published in the **Federal Register** finalizing the designation of a new High-Priority Substance, EPA will identify the complete or near-complete risk evaluation that the new High-Priority Substance will replace. So long as the designation occurs within a reasonable time before or after the completion of the risk evaluation, this will satisfy Congress' intent while avoiding unnecessary delay and the logistical challenges that would be associated with more perfectly aligning a High-Priority Substance designation with the completion of a risk evaluation.

M. Effect of Final Priority Designation

Final designation of a chemical substance as a High-Priority Substance requires EPA to immediately begin a risk evaluation on that chemical substance. It is important to note that High-Priority Substance designation does not mean that the Agency has determined that the chemical substance presents a risk to human health or the environment—only that the Agency intends to consider the chemical substance for further risk review and evaluation. A High-Priority Substance designation is not a final agency action and is not subject to judicial review or review under the Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.*

Final designation of a chemical substance as a Low-Priority Substance means that a risk evaluation of the chemical substance is not warranted at the time, but does not preclude EPA from later revising the designation, if warranted. Notably, a Low-Priority Substance designation is explicitly subject to judicial review. 15 U.S.C. 2618(a)(1)(C).

N. Revision of Designation

TSCA provides that EPA may revise a final designation of a chemical substance from a Low-Priority Substance to a High-Priority Substance at any time based on information available to the Agency. The proposed rule outlines the process the Agency will take to revise such a designation. Specifically, EPA would (1) re-screen the chemical substance incorporating the relevant information, (2) re-initiate the prioritization process and take public comment, (3) re-propose a priority designation and take public comment, and (4) re-finalize the priority designation. EPA will not revise a final designation of a chemical substance from High-Priority Substance to Low-Priority Substance, but rather see the risk evaluation process through to its conclusion.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. October 2014. Available online at: *https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.*
2. EPA. Framework for Metals Risk Assessment. EPA 120/R–07/001. March 2007. Available online at: *https://www.epa.gov/sites/production/files/2013-09/documents/metals-risk-assessment-final.pdf.*
3. EPA. Science Policy Council Handbook: Risk Characterization. EPA/100/B–00/002. December 2000. Available online at: *https://www.epa.gov/risk/risk-characterization-handbook.*
4. EPA. TSCA Work Plan Chemicals: Methods Document. February 2012. Available online at: *https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.*
5. EPA. 2012 TSCA Work Plan Chemicals. June 2012. Available online at: *https://www.epa.gov/sites/production/files/2014-02/documents/work_plan_chemicals_web_final.pdf.*
6. EPA. Safer Chemical Ingredients List (SCIL). Available online at: *https://www.epa.gov/saferchoice/safer-ingredients.* See also Master Criteria, September 2012, Version 2.1, available online at: *https://www.epa.gov/sites/production/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf.*

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be

found at *http://www2.epa.gov/laws-regulations/laws-and-executive-order*s.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket.

B. Paperwork Reduction Act (PRA)

This action does not contain any information collection activities that require approval under the PRA, 44 U.S.C. 3501 *et seq*. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public.

C. Regulatory Flexibility Act (RFA)

I certify under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* that this action will not have a significant economic impact on a substantial number of small entities. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public, including small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not establish an environmental health or safety standard, and is therefore not is not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This rulemaking addresses internal EPA operations and procedures and does not have any impact on human health or the environment.

List of Subjects in 40 CFR Part 702

Environmental protection, Chemicals, Chemical substances, Hazardous substances, Health and safety, Prioritization, Screening, Toxic substances.

Dated: December 27, 2016

Gina McCarthy,

Administrator.

Therefore, 40 CFR chapter I, subchapter R, is proposed to be amended as follows:

PART 702—[AMENDED]

■ 1. The authority citation for part 702 is revised to read as follows:

Authority: 15 U.S.C. 2605 and 2619.

■ 2. Add subpart A to read as follows:

PART 702—GENERAL PRACTICES AND PROCEDURES

Subpart A—Procedures for Prioritization of Chemical Substances for Risk Evaluation

* * * * *

Authority: 15 U.S.C. 2605 and 2619.

Subpart A—Procedures for Prioritization of Chemical Substances for Risk Evaluation

§ 702.1 General Provisions.

(a) *Purpose.* This regulation establishes the risk-based screening process for designating chemical substances as a High-Priority Substance or a Low-Priority Substance for risk evaluation as required under section 6(b) of the Toxic Substances Control Act, as amended (15 U.S.C. 2605(b)).

(b) *Scope of designations.* EPA will make priority designations pursuant to these procedures for a chemical substance, not for a specific condition or conditions of use of a chemical substance.

(c) *Categories of chemical substances.* Nothing in this subpart shall be interpreted as a limitation on EPA's authority under 15 U.S.C. 2625(c) to take action, including the actions contemplated in this subpart, on a category of chemical substances.

(d) *Prioritization timeframe.* The Agency will publish a final priority designation for a chemical substance in no fewer than 9 months and no longer than 1 year following initiation of prioritization pursuant to 40 CFR 702.9.

(e) *Metals or metal compounds.* In identifying priorities for chemical

substances that are metals or metal compounds, EPA will, as appropriate, refer to relevant considerations from the Framework for Metals Assessment of the Office of the Science Advisor, Risk Assessment Forum, dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

(f) *Applicability.* These regulations do not apply to any chemical substance for which a manufacturer requests a risk evaluation under TSCA section 6(b)(4)(C) (15 U.S.C. 2605(b)(4)(C)).

§ 702.3 Definitions.

For purposes of this subpart, the following definitions apply:

Act means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*)

EPA means the U.S. Environmental Protection Agency.

High-Priority Substance means a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Low-Priority Substance means a chemical substance that EPA concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance.

§ 702.5 Consideration of Potential Candidates for Prioritization.

(a) *Potential High-Priority Substance Candidates.* In identifying potential candidates for High-Priority Substances, EPA will generally consider whether information available to the Agency suggests there is hazard and exposure under a condition or conditions of use, and whether a risk evaluation would be needed to determine whether there is an unreasonable risk of injury to health or the environment.

(b) *Potential Low-Priority Substance Candidates.* In identifying potential candidates for Low-Priority Substances, EPA will generally consider whether information available to the EPA suggests such low hazard and/or exposure under all conditions of use that EPA is confident the chemical substances does not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA, even in the absence of a risk evaluation.

(c) *Exposure and Hazard Considerations for Potential Candidates.*

In identifying potential candidates for prioritization, EPA will generally evaluate whether or not the chemical substance meets one or more of the following exposure or hazard considerations:

(1) Persistent, bioaccumulative, and toxic;

(2) Used in children's products;

(3) Used in consumer products;

(4) Detected in human and/or ecological biomonitoring programs;

(5) Potentially of concern for children's health;

(6) High acute and chronic toxicity;

(7) Probable or known carcinogen;

(8) Neurotoxicity; or

(9) Other emerging exposure and hazard concerns to human health or the environment, as determined by the Agency.

A chemical substance that meets one or more of these criteria will generally be considered as a potential candidate for further consideration as a High-Priority Substance. A chemical substance that meets none of these criteria will generally be considered as a potential candidate for further consideration as a Low-Priority Substance.

(d) *Available Information and Resources.* EPA expects it will often be difficult to timely require development of necessary chemical information, and receive, evaluate, and incorporate that information into analyses, during the prioritization and risk evaluation processes, within the statutory deadlines under the Act for prioritization and risk evaluation at 15 U.S.C. 2605 (b)(1)(C) and (b)(4)(G). Therefore, EPA will generally review and analyze the information necessary for both prioritization and risk evaluation prior to initiating the prioritization process for a chemical substance pursuant to 40 CFR 702.9. Specifically, in identifying potential candidates for prioritization, EPA expects to consider:

(1) The availability of information and resources necessary and sufficient to support a priority designation pursuant to 40 CFR 702.11, a risk evaluation pursuant to 40 CFR 702, subpart B, or other such action as determined by the Administrator; and

(2) The ability of EPA to timely develop or require development of information necessary and sufficient to support a priority designation pursuant to 40 CFR 702.11; a risk evaluation pursuant to 40 CFR 702, subpart B; or other such action as determined by the Agency.

(e) *Insufficient Information.* In the absence of sufficient information to support a priority designation pursuant to 40 CFR 702.11, a risk evaluation pursuant to 40 CFR 702, subpart B, or other such action as determined by the Agency, EPA may use its authorities under the Act, and other information gathering authorities, to gather or require the generation of the needed information on a chemical substance before initiating the prioritization process for that chemical substance.

§ 702.7 Candidate Selection and Screening Review.

(a) *Preferences and TSCA Work Plan.* In selecting a candidate for prioritization as a High-Priority Substance, EPA will:

(1) Give preference to:

(A) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a persistence and bioaccumulation score of 3, and

(B) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity; and

(2) Identify a sufficient number of candidates from the 2014 update of the TSCA Work Plan for Chemical Assessments to ensure that, at any given time, at least 50 percent of risk evaluations being conducted by EPA are drawn from that list until all substances on the list have been designated as either a High-Priority Substance or Low-Priority Substance pursuant to 40 CFR 702.13.

(b) General Objective. In selecting candidates for a High-Priority Substance designation, it is EPA's general objective to select those chemical substances with the greatest hazard and exposure potential first, considering available information on the relative hazard and exposure of potential candidates. EPA may also consider the relative hazard and exposure of a potential candidate's substitutes. EPA is not required to select candidates or initiate prioritization pursuant to 40 CFR 702.9 in any ranked or hierarchical order.

(c) Screening Review. Following selection of a candidate chemical substance, EPA will generally use available information to screen the candidate chemical substance against the following criteria and considerations:

(1) The chemical substance's hazard and exposure potential;

(2) The chemical substance's persistence and bioaccumulation;

(3) Potentially exposed or susceptible subpopulations;

(4) Storage of the chemical substance near significant sources of drinking water;

(5) The chemical substance's conditions of use or significant changes in conditions of use;

(6) The chemical substance's production volume or significant changes in production volume; and

(7) Any other risk-based criteria relevant to the designation of the chemical substance's priority, in EPA's discretion.

(d) *Information sources.* In conducting the screening review in paragraph (c) of this section, EPA expects to consider sources of information relevant to the listed criteria, including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the TSCA Work Plan Chemicals: Methods Document (February 2012).

(e) The purpose of the preferences and criteria in paragraph (a) of this section and the screening review in paragraph (c) of this section are to inform EPA's decision whether or not to initiate the prioritization process pursuant to 40 CFR 702.9, and the proposed designation of the chemical substance as either a High-Priority Substance or a Low-Priority Substance pursuant to 40 CFR 702.11.

(f) If, after the screening review in paragraph (c) of this section, EPA believes it will not have sufficient information to support a proposed priority designation pursuant to 40 CFR 702.11, a risk evaluation pursuant to 40 CFR 702, subpart B, or other such action as determined by the Agency, EPA is likely to use its authorities under the Act, and other information gathering authorities, to generate the needed information before initiating prioritization pursuant to 40 CFR 702.9.

§ 702.9 Initiation of Prioritization Process.

(a) EPA generally expects to initiate the prioritization process for a chemical substance only when it believes that all or most of the information necessary to prioritize and perform a risk evaluation on the substance already exists.

(b) EPA will initiate prioritization by publishing a notice in the **Federal Register** identifying a chemical substance for prioritization and the results of the screening review conducted pursuant to 40 CFR 702.7(c).

(c) The prioritization timeframe in 40 CFR 702.1(d) begins upon EPA's publication of the notice described in paragraph (b) of this section.

(d) The results of the screening review published pursuant to paragraph (b) of this section will identify, in a form and manner that EPA deems appropriate, the information analysis and basis used in conducting the screening process. Subject to 15 U.S.C. 2613, copies of the information will also be placed in a public docket established for each chemical substance.

(e) Publication of a notice in the **Federal Register** pursuant to paragraph (b) of this section will initiate a period of 90 days during which interested persons may submit relevant information on that chemical substance. Relevant information might include, but is not limited to, any information regarding the results of the screening review conducted pursuant to 40 CFR 702.7(c), and any additional information on the chemical substance that pertains to the criteria and considerations at 40 CFR 702.7(c).

(f) EPA may, in its discretion, extend the public comment period in paragraph (b) of this section for up to three months in order to receive or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B). The length of the extension will be based upon EPA's assessment of the time necessary for EPA to receive and/or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B).

§ 702.11 Proposed Priority Designation.

(a) Based on the results of the screening review in 40 CFR 702.7(c), relevant information received from the public as described in 40 CFR 702.9(e), and other information as appropriate and in EPA's discretion, EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance.

(b) EPA will not consider costs or other non-risk factors in making a proposed priority designation.

(c) If information available to EPA remains insufficient to enable the proposed designation of the chemical substance as a Low-Priority Substance, including after any extension of the initial public comment period pursuant to 40 CFR 702.9(f), EPA will propose to designate the chemical substance as a High-Priority Substance.

(d) EPA may propose to designate a chemical substance as a High-Priority Substance based on the proposed conclusion that the chemical substance satisfies the definition of High-Priority Substance in 40 CFR 702.3 under any one or more uses that the Agency determines constitute conditions of use as defined in 15 U.S.C. 2602. EPA will propose to designate a chemical substance as a Low-Priority Substance based only on the proposed conclusion that the chemical substance satisfies the definition of Low-Priority Substance in 40 CFR 702.3 under all uses that the Agency determines constitute conditions of use as defined in 15 U.S.C. 2602.

(e) EPA will publish the proposed designation in the **Federal Register**, along with an identification of the information, analysis and basis used to support a proposed designation, in a form and manner that EPA deems appropriate, and provide a comment period of 90 days, during which time the public may submit comment on EPA's proposed designation. EPA will open a docket to facilitate receipt of public comment.

(f) For chemical substances that EPA proposes to designate as Low-Priority Substances, EPA will specify in the notice published pursuant to paragraph (e) of this section that all comments that could be raised on the issues in the proposed designation must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

§ 702.13 Final Priority Designation.

(a) After considering any additional information collected from the proposed designation process in 40 CFR 702.11, as appropriate, EPA will finalize its designation of a chemical substance as either a High-Priority Substance or a Low-Priority Substance.

(b) EPA will not consider costs or other non-risk factors in making a final priority designation.

(c) EPA will publish each final priority designation in the **Federal Register**.

(d) EPA will finalize a designation for at least one High-Priority Substance for each risk evaluation it completes, other than a risk evaluation that was requested by a manufacturer pursuant to 40 CFR 702, subpart B. The obligation in 15 U.S.C. 2605(b)(3)(C) will be satisfied by the designation of at least one High-Priority Substance where such designation specifies the risk evaluation that the designation corresponds to, and where the designation occurs within a reasonable time before or after the completion of the risk evaluation.

(e) If information available to EPA remains insufficient to enable the final designation of the chemical substance as a Low-Priority Substance, EPA will finalize the designation of the chemical substance as a High-Priority Substance.

§ 702.15 Revision of Designation.

EPA may revise a final designation of chemical substance from Low-Priority to High-Priority Substance at any time based on information available to the Agency. To revise such a designation, EPA will re-screen the chemical substance pursuant to 40 CFR 702.7(c), re-initiate the prioritization process on that chemical substance in accordance with 40 CFR 702.9, propose a priority designation pursuant to 40 CFR 702.11, and finalize the priority designation pursuant to 40 CFR 702.13. EPA will not revise a final designation of a chemical substance from a High-Priority Substance designation to Low-Priority.

§ 702.17 Effect of Designation as a Low-Priority Substance.

Designation of a chemical substance as a Low-Priority Substance under 40 CFR 702.3 means that a risk evaluation of the chemical substance is not warranted at the time, but does not preclude EPA from later revising the designation pursuant to 40 CFR 702.15, if warranted.

§ 702.19 Effect of Designation as a High-Priority Substance.

Final designation of a chemical substance as a High-Priority Substance under 40 CFR 702.13 initiates a risk evaluation pursuant to 40 CFR 702, subpart B. Designation as a High-Priority Substance is not a final agency action and is not subject to judicial review.

* * * * *

[FR Doc. 2017–00051 Filed 1–13–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket No. 02–278; Report No. 3066]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: A Petition for Reconsideration (Petition) has been filed in the Commission's rulemaking proceeding, Sarah E. Ducich and Mark W. Brennan on behalf of Navient Corp., Joseph Popevis and Rich Benenson on behalf of Nelnet Servicing LLC, Rebecca Emily Rapp on behalf of Great Lakes Higher Education Corporation, Jason L. Swartley on behalf of Pennsylvania Higher Education Assistance Agency, and Winfield P. Crigler on behalf of Student Loan Servicing Alliance.

DATES: Oppositions to the Petition must be filed on or before February 1, 2017. Replies to an opposition must be filed on or before February 13, 2017.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Kristi Thornton, Consumer Policy Division, Consumer and Governmental Affairs Bureau, at (202) 418–2467 or email: *Kristi.Thornton@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3066, released January 6, 2017. The full text of the Petition is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554. It also may be accessed online via the Commission's Electronic Comment Filing System at: *https://www.fcc.gov/ecfs/filing/1217190700960/document/1217190700960fd71.* The Commission will not send a copy of this document pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this document does not have an impact on any rules of particular applicability.

Subject: In the Matter of Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991, FCC 16–99, published at 81 FR 80594, November 16, 2016, in CG Docket No. 02–278. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 1.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2017–00848 Filed 1–13–17; 8:45 am]

BILLING CODE 6712–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA–HQ–OPPT–2016–0654; FRL–9957–75]

RIN 2070–AK20

Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: As required under section 6(b)(4) of the Toxic Substances Control Act (TSCA), EPA is proposing to establish a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. Risk evaluation is the second step, after Prioritization, in a new process of existing chemical substance review and management established under recent amendments to TSCA. This proposed rule identifies the steps of a risk evaluation process including scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination. EPA is proposing that this process be used for the first ten chemical substances to be evaluated from the 2014 update of the TSCA Work Plan for Chemical Assessments, chemical substances designated as High-Priority Substances during the prioritization process, and those chemical substances for which EPA has initiated a risk evaluation in response to manufacturer requests. The proposed rule also includes the required ''form and criteria'' applicable to such manufacturer requests.

DATES: Comments must be received on or before March 20, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0654, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Susanna W. Blair, Immediate Office, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–4371; email address: *blair.susanna@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

EPA is primarily proposing to establish requirements on the Agency. However this proposal also includes the process and requirements that manufacturers (including importers) would be required to follow when they request an Agency-conducted risk evaluation on a particular chemical substance. This action may, therefore, be of interest to entities that are manufacturing or importing, or may manufacture or import a chemical substance regulated under TSCA (*e.g.,* entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What action is the agency taking?

EPA is proposing to establish the process by which the Agency would conduct risk evaluations on chemical substances under TSCA. The proposal identifies the necessary components of a risk evaluation, including a scope (composed of a conceptual model and an analysis plan), a hazard assessment, an exposure assessment, a risk characterization, and a risk determination. The proposed rule would also establish the process by which manufacturers (including importers) would request an Agency-conducted risk evaluation, and the criteria by which the EPA would evaluate such requests.

C. What is the agency's authority for taking this action?

EPA is proposing this rule pursuant to the authority in TSCA section 6(b)(4), as amended (15 U.S.C. 2605(b)). See also the discussion in Units II.A. and B.

D. What are the estimated incremental impacts of this action?

Although this proposal focuses on the process and activities that apply to EPA, it also proposes the process and requirements that manufacturers (including importers) would be required to follow when they request an Agency-conducted risk evaluation on a particular chemical substance. Since these requirements qualify as an information collection under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* EPA has prepared an Information Collection Request (ICR) to estimate the potential burden and costs associated with the proposed requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. The ICR, which is available in the docket, is discussed in Unit VI.B. and is briefly summarized here. (Ref. 1).

The total estimated annual burden is 960.3 hours and $69,353, which is based on an estimated per request burden of 96.03 hours.

E. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets*.

II. Background

A. Recent Amendments to TSCA

On June 22, 2016, the President signed into law the ''Frank R. Lautenberg Chemical Safety for the 21st Century Act,'' which imposed sweeping reforms to TSCA. The bill received broad bipartisan support in the U.S. House of Representatives and Senate, and its passage was heralded as the most significant update to an environmental law in over 20 years. The amendments give EPA improved authority to take actions to protect people and the environment from the effects of dangerous chemical substances. Additional information on the new law is available on EPA's Web site at: *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act.*

When TSCA was originally enacted in 1976, it established an EPA-administered health and safety review process for new chemical substances prior to allowing their entry into the marketplace. However, tens of thousands of chemical substances in existence at that time were ''grandfathered in'' with no requirement for EPA to ever evaluate their risks to health or the environment. The absence of a review requirement or deadlines for action, coupled with a burdensome statutory standard for taking risk management action on existing chemical substances, resulted in very few chemical substances ever being assessed for safety by EPA, and even fewer subject to restrictions to address identified risks.

One of the key features of the new law is the requirement that EPA now systematically prioritize and assess existing chemicals, and manage identified risks. Through a combination of new authorities, a risk-based safety standard, deadlines for action, and minimum throughput requirements, TSCA effectively creates a ''pipeline'' by which EPA will conduct existing chemicals review and management. This new pipeline—from prioritization to risk evaluation to risk management (when warranted)—is intended to drive steady forward progress on the backlog of existing chemical substances left largely unaddressed by the original law. Risk evaluation is the second step of this process, after prioritization, which is being addressed in a separate rulemaking.

B. Statutory Requirements for Risk Evaluation

TSCA section 6(b)(4) requires EPA to establish, by rule, a process to conduct risk evaluations. Specifically, EPA is directed to use this process to ''determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.'' (15 U.S.C. 2605(b)(4)(A)). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances must undergo evaluation, the development of criteria for manufacturer-requested evaluations, the minimum components of an Agency risk evaluation, and the timelines for public comment and ultimate completion of the risk evaluation.

1. Chemical substances to undergo risk evaluation. TSCA section 6(b) identifies the chemical substances that are subject to this process; these are: (1) Ten chemical substances the Agency is required to identify from the 2014 update to the TSCA Work Plan within the first 180 calendar days after the signing of TSCA (15 U.S.C. 2605(b)(2)); (2) the chemical substances determined as High-Priority Substances through the prioritization process that is being proposed in a separate rulemaking; and (3) requested chemicals submitted by manufacturers that have met the criteria for EPA to conduct a risk evaluation as outlined by this rule. Assuming a sufficient number of requests that have met the criteria outlined in this proposed rule are received, subsection (E) specifies that the number of manufacturer-requested evaluations be 25 to 50 percent of the number of ''High Priority'' risk evaluations ongoing at any one time. Since the number of manufacturer-requested evaluations is expressed as a percentage of the number of High-Priority Substance evaluations, not as a percentage of the total, the number of manufacturer-requested evaluations will likely comprise between 1/5 and 1/3 of the number of total ongoing evaluations, assuming a sufficient number of compliant requests are received. Any manufacturer requested chemical substances on the 2014 update of the TSCA Work Plan (Ref. 2) are exempt from the percentage limitations.

2. Manufacturer-requested risk evaluations. TSCA section 6(b)(4)(C) directs EPA to establish the ''form and manner'' and ''criteria'' that govern manufacturer requests that a substance that they manufacture undergo an EPA conducted risk evaluation. EPA has broad discretion to establish these criteria, but relatively less discretion over whether to grant requests that comply with EPA's criteria. EPA must grant any request that complies with EPA's criteria, until the statutory minimum of 25 percent has been met. Assuming EPA receives requests in excess of this threshold, EPA interprets this provision to grant EPA discretion to determine whether to grant further requests, up to the maximum 50 percent level. In such circumstances, the EPA is directed to give preference to manufacturer requests for which the EPA determines that restrictions imposed by one or more states have the potential to significantly impact interstate commerce, or health or the environment. 15 U.S.C. 2605(b)(4)(E)(iii). As discussed elsewhere in this preamble, EPA is also proposing to give preference to requests where EPA estimates there may be relatively high exposure(s) and/or hazard(s) under one or more conditions of use.

3. Components of a risk evaluation. The statute identifies the minimum components EPA must include in all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation that will be conducted, and that includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the EPA expects to consider. 15 U.S.C 2605(b)(4)(D). The statute provides that the scope of the risk evaluation must be published no later than six months after the initiation of the risk evaluation.

Each risk evaluation must also: (1) ''integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations;'' (2) ''describe whether aggregate or sentinel exposures were considered and the basis for that consideration;'' (3) ''take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use;'' (4) ''describe the weight of scientific evidence for the identified hazards and exposure.'' 15 U.S.C. 2605(b)(4)(F)(i),(iii)–(v). The risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(ii).

Many stakeholders have expressed concern as to how EPA will apply ''weight of scientific evidence'' under

the amended TSCA. EPA is providing, for the purposes of background, a description of how the Agency has consistently interpreted and applied that concept. EPA is not proposing to modify this process as part of this rule. Nor is EPA proposing to codify it; this process has and will continue to evolve with changing scientific methods and innovation. Codifying a specific definition can inhibit the flexibility of the Agency to quickly adopt and implement changing science.

The phrase weight-of-evidence (WoE) is used by EPA and other scientific bodies to describe the strength of the scientific inferences that can be drawn from a given body of evidence, specifically referring to how studies are selected, the quality of the studies evaluated, and how findings are assessed and integrated. Weight-of-evidence is a complex issue and as stated by the National Academies this is ''because scientific evidence used in WOE evaluations varies greatly among chemicals and other hazardous agents in type, quantity, and quality, it is not possible to describe the WoE evaluation in other than relatively general terms. It is thus not unexpected that WoE judgements in particular cases can vary among experts and that consensus is sometimes difficult to achieve'' (NAS, 2009) (Ref. 3). The following is a brief description of how WoE is used at EPA, serving as an example of successful application of WOE in making the scientific determinations.

EPA utilizes the WoE approach in existing programs including IRIS and the Endocrine Disruptor Screening Program among others, and in the classification of carcinogens. In the 1999 Guidelines for Carcinogen Risk Assessment (Ref. 4) EPA refers to the WoE approach as ''. . . a collective evaluation of all pertinent information so that the full impact of biological plausibility and coherence is adequately considered (Ref. 5). The Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) referred to the WoE approach as ''. . . a process by which trained professionals judge the strengths and weaknesses of a collection of information to render an overall conclusion that may not be evident from consideration of the individual data'' (Ref. 6).

WoE is the process for characterizing the extent to which the available data support a hypothesis that an agent causes a particular effect (Ref. 4 and 5). This process involves a number of steps starting with assembling the relevant data, evaluating that data for quality and relevance, followed by an integration of the different lines of evidence to support conclusions concerning a property of the substance. WoE is not a simple tallying of the number of positive and negative studies, but rather it relies on professional judgment. The significant issues, strengths, and limitations of the data and the uncertainties that deserve serious consideration are presented, and the major points of interpretation are highlighted.

This WoE analysis is conducted on a case-by-case basis by first assembling and assessing the individual lines of evidence and then performing an integrated analysis of those lines of evidence. All data considered in the WoE analysis need to be documented and scientifically acceptable. A WoE analysis typically begins with a careful evaluation of each individual study. The process of evaluating the individual lines of evidence includes assembling the data, evaluating that data against current acceptance and quality criteria, and presenting the conclusions regarding the results for each study. The reviews of the available studies need to be transparent about what studies were considered or not, and how the quality of a study was judged.

After assembling and assessing the individual lines of data, an integrated analysis is performed. This means the results from all scientifically relevant published or publically available peer-reviewed studies, which are of sufficient quality and reliability, are evaluated across studies and endpoints into an overall assessment. In general, the WoE analysis examines multiple lines of evidence considering a number of factors, including for example the nature of the effects within and across studies, including number, type, and severity/magnitude of effects and strengths and limitations of the information.

A summary WoE narrative or characterization generally accompanies the detailed analysis of the individual studies and the integrative analysis of the multiple lines of evidence. Inclusion of a WoE narrative is common in WoE assessments and judgments (Ref. 4 and 7). The narrative/characterization is intended to be transparent and allow the reader to clearly understand the reasoning behind the conclusions. The narrative will generally explain the selection of the studies or effects used as the main lines of evidence and relevant basis for conclusions. The overall strength of the evidence supporting a conclusion from the WoE evaluation needs to be described.

The National Toxicology Program of the National Institute of Environmental Health Sciences has developed a tool called ''systematic review'' to assist in WoE evaluations particularly for hazard identification (*https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html*). This tool uses a defined set of processes to identify, select, critically assess, and synthesize evidence to arrive at a hazard conclusion for a chemical. It is designed to enhance transparency and informs scientific judgments. The evidence synthesis step involves considering factors that decrease confidence in the body of evidence for a particular health endpoint (*e.g.* risk of bias, inconsistencies across studies, imprecision) as well as factors that increase confidence (*e.g.* magnitude of the effect, residual confounding, consistency). By evaluating study design (*e.g.,* consistent with study guidelines issued by OECD, and test guidelines issued by the Office of Chemical Safety and Pollution Prevention), and study quality (*e.g.,* studies that comply with Good Laboratory Practices (GLP) like those applicable generally (*https://www.federalregister.gov/documents/2016/08/24/2016–19875/good-laboratory-practice-for-nonclinical-laboratory-studies*) and those issued by EPA for studies submitted under TSCA and FIFRA (*https://www.epa.gov/compliance/good-laboratory-practices-standards-compliance-monitoring-program*)), and integrating negative data (and consideration of the quality of those data), the confidence in hazard conclusions can be increased.

The NIEHS systematic review tool is one example of a documented systematic review approach. EPA believes the proposed risk evaluation process generally reflects the use of systematic review approaches that are appropriate for the types and quantity of information used in a chemical risk evaluation. EPA requests comment on this view. EPA is also requesting comment on the need for regulatory text requiring the use of specific elements of a systematic review approach for hazard identification, including the appropriateness of specific elements that might be included and/or concerns about codifying such an approach.

4. Timeframe. TSCA requires that the risk evaluation process last no longer than three years with a possible six-month extension. 15 U.S.C. 2605(b)(4)(G).

5. Opportunities for public participation. The statute requires that the Agency allow for at least one 30 day public comment period on the draft risk evaluation, prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

6. Metals and metal compounds. When evaluating metals or metal compounds, EPA must ''use'' the March

2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 8) or a successor document that addresses metals risk assessment and is peer-reviewed by the Science Advisory Board.

7. Other statutory requirements. TSCA imposes new requirements on EPA in a number of different areas that EPA is not proposing to incorporate or otherwise address in this proposed rule. For example, amendments to TSCA section 4 require EPA to ''. . . reduce and replace, to the extent practicable, [. . .] the use of vertebrate animals in the testing of chemical substances . . .'' and to develop a strategic plan to promote such alternative test methods. 15 U.S.C. 2603(h). Likewise, TSCA section 26 requires, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, that EPA uses certain scientific standards and bases those decisions on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). While these requirements are relevant to the risk evaluation of chemical substances, EPA is not obliged to repeat them in this proposed rule. As statutory requirements, they apply to EPA's decisions under TSCA section 6. Moreover, in contrast to TSCA section 6, Congress has not directed EPA to implement these other requirements ''by rule;'' it is well-established that where Congress has declined to require rulemaking, the implementing agency has complete discretion to determine the appropriate method by which to implement those provisions.

C. EPA Risk Assessment

Since EPA's inception, human health and ecological risk assessment has informed decisions made to protect humans and the environment. Risk assessments performed by the Agency inform a broad range of regulatory decisions, and, over time, the scientific approaches and methods employed for these risk assessments have evolved. In developing and refining risk assessment processes, frameworks, and guidance documents, EPA has incorporated recommendations from expert technical panels, internal and external peer reviews, and a number of influential reports from the National Academy of Sciences (NAS) National Research Council (NRC) including Risk Assessment in the Federal Government (1983) (Ref. 9), Science and Judgement in Risk Assessment. (1994) (Ref. 10), Understanding Risk: Informing Decisions in a Democratic Society (1996) (Ref. 11), Toxicity Testing in the 21st Century: A Vision and a Strategy (2007) (Ref. 12), Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008) (Ref. 8), and Science and Decisions: Advancing Risk Assessment (2009) (Ref. 3). Specifically, the NAS NRC Science and Decisions Report (Ref. 3) recommended that EPA focus on the important roles of scoping or problem formulation so that a risk assessment will serve a specific and documented purpose. An additional recommendation encouraged EPA to develop risk assessments that are well-tailored to the problems and decisions at hand so that they can inform the decision-making process in the most meaningful way. EPA has evaluated, and will continue to evaluate chemical risks in a manner that is best suited for the particular chemical substance, including its manufacture, processing, formulation, uses, and disposal, and the evaluations may vary as necessary to best characterize potential risks related to the chemical substance under review.

As stated, TSCA requires EPA to evaluate risk to relevant potentially exposed or susceptible subpopulations identified by EPA as relevant to the risk evaluation under the conditions of use. 15 U.S.C. 2605(b)(4)(A). Although this was added as a component of the newly amended law, this will not be a new consideration for the Agency; for example, see EPA's Policy on Evaluating Health Risks to Children (1995) (Ref. 14). The Agency has evaluated the risk of chemical substances to all sectors of the population, with particular attention to workers, indigenous peoples, pregnant women, children, infants, the elderly, environmental justice communities, and fence-line communities, among others. The Agency utilizes a number of existing guidance documents (including but not limited to Ref. 15, 16, 17, 18, and 19) to evaluate risk at various life stages, and will use and refine these processes to protect the most vulnerable.

1. Differences between previous EPA risk assessments under TSCA and proposed new risk evaluations. In this proposed rule, EPA does not propose a new method of risk evaluation, but builds upon existing and proven methodologies for evaluating risk. Also as required by the statute, the rule includes opportunities for public participation, statutory deadlines, necessary components of a risk evaluation, and methods for manufacturer requested risk evaluation. Above and beyond the statute, the proposed rule provides an additional opportunity for public participation, added detail as to components of the scope, hazard and exposure assessments, risk characterization, and increases transparency in the risk evaluation process. EPA requests comment on whether and how the proposed rule could provide additional transparency, public accountability, opportunities for public participation, or incorporation of statutory deadlines.

There are several key differences between previous chemical risk assessments conducted under TSCA and the new risk evaluation process mandated by TSCA amendments and established under these proposed regulations. These differences include considerations of conditions of use, timelines, and determination of unreasonable risk, and are discussed in more detail under those topics in this unit. This proposed rule and procedures described herein apply to risk evaluations conducted under TSCA, and do not apply to risk evaluations conducted by EPA pursuant to other statutes or programs.

2. Conditions of use. Prior to the amended TSCA, EPA was free to and did conduct risk assessments on selected uses of chemical substances. In contrast, EPA interprets the amended TSCA as requiring that risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities that constitute the conditions of use within the meaning of TSCA section 3. That is to say, a risk evaluation must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance. This issue has been the subject of considerable discussion since the enactment of the new law, and EPA acknowledges that different readings of the law may be possible. For example, TSCA section 6(b)(4)(D) requires EPA to identify the conditions of use that the Agency expects to consider in a risk evaluation, suggesting that EPA does not need to consider all conditions of use.

Overall, the statutory text and purpose are best effectuated through a more encompassing reading. TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether ''a chemical substance'' presents an unreasonable risk of injury to health or the environment ''under the conditions of use.'' The evaluation is on the chemical substance—not individual conditions of use—and it must be based on ''*the* conditions of use.'' In this context, EPA believes the word ''the'' is best interpreted as calling for evaluation that considers all conditions of use. First, if EPA were free to base its determination of whether a chemical substance, as a whole, presents an unreasonable risk or injury (as the statute requires) on merely a subset of individual uses, it could, for example,

determine that a chemical substance with 10 known uses does not present an unreasonable risk of injury based on an evaluation of a single one of those uses, with no further obligation to evaluate the remaining uses within the three-year statutory deadline. This is a strained reading of the commands to determine whether the chemical substance presents an unreasonable risk, under the conditions of use, and to complete that evaluation ''for a chemical substance'' within three years of initiation. See 15 U.S.C (b)(4)(G)(i).

Second, a major objective of the new law is to require EPA to systematically evaluate existing chemical substances to determine whether or not they present unreasonable risk, and, if necessary, regulate them based on the results of the evaluation. Given the large number of existing chemical substances, it would not be feasible to complete risk evaluations on any significant number of them if EPA were to continually need to re-evaluate chemical substances based on different subset of uses. Rather the law's purposes will be best fulfilled by judging in a comprehensive way whether a chemical substance, under the known, intended, and reasonably foreseen uses and other activities, presents an unreasonable risk; ensuring through regulation that it does not present an unreasonable risk, if necessary; and then presumptively being done with that chemical substance (pending re-prioritization for some unforeseen reason). Finally, EPA notes that, if the law is read as allowing EPA to select particular conditions of use, it provides no criteria for EPA to apply in making such a selection.

Given these considerations, the instruction in TSCA section 6(b)(4)(D) for the Agency to identify the conditions of use it expects to consider in a risk evaluation is best read as directing the Agency to identify the uses and other activities that it has determined constitute the conditions of use, not as a license to choose among conditions of use.

Concerns have been raised about EPA's ability to meet the statutory risk evaluation deadlines if all conditions of use must be considered. Concerns have also been raised about ensuring that EPA can act promptly to address any unreasonable risks identified for particular conditions of use. EPA acknowledges that this will be challenging but based on the procedures outlined in this proposal, expects it will be manageable. First, a use or other activity constitutes a condition of use under the definition only if EPA determines that it does. EPA has authority to exercise judgment in making its determination of whether a condition of use is known, intended, or reasonably foreseen. Moreover, in this proposed rule EPA proposes to ''lock down'' the conditions of use included in a risk evaluation at the time of scoping, by providing opportunity for comment on the scoping document and specifying that any objections to the draft scope document are waived if not raised during this process. It will not be practicable to meet the statutory deadlines if stakeholders are free to identify additional conditions of use later in the process—for example, on the proposed risk determination.

As explained elsewhere in this preamble, EPA also generally intends to initiate risk evaluation on a chemical substance only when EPA determines that sufficient reasonably available information exists to complete the evaluation, and when it has already identified all of the conditions of use. As also explained elsewhere in this preamble, under certain circumstances EPA may expedite an evaluation for a particular condition of use to move more rapidly to risk management under TSCA section 6(a).

Finally, the proposed rule provides that EPA will rely on a combination of information, accepted science policies (*e.g.,* defaults and uncertainty factors), models and screening methodologies in conducting risk evaluations, with considerations of evolving science and technology. It further provides that the balance of information, science policy decisions, models, and screening methodologies used in risk evaluation will be informed by the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluations, and by the extent to which the generation of additional information is warranted by the reduction in uncertainty that the information would afford in determining whether a chemical substance presents an unreasonable risk of injury to health or the environment.

In this regard, EPA is also proposing to require that the components of its risk evaluations will be ''fit for purpose.'' All conditions of use will not warrant the same level of evaluation, and EPA expects it may be able to reach conclusions without extensive or quantitative evaluations of risk. For example, lower-volume or less dispersive uses might receive less quantitative, data-driven evaluations than uses with more extensive or complicated exposure patterns. Consistent with EPA's current practice in conducting risk assessments, technically sound risk determinations can be made, consistent with the best available science, through a combination of different types of information and other approaches.

In sum, Congress intended to create obligations that EPA can actually meet, and EPA intends to conduct risk evaluations in a way that is manageable given the statutory deadlines.

3. Timelines and guidance regarding assessing risks of existing chemical substances. Prior to the amended TSCA, EPA was not required to evaluate or manage the risk of the thousands of existing chemical substances grandfathered in under the 1976 Act. As discussed previously, the amended TSCA affirmatively requires EPA to evaluate existing chemical substances more quickly, instructs EPA on how many of these chemical substances the Agency must evaluate at any given time, and places time limits on when these evaluations must be completed. 15 U.S.C. 2605(b)(2)–(4).

4. Determination of unreasonable risk. Under TSCA section 6(b) (15 U.S.C. 2605(b)(4)(B)), EPA must establish a risk evaluation process to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. Prior to the passage of the amended TSCA, chemical substance risk assessments did not include a determination of unreasonable risk. This step was reserved for risk management rulemaking. The amended statute now requires that a risk evaluation include a risk assessment as well as the EPA's determination of unreasonable risk, and, most significantly, requires that this determination be independent of cost or other non-risk factors. 15 U.S.C. 2506(b)(4)(A) and (F)(iii).

In general, EPA may weigh a variety of factors in determining unreasonable risk. These factors include, but are not limited to, characterization of cancer and non-cancer risks (including margins of exposure for non-cancer risks), the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard), the irreversibility of hazard, uncertainties, and estimates of cumulative exposure. Because of the case-by-case nature of each of these factors EPA has purposely not proposed a definition of unreasonable risk in this rule. However, EPA is specifically requesting comments on whether EPA should define unreasonable risk in the final rule. If so, acknowledging that the statute precludes consideration of costs and other non-risk factors at this step, what factors should EPA consider in making such a determination?

5. Manufacturer-requested evaluations and draft risk evaluations by interested persons. The newly

amended TSCA requires that a portion of ongoing risk evaluations be conducted on chemical substances requested by manufacturers ''in a form and manner and using criteria'' EPA prescribes by rule. 15 U.S.C. 2605(b)(4)(C)(ii),(E)(i). The statute also requires EPA to develop guidance (which will be forthcoming) to assist interested persons in submitting draft risk evaluations, and requires EPA to consider such submitted drafts. 15 U.S.C. 2625(l)(5).

D. Stakeholder Feedback

On August 9, 2016, EPA held a one-day public meeting to obtain public comment and feedback regarding the development and implementation of the risk evaluation rule. The meeting began with an explanation of how the Agency currently conducts risk assessments (see *https://www.epa.gov/sites/production/files/2016-08/documents/risk_evaluation_9_august_2016.pdf*). The remainder of the day was reserved for public comment. Each commenter was provided four minutes to comment and there was a total of 47 oral comments on the risk evaluation rule. Additionally, EPA opened a docket for submission of written comments and received 57 comments, many of which were from the same commenters at the public meeting. These comments, and a transcript of the meeting are accessible in the meeting's docket, identified by Docket ID No. EPA–HQ–OPPT–2016–0399, which is available online at *https://www.regulations.gov/*.

The commenters included industry, environmental groups, academics, private citizens, trade associations, and health care interest groups and representatives. The comments were very informative for both rule development and risk evaluation implementation. While not all of the comments are captured here, there were a number of themes that emerged. Overall, there was a general expression of support for the new law and EPA's inclusive approach to implementation. Many of the commenters agreed the rule has the potential to increase transparency in EPA's chemical substance risk evaluation process. Many urged the Agency to work towards this goal, while creating an open scientific dialogue.

Questions arose about how the Agency will determine ''unreasonable risk'' and implement TSCA section 26 requirements including ''best available science'' and ''weight of scientific evidence.'' Some suggested that EPA should codify in this rule the meaning of these terms along with other details of the risk evaluation process. Due to changes in the law, manufacturers are now able to submit their own draft risk evaluations. Commenters noted that if these submitted evaluations are to be equivalent as Agency draft risk evaluations, having specific criteria, such as specific types of exposure and hazard information would ensure the Agency and the manufacturers were held to the same standard. Stakeholders also suggested that holding a public comment period for the draft risk evaluation scope would increase the transparency of each risk evaluation early in the process and allow the public to comment on any data gaps or discrepancies.

Other stakeholders urged the Agency to reserve specific scientific processes regarding hazard and exposure information for Agency guidance and discretion, suggesting the rule should address only the process and procedure. This approach would allow the Agency to be flexible and adapt to the changing science of risk evaluation and the science that informs risk evaluation.

A number of commenters spoke about the statute's requirement that the Agency determine the specific risk to ''potentially exposed or susceptible subpopulation[s]''. Although the law defines this term to include ''infants, children, pregnant women, workers, or the elderly,'' many encouraged the Agency to consider expanding the definition to include for example: environmental justice communities, Arctic communities, American Indian communities, communities with little access to preventative health-care, subsistence fishers, and fence-line communities. There were a number of stakeholders who encouraged the Agency to work with the Occupational Safety & Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and the Consumer Product Safety Commission (CPSC), among other federal agencies, to better protect against occupational and consumer exposures. Also regarding exposure, stakeholders encouraged the examination of cumulative and low dose exposures in risk evaluations, which are not specifically mentioned in the new statute.

A number of commenters emphasized the need for EPA to maximize transparency throughout the evaluation process. The EPA received a number of comments about the science used to inform individual risk evaluations, including the types of data, models, policy assumptions (*e.g.,* default factors) and computational approaches. A number of commenters argued that a lack of data does not equate to a lack of risk. Stakeholders encouraged the Agency to engage with industry to obtain hazard and exposure data and to utilize the new order authority allowed under the law (TSCA section 4). Commenters suggested an increased use of EPA's Office of Research and Development (ORD) and internationally accepted data, models, and products. A number of stakeholders expressed their support for the new provision in the law that requires the Agency to reduce and replace vertebrate testing (TSCA section 4(h)) in obtaining chemical substance hazard and exposure data.

EPA considered all of these comments in the development of this proposed rule, and welcomes additional feedback from stakeholders on the proposed process and requirements presented in this document.

III. The Proposed Rule

A. Policy Objectives

The risk evaluation process under TSCA is ultimately how EPA will determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. The overall objective of this action is to propose to codify the process by which the Agency evaluates risk from chemical substances for purposes of TSCA section 6. In this proposed rule, the Agency details those components of TSCA risk evaluation and key factors that EPA deems are necessary to consider in each risk evaluation to ensure that the public has a full understanding of how risk evaluations will be conducted. However, EPA is not proposing to establish highly detailed provisions that will address every eventuality or possible consideration that might arise. Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.

B. Interagency Collaboration

EPA recognizes that other Federal agencies may be able to provide important use, exposure and hazard information that is likely to be relevant to a risk evaluation of chemical substances. EPA is committed to interagency engagement and dialogue throughout its risk evaluation process, including data sharing, information requests, and consultation regarding specific chemicals of interest. As such,

EPA has reached out to other agencies, inviting them to join the agency in an open and collaborative dialogue. EPA intends to continue and expand its interagency collaboration efforts for chemicals management and risk evaluations under TSCA.

To coordinate with other agencies on TSCA implementation generally, EPA intends to continue to use—and expand where appropriate—existing interagency groups, such as the OMNE (OSHA–MSHA–NIOSH–NIEHS–EPA) Committee and the National Science and Technology Council (NSTC)'s Committee on Environment, Natural Resources, and Sustainability's new Toxicity Assessment Committee. EPA is also committed to interagency engagement at the working level on individual chemical evaluations.

To ensure that such collaboration can occur in a timely manner when needed, EPA intends to initiate interagency consultation through the existing mechanisms early in the process, and document these measures in the scope document. However, EPA is concerned that imposing a single, pre-determined consultation step might lead to an overly bureaucratic process that could limit or complicate ongoing collaboration efforts, and so is not proposing to codify any particular process in this regulation.

C. Scope of Evaluations

TSCA requires risk evaluations to determine whether or not a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, with conditions of use being defined as ''the circumstances, as determined by the EPA, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.'' 15 U.S.C. 2602(4).

Although some of the commenters during the public meeting suggested that EPA could evaluate a specific use of a chemical substance, EPA is not choosing to adopt such an interpretation, for the reasons explained previously. Also, EPA recognizes that under certain circumstances it may be necessary to expedite an evaluation for a particular condition of use to move more rapidly to risk management under TSCA section 6(a) (15 U.S.C. 2605(a)): this could include a situation in which a single use presented an unreasonable risk of injury for the population as a whole or for a susceptible subpopulation (*e.g.,* one use results in risks that EPA would determine unreasonable regardless of the risk posed by other uses). However, in any case where EPA would find it necessary to pursue a risk evaluation in phases, the Agency will still complete the full risk evaluation on all identified conditions of use within the statutory 3-year deadline. Therefore, relying on this discretion, EPA is proposing to explicitly recognize its authority to complete risk evaluations in phases, and to manage unreasonable risks as they are identified through those phases under TSCA section 6(a) in the regulation.

D. Definitions

TSCA defines a number of key terms necessary for interpretation of the new law. The definitions within the law apply to this proposed rule. EPA has also included some additional definitions in the proposed rule for further clarification; these are noted and defined later in this document. The law requires EPA to evaluate risk to ''potentially exposed or susceptible subpopulation[s],'' and although the law elaborates on this phrase, EPA is proposing to expand the definition for TSCA purposes. TSCA states that ''the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.'' 15 U.S.C. 2602(12). EPA is proposing to incorporate the phrase ''including but not limited to'' before the specific subpopulations identified in the statutory definition, to further clarify that EPA may identify additional subpopulations, where warranted. As suggested by the statute, EPA is also proposing to include specific authorization for EPA to consider both intrinsic (*e.g.,* life stage, reproductive status, age, gender, genetic traits) and acquired (*e.g.,* pre-existing disease, geography, socioeconomic, cultural, workplace) factors when identifying this population.

TSCA section 26(k) (15 U.S.C. 2625(k)) states that in carrying out risk evaluations, EPA shall consider information that is ''reasonably available,'' but the statute does not further define this phrase. EPA is proposing a definition for ''reasonably available'' to mean existing information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. Generally speaking, EPA does not consider information that has not yet been generated, as reasonably available, because it will typically not be feasible for EPA to require significant chemical testing and receive and assess those test results during the three to three and a half year window allotted for risk evaluation. Accordingly, EPA intends to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation (indeed, prior to initiating prioritization). EPA also generally intends to use its authority under TSCA to require the development of new information, as necessary, prior to risk prioritization.

TSCA requires EPA, as a part of the risk evaluation, to document whether the Agency has considered aggregate or sentinel exposure, and the basis for that decision. 15 U.S.C. 2605(b)(4)(F)(ii). These terms are not defined in the law, so EPA has proposed a definition for aggregate exposure that is consistent with current Agency policies and practices. ''Aggregate exposure'' means the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (Ref. 20). ''Sentinel'' means the exposure(s) of greatest significance, which may be the maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof). Although sentinel exposure is not a novel way of characterizing exposure, this is a new term for EPA.

Other terms defined in the proposed rule are designed to provide clarity regarding the science that will be used to conduct an evaluation. ''Pathways'' of exposure refers to the mode through which one is exposed to a chemical substance, including but not limited to: food, water, soil, and air (Ref. 20). ''Routes'' of exposure refer to the particular manner which a chemical substance may contact the body, including absorption via ingestion, inhalation, or dermally (Ref. 20). The statute requires EPA to consider ''the extent to which the variability and uncertainty . . . are evaluated and characterized.'' 15 U.S.C. 2625(h). EPA is adopting definitions for both ''variability'' and ''uncertainty'' from existing Agency guidance. ''Uncertainty'' means the imperfect knowledge or lack of precise knowledge either for specific values of interest or in the description of a system (Ref. 21). ''Variability'' means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population (Ref. 21).

E. Timing of Risk Evaluations

As indicated, the statute requires EPA to complete risk evaluations within three years, with the possibility of a six month extension beyond the three year timeframe. This proposed rule simply adopts these timeframes without modification or elaboration. EPA acknowledges this is a relatively short timeframe, and, as discussed elsewhere in this preamble, is proposing to adopt other procedures that will allow the Agency to meet these deadlines.

F. Chemical Substances for Risk Evaluation

As identified previously, chemical substances that will undergo risk evaluation can be put into three groups: (1) The first ten chemical substances the Agency is required to identify within the first 180 calendar days of enacting the amendments to TSCA (15 U.S.C. 2605(b)(2)); (2) the chemical substances determined as High-Priority Substances through the prioritization process proposed in a separate rulemaking; and (3) requested chemical substances submitted by manufacturers that meet the criteria for EPA to conduct an Agency risk evaluation.

G. Process for Manufacturer Requested Risk Evaluations

TSCA allows a manufacturer or group of manufacturers to submit requests for Agency conducted risk evaluations for chemical substances that they manufacture. EPA is proposing the necessary components of the request in the proposed regulatory text. EPA is proposing to require that manufacturers demonstrate in their request that there is sufficient, reasonably available information for the Agency to conduct a risk evaluation on the chemical substance under the conditions of use. EPA must complete any manufacturer-requested risk evaluation that it determines meets the criteria within the statutory three years. Unlike those chemical substances that have come through the prioritization process, manufacturer-requested chemical substances have not undergone initial risk screening and therefore EPA will not assign such chemicals a high- or low-priority designation. The purpose of the requirements proposed as the necessary components of the request, is to allow the Agency to determine whether sufficient information is ''reasonably available'' for EPA to complete a risk evaluation of the requested chemical under the conditions of use, as that term is defined under TSCA section 3.

EPA is proposing to require a manufacturer to submit a list (*e.g.,* citations) of the reasonably available information on hazard and exposure for all the conditions of use. EPA is not requesting manufacturers submit copies of the cited information. Manufacturers must include a commitment to provide EPA any referenced data if they are not publicly available, and must certify that the information submitted is accurate and complete. EPA will not accept a manufacturer request where any of the relevant data is not in the possession of the requestor but is with another entity.

Consistent with TSCA section 6(b)(4)(E)(iii), EPA will prioritize requests where there is evidence that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and is therefore proposing to allow (but not require) manufacturers to include any evidence to support such a finding. Following this required initial prioritization, EPA is proposing to further prioritize chemical substances for risk evaluation based on initial estimates of exposure(s) and/or hazard(s) under one or more conditions of use or any other factor that EPA determines may be relevant. In general, EPA plans to prioritize those chemical substances where there is evidence of relatively high risk over those with less evidence of risk.

Instructions for submitting CBI are also included in the proposed rule. EPA believes that TSCA section 14(c)(3) is best read as requiring upfront substantiation of non-exempt CBI claims. In addition, EPA believes the obligation to review all non-exempt chemical identification claims and 25 percent of all other non-exempt claims will be best effectuated by requiring substantiation at the time of submission.

Chemical substances that EPA has prioritized through the prioritization process (proposed in a separate rulemaking), are subject to two separate public comment periods prior to the completion of the prioritization process. EPA expects that these comment periods will ensure that EPA has the necessary information to evaluate the chemical substances, including information on all conditions of use. Consequently, in order to ensure that chemical substances subject to manufacturer requests undergo risk evaluation only if the available information is comparable to what EPA will identify or generate through the measures identified in the proposed prioritization framework rule, EPA is proposing opportunities to collect additional information from the public.

Upon receipt of the request, EPA is proposing to verify that the request is facially valid, *i.e.,* that information has been submitted that is consistent with the regulatory requirements. EPA is proposing that within 30 business days of a receiving a facially valid request, EPA will submit for publication an announcement of the receipt of the request in the **Federal Register**, open a docket for the request, and provide no less than a 30 calendar day comment period, to allow the public to identify and/or submit any reasonably available information regarding hazard, exposure, potentially exposed population(s) and subpopulation(s), and conditions of use that may help inform a risk evaluation, including identifying information gaps. The requesting manufacturer may also submit any additional material during this time.

Within 9 months after the end of the comment period, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the regulatory criteria and will notify the manufacturer(s) accordingly. This time will allow EPA to develop the equivalent of a conceptual model to describe actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, or disposal. If EPA determines that the request is compliant (*i.e.,* it has the required information necessary for conducting a risk evaluation), EPA will begin the risk evaluation process consistent with TSCA section 6(b)(4)(E)(i). If the request is found insufficient EPA will identify the information that would be necessary to conduct the risk evaluation in its notification to the manufacturer. The manufacturer will have 60 calendar days from receipt of EPA's determination to submit the additional information. EPA will consider the request withdrawn if the manufacturer(s) fails to submit the additional information identified. The process for conducting the risk evaluation will otherwise be identical to the process for those chemical substance identified as a High-Priority Substance through the Prioritization Process, which is addressed in a separate proposed rule.

H. Risk Evaluation General Provisions

1. Agency guidance. EPA has a number of existing guidance documents that inform Agency risk assessment.

EPA has been using risk assessments to characterize the nature and magnitude of health risks to humans and ecological receptors from chemical contaminants and other stressors that may be present in the environment since its inception. Over the years, EPA has worked with the scientific community and other stakeholders to develop a variety of guidance, guidelines, methods and models for use in conducting different kinds of assessments. A compendium of existing Agency guidance related to risk assessments is maintained at *https://www.epa.gov/risk/risk-assessment-guidelines*. A compendium of guidance, databases and models used for assessing pesticide risks is available at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks*, and information about available predictive models and tools for assessing chemicals under TSCA can be found at *https://www.epa.gov/tsca-screening-tools*. Each of these Web sites identify and link to a number of written guidance documents, tools and models. Rather than starting anew, EPA intends to take advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program.

Since the law requires the development of additional ''policies, procedures, and guidance the Administrator determines are necessary'' to carry out the process in TSCA (15 U.S.C. 2625(l)). EPA may also develop additional guidance(s) for risk evaluation in the future.

2. Categories of chemical substances. TSCA provides EPA with authority to take action on categories of chemical substances: groups of chemical substances which are, for example, similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment. Although the proposed rule most often references ''chemical substances,'' EPA is also proposing to include a clear statement in the regulation that nothing in the proposed rule shall be construed as a limitation on EPA's authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can prioritize and evaluate categories of chemical substances.

3. Information and information sources. As discussed, the timeframe for completing risk evaluation is compressed. For those chemical substances chosen by EPA to undergo the risk evaluation process, EPA expects to only initiate the process when EPA has determined that most of the information necessary to complete the evaluation is reasonably available, which in most cases means the information already exists. As appropriate, however, EPA will exercise its TSCA information collection, testing, and subpoena authorities, including those under TSCA sections 4, 8, and 11(c) to develop the information needed for a risk evaluation. Pursuant to TSCA section 8(e), the law requires that any person who manufacturers, processes, or distributes in commerce a chemical substance or mixture and who obtains information which supports the conclusion that this substance presents a substantial risk of injury to health or the environment, shall immediately inform the Agency.

To conduct a risk evaluation, EPA will rely on a combination of information, models, screening methods, and accepted science policies, which include defaults, reasonable estimates, and uncertainty factors, in addition to considering information generated from evolving science and technology. EPA expects to obtain scientific advice from the Science Advisory Committee on Chemicals, which the Agency is required to develop and convene under TSCA section 26(o). In compliance with the statute, EPA will work to reduce and replace, to the extent practicable, the use of vertebrate animals in testing chemical substances as outlined in TSCA section 4(h).

I. Risk Evaluation Steps

1. Scope. The first step of a risk evaluation is the development of the scope. In compliance with the statute, the scope will identify the conditions of use, hazards, exposures, and any potentially exposed or susceptible subpopulations that the EPA expects to consider. EPA is also proposing to include additional information in the scoping document, including any models, screening methods, and any accepted science policies expected to be used during the risk evaluation. EPA is further proposing to include a conceptual model that will describe the actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, to release or disposal. Also included will be an analysis plan, which will identify the approaches and methods EPA plans to use to assess exposure, effects, and risk, including associated uncertainty and variability, as well as a strategy for approaching science policy decisions (*e.g.,* defaults or uncertainty factors).

The announced availability of the final scope will be published in the **Federal Register** within six months of the initiation of the risk evaluation. Although not required under the statute, EPA has proposed to provide a draft scope for a 45 calendar day public comment period during this six month period. EPA welcomes all public participation, but specifically encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. That said, EPA expects to use the comment periods during the prioritization process to reduce the likelihood of significant comments on the draft scope. Consequently, the proposed rule makes clear that all comments that could be raised on information and approaches presented in the scope must be presented during this comment period. Any issues related to scope not raised in comments at this time cannot form the basis for an objection or challenge in a future administrative or judicial proceeding. This is a well-established principle of administrative law and practice, see, *e.g.,* Nuclear Energy Institute v. EPA, 373 F.3d 1251, 1290–1291 (D.C. Cir. 2004), and the need for such a provision is reinforced by the statutory deadlines under which EPA must operate for completing TSCA risk evaluations. Note that EPA is not proposing to preclude parties from raising newly discovered information, or from raising issues that could not have been fairly raised during this comment period. Rather, EPA seeks merely to prevent parties from delaying the risk evaluation by withholding information or by providing it piecemeal.

2. Hazard assessment. In compliance with TSCA section 6(b)(4)(F), EPA is proposing that a hazard assessment be conducted on each chemical substance or category. A hazard assessment identifies the types of adverse health or environmental effects that can be caused by exposure to some agent in question, and to characterize the quality and weight of evidence supporting this identification. Hazard Identification is the process of determining whether exposure to a stressor can cause an increase in the incidence of specific adverse health or environmental effects (*e.g.,* cancer, developmental toxicity).

This hazard assessment may include, but may not be limited to, evaluation of the potential toxicity of the chemical substance with respect to cancer, mutation, reproductive, developmental, respiratory, immune, metabolic, and cardiovascular impacts, and

neurological impairments. The assessment will evaluate effects at life stage(s) most appropriate for a receptor target. The hazard assessment will consider the dose or concentration and resulting effect or response. Potential information sources that may support the health assessment include but are not limited to: Human epidemiological studies; *in vivo* and/or *in vitro* laboratory studies; mechanistic or kinetic studies in a variety of test systems, including but not limited to toxicokinetics and toxicodynamics, computational toxicology; data from structure-activity relationships, high-throughput assays, genomic response assays, and ecological field data. Specifically, for human health hazards, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope and use appropriate combination, if available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing health effects to the population, and any other relevant, scientifically valid information or methodology. In an environmental hazard assessment, the relationship between the chemical substance and the occurrence of an ecological response will be evaluated using field or laboratory data, modeling strategies, and species extrapolations.

Where possible, a hazard assessment also will include a dose-response assessment. A dose-response relationship describes how the likelihood and severity of adverse health effects (the responses) are related to the amount and condition of exposure to an agent (the dose provided). The same principles generally apply for studies where the exposure is to a concentration of the agent (*e.g.,* airborne concentrations applied in inhalation exposure studies or water or other media concentrations for ecological exposure studies), and the resulting information is referred to as the concentration-response.

3. Exposure assessment. Pursuant to TSCA section 6(b)(4)(F), EPA, where relevant, will take into account the likely duration, intensity, frequency, and number of exposures under the conditions of use in an exposure assessment. An exposure assessment includes some discussion of the size, nature, and types of individuals or populations exposed to the agent, as well as discussion of the uncertainties in this information. Exposure can be measured directly, but more commonly is estimated indirectly through consideration of measured concentrations in the environment, consideration of models of chemical transport and fate in the environment, and estimates of human intake or environmental exposure over time.

Using reasonably available information, exposures will be estimated (usually quantitatively) for the identified conditions of use. For human health exposure, the assessment would consider all potentially exposed or susceptible subpopulation(s) identified in the scope and utilize any combination, as available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing exposures to the population, measurements in human tissues or relevant environmental or exposure media, and any other relevant, scientifically valid information or methodology. In an environmental health exposure assessment, the interaction of the chemical substance with any ecological characteristics identified in the scope will be characterized and evaluated.

4. Risk characterization. TSCA requires that a risk evaluation ''integrate and assess available information on hazards and exposures''. (15 U.S.C 2605(b)(4)(F). A risk characterization conveys the risk assessor's judgment as to the nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made. Risk characterization takes place for both human health risk assessments and ecological risk assessments.

In practice, each component of the risk assessment (*e.g.* hazard assessment, dose-response assessment, exposure assessment) has an individual characterization written to carry forward the key findings, assumptions, limitations, and uncertainties. The set of these individual characterizations provide the information basis to write an integrative risk characterization analysis. The final, overall risk characterization thus consists of the individual component characterizations plus an integrative analysis.

Each risk evaluation will quantitatively and/or qualitatively estimate and characterize risk for the identified populations and ecological characteristics under the conditions of use. The risk characterization will also describe whether aggregate or sentinel exposures were considered and provide the evidence and information to support the consideration.

In the risk characterization, EPA will further carry out the obligations under TSCA section 26(h) (15 U.S.C 2625(h)); for example, by assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. EPA also may exercise it discretion to include a discussion of any alternative interpretation of results generated from the risk evaluation. For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

5. Peer review. For each risk evaluations conducted on chemicals identified pursuant to TSCA section 6(b)(4)(A), EPA will conduct peer reviews using the guidance provided in executive branch peer review directives included in the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin) (Ref. 22) and the guidance set forth in the EPA Peer Review Handbook (2015) (Ref. 23) or its updates.

The goal of the peer review process is to obtain independent review from experts who have not contributed to its development. According to EPA's peer review policy, peer review of all scientific and technical information that is intended to inform or support Agency decisions is encouraged and expected. Both the EPA Peer Review Handbook and the OMB Bulletin provide standards for when and how to conduct peer review on science documents. The documents do not contemplate that peer review is necessary for every document or risk assessment, but is expected to occur for those documents that have either:

- Influential scientific information: scientific information that the Agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions, or
- Highly influential scientific assessment: a subset of influential scientific information that could have a potential impact of more than $500 million in any year on either the public or private sector or is novel, controversial, or precedent-setting, or has significant interagency interest.

The EPA Peer Review Handbook, first released in 1998 and last updated in

2015, has also been instrumental in providing guidance on the methods for conducting peer review at the Agency for the past two decades. According to the Handbook the peer review approach can consist of internal or external reviewers and can range from a letter review, an *ad hoc* expert panel review, review of a journal manuscript by a referred scientific journal, review by an established Federal Advisory Committee (FAC), review by an Agency-appointed special board or commission, or review by the National Academy of Science. Given that this guidance reflects long-standing and well-accepted EPA practices on peer review, and given the public's familiarity with it, the Agency is proposing to continue to rely on that established guidance, rather than attempt to modify it or create some new methodology in this rulemaking. As discussed earlier in this proposal, EPA will identify aspects of the analysis on which peer review will be conducted, and the planned methodologies, as part of the draft scoping document that will undergo public comment for each chemical substance that undergoes risk evaluation. These may include novel models or analyses that warrant an in-depth peer review. In addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment will also undergo peer review, as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization which will form the basis of an unreasonable risk determination.

The peer review will address aspects of the science underlying the assessment, including, but not limited to hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. Please note, however, EPA will not seek review of any determination as to whether the risks are ''unreasonable'', which is an Agency policy judgement. The purpose of peer review is for independent review of the science underlying the risk assessment, not to evaluate EPA's policy judgments. TSCA expressly reserves to the Agency the final determination of whether risk posed by a chemical substance is ''unreasonable.'' 15 U.S.C 2605(i). EPA nevertheless will include its unreasonable risk judgment as part of the risk evaluation that is subject to public review and comment.

6. Unreasonable risk determination. The final step of a risk evaluation is for the EPA to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment. The EPA may find that the substance does not present an unreasonable risk of injury to health or the environment under the conditions of use. This will be issued by order, published in the **Federal Register**, and considered to be a final EPA action. Alternatively, the EPA may determine that the substance does present an unreasonable risk under one or more conditions of use, in which case EPA must, pursuant to TSCA section 6(a) (15 U.S.C. 2605(a)), impose requirements to the extent necessary so that the substance no longer presents such risk.

EPA will announce in the **Federal Register** the availability of and solicit public comment on the draft risk evaluation, including the unreasonable risk determination. All comments that could be raised on components of the draft risk evaluation must be presented during this comment period. Any issues not raised during this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

7. Additional publically available information. Pursuant to TSCA section 26(j), EPA will make available: (1) All notices, determinations, findings, consent agreements, and orders; (2) any information required to be provided by the EPA under 15 U.S.C. 2603; (3) a nontechnical summary of the risk evaluation; (4) a list of the studies with the results of the studies, considered in carrying out each risk evaluation; and (5) the final peer review report, including the response to peer review comments.

8. Reassessment of unreasonable risk determination. EPA may reassess a final unreasonable risk determination of a chemical substance at any time based on information available to the Agency.

IV. Request for Comments

While EPA is seeking public comment on all aspects of this proposed rule, there are areas where the Agency specifically requesting public input.

1. Redefining scientific terms. EPA received a number of stakeholder comments regarding EPA's approach to defining a number of important terms within this rule. These terms include ''best available science'', ''weight-of-the-evidence'', ''sufficiency of information'', ''unreasonable risk'', and ''reasonably available information'' among others. Many of the terms used in the proposed rule are not novel concepts and are already in use and the meaning of which is discussed extensively in existing Agency guidance. For example, extensive descriptions for the phrases ''best available science'', ''weight-of-the-evidence'', and ''sufficiency of information'' can be found in EPA's Risk Characterization Handbook (Ref. 24), and in other existing Agency guidance.

EPA believes further defining these and other terms in the proposed rule is unnecessary and ultimately problematic. These terms have and will continue to evolve with changing scientific methods and innovation. Codifying specific definitions for these phrases in this rule may inhibit the flexibility of the Agency to quickly adapt and implement changing science. The Agency intends to use existing guidance definitions and will update definitions and guidance as necessary.

However, the Agency welcomes public comments regarding the pros and cons of codifying these or other definitions and/or approaches for these or any other terms. EPA encourages commenters to suggest alternative definitions the Agency should consider for codification in this procedural rule. Please explain your views as clearly as possible, providing specific examples to illustrate your concerns and suggest alternate wording, where applicable. EPA is specifically requesting comments on whether EPA should define unreasonable risk in the final rule. If so, acknowledging that the statute precludes consideration of costs and other non-risk factors at this step, what factors should EPA consider in making such a determination.

2. Margin of exposure. EPA currently uses a margin-of-exposure (MOE) approach in risk characterization of TSCA risk assessments. Please comment on the strengths and weaknesses of the MOE approach. Are there other approaches (*e.g.* use of hazard indices, use of probabilistic risk assessment) that might better suit the TSCA Risk Evaluation Program? Are there other approaches that provide quantifiable non-cancer risks?

3. Systematic Review. While EPA has included a systematic review approach in the past, and intends to continue to do so, please comment on the need for regulatory text prescribing a specific systematic review approach for hazard identification, including the appropriateness of elements that might be included or concerns about codifying an approach.

4. *Manufacturer Requests.* EPA anticipates that some chemical substances prioritized for risk evaluation have been manufactured by persons who possess unpublished information that could impact the chemical's risk determination. For chemical substances prioritized for risk evaluation, the Agency generally expects to exercise, as needed, among

other authorities, its information-gathering authority pursuant to 15 U.S.C. 2607(a) and 2607(d), likely very early in the process. EPA is specifically requesting comment on approaches to utilizing its information gathering authorities to assure that EPA has the most complete information to make its risk determination. For example, one option might be to incorporate its 15 U.S.C. 2607(a) and 2607(d) authority into the ''Information and information sources'' section of this rule to allow EPA to require, by notice in the **Federal Register**, manufacturers with information subject to 15 U.S.C. 2607(a)(2) and 2607(d) to submit that information to EPA for use in a risk evaluation. EPA is requesting comment on this option and on any more effective alternative methods to exercise this authority within the rule to assure the completeness of the information relevant to the risk evaluation.

The Agency also anticipates the possibility that one manufacturer requests a risk evaluation but other manufacturers of the same chemical who have not joined in the request also possess relevant unpublished information. For manufacturer requests for risk evaluation, the burden is on the requester to include or reference all information that is necessary for EPA to conduct a risk evaluation. Although EPA could use its data collection authority to access information, including unpublished studies, held by entities other than the requestor, the Agency intends to deny requests for risk evaluation if the requester does not have access to the information necessary for risk evaluation.

5. *Peer Review.* As discussed in both the OMB Bulletin and the EPA Peer Review Handbook, there are specific exemption criteria for information that does not necessitate peer review, even if it might be considered to be influential or highly influential. A number of specific circumstances where peer review is not necessary are discussed in section 3.3 of the EPA Peer Review Handbook. Examples of these circumstances include information involving a health or safety issue where the Agency determines that the dissemination is time-sensitive or if an application of an adequately peer-reviewed work product does not depart significantly from its scientific or technical approach. In addition, EPA expects that there will be individual circumstances where a chemical substance is found to not present an unreasonable risk or that findings are similar or the same as other jurisdictions (states or countries) that have reached similar conclusions based on the same information, such that the Agency could determine that peer review is not necessary for that chemical risk evaluation.

EPA expects that many of the risk evaluations conducted under TSCA will necessitate peer review. In cases in which a chemical substance is determined to present an unreasonable risk, the Agency must promptly move to manage the risk, a circumstance that would typically qualify the assessment as ''influential scientific information'' under current guidance and practice. The Agency also expects that some risk evaluations would also be highly influential scientific assessments, *e.g.,* contain novel, controversial, or precedent-setting science with significant interagency interest. EPA also expects that peer review will be warranted in many cases where the Agency determines a chemical substance does not present an unreasonable risk. Aspects of the evaluation may qualify as influential scientific information or highly influential scientific assessment, and thus warrant peer review. Other circumstances where the Agency may determine that peer review is warranted could include circumstances where there are existing private sector standards suggesting concern for a given chemical substance, where existing state assessments differ from the EPA evaluation, or where the public has expressed general concern about the chemical substances effects.

As required under the amended TSCA, chemical substances must be prioritized as either low or high. Those categorized as high are subject to a risk evaluation, and those determined to be low are not. The bar for prioritizing a chemical as a low priority as required under the amended TSCA is fairly high. As such, EPA expects that, as an increasing number of chemical risk evaluations are completed, those chemical substances that present risk to human health or the environment will be managed accordingly, leaving an increasing number of chemicals that do not present an unreasonable risk. The Agency questions whether all future risk evaluations warrant peer review.

EPA is specifically requesting public comment on whether there are circumstances where conducting peer review may not be warranted. What circumstances might qualify, and whether the regulatory text should be adjusted to require EPA to make a case by case determination of whether and to what extent, consistent with the EPA Peer Review Handbook, peer review is warranted for the chemical substance undergoing a risk evaluation. In all cases, the rule would require that this determination, and any peer review activities that are conducted, be documented for each chemical evaluation, starting with the scope document.

6. Reliance on existing guidance and procedures for conducting risk evaluations. As discussed in Unit III.G.1., EPA intends to take advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program. Since each risk evaluation is based on the specific circumstances surrounding the chemical being assessed, EPA has not attempted to codify any specific guidance, method or model. EPA believes that this is necessary to ensure that there is flexibility to address potentially unique circumstances on a chemical basis. EPA is interested in your comments about this approach, and where there is any existing guidance that may be of particular interest for consideration in conducting these risk evaluations. Additionally, EPA asks if the current guidance documents are sufficient and whether there are additional guidance documents that should be relevant but may not be on the lists available on EPA's Web site (*https://www.epa.gov/risk/risk-assessment-guidelines*). Finally, should EPA consider requiring that a list of appropriate guidance documents be included on a case-by-case basis as part of the scoping document that undergoes public review and comment.

7. Interagency collaboration. As discussed in Unit III.B., EPA is committed to ensuring there is interagency engagement and dialogue throughout its risk evaluation process, and has chosen not the limit the potential interagency collaboration by proposing to codify any particular process. EPA is concerned that imposing a single, pre-determined consultation step might lead to an overly bureaucratic process that could limit or complicate ongoing collaboration efforts, and so is not proposing to codify any particular process in this regulation. However, EPA is requesting specific public comment on whether codifying this collaboration at a specific point in the regulation is necessary.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included

in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. USEPA. Information Collection Request (ICR) for the Proposed Rule: Procedures for Chemical Risk Evaluation Under TSCA. EPA ICR No.: 2559.01 and OMB No. 2070—[NEW].
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13. National Research Council. Phthalates and Cumulative Risk Assessment: The Tasks Ahead. National Academy Press. Washington, DC 2008. *http://www.nap.edu/catalog.php?record_id=12528*.
14. USEPA. Policy on Evaluating Health Risks to Children. 1995. *https://www.epa.gov/sites/production/files/2014-05/documents/1995_childrens_health_policy_statement.pdf*.
15. USEPA. Guidelines for Developmental Toxicity Risk Assessment. EPA/600/FR–91/001. Risk Assessment Forum. Washington, DC 1991. *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=23162*.
16. USEPA. Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children. Office of Policy, Economics and Innovation. Washington, DC 2006. *http://yosemite.epa.gov/ochp/ochpweb.nsf/content/ADPguide.htm/$File/EPA_ADP_Guide_508.pdf*.
17. USEPA. Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants. Final. EPA/630/P–03/003F. Risk Assessment Forum. Washington, DC 2005. *http://www.epa.gov/raf/publications/guidance-on-selecting-age-groups.htm*.
18. USEPA. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. EPA/630/R–03/003F. Risk Assessment Forum. Washington, DC 2005. *http://www.epa.gov/ttn/atw/childrens_supplement_final.pdf*.
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21. USEPA. Framework for Human Health Risk Assessment to Inform Decision Making. EPA/100/R–14/001. Office of the Science Advisor, Risk Assessment Forum. 2014. *https://archive.epa.gov/raf/web/pdf/hhra-framework-final-2014.pdf*.
22. Office of Management and Budget Final Information Quality Bulletin for Peer Review.
23. USEPA. Peer Review Handbook. 3rd ed. EPA/100/B–06/002. Science Policy Council. Washington, DC 2006. *https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015*.
24. Risk Characterization Handbook. Science Policy Council Handbook: Risk Characterization, EPA 100–B–00–002, Washington, DC December 2000. *https://www.epa.gov/risk/risk-characterization-handbook*.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket.

B. Paperwork Reduction Act (PRA)

The information collection activities associated with this proposed rule have been submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq.* Specifically, EPA has prepared an ICR to estimate the potential burden and costs associated with the proposed requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. The ICR, which is available in the docket, has been assigned the EPA ICR number 2559.01. You can find a copy of the ICR in the docket for this proposed rule (Ref. 1), and it is briefly summarized here.

Respondents/affected entities: Manufacturers (including importers).

Respondent's obligation to respond: Optional, *i.e.,* needed only if they are requesting an EPA-conducted risk evaluation for a particular chemical substance.

Estimated number of respondents: 10.

Frequency of response: On occasion.

Total estimated annual burden: 960.3 hours. Burden is defined in 5 CFR 1320.3(b).

Total estimated annual cost: $69,353 for burden hours. There are no M&O costs.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of

Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 calendar days after receipt, OMB must receive comments no later than February 21, 2017. Any ICR-related comments will be addressed with the final rule.

C. Regulatory Flexibility Act (RFA)

EPA certifies under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* that this action will not have a significant economic impact on a substantial number of small entities. Although this proposed rule primarily addresses internal EPA procedures and activities associated with conducting risk evaluations for chemical substances as required by TSCA, EPA is also proposing the process and content requirements for a manufacturer (including importer) to request that EPA conduct a risk evaluation on a particular chemical substance. EPA has determined that the process and content requirements proposed will have minimal impact on an entity, regardless of size, because there is no mandate for them to make such a request, and the information they must provide should they decide to make such a request, which involves basic information about the chemical substance and the manufacturer's reasons for requesting the EPA-conducted risk evaluation on that chemical substance, should be readily available to the manufacturer. Estimated potential burden and costs are presented in the ICR (Ref. 1).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not establish an environmental health or safety standard, and is therefore not is not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This is procedural rule that will not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 702

Environmental protection, Chemicals, Chemical Substance, Hazardous substances, Health and safety, Risk Evaluation.

Dated: January 12, 2017,

Gina McCarthy,

Administrator.

Therefore, it is proposed that 40 CFR chapter I, subchapter R, be amended as follows:

PART 702—GENERAL PRACTICES AND PROCEDURES

■ 1. The authority citation for part 702 is revised to read as follows:

Authority: 15 U.S.C. 2605 and 2619.

■ 2. Add subpart B to part 702 to read as follows:

Subpart B—Procedures for Chemical Substance Risk Evaluations

Sec.

§ 702.31 General provisions.

(a) *Purpose.* This subpart establishes the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B) (15 U.S.C. 2605(b)(4)(B)).

(b) *Scope.* These regulations establish the general procedures, key definitions, and timelines EPA will use in a risk evaluation conducted pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(c) *Applicability.* The requirements of this part apply to all chemical substance risk evaluations initiated pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(d) *Enforcement.* Submission to EPA of inaccurate, incomplete, or misleading information by a manufacturer pursuant to a risk evaluation conducted pursuant to 15 U.S.C. 2605(b)(4)(B) is a prohibited act under 15 U.S.C. 2614, subject to penalties under 15 U.S.C. 2615 and Title 18 of the U.S. Code.

§ 702.33 Definitions.

All definitions in TSCA apply to this subpart. In addition the following definitions apply:

Act means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*).

Aggregate exposure means the combined exposures to an individual

from a single chemical substance across multiple routes and across multiple pathways.

EPA means the U.S. Environmental Protection Agency.

Pathways means the mode through which one is exposed to a chemical substance, including but not limited to: Food, water, soil, and air.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Agency who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, including but not limited to, infants, children, pregnant women, workers, or the elderly. EPA may identify a susceptible subpopulation in an individual risk evaluation upon consideration of various intrinsic (*e.g.,* life stage, reproductive status, age, gender, genetic traits) or acquired (*e.g.,* pre-existing disease, geography, workplace) characteristics that may affect exposure or modify the risk of illness or disease.

Reasonably available information means existing information that EPA possesses or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation.

Routes means the particular manner which a chemical substance may contact the body, including absorption via ingestion, inhalation, or dermally (integument).

Sentinel exposure means the exposure(s) of greatest significance, which may be the plausible maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof).

Uncertainty means the imperfect knowledge or lack of precise knowledge either for specific values of interest or in the description of a system.

Variability means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population.

§ 702.35 Chemical substances designated for risk evaluation.

(a) *Chemical Substances Undergoing Risk Evaluation.* A risk evaluation for a chemical substance designated by the Agency as a High-Priority Substance pursuant to the prioritization process described in subpart A, identified under 15 U.S.C. 2605(b)(2)(A), or initiated at the request of a manufacturer or manufacturers under 40 CFR 702.37, will be conducted in accordance with this part, except that risk evaluations that are initiated prior to the effective date of this rule will be conducted in accordance with this part to the maximum extent practicable.

(b) *Percentage Requirements.* The Agency will ensure that, of the number of chemical substances that undergo risk evaluation under 15 U.S.C. 2605(b)(4)(C)(i), the number of chemical substances undergoing risk evaluation under 15 U.S.C. 2605(b)(4)(C)(ii) is not less than 25%, if sufficient requests that comply with 40 CFR 702.37 are made by manufacturers, and not more than 50%.

(c) *Manufacturer Requests for Work Plan Chemical Substances.* Manufacturer requests for risk evaluations, described in 40 CFR 702.35(a), for chemical substances that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or its relevant and applicable successor document will be granted at the discretion of the Agency. Such evaluations are not subject to the percentage requirements in 40 CFR 702.35(b).

§ 702.37 Submission of manufacturer requests for risk evaluations.

(a) *General Provision.* Any request for EPA to conduct a risk evaluation on a chemical substance pursuant to this part must comply with all the procedures and criteria in this section to be eligible to be granted by EPA. A request will meet EPA's criteria if the request includes or references all the information that is necessary for EPA to conduct a risk evaluation addressing all the circumstances that constitute conditions of use of the chemical substance within the meaning of TSCA section 3 (*i.e.,* all circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of).

(b) *Method for Submission.* One or more manufacturers of a chemical substance can request that EPA conduct a risk evaluation on the chemical substance by providing all the following information:

(1) Name, mailing address, and contact information of the entity (or entities) submitting the request. If more than one manufacturer submits the request, all individual manufacturers must provide their contact information.

(2) Full information on the chemical identity of the chemical substance that is the subject of the request. At a minimum, this includes, all known names of the chemical substance, including common or trades names, chemical identity, CAS number, and molecular structure of the chemical substance.

(3) A complete list of the reasonably available information that is consistent with the standards in TSCA section 26(h) and that is relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing all the circumstances that constitute conditions of use of the chemical substance within the meaning of TSCA section 3 (*i.e.,* all circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of). The request need not include copies of the information; citations are sufficient. The request must include or reference all reasonably available information on the health and environment hazard(s) of the chemical substance, health and environmental exposure(s), and exposed population(s). At a minimum this must include information relevant to the following:

(i) The chemical substance's hazard and exposure potential;

(ii) The chemical substance's persistence and bioaccumulation;

(iii) Potentially exposed or susceptible subpopulations they believe to be relevant and that EPA should evaluate in the risk evaluation;

(iv) Whether there is any storage of the chemical substance near significant sources of drinking water;

(v) The chemical substance's conditions of use or significant changes in conditions of use;

(vi) The chemical substance's production volume or significant changes in production volume; and

(vii) Any other information relevant to the risks potentially presented by the chemical substance.

(4) The request must include a commitment to provide to EPA any referenced information upon request. In addition, if the manufacturer previously conducted its own risk assessment of the chemical substance, or possesses or can reasonably obtain any other pre-existing risk assessment, the request must include a commitment to provide such assessments to EPA upon request.

(5) A signed certification that all information contained in the request is accurate and complete, as follows:

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of

my knowledge is, true, accurate, and complete and I have not withheld any relevant information. I am aware there are significant penalties for submitting incomplete, false and/or misleading information, including the possibility of fine and imprisonment for knowing violations.

(c) *Optional Elements.* A manufacturer may provide evidence to demonstrate that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and that as a consequence the request is entitled to preference pursuant to 15 U.S.C. 2605(b)(4)(E)(iii).

(d) *Confidential Business Information.* (1) Persons submitting a request under this subpart are subject to EPA confidentiality regulations at 40 CFR part 2, subpart B.

(2) In submitting a claim of confidentiality, a person must certify the truth of the following statements concerning all information claimed as confidential:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(3) Each claim of confidentiality, other than a claim pertaining to information described in TSCA section 14(c)(2), must be accompanied by a substantiation in accordance with 40 CFR 2.204(e)(4).

(4) Manufacturers must supply a structurally descriptive generic name where specific chemical identity is claimed as CBI.

(5) Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

(e) *EPA Process for Evaluating Manufacturer Requests.* (1) *Review for completeness.* Upon receipt of the request, EPA will verify that the request is facially valid, *i.e.,* that information has been submitted that is consistent with the requirements in 40 CFR 702.37(b) through (d). EPA will inform the submitting manufacturer(s) if EPA has determined that the request is incomplete and cannot be processed. Complete requests will be processed as described in this subpart.

(2) *Public notice and comment.* Within 30 business days of receiving a request that EPA has determined to be valid under paragraph (e)(1) of this section, EPA will submit for publication the receipt of the request in the **Federal Register**, open a docket for that request and provide no less than a 30 calendar day public comment period, during which time the public may submit comments and information relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. In particular, comments identifying any information gaps in the request (*e.g.,* any conditions of use not identified in the request).

(3) *Supplementation of original request.* (i) At any time prior to the end of the comment period, manufacturer(s) may supplement the original request with any new information it receives/obtains.

(ii) At any point prior to the completion of a risk evaluation conducted on a chemical substance at the request of a manufacturer(s), manufacturer(s) are required to supplement the original request upon receipt of information that meets the criteria in 15 U.S.C. 2607(e) and 40 CFR 702.37, or other information that has the potential to change EPA's evaluation of the risk of the chemical substance. Such information must be submitted within 30 calendar days of discovery.

(4) *EPA determination.* Within 9 months of the end of the comment period provided in paragraph (e)(2) of this section, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the criteria and requirements of 40 CFR 702.37. EPA will notify the submitting manufacturer(s) of its determination.

(i) *Request is lacking required information.* (A) The manufacturer(s) have 60 calendar days from receipt of EPA's determination to submit any additional information identified as lacking in the notification.

(B) Failure to submit the additional information will be considered to be a withdrawal of the request to initiate a risk evaluation on the named chemical substance.

(C) Notwithstanding any such withdrawal, manufacturer(s) may submit a subsequent request on the same chemical substance.

(ii) *Compliant request.* EPA will initiate a risk evaluation for all requests for non-TSCA Work Plan Chemicals that meet the criteria in this subpart, until EPA determines that the number of manufacturer-requested chemical substances undergoing risk evaluation is equal to 25% of the High-Priority Substances identified in subpart A as undergoing risk evaluation. Once that level has been reached, EPA will initiate one new manufacturer-requested risk evaluation for each manufacturer-requested risk evaluation completed, as needed to ensure that the number of manufacturer-requested risk evaluations is equal to at least 25% of the High-Priority substances risk evaluation.

(5) *Preferences.* In conformance with 40 CFR 702.35(c), in evaluating requests for TSCA Work Plan Chemicals and requests for non-TSCA Work Plan chemicals in excess of the 25% threshold in paragraph (e)(4)(ii) of this section, EPA will give preference to requests for risk evaluations on chemical substances:

(i) That demonstrate that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce, health or the environment.

(ii) EPA will also give preference to requests where EPA has determined there are relatively high estimates of hazard and/or exposure for the chemical substance.

(iii) Any other factor EPA determines to be relevant.

(6) *Conditions of use considered.* EPA will conduct the risk evaluation on all of the conditions of use of a chemical substance undergoing risk evaluation at the request of a manufacturer, as determined through the scoping process outlined in 40 CFR 702.39(c).

(7) *No preferential treatment.* EPA will not expedite or otherwise provide special treatment to a risk evaluation conducted as a result of a manufacturer request.

(f) *Fees.* Manufacturers must pay fees to support risk evaluations under 15 U.S.C. 2605(b)(4)(C)(ii).

§ 702.39 Evaluation Requirements and Peer Review Procedures.

(a) *Considerations.* (1) Each risk evaluation will include the following components: a Scope, including a Conceptual Model and an Analysis Plan; a Hazard Assessment; an Exposure Assessment; a Risk Characterization; and a Risk Determination.

(2) Existing EPA guidance, where available and relevant, will be used in conducting the risk evaluation. In addition, other scientifically relevant methods or guidance may be used in a risk evaluation.

(3) Where appropriate, a risk evaluation may be conducted on a category of chemical substances. EPA will determine whether to conduct an evaluation on a category of chemical substances, and the composition of the category based on the considerations listed in 15 U.S.C. 2625(c). In addition to the factors specifically enumerated in that provision, EPA may consider the hazards and exposures associated with the category of chemical substances, and the populations likely to be exposed.

(4) EPA will ensure that all supporting analyses and components of the risk evaluation are suitable for their intended purpose, and well-tailored to the problems and decision at hand, in order to inform the development of a technically sound determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment, based on the weight of the scientific evidence.

(5) The extent to which EPA will refine its evaluations for particular conditions of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. To the extent a determination as to the level of risk presented by a condition of use can be made, for example, by the use of accepted science policies (*e.g.,* defaults assumptions or uncertainty factors), and models or screening methodologies, EPA may determine that no further information or analysis is needed to complete its risk evaluation of the use(s).

(6) EPA may conduct a risk evaluation on a chemical substance in phases to allow the Agency to proceed with risk management on particular conditions of use. For example, EPA may determine that a chemical substance presents an unreasonable risk of injury to health or the environment under one or more conditions of use, and address such unreasonable risk through rulemaking under TSCA section 6(a), while other conditions of use remain under evaluation. In all cases in which EPA conducts its risk evaluations in phases, EPA will nevertheless complete a full risk evaluation of the chemical substance for all of the conditions of use identified through the scoping process in 40 CFR 702.39(c) within the time frame in 40 CFR 702.43(d).

(7) In evaluating chemical substances that are metals or metal compounds, EPA will use the *Framework for Metals Assessment of the Office of the Science Advisor, Risk Assessment Forum* dated March 2007, or a successor document that addresses metal risk assessment and is peer reviewed by the Science Advisory Board.

(b) *Information and information sources.* (1) EPA will base each risk evaluation on reasonably available information.

(2) EPA generally expects to initiate a risk evaluation for a chemical substance only when EPA believes that all or most of the information necessary to perform the risk evaluation already exists and is reasonably available. EPA expects to use its authorities under the Act, and other information gathering authorities, when necessary to generate the information needed to perform a risk evaluation for a chemical substance before initiating the risk evaluation for such substance. EPA will use such authorities on a case-by-case basis during the performance of a risk evaluation to obtain or generate information as needed to ensure that EPA has adequate, reasonably available information to perform the evaluation.

(3) Among other sources of information, the Agency will consider information and advice provided by the Science Advisory Committee on Chemicals established pursuant to 15 U.S.C. 2625.

(4) In conducting risk evaluations, EPA will rely on an appropriate combination of information, accepted science policies (*e.g.,* defaults and uncertainty factors), models and screening methodologies. The balance of information, accepted science policies models, and screening methodologies used in risk evaluation will be informed by the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluations. It will also be informed by consideration of the extent to which additional information would reduce the uncertainty in determining whether a chemical substance presents an unreasonable risk of injury to health or the environment.

(5) Where appropriate, to the extent practicable, and scientifically justified, EPA will use information generated without the use of testing on vertebrates in performing risk evaluation.

(c) *Scope of the risk evaluation.* EPA will determine the scope of the risk evaluation to be conducted for each chemical substance based on all of the following:

(1) EPA will identify those uses that constitute the conditions of use that will be assessed during the risk evaluation. Those uses shall be all circumstances under which the Agency determines that the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

(2) When determining the scope, EPA will identify the exposed individuals and populations, including any potentially exposed or susceptible subpopulations as identified by the Agency that EPA plans to evaluate; the ecological characteristics that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.

(3) The combination of reasonably available information, accepted science policies (*e.g.,* defaults and uncertainty factors), models, and screening methodologies that EPA plans to use in the risk evaluation will be documented.

(4) *Conceptual model.* (i) The scope documents will include a Conceptual Model that describes actual or predicted relationships between the chemical substance and human and environmental receptors.

(ii) The Conceptual Model will identify human and ecological health endpoints the EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.

(iii) Conceptual Model development will consider the life cycle of the chemical substance, including manufacture, processing, distribution in commerce, storage, use, and disposal.

(5) *Analysis plan.* (i) The scope documents will include an analysis plan that identifies the approaches, methods, and/or metrics that the EPA plans to use to assess exposures, effects, and risk, including associated uncertainty and variability for each risk evaluation. The analysis plan will also identify the strategy for using information, accepted science policies, models, and screening methodologies.

(ii) Hypotheses about the relationships described in the conceptual model will be described. The relative strengths of (any) competing hypotheses will be evaluated to determine the appropriate risk assessment approaches.

(6) *Developing the Scope.* (i) *Draft scope.* For each risk evaluation to be conducted EPA will publish a document in the **Federal Register** that specifies the draft scope of the risk evaluation the Agency plans to conduct. The document will address the elements in paragraphs (c)(1) through (5) of this section.

(ii) *Timeframes.* EPA generally expects to publish the draft scope no later than 3 months from the initiation of the risk evaluation process for the chemical substance, and to allow a period of 30 calendar days during which interested persons may submit comment on EPA's draft risk evaluation scope. EPA will open a docket to facilitate receipt of public comments.

(iii) *Public comments.* All comments that could be raised on the matters addressed and issues presented in the

published risk evaluation scope document must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

(iv) *Final scope.* (A) The Agency will, no later than 6 months after the initiation of a risk evaluation, publish a document in the **Federal Register** that specifies the final scope of the risk evaluation the Agency plans to conduct. The document shall address the elements in paragraphs (c)(1) through (5) of this section.

(B) For a chemical substance designated as a High-Priority Substance under 40 CFR part 702 subpart A, EPA will not publish the final scope of the risk evaluation until at least 12 months have elapsed from the initiation of the prioritization process for the chemical substance.

(d) *Hazard assessment.* (1) The hazard information relevant to the chemical substance will be evaluated using endpoints identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section, for the identified exposure scenarios, including any identified potentially exposed or susceptible subpopulation(s).

(2) The hazard assessment process will identify the types of hazards to health or the environment posed by the chemical substance. This process includes the identification, evaluation, and synthesis of information to describe the potential health effects of the chemical substance.

(3) Based on the final scope document published pursuant to paragraph (c)(6)(iv) of this section, potential human and environmental hazard endpoints will be evaluated, including, as appropriate; acute, subchronic, and chronic effects during various stages of reproduction or life stage.

(4) The relationship between the dose of the chemical substance and the occurrence of human and environmental health effects or outcomes will be evaluated.

(5) Studies evaluated may include, but would not be limited to: Human epidemiological studies, in vivo and/or in vitro laboratory studies, mechanistic or kinetic studies in a variety of test systems, including but not limited to toxicokinetics and toxicodynamics, computational toxicology, data from structure-activity relationships, high-throughput assays, genomic response assays, and ecological field data.

(6) Hazard identification will include an evaluation of the strengths and limitations of the reasonably available information.

(7) *Human health hazard assessment.* The hazard assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section. Reasonably available information used to characterize risk to susceptible subpopulation(s) may include, but may not be limited to:

(i) Population-based epidemiology studies that identify risk factors and susceptible subpopulations;

(ii) Information related to geographic location of subpopulations;

(iii) Models that represent health effects of relevant subpopulations; and

(iv) Any other relevant, scientifically valid information, methodology, or extrapolation.

(8) *Environmental health hazard assessment.* The relationship between the chemical substance and the occurrence of an ecological hazard elicited will be evaluated using reasonably available information including but not limited to: Field or laboratory measurements, modeling strategies, extrapolations or incident data.

(e) *Exposure assessment.* (1) Where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use will be considered.

(2) For the conditions of use, exposures will be evaluated using reasonably available information.

(3) Chemical-specific factors including, but not limited to: Physical-chemical properties and environmental fate parameters will be examined.

(4) *Human health exposure assessment.* The exposure assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section. Reasonably available information used to characterize exposure to susceptible subpopulation(s) may include:

(i) Population-based epidemiology studies that identify risk factors and susceptible subpopulations;

(ii) Information related to geographic location of subpopulations;

(iii) Models that represent exposure or health effects of relevant subpopulations; and

(iv) Any other relevant, scientifically valid information or methodology.

(5) *Environmental health exposure assessment.* (i) The environmental health exposure assessment will characterize and evaluate the interaction of the chemical substance with the ecological characteristics identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section.

(ii) Exposures considered will include individuals as well as communities, depending on the chemical substance and the ecological characteristic involved.

§ 702.41 Risk characterization and peer review procedures.

(a) *Risk Characterization Considerations.* EPA will: (1) Integrate the hazard and exposure assessments into quantitative and/or qualitative estimates of risk for the identified populations (including any potentially exposed or susceptible subpopulation(s) identified in the final scope document published pursuant to 40 CFR 703.39(c)(6)(iv) and ecological characteristics for the conditions of use; and

(2) Describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for that consideration.

(b) The Risk Characterization will summarize, as applicable, the considerations addressed throughout the evaluation components, in carrying out the obligations under 15 U.S.C. 2625(h). This summary will include, as appropriate, a discussion of:

(1) *Considerations regarding uncertainty and variability.* Information about uncertainty and variability in each step of the risk evaluation (*e.g.,* use of default assumptions, scenarios, choice of models and information used for quantitative analysis) will be integrated into an overall characterization and/or analysis of the impact of the uncertainty and variability on estimated risks. EPA may describe the uncertainty using a qualitative assessment of the overall strength and limitations of the data used in the assessment.

(2) *Considerations of data quality.* A discussion of issues associated with data quality (*e.g.,* reliability, relevance, and whether methods employed to generate the information are reasonable for and consistent with the intended use of the information), as well as assumptions used, will be included to the extent necessary. EPA also expects to include a discussion of the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models used in the risk evaluation.

(3) *Considerations of alternative interpretations.* If appropriate and

relevant, a discussion of alternative interpretations of the data and analyses will be included.

(4) *Considerations for environmental risk evaluations.* For environmental risk evaluations, it may be necessary to discuss the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

(c) *Peer Review.* The *EPA Peer Review Handbook* (2015), the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin), or other available, relevant and applicable methods consistent with 15 U.S.C. 2625, will serve as the guidance for peer review activities. Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A).

§ 702.43 Unreasonable risk determination.

The EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use as identified in the final scope document published pursuant to 40 CFR 702.39(c)(6)(iv).

§ 702.45 Risk evaluation timeframes and actions.

(a) *Draft risk evaluation timeframe.* The EPA will publish a draft risk evaluation in the **Federal Register** and provide no less than a 30-day comment period, during which time the public may submit comment on EPA's draft risk evaluation.

(1) EPA will open a docket to facilitate receipt of public comment.

(2) All comments that could be raised on the matters addressed and issues presented in the draft risk evaluation must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

(b) *Final risk evaluation.* (1) EPA will complete a risk evaluation for the chemical substance as soon as practicable, but not later than 3 years after the date on which the Agency initiates the risk evaluation.

(2) The Agency may extend the deadline for a risk evaluation for not more than 6 months.

(3) EPA will publish the final risk evaluation in the **Federal Register**.

(c) *Final determination of unreasonable risk.* Upon determination by the EPA that a chemical substance does present an unreasonable risk of injury to health or the environment, the Agency will initiate action as required pursuant to 15 U.S.C. 2605(a).

(d) *Final determination of no unreasonable risk.* A determination by the EPA that the chemical substance does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final EPA action, effective on the date of issuance of the order.

(c) *Reassessment.* EPA may reassess an unreasonable risk determination based on a review of available information.

§ 702.47 Publically available information.

For each risk evaluation, EPA will maintain a public docket at *http://www.regulations.gov* to provide public access to the following information, as applicable for that risk evaluation:

(1) The draft scope, final scope, draft risk evaluation, and final risk evaluation;

(2) All notices, determinations, findings, consent agreements, and orders;

(3) Any information required to be provided to the Agency under 15 U.S.C. 2603;

(4) A nontechnical summary of the risk evaluation;

(5) A list of the studies, with the results of the studies, considered in carrying out each risk evaluation;

(6) The final peer review report, including the response to peer review comments; and

(7) Response documents to the public comments on the draft risk evaluation.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2016–0231; FRL–9958–57]

RIN 2070–AK07

Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Methylene chloride, also called dichloromethane, is a volatile chemical that has a variety of uses, including paint and coating removal. N-methylpyrrolidone (NMP) is a solvent used in a variety of applications, including paint and coating removal. For each of these chemicals, EPA has identified risks of concern associated with their use in paint and coating removal. EPA proposes a determination that these are unreasonable risks. EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for consumer and most types of commercial paint and coating removal under section 6 of the Toxic Substances Control Act (TSCA). EPA is also proposing to prohibit the use of methylene chloride in these commercial uses; to require manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require recordkeeping. EPA is proposing an initial ten-year time-limited exemption from these proposed regulations on methylene chloride for coating removal uses critical for national security. First, EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal; to prohibit the use of NMP for all commercial paint and coating removal; to require, consistent with methylene chloride restrictions, downstream notification of these prohibitions throughout the supply chain; to require recordkeeping; and to provide a time-limited exemption from these proposed regulations on NMP for coating removal uses critical for national security. For NMP, as an alternate proposal, EPA is proposing that (1) commercial users of NMP for paint and coating removal establish a worker protection program for dermal and respiratory protection and not use paint and coating removal products that contain greater than 35 percent NMP by weight (except for product formulations destined to be used by DoD or its contractors performing work only for DOD projects); and (2) processors of products containing NMP for paint and coating removal reformulate products such that these products do not exceed a maximum of 35 percent NMP by weight, identify gloves that provide effective protection for the formulation, and provide warning and instruction labels on the products.

DATES: Comments must be received on or before April 19, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0231, at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods (*e.g.,* mail or hand delivery), the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

Docket. Docket number EPA–HQ–OPPT–2016–0231 contains supporting information used in developing the proposed rule, comments on the proposed rule, and additional supporting information. A public version of the docket is available for inspection and copying between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding federal holidays, at the U.S. Environmental Protection Agency, EPA Docket Center Reading Room, WJC West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Ana Corado, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number 202–564–0140; email address: *corado.ana@epa.gov*. *For other information contact:* Niva Kramek, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: 202–564–4830; email address: *kramek.niva@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may potentially be affected by this proposed action if you manufacture (defined under Toxic Substances Control Act (TSCA) to include import), process, distribute in commerce, or use methylene chloride or NMP for paint and coating removal. Paint and coating removal, also referred to as paint stripping, is the process of removing paint or other coatings from a surface. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Chemical and Allied Products Manufacturers (NAICS code 32411).
- Ship building and repairing (NAICS code 336611)
- Aircraft manufacturing (NAICS code 336411)
- Museums (NAICS code 712110)
- Independent Artists, Writers, and Performers (NAICS code 711510)
- Reupholster and furniture repair (NAICS code 811420)
- Automotive body, paint, and interior repair and maintenance (NAICS code 811121)
- Flooring contractors (NAICS code 238330)
- Painting and wall covering contractors (NAICS code 238320)

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final TSCA section 6(a) rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR

12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) (15 U.S.C. 2625(l)(4)) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6. Methylene chloride and NMP are such chemical substances (Ref. 1). They are listed in the 2014 update to the TSCA Work Plan and the completed risk assessments were published in 2014 and 2015, respectively. The scope of each completed risk assessment includes consumer and commercial paint and coating removal.

C. What action is the Agency taking?

EPA proposes a determination that the uses of methylene chloride or NMP in paint and coating removal present an unreasonable risk of injury to health. Accordingly, for methylene chloride, EPA is proposing under section 6 of TSCA to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer and for most types of commercial paint and coating removal uses. EPA is also proposing under TSCA section 6 to prohibit the use of methylene chloride for commercial paint and coating removal in the specified sectors, which include painting and decorating, floor refinishing, automotive refinishing, civilian aircraft refinishing, graffiti removal, renovations and contracting, bridge repair and repainting, and marine craft refinishing and repair. EPA is not proposing at this time to regulate the use of methylene chloride in commercial furniture refinishing, also referred to as furniture stripping or refinishing conducted by professionals or commercial workers. EPA is also proposing to exempt certain uses of methylene chloride for coating removal that EPA proposes are critical for national security.

EPA is also proposing to require that any paint or coating removal products containing methylene chloride that continue to be distributed be packaged in containers with a volume no less than 55 gallons, except for formulations specifically manufactured for the Department of Defense, which may be distributed in containers with volumes no less than 5 gallons. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of these requirements and prohibitions throughout the supply chain; and to require limited recordkeeping. More details on this supply chain approach are in Unit VI.C.3.

EPA intends to issue a separate proposal on methylene chloride in paint and coating removal in commercial furniture refinishing, but plans to issue one final rule covering both this proposal and the future proposed rule on methylene chloride in paint and coating removal in commercial furniture refinishing. More information on such a future proposal that would directly address methylene chloride in paint and coating removal in furniture refinishing is in Unit XI.

For NMP, EPA is co-proposing two different options to reduce the unreasonable risks presented by NMP in paint and coating removal for consumers and commercial users. EPA is co-proposing these two options because the Agency is interested in public consideration of these approaches, and is soliciting comments regarding the extent to which these approaches could reduce the unreasonable risks the Agency has identified.

Under the first approach co-proposed for NMP (option 1), EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal, with exemptions for certain coating removal uses that EPA proposes are critical to national security. EPA is also proposing to prohibit the commercial use of NMP for paint and coating removal, with exemptions for certain coating removal uses that EPA proposes are critical to national security. These exemptions include the condition that any exempt paint and coating removal products containing NMP be packaged in containers with a volume no less than 5 gallons. Unlike the option proposed for methylene chloride, these exemptions do not include the use of NMP in furniture refinishing. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of NMP for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping.

Under the second approach proposed for NMP, EPA is proposing a reformulation, PPE, and labeling approach. This would require product reformulation to limit the concentration of NMP in paint and coating removal products; testing of product formulations to identify specialized gloves that provide protection; relabeling of products to provide additional information to consumers; an occupational dermal and respiratory protection program for commercial use of NMP in paint and coating removal, downstream notification when distributing NMP for other uses, and limited recordkeeping. Under this approach, no exemption is proposed for coating removal identified as critical for national security because paint and coating removal products containing NMP would continue to be available for these national security uses under this option, even without establishing a national security exemption.

EPA is requesting public comment on these proposals.

D. Why is the Agency taking this action?

Based on EPA's analysis of worker and consumer populations' exposures to methylene chloride and NMP in paint and coating removal, EPA proposes a determination that methylene chloride and NMP in paint and coating removal present an unreasonable risk to human

health. For methylene chloride, the health impacts of its use in paint and coating removal include death (due to asphyxiation), liver toxicity, kidney toxicity, reproductive toxicity, specific cognitive impacts, and cancers such as brain cancer, liver cancer, certain lung cancers, non-Hodgkin's lymphoma, and multiple myeloma (Ref. 2). Some of these effects result from a very short, acute exposure; others follow years of occupational exposure. For NMP, these health effects include developmental toxicity (*e.g.,* fetal death or decreased infant birth weight), neurotoxicity, immunotoxicity, liver and kidney toxicity, and reproductive toxicity (Ref. 3).

It is important to note that while both methylene chloride and NMP are used in paint and coating removal, products containing NMP have in recent years become increasingly popular substitutes for users interested in avoiding the health effects or odors known to be associated with products containing methylene chloride. While exposures to these chemicals have been assessed using different health endpoints, EPA proposes a determination that the use of either methylene chloride or NMP in paint and coating removal presents unreasonable risks. For this reason, EPA proposes to address the unreasonable risks presented by both chemicals in one rule.

Although EPA proposes to determine that the identified risks to workers exposed to methylene chloride in commercial furniture refinishing are unreasonable, EPA is not proposing to regulate these risks at this time. EPA intends to issue a separate proposal addressing the use of methylene chloride in paint and coating removal in commercial furniture refinishing. See Unit XI.

As discussed in Unit V.C., EPA is not proposing to prohibit all manufacturing, processing, distribution in commerce, and use of methylene chloride or NMP, of which paint and coating removal is estimated to comprise 25% and 9% of the use of each chemical, respectively (Refs. 2 and 3).

E. What are the estimated incremental impacts of this action?

EPA proposes to determine that the identified risks from methylene chloride and NMP in paint and coating removal are unreasonable. Apart from that proposed determination, EPA has evaluated the potential costs of the proposed approach of (1) prohibiting the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer paint and coating removal in the sectors specified in section I.C of this preamble, exempting specific uses critical to national security; (2) prohibiting the commercial use of methylene chloride for paint and coating removal in the specified sectors; (3) requiring any paint and coating removal products containing methylene chloride to be packaged for distribution in commerce in containers with volumes no less than 55 gallons so as to reduce diversion to restricted uses, except for formulations specifically manufactured for the Department of Defense; (4) requiring manufacturers (including importers), processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain; and (5) requiring associated recordkeeping requirements. EPA has also evaluated the costs of the two co-proposed options for NMP. Under the first option, this includes (1) prohibiting the manufacture (including import), processing, and distribution in commerce of NMP for all paint and coating removal, exempting specific uses critical to national security; (2) prohibiting the commercial use of NMP for paint and coating removal exempting specific uses critical to national security; (3) requiring any paint and coating removal products containing NMP to be packaged for distribution in commerce in containers with a volume no less than 5 gallons; (4) requiring manufacturers (including importers), processors, and distributors of NMP for any use, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain; and (5) requiring associated recordkeeping requirements. Under the second option, this includes: (1) Prohibiting the manufacture, processing, and distribution in commerce of paint and coating removal products containing more than 35 percent NMP by weight except for products used for critical national security uses; (2) Requiring product formulators to test gloves for the product formulations being processed and distributed in commerce for other than exempt critical national security uses to identify specialized gloves that provide protection for users and keep records relevant to these tests; (3) Requiring product formulators to label products with information for consumers about the risks presented by the products and how to reduce these risks during use, including identifying which specialized gloves provide protection against the specific formulation; (4) Requiring product formulators to provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication, and to keep records; (5) Prohibiting the commercial use of paint and coating removal products that contain more than 35 percent by weight of NMP, except for critical national security uses; and (6) Requiring commercial users to establish worker protection programs for dermal and respiratory protection, including hazard communication and training, and to require their employees to wear specialized gloves, impervious clothing that covers most of the body, and a respirator with an assigned protection fact (APF) of 10 or compliance with an alternative air exposure limit.

This analysis, which is available in the docket, is discussed in Units VII.A. and XVII.A., and is briefly summarized here.

Costs of the proposed approach and relevant alternate approaches for each chemical are discussed in Units VII.A. for methylene chloride and XVII.A. for NMP. Costs for the whole proposal follow. Costs to users of methylene chloride or NMP for paint and coating removal under the first co-proposed approach for NMP are $2,517,000 to $50,801,000 annualized for 20 years at a discount rate of 3% and $3,114,000 to $50,916,000 at a discount rate of 7%. Costs to users of methylene chloride or NMP for paint and coating removal under the second co-proposed approach for NMP are $114,164,860 to $124,893,000 annualized for 20 years at a discount rate of 3% and $114,658,000 to $125,438,000 at a discount rate of 7%. As described in more detail in the Economic Analysis (Ref. 4) and supplement to the Economic Analysis (Ref. 127), there are estimated to be approximately 13,000 commercial firms and 2,002,000 consumers who use methylene chloride or NMP in paint and coating removal that would be affected; costs per firm and for each household are estimated to include costs of alternative formulations of paint removal products, additional time spent applying or removing paint with alternative methods or substitute products, and other cost factors. For product processors and formulators, the costs of paint and coating removal product reformulations for methylene chloride and NMP under the first co-proposed approach for NMP are estimated to be approximately $17,000 to $34,000 per year (annualized at 3% over 20 years) and $23,000 to $43,000 (annualized at 7% over 20 years). For product processors and formulators, the costs of paint and coating removal product reformulations for methylene

chloride and NMP under the second co-proposed approach for NMP are estimated to be approximately $25,140 to $41,140 per year (annualized at 3% over 20 years) and $34,160 to $55,160 (annualized at 7% over 20 years). Only 17 firms are estimated to be affected. For manufacturers, processors, and distributors of methylene chloride or NMP under the first co-proposed approach for NMP, the costs of downstream notification and recordkeeping on an annualized basis over 20 years are $140 and $160 using 3% and 7% discount rates respectively. For manufacturers, processors, and distributors of methylene chloride or NMP under the second co-proposed approach for NMP, the costs of downstream notification and recordkeeping on an annualized basis over 20 years are $140 and $160 using 3% and 7% discount rates respectively (the same as under the first co-proposed approach). Approximately 30 firms are estimated to be affected. Agency costs for enforcement for each chemical, under the first co-proposed approach for NMP, are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively (Ref. 4). Total Agency costs for enforcement, for both chemicals together under the first co-proposed approach for NMP, are estimated to be approximately $228,802 and $223,436 annualized over 20 years at 3% and 7%. Agency costs for enforcement for each chemical, under the second co-proposed approach for NMP, are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively for methylene chloride and $1,024,144 and $998,711 annualized over 20 years at 3% and 7% respectively for NMP (Ref. 127). Total Agency costs for enforcement, for both chemicals together under the second co-proposed approach for NMP, are estimated to be approximately $1,138,545 and $1,110,429 annualized over 20 years at 3% and 7%.

In summary, total costs of the proposed rule under the first co-proposed approach for NMP are estimated to be $2,763,000 to $51,070,000 annualized over 20 years at 3% and $3,361,000 to $51,163,000 annualized over 20 years at 7% (Ref. 4). Total costs of the proposed rule under the second co-proposed approach for NMP are estimated to be $114,196,000 to $124,893,000 annualized over 20 years at 3% and $114,658,000 to $125,438,000 annualized over 20 years at 7% (Ref. 127).

Although methylene chloride in paint and coating removal can cause a wide range of non-cancer adverse effects, cancer, and death and NMP can cause a variety of developmental non-cancer adverse effects, monetized benefits included only the subset of benefits associated with reducing cancer risks or deaths that occur at a known rate among users or bystanders. Methodological limitations prevent EPA from being able to include a quantification or monetary valuation estimate of the other non-cancer benefits at this time, and thus there is not a quantification or monetary valuation estimate for the overall total benefits. Based on the costs and benefits that EPA can estimate, the monetized benefits for the proposed approach range from approximately $14,354,000 to $14,558,000 on an annualized basis over 20 years at 3% and $13,791,000 to $13,919,000 at 7% (Ref. 4). EPA also considered non-monetized benefits that would result from the prevention of non-cancer adverse effects associated with methylene chloride or NMP in paint and coating removal, including nervous system effects, liver toxicity, kidney toxicity, and reproductive effects from exposure to methylene chloride in paint and coating removal; and developmental toxicity, fetal death, fetal body weight reductions, kidney toxicity, liver toxicity, immunotoxicity, and reproductive toxicity from exposure to NMP in paint and coating removal (Refs. 2 and 3).

F. Children's Environmental Health

This action is consistent with the 1995 EPA Policy on Evaluating Health Risks to Children (*http://www.epa.gov/children/epas-policy-evaluating-risk-children*). In its risk assessments for methylene chloride and NMP, EPA identified risks to children from exposure to methylene chloride and NMP used in paint and coating removal. EPA has also identified women of childbearing age as a potentially exposed or susceptible subpopulation who may be at greater risk than the general population of adverse health effects from exposure to NMP. EPA has identified this subpopulation as relevant to EPA's risk assessment for NMP due to NMP's effects on the developing fetus. Therefore, the risk management standard under Section 6 of TSCA, with respect to NMP, is to reduce the risk posed by NMP so that it no longer presents an unreasonable risk (either to users in the general population or to users who are women of childbearing age). In its TSCA Work Plan Risk Assessment for methylene chloride, EPA identified risks from inhalation exposure to children who may be present as bystanders in homes where paint removal occurs. These risks include neurological effects such as cognitive impairment, sensory impairment, dizziness, incapacitation, and loss of consciousness (leading to risks of falls, concussion, and other injuries). The supporting non-cancer risk analysis of children as bystanders conducted in the TSCA Work Plan Risk Assessment for methylene chloride meets the 1995 EPA Policy on Evaluating Health Risks to Children. Supporting information on the health effects of methylene chloride exposure to children is available in the Toxicological Review of Methylene Chloride (Ref. 5) and the Final Risk Assessment on Methylene Chloride (Ref. 2), as well as Units VI.C.1. and VI.D.

In the TSCA Work Plan Risk Assessment for NMP, EPA identified developmental toxicity as the most sensitive endpoint for NMP exposure (*i.e.,* fetal death and decreased fetal birth weight) for the most sensitive human life stages (*i.e.,* women of childbearing age between the ages of 16 and 49 years and the fetus) (Ref. 3). The supporting non-cancer risk analysis of children and women of childbearing age conducted in the TSCA Work Plan Risk Assessment for NMP meets the 1995 EPA Policy on Evaluating Health Risks to Children.

II. Overview of Methylene Chloride and Uses Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule would apply to methylene chloride (CASRN 75–09–2) when used in paint and coating removal except for several specified uses, including as part of commercial furniture refinishing and uses critical to national security.

B. What are the uses of methylene chloride?

Methylene chloride is a solvent used in a variety of industrial, commercial and consumer use applications, including (Ref. 2):

- Paint remover
- Adhesive
- Aerosol propellant
- Metal cleaner and degreaser
- Chemical processor for polycarbonate resins and cellulose triacetate (photographic film)
- Feedstock in the production of the refrigerant hydrofluorocarbon-32

Minor uses of methylene chloride include (Ref. 2):

- Extraction solvent for oils, waxes, fats, spices, and hops
- Tablet coating for pharmaceuticals

According to the 2012 Chemical Data Reporting (CDR) information, approximately 260 million pounds of

methylene chloride were produced or imported into the United States that year, with between 80% to 96% produced in the United States (Ref. 2). In terms of environmental releases, 277 facilities reported a total of 3.2 million pounds of releases of methylene chloride to the 2014 Toxics Release Inventory (Ref. 6).

Individuals, including workers, consumers, and the general population, are exposed to methylene chloride from industrial/commercial and consumer sources in different settings such as homes and workplaces, and through multiple routes (inhalation, dermal, and ingestion).

The use assessed by EPA that is the subject of this proposal, methylene chloride in paint and coating removal, represents about 25% of total use of methylene chloride. This is a decrease from the 1980s, when approximately 50% of the total methylene chloride market was composed of paint removal use (Ref. 2). Paint and coating removal is the application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coatings from a substrate. Substrates can include objects, vehicles, architectural features, or structures. This use is discussed in detail in Unit VI.B.

Although the TSCA Work Plan Chemical risk assessment for methylene chloride focused on the chemical's use in paint and coating removal, EPA announced in December 2016 its designation of methylene chloride as one of the ten chemical substances that will undergo risk evaluation pursuant to section 6(b)(2)(A) of TSCA (81 FR 91927). The Agency is proceeding with this proposed rule addressing methylene chloride in paint and coating removal in accordance with TSCA section 26(l) and asks for comment on its decision to pursue risk management for specific conditions of use of methylene chloride while preparing to conduct a risk evaluation of remaining conditions of use of methylene chloride under TSCA section 6(b).

C. What are the potential health effects of methylene chloride?

Methylene chloride is a likely human carcinogen, a neurotoxicant, and acutely lethal. Acute and chronic exposures to methylene chloride are primarily associated with neurological and hepatic effects. The primary target organ of methylene chloride acute toxicity is the brain, and neurological effects result from either direct narcosis or the formation of carbon monoxide. Carbon monoxide is one of the metabolic byproducts of methylene chloride, and reversibly binds to hemoglobin as carboxyhemoglobin. Part of the effect of methylene chloride on the central nervous system comes from the accumulation of carboxyhemoglobin in the blood, which can lead to sensory impairment, dizziness, incapacitation, loss of consciousness, heart failure, and death (Ref. 2). Hemoglobin in the fetus has a higher affinity for carbon monoxide than does adult hemoglobin. Thus, the neurotoxic and cardiovascular effects may be exacerbated in fetuses and in infants with higher residual levels of fetal hemoglobin when exposed to high concentrations of methylene chloride (Ref. 2).

During acute exposures, methylene chloride primarily affects the brain, though effects on lung, liver, and kidney have also been reported in humans following acute exposures. Acute exposures to methylene chloride can be fatal; acute lethality in humans following inhalation exposure is related to central nervous system depressant effects. Effects include loss of consciousness and respiratory depression, resulting in irreversible coma, hypoxia, and eventual death. Acute non-lethal effects in humans are similarly related to the central nervous system and can include incapacitation, loss of consciousness, heart failure, and coma. Other acute non-lethal effects in humans include neurobehavioral deficits measured in psychomotor tasks, such as tests of hand-eye coordination, visual evoked response changes, and auditory vigilance (Ref. 2).

Since 1976, more than 40 deaths have been attributed to methylene chloride when used in paint and coating removal (Ref. 7); in some cases, two or more individuals have died during a single job when air concentrations quickly reached lethal levels, potentially in less than 10 minutes. In other situations, individuals have died when entering rooms or facilities in which paint or coating removal was previously conducted and air concentrations of methylene chloride remained dangerously high (Ref. 7).

Chronic exposures to methylene chloride are associated with cancer and non-cancer hepatic effects. Methylene chloride is likely to be carcinogenic in humans with a mutagenic mode of action. This mutagenic mode of action is supported by the weight of evidence from multiple *in vivo* and *in vitro* studies. There is a risk for some specific cancers, including brain cancer, liver cancer, non-Hodgkin lymphoma, and multiple myeloma. Additionally, several cancer bioassays in animals have identified the liver and lung as the most sensitive target organs for tumor development induced by methylene chloride (Ref. 2).

Non-cancer effects of chronic exposure to methylene chloride are primarily hepatic; the liver is the most sensitive target for non-cancer toxicity. Lifetime exposure in rats dosed with different concentrations is associated with hepatic vacuolation, degeneration, or liver necrosis. Other non-cancer effects of chronic methylene chloride exposure include renal tubular degeneration in rats and mice, testicular atrophy in mice, and ovarian atrophy in mice (Ref. 2).

D. What are the environmental impacts of methylene chloride?

Pursuant to TSCA section 6(c), EPA in this unit describes the effects of methylene chloride on the environment and the magnitude of the exposure of the environment to methylene chloride. The proposed unreasonable risk determination, however, is based solely on risks to human health since these risks are the most serious consequence of use of methylene chloride and are sufficient to support this proposed action.

1. *Environmental effects and impacts.* Methylene chloride is mainly released to the environment in air, and to a lesser extent in water and soil, due to industrial and consumer uses as a solvent, in aerosol products, and in paint and coating removal. Many chemical waste sites contain methylene chloride and these might act as additional sources of environmental contamination through spills, leaks, or evaporation. Because methylene chloride evaporates readily, most releases enter the air. In the air, it is broken down by sunlight and by reaction with other chemicals present in the air. In the air, methylene chloride's half-life is between 53 to 127 days (Ref. 8).

Ecotoxicity studies for methylene chloride have been conducted in fish, aquatic invertebrates, and aquatic plants. Based on available data, in the methylene chloride risk assessment EPA concluded that methylene chloride has low aquatic toxicity for fish, aquatic invertebrates, and aquatic plants (Ref. 2).

While methylene chloride is moderately persistent, given its low bioaccumulation and low hazard for aquatic toxicity, the magnitude of potential environmental impacts on ecological receptors is judged to be low for the environmental releases associated with methylene chloride in paint removal. This should not be misinterpreted to mean that methylene chloride does not pose environmental

concerns. Through other regulations, EPA is addressing methylene chloride releases to air and contamination of groundwater, drinking water, and contaminated soils. While the primary concern with this contamination has been human health, there is potential for methylene chloride exposures to ecological receptors in some cases (Ref. 2). More information about regulations to reduce environmental impacts of methylene chloride is in Unit III.

2. *What is the global warming potential of methylene chloride?* Global warming potential (GWP) measures the potency of a greenhouse gas over a specific period of time, relative to carbon dioxide, which has a high GWP of 1 regardless of the time period used. Due to its volatility, methylene chloride enters the atmosphere where it reacts slowly enough to undergo atmospheric transport and act as a greenhouse gas. Methylene chloride has been reported to the Intergovernmental Panel on Climate Change as a global warming potential chemical with a value of 8.7 GWP, or approximately 8.7 times more heat absorptive than carbon dioxide (Ref. 2).

3. *What is the ozone depletion potential of methylene chloride?* Methylene chloride is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy program for metal and electronic cleaning (degreasing), aerosol solvents, foam blowing agents, and other uses (59 FR 13044, March 18, 1994).

4. *Is methylene chloride a volatile organic compound (VOC)?* Though volatile, methylene chloride is exempt from being classified as a VOC as defined at 40 CFR 51.100(c). A VOC is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions. Because methylene chloride has negligible atmospheric photochemical reactions, it is not classified as a VOC (40 CFR 51.100(s)(1)).

5. *Does methylene chloride persist in the environment and bioaccumulate?* Due to its volatility, methylene chloride does not significantly partition to solid phases. Therefore, releases of methylene chloride to the environment are likely to evaporate to the atmosphere, or if released to soil, migrate to groundwater. Methylene chloride has been shown to biodegrade over a range of rates and environmental conditions. Measured bioconcentration factors for methylene chloride suggest its bioconcentration potential is low (Ref. 2).

III. Regulatory Actions Pertaining to Methylene Chloride

This section summarizes current state, federal, and international regulations and restrictions on methylene chloride, with a focus on its use in paint and coating removal. None of these actions imposes requirements to the extent necessary so that methylene chloride does not present the unreasonable risk described in this proposed rule.

A. Federal Actions Pertaining to Methylene Chloride

Methylene chloride has been the subject of U.S. federal regulations by EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). EPA and other agencies have taken actions (see below) to address the serious human health risks from specific sources and routes of methylene chloride exposure, but none of these actions sufficiently mitigate the risks that EPA is proposing to address under TSCA section 6(a).

EPA has issued several final rules and notices pertaining to methylene chloride under EPA's various authorities.

- *Clean Air Act:* Methylene chloride is designated as a hazardous air pollutant (HAP) under the Clean Air Act (42 U.S.C. 7412(b)(1))CAA). EPA issued a final rule in January 2008 that promulgated National Emission Standards for Hazardous Air Pollutants (NESHAP) for area sources engaged in paint stripping, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating operations. In this NESHAP, EPA listed ''Paint Stripping,'' ''Plastic Parts and Products (Surface Coating),'' and ''Autobody Refinishing Paint Shops'' as area sources of HAPs that contribute to the risk to public health in urban areas. The final rule included emissions standards that reflect the generally available control technology or management practices in each of these area source categories, and applies to paint stripping operations using methylene chloride (73 FR 1738, January 9, 2008). In 2014, EPA issued a final rule for Flexible Polyurethane Foam Manufacturing that banned the use of methylene chloride as a foam-blowing agent (79 FR 48073, August 15, 2014). In 2015, EPA issued a final rule for Aerospace Manufacturing and Rework Facilities, which updated a NESHAP from 1995 by adding limitations to reduce organic and inorganic emissions HAPs, including methylene chloride, from specialty coating application operations; and removed exemptions for periods of startup, shutdown and malfunction so that affected units would be subject to the emission standards at all times (80 FR 76152, December 7, 2015).
- *Solid Waste Disposal Act:* Methylene chloride is listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA) (Code U080) (Ref. 2).
- *Emergency Planning and Community Right-to-Know Act:* Methylene chloride is listed on the Toxics Release Inventory (TRI) pursuant to section 313 of the Emergency Planning and Community Right-to-Know Act (Ref. 2).
- *Safe Drinking Water Act:* The Safe Drinking Water Act (SDWA) requires EPA to determine the level of contaminants in drinking water at which no adverse health effects are likely to occur. EPA has set a maximum contaminant level goal of zero and an enforceable maximum contaminant level for methylene chloride at 0.005 mg/L or 5 parts per billion (57 FR 31776, July 17, 1992).

Regulation of methylene chloride by other agencies includes:

- In 1987, CPSC issued a statement of policy explaining that CPSC considers household products containing methylene chloride to be hazardous substances and providing guidance on labeling of such products. Labels of products containing methylene chloride are required to state that inhalation of methylene chloride vapor has caused cancer in certain laboratory animals, and the labels must specify precautions to be taken during use by consumers (52 FR 34698, September 14, 1987). In 2016, CPSC was petitioned by the Halogenated Solvents Industry Alliance to amend the statement of interpretation and enforcement policy regarding labeling of household products containing methylene chloride; CPSC published that petition for public comments (81 FR 60298, September 1, 2016).
- In 1989, FDA banned methylene chloride as an ingredient in all cosmetic products because of its animal carcinogenicity and likely hazard to human health (21 CFR 700.19). Before 1989, methylene chloride had been used in aerosol cosmetic products, such as hairspray (54 FR 27328 (June 29, 1989)).
- OSHA has taken steps to reduce exposure to methylene chloride in occupational settings. In 1997, OSHA lowered the permissible exposure limit (PEL) for methylene chloride from an eight-hour time-weighted average (TWA) of 500 parts per million (ppm) to an eight-hour TWA of 25 ppm and a 15-minute short-term exposure limit

(STEL) of 125 ppm. This standard also includes provisions for initial exposure monitoring, engineering controls, work practice controls, medical monitoring, employee training, personal protective equipment, and recordkeeping (29 CFR 1910.1052).

- The Department of Housing and Urban Development (HUD) has prohibited methylene chloride and other hazardous chemicals for use in removing lead-based paint by HUD contractors and anyone receiving grants or engaging in the HOME Program, which was created by the National Affordable Housing Act of 1990 (Ref. 9).
- The National Institute for Occupational Safety and Health (NIOSH) considers methylene chloride a potential occupational carcinogen and currently recommends an exposure limit of the ''lowest feasible concentration'' of methylene chloride (Ref. 10). NIOSH and OSHA in 2013 issued a hazard alert for bathtub refinishing with methylene chloride, warning that methylene-chloride based products are extremely dangerous and that the best way to prevent exposure is to use products that do not contain methylene chloride (Ref. 11).

B. State Actions Pertaining to Methylene Chloride

Several states have taken actions to reduce or make the public aware of risks from methylene chloride. For example, since 2011 methylene chloride has been prohibited from use in graffiti removal in the District of Columbia and 11 states (California, Connecticut, Delaware, Illinois, Indiana, Maine, Maryland, Michigan, New Jersey, New York, and Rhode Island) (Ref.12). Iowa, Indiana, South Carolina, and other states have established detection monitoring regulations for methylene chloride (567 IAC 113.15, 329 IAC 10–21–15, S.C. Code Regs. 16–107.198, Appx. III). In Alaska, methylene chloride is listed as a carcinogenic hazardous substance (18 AAC 75.341). Methylene chloride is listed on California's Safer Consumer Products regulations candidate list of chemicals that exhibit a hazard trait and are on an authoritative list of either chemical hazard traits or potential exposure concerns (Ref. 13). Methylene chloride is also listed on California's Proposition 65 list of chemicals known to cause cancer, birth defects, or reproductive harm (Ref. 13). In Minnesota, it has been found that methylene chloride may negatively affect the nervous system and cause cancer (Minn. R. 4717.8200, Minn. R. 4717.8100). The state of Washington has listed methylene chloride as a human carcinogen and a chemical of high concern to children (WAC 296–62–07473, WAC 173–334–130). In Pennsylvania, it is listed as an environmental and special hazardous substance (34 Pa. Code XIII, Ch. 323.2(a)).

All states have set PELs identical to the OSHA 25 ppm eight-hour time weighted average (TWA) PEL (79 FR 61384, October 10, 2014), however it is worth noting that California, Oregon, and Washington, which have a state PEL identical to the OSHA PEL, have slightly different requirements than OSHA for medical evaluation, fit testing for respirators, and implementation timelines related to methylene chloride (8 CCR 5502, OAR 437–002–1052, WAC 296–62–07470). The OSHA PEL is considerably higher than the levels at which EPA identified risks of concern for methylene chloride in paint and coating removal and would not be protective for the unreasonable risks identified.

C. International Actions Pertaining to Methylene Chloride

Methylene chloride is also regulated internationally and industrial and commercial sectors in certain other countries have moved to alternatives.

In Canada, the Canadian Minister of the Environment published in 2003 a Notice under Part 4 of the ''Canadian Environmental Protection Act, 1999'' requiring the preparation and implementation of pollution prevention plans for methylene chloride (Ref. 14). This Notice targets persons involved in the use of methylene chloride for the following activities: Aircraft paint stripping; flexible polyurethane foam blowing; pharmaceuticals and chemical intermediates manufacturing and tablet coating; industrial cleaning; and adhesive formulations. Also in 2003, Environment Canada published a Code of Practice for the reduction of methylene chloride emissions from the use of paint and coating removal products in commercial furniture refinishing and other stripping applications (Ref. 14). This Code of Practice was developed by a multi-stakeholder technical working committee, which consisted of industry representatives (*i.e.,* furniture refinishers, auto body shops, formulators of paint and coating removal products, solvent recovery firms), government personnel, and environmental non-governmental organizations.

In the European Union, the European Commission amended its Registration, Evaluation, Authorization, and Restriction of Chemical substances in 2010 to incorporate restrictions for the use of methylene chloride in paint removers. Methylene chloride is banned in the European Union from: (1) Placement on the market in a new product for consumers/professionals after December 2010; (2) placement on the market in any product for consumers/professionals after December 2011; and (3) use by professionals after June 2012. Member States could allow the use of methylene chloride if they have a program to license and train professionals in the following: Awareness; evaluation and management of risks; use of adequate ventilation; and use of appropriate personal protective equipment (Ref. 15). The United Kingdom has issued a derogation to allow professional use of methylene chloride (Ref. 16). In addition, industrial installations using methylene chloride must have effective ventilation, minimize evaporation from tanks, and have measures for safe handling of methylene chloride in tanks, adequate personal protective equipment, and adequate information and training for operators. Paint and coating removers containing methylene chloride in a concentration equal to or greater than 0.1% by weight must include a label: ''Restricted to industrial use and to professionals approved in certain EU Member States—verify where use is allowed'' (Ref. 15).

IV. Methylene Chloride Risk Assessment and Outreach

In 2013, EPA identified methylene chloride in paint and coating removal as a priority for risk assessment under the TSCA Work Plan. This unit describes the development of the methylene chloride risk assessment and supporting analysis and expert input on the uses that are the subject of this proposed rule. A more detailed discussion of the risks associated with methylene chloride in paint and coating removal can be found in Unit VI.C.1.

A. TSCA Work Plan for Chemical Assessments

In 2012, EPA released the ''TSCA Work Plan Chemicals: Methods Document'' in which EPA described the process the Agency intended to use to identify potential candidate chemicals for near-term review and assessment under TSCA (Ref. 17). EPA also released the initial list of TSCA Work Plan chemicals identified for further assessment under TSCA as part of its chemical safety program (Ref. 1).

The process for identifying these chemicals for further assessment under TSCA was based on a combination of hazard, exposure, and persistence and bioaccumulation characteristics, and is

described in the TSCA Work Plan Chemicals Methods Document (Ref. 17). Using the TSCA Work Plan chemical prioritization criteria, methylene chloride ranked high for health hazards and exposure potential and was included on the initial list of TSCA Work Plan chemicals for assessment. Methylene chloride appeared in the 2012 TSCA Work Plan for Chemical Assessments and in the 2014 update of the TSCA Work Plan for Chemical Assessments.

B. Methylene Chloride Risk Assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for methylene chloride (methylene chloride risk assessment) in August 2014, following the 2013 peer review of the 2012 draft methylene chloride risk assessment. All documents from the 2013 peer review of the draft methylene chloride risk assessment are available in EPA Docket Number EPA–HQ–OPPT–2012–0725. The completed risk assessment is included in that docket.

The methylene chloride risk assessment evaluated health risks to consumers, workers, and bystanders from inhalation exposures to methylene chloride when used in paint and coating removal (Ref. 2). EPA assumes workers and consumers would be adults of both sexes 16 and older, including pregnant women. EPA assumes bystanders in commercial or occupational settings would be worker non-users or adjacent workers, while bystanders in residential settings would be individuals of any age group (*e.g.,* children, adults, the elderly) nearby during product application. During scoping and problem formulation for the risk assessment, EPA focused on paint and coating removal because it was expected to involve frequent or routine use of methylene chloride in high concentrations and/or have high potential for human exposure (Ref. 2). However, this does not mean that EPA found that other uses not included in the methylene chloride risk assessment present low risk.

The methylene chloride risk assessment characterized human health effects associated with paint removal with methylene chloride. Based on the physical-chemical properties of methylene chloride and the paint and coating removal use scenarios described in the assessment, EPA assessed inhalation as the predominant route of exposure to methylene chloride during paint removal. Though highly volatile compounds such as methylene chloride may also be absorbed through the skin, EPA does not have the data nor the methodology to assess methylene chloride dermal exposure during paint removal. As a result, the assessment may underestimate total exposures to methylene chloride during paint removal due to this inability to evaluate dermal exposure (Ref. 2).

The methylene chloride risk assessment identified risks of concern following acute (short-term) and chronic exposures for workers and consumers conducting paint removal with methylene chloride, as well as for exposed bystanders, including residents of homes in which paint removal is conducted and worker non-users adjacent to other workers conducting paint removal. The acute risks identified include death; neurological impacts such as coma, incapacitation, loss of consciousness, and dizziness; and liver effects. The chronic risks identified include brain, liver, lung, and hematopoietic cancers and liver damage (Ref. 2).

Margins of exposure (MOEs) were used in this assessment to estimate non-cancer risks for acute exposures (for consumers and workers) and chronic exposures (for workers). The MOE is the point of departure (an approximation of the no-observed adverse effect level (NOAEL)) for a specific health endpoint divided by the exposure concentration for the specific scenario of concern. The benchmark MOE accounts for the total uncertainty in a point of departure, including: (1) The variation in sensitivity among the members of the human population (*i.e.,* interhuman or intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (*i.e.,* interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (*i.e.,* extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a lowest observed adverse effect level rather than from a NOAEL (Ref. 18). MOEs provide a non-cancer risk profile by presenting a range of estimates for different non-cancer health effects for different exposure scenarios, and are a widely recognized method for evaluating a range of potential non-cancer health risks from exposure to a chemical. For non-cancer effects EPA estimated exposures that are significantly larger than the point of departure, thus resulting in MOEs that are significantly less than the benchmark MOE (Ref. 2). For methylene chloride, EPA identified acute or chronic non-cancer risks of concern if the MOE estimates were less than the benchmark MOE of 10 (Ref. 2). The health endpoint used for the benchmark MOE for acute exposure to methylene chloride is central nervous system effects, such as dizziness or incapacitation; the health endpoint used for the benchmark MOE for chronic exposure to methylene chloride is liver toxicity. These are the most sensitive adverse health effects from exposure to methylene chloride.

Methylene chloride is a likely human carcinogen; cancer risks determine the estimated incremental increased probability of an individual in an exposed population developing cancer over a lifetime following exposure to the chemical under specified use scenarios. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk of 1 in 1,000,000 ranging to 1 in 10,000 (*i.e.,* 1×10^{-6} to 1×10^{-4}). For cancer effects, EPA estimated that workers and occupational bystanders exposed to methylene chloride in paint and coating removal have an increase in cancer risk that ranged from 10 times to almost 1,000 times greater than a cancer benchmark of 1 in 1,000,000, depending on the specific way paint or coating removal was conducted with methylene chloride (Ref. 2).

The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also result in low risk for cancer.

The assessment identified the following risks from acute exposures to methylene chloride when used in paint and coating removal (Ref. 2):

- Acute risks of incapacitation, coma, or death in workers exposed to methylene chloride in paint removers when no respiratory protection is used. In some industries with high exposure scenarios, these risks of incapacitation or death are present even when respiratory protection is used.
- Acute risks of neurological effects for most workers. These risks are present even when respiratory protection is used.
- Acute risks of neurological effects for consumer users of methylene chloride as a paint remover.
- Acute risks of neurological effects for bystanders (including children and worker non-users) in the location in which paint removers containing methylene are used by either residents or commercial users. These risks are also present for exposures to methylene chloride in a location after the paint removal work is complete, because methylene chloride can remain in the air in spaces that are enclosed, confined, or lacking ventilation.

Based on the risk assessment scenarios, EPA identified the following non-cancer risks from chronic exposures to methylene chloride in paint and coating removal (Ref. 2):

• Non-cancer risks for liver effects for most workers (including worker non-users, or adjacent workers) in industries conducting paint removal.

• Non-cancer risks occur for most workers (including adjacent workers) when exposed to paint removers containing methylene chloride even when wearing respiratory protection in the exposure scenarios that predominantly demonstrate variations in exposure conditions (*i.e.,* exposure frequency and working years) in facilities reporting central tendency or high-end air levels of methylene chloride. Among all the occupational scenarios, the greatest risk of concern is for workers engaging in long-term use of or exposure to methylene chloride as a paint remover (*i.e.,* 250 days/year for 40 years) with no respiratory protection.

The assessment identified the following cancer risks from chronic exposures to methylene chloride when used in paint removal (Ref. 2):

• Cancer risks for workers (including adjacent workers) exposed to methylene chloride as a paint remover in various industries. These cancer risks include liver cancer, lung cancer, brain cancer, non-Hodgkin lymphoma, and multiple myeloma.

• The greatest cancer risks occur for workers exposed to methylene chloride when used as a paint remover who have no respiratory protection and are exposed for an extended period.

C. Supplemental Analysis Consistent With the Methylene Chloride Risk Assessment

Following the methylene chloride risk assessment, EPA conducted supplemental analyses to inform risk management. These analyses are consistent with the scope of the methylene chloride risk assessment and were based on the peer-reviewed methodology used in the methylene chloride risk assessment. They included identification of baseline and central tendency exposure scenarios, impacts of reduced methylene chloride content in paint removers, addition of local exhaust ventilation (LEV), use of personal protective equipment (PPE), additional consumer exposure scenarios, and methods of monitoring to determine workplace exposures. The results of EPA's analyses are available in this rulemaking docket (Refs. 19, 20, and 21). Prior to promulgation of the final rule, EPA will peer review the ''Respirator and Glove Specifications for Workers Exposed to Methylene Chloride in Paint and Coating Removal,'' ''Supplemental Consumer Exposure and Risk Estimation Technical Report for Methylene Chloride in Paint and Coating Removal'', and ''Recommendation for an Existing Chemical Exposure Concentration Limit (ECEL) for Occupational Use of Methylene Chloride and Workplace Air Monitoring Methods for Methylene Chloride'' (Refs. 19, 20, 21).

D. Outreach

In addition to the consultations described in Unit XXIII.C., EPA engaged in discussions with experts on and users of paint removers (Ref. 22). The purpose of these discussions was to hear from users, academics, manufacturers, and members of the public health community about practices related to paint removal in various industries and by consumers; the importance of methylene chloride and NMP in paint removal; frequently-used substitute chemicals or alternative paint removal methods; engineering control measures and personal protective equipment currently in use or feasibly adoptable for paint removal; and other risk reduction approaches that may have already been adopted or considered for commercial or consumer paint removal. Informed by these discussions and by industry and other governmental research, EPA has concluded that alternatives to methylene chloride and NMP are available for nearly all paint removal uses.

EPA is continuing to gather information, to the extent practicable, regarding the availability of alternatives to methylene chloride for furniture refinishing. EPA plans to continue to engage stakeholders to identify what methods may be available as alternatives to methylene chloride. After collecting the information, EPA expects to address this use of methylene chloride so that the substance no longer poses an unreasonable risk and intends to issue separately a proposal in the future. Also see Unit XI.

V. Regulatory Approach for Methylene Chloride in Paint and Coating Removal

A. TSCA Section 6(a) Unreasonable Risk Analysis

Under TSCA section 6(a), if the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the Agency's risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

TSCA section 6(a) requirements can include one or more, or a combination of, the following actions:

• Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).

• Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration (§ 6(a)(2)).

• Require minimum warning labels and instructions (§ 6(a)(3)).

• Require recordkeeping or testing (§ 6(a)(4)).

• Prohibit or regulate any manner or method of commercial use (§ 6(a)(5)).

• Prohibit or otherwise regulate any manner or method of disposal (§ 6(a)(6)).

• Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances (§ 6(a)(7)).

EPA analyzed a wide range of regulatory options under section 6(a) for each use in order to select the proposed regulatory approach (Refs. 23 and 24). For each use, EPA considered whether a regulatory option (or combination of options) would address the identified unreasonable risks so that the chemical substance no longer presents such risks. EPA found that an option that could reduce exposures such that they would achieve the benchmark MOE for the most sensitive non-cancer endpoint would address the risk of concern for other non-cancer endpoints. Additionally, EPA's assessments for methylene chloride in paint and coating removal found that exposures that meet the benchmark MOE for the most sensitive non-cancer endpoint would also not result in cancer risks of concern.

After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered how reliably the regulatory options would actually reach these benchmarks. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In considering whether a regulatory option would ensure the chemical no longer presents the unreasonable risk, the Agency considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks

in relation to the benchmarks, as well as whether the option's protectiveness was influenced by concerns related to environmental justice, children's health, and potentially exposed or susceptible subpopulations identified as relevant to the Agency's risk evaluation.

B. TSCA Section 6(c)(2) Considerations

TSCA section 6(c)(2) requires EPA to consider and publish a statement based on reasonably available information with respect to the:

- Health effects of the chemical substance or mixture (in this case, methylene chloride) and the magnitude of human exposure to methylene chloride;
- Environmental effects of methylene chloride and the magnitude of exposure of the environment to methylene chloride;
- Benefits of methylene chloride for various uses;
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost-effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

In addition, in selecting among prohibitions and other restrictions available under TSCA section 6(a), EPA must factor in, to the extent practicable, these considerations. Further, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's analysis of the health effects and magnitude of exposure to methylene chloride can be found in Units IV.B., VI.C.1. and VI.D., which discuss the methylene chloride risk assessment and EPA's regulatory assessment of methylene chloride in paint and coating removal. A discussion of the environmental effects of methylene chloride is in Unit II.D.

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the Economic Analysis (Ref. 4). To the extent information was reasonably available, EPA considered the benefits realized from risk reductions (including monetized benefits, non-monetized quantified benefits, and qualitative benefits), offsets to benefits from countervailing risks (*e.g.,* risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children and other potentially exposed or susceptible subpopulations (as compared to the general population), the cost of regulatory requirements for the various options, and the cost effectiveness of the proposed action and the one or more primary alternate regulatory options. A discussion of the benefits EPA considered can be found in Units VI.D. and VII.B. as well as in the Economic Analysis (Ref. 4).

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. For example, an option that includes use of a respirator would include inspections to evaluate compliance with all elements of a respiratory protection program (Ref. 25). In understanding the burden, EPA took into account reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives. Reasonably available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options. A discussion of the costs EPA considered and a discussion of the cost-effectiveness of the proposal and the primary alternate regulatory options that EPA considered is in Units VI.F. and VII.A. In addition, a discussion of the impacts on small businesses is in Unit XXIII. and in the Initial Regulatory Flexibility Analysis and Report from the Small Business Advocacy Review Panel (Refs. 26 and 27).

With respect to the anticipated effects of this proposal on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers. In addition, EPA considered the employment impacts of this proposal, as discussed in section 9.2 of the Economic Analysis (Ref. 4). EPA found that the direction of change in employment is uncertain, but EPA expects the short term and longer-term employment effects to be small.

The benefits of methylene chloride in paint and coating removal are discussed in Unit VI.B., along with the availability of alternatives. The dates that the proposed restrictions would take effect are discussed in Unit X. The availability of alternatives to methylene chloride in paint and coating removal on those dates is discussed in Unit VI.E.

Finally, with respect to this proposal's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. An impending prohibition on this use of methylene chloride is likely to increase demand for alternatives, which EPA expects would result in the development of new alternatives. See also section 9.3 in the Economic Analysis (Ref. 4).

C. Regulatory Options Receiving Limited Evaluation

EPA analyzed a wide range of regulatory options under TSCA section 6(a). There are a range of regulatory options under TSCA; only those pertaining to these risks were evaluated in detail. An overview of the regulatory options not evaluated in detail follows.

First, EPA reasoned that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture, processing or distribution in commerce of methylene chloride or limit the amount of methylene chloride which may be manufactured, processed or distributed in commerce is not germane because EPA is not proposing to ban or limit the manufacture, processing or distribution in commerce of methylene chloride for uses other than paint and coating removal.

In addition, EPA determined that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not assess risks associated with methylene chloride disposal.

Another option EPA evaluated would require warning labels and instructions on paint and coating removal products containing methylene chloride, pursuant to TSCA section 6(a)(3) (Ref. 28). However, EPA reasoned that warning labels and instructions alone could not significantly mitigate the unreasonable risks presented by methylene chloride in paint and coating removal. EPA based its reasoning on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers

and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies (Ref. 28). Additionally, workers being exposed may not be in a position to influence their employer's decisions about the type of paint removal method, or ensure that their employer provides appropriate PPE and an adequate respiratory protection program.

These conclusions are based on the weight-of-evidence analysis that EPA conducted of the available literature on the efficacy of labeling and warnings. This analysis indicates that a label's effectiveness at changing user behavior to comply with instructions and warnings depends on the attributes of the label and the user, and how those interact during multiple human information processing stages, including attention, comprehension, judgement, and action (Ref. 28).

Numerous studies have found that product labels and warnings are effective to some degree. However, the extent of the effectiveness has varied considerably across studies and some of the perceived effectiveness may not reflect real-world situations. This is because interactions among labels, users, the environment, and other factors greatly influence the degree of a label's effectiveness at changing user behavior (Ref. 28). In addition, while some studies have shown that certain components of labels and warnings tend to have some influence, it is less clear how effective labels and warnings are likely to be over time, as users become habituated to both the labels and the products.

Presenting information about methylene chloride on a product label would not adequately address the unreasonable risk presented by this use of this chemical because the nature of the information the user would need to read, understand, and act upon is extremely complex. When the precaution or information is simple or uncomplicated (*e.g.,* do not mix this cleaner with bleach or do not mix this cleaner with ammonia), it is more likely the user will successfully understand and follow the direction. In contrast, it would be challenging to most users to follow the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from methylene chloride. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor, and effects to bystanders. Currently, though some paint removers containing methylene chloride are labeled with information about its fatal effects if used without ''adequate ventilation'' (Ref. 28) and this information appears on the product safety data sheet, deaths continue to occur. It is unlikely that label language changes for this use of methylene chloride will result in widespread, consistent, and successful adoption of risk reduction measures by users.

Any use of labels to promote or regulate safe product use should be considered in the context of other potential risk reduction techniques. As highlighted by a 2014 expert report for the Consumer Product Safety Commission (CPSC), ''safety and warnings literature consistently identify warnings as a less effective hazard-control measure than either designing out a hazard or guarding the consumer from a hazard. Warnings are less effective primarily because they do not prevent consumer exposure to the hazard. Instead, they rely on persuading consumers to alter their behavior in some way to avoid the hazard'' (Ref. 29). Specifically regarding methylene chloride, effective personal protection resulting in risk reduction would require this altered behavior to include the appropriate use of a supplied-air respirator. Consumer users are particularly unlikely to acquire and correctly use such an apparatus in response to reading a warning label (Ref. 19). Any labeling aiming to reduce risks to consumer or commercial users of these products would need to sufficiently and clearly explain the importance of the supplied-air respirator, and would still leave the user with the problem of obtaining and properly using the supplied-air respirator, which is a particularly expensive piece of equipment (Ref. 4). Further, for the effective use of a respirator, particularly an air-supplied respirator, there would need to be fit-testing of the respirator and training in its use.

While EPA reasons that revised labeling will not address the unreasonable risk presented by methylene chloride in paint and coating removal, as a result of recommendations from the Small Business Advocacy Review (SBAR) Panel to solicit information from the public about the potential efficacy of labeling, following advice from the small entity representatives who participated in the SBAR process (Ref. 27), EPA requests public comments on enhanced labeling requirements for consumer paint and coating removal products containing methylene chloride as a method for reducing exposure to methylene chloride in these products. More information about the SBAR process, the Panel recommendations, and advice from small businesses related to this proposal are in Unit XXIII. and in the Panel Report (Ref. 27).

While this regulatory option alone would not adequately address the unreasonable risks, EPA recognizes that the TSCA section 6(a)(3) warnings and instruction requirement can be an important component of an approach that addresses unreasonable risks associated with a specific use prohibition. EPA has included a downstream notification requirement as part of the proposed rule to ensure that users would be made aware of the prohibition on the use of methylene chloride in paint and coating removal.

An additional regulatory option receiving limited evaluation was a training and certification program for commercial paint and coating removers, similar to the certification process required under EPA's Lead-Based Paint Renovation, Repair, and Painting Rule (73 FR 21692, April 22, 2008). This option was recommended by the small entity representatives as part of the SBAR process (Ref. 27). EPA considered this option as an approach to reducing risks from methylene chloride in paint and coating removal. However, unlike the process for training and certification of commercial workers required under the Lead-Based Paint Renovation, Repair, and Painting Rule, effective risk reduction from commercial use of methylene chloride for paint and coating removal would require additional regulation of distributors of these products. When considering this approach, given the Agency's experience with the training and certification program under the Lead-Based Paint Renovation, Repair, and Painting Rule, EPA viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach. EPA seeks public comment on the feasibility of such a program and its potential to reduce risks of exposure to methylene chloride for workers and bystanders so that those risks are no longer unreasonable.

VI. Regulatory Assessment of Methylene Chloride in Paint and Coating Removal

This unit describes the current use of methylene chloride in paint and coating removal, the unreasonable risks presented by this use, and how EPA identified which regulatory options reduce the risks so that they are no longer unreasonable.

A. Methylene Chloride Uses That Are the Focus of This Regulation

The methylene chloride uses that are the focus of this action are:

1. Any consumer use of methylene chloride for paint and coating removal, and

2. Any commercial use of methylene chloride for paint and coating removal except for commercial furniture refinishing, which EPA intends to address in a separate proposal, as described in Unit XI. While EPA proposes to determine that the identified risks from methylene chloride in commercial furniture refinishing are unreasonable, EPA plans to continue public engagement before proposing regulations for methylene chloride in this industry. Additional information is in Unit XI. This is one of the recommendations from SBAR Panel (Ref. 27),

EPA proposes to exempt specific paint and coating removal with methylene chloride from critical corrosion-sensitive components of military aviation and vessels, which the Department of Defense identified as critical for national security purposes. The details of this national security use are in Unit VIII.

B. Methylene Chloride in Paint and Coating Removal

Methylene chloride has been used for decades in paint and coating removal in products intended for both commercial and consumer uses. Paint and coating removal, also referred to as paint stripping, is the process of removing paint or other coatings from a surface. Coatings can include paint, varnish, lacquer, graffiti, polyurethane, or other coatings sometimes referred to as high-performance or specialty coatings; surfaces may be the interior or exterior of buildings, structures, vehicles, aircraft, marine craft, furniture, or other objects. Paint and coating removal can be conducted in occupational or consumer settings. These surfaces, or substrates, include a variety of materials, such as wood, metals, plastics, concrete, and fiberglass. A variety of industries include paint and coating removal in their business activities, including professionals involved in renovations, bathtub refinishing, automotive refinishing, furniture refinishing, art restoration and conservation, aircraft repair, marine craft repair, and graffiti removers (Ref. 3).

Paint and coatings can be removed by chemical, mechanical, or thermal means. Chemical paint removers can include solvents, such as methylene chloride or NMP, caustic chemicals, or other categories of chemicals. Solvents aid in removing paints and coatings by permeating the top of the coating and dissolving the bond between the coating and the substrate (Ref. 30). Following the application of the chemical paint remover, the coating can be more easily peeled, scraped, or mechanically removed from the substrate. Techniques for applying the paint remover chemical include manual coating or brushing, tank dipping, flow-over systems, and spray applications (manually or through automation). Pouring, wiping and rolling are also possible application techniques and application can be manual or automated (Ref. 3).

In the construction trades, methylene chloride is used to remove paint and coatings from walls, trim, architectural features, patios or decks, ceilings, bathtubs, floors, etc. to prepare them for new coatings during residential and commercial building renovation. Methylene chloride is typically applied to the surface using a hand-held brush. It is then left on to soften the old coating (Ref. 4). Once curing has occurred, the old coating is scraped or brushed off and the surface is cleaned. For bathtub refinishing, methylene chloride is poured and brushed onto a bathtub using a paintbrush and then scraped from the bathtub after leaving the remover to cure for 20 to 30 minutes (Ref. 4). Consumers use methylene chloride in similar ways.

Commercially, methylene chloride is also used to remove paint and coatings from civilian aircraft, marine craft, cars, trucks, railcars, tankers, storage vessels, and other vehicles or their component parts to prepare for new coatings. Similar to the constructions trades, applications in the transportation industry tend to be brushed on and scraped off. More information on specific techniques for commercial paint removal and by consumers are in the methylene chloride risk assessment and supplemental materials (Refs. 2, 19, 20, 21, and 31).

Though many users are switching to substitutes and alternative methods, methylene chloride use persists because it is readily available and works quickly on nearly all coatings without damaging most substrates. In addition, some users may prefer methylene chloride because it is less flammable than some other solvents. However, it is extremely volatile, has strong fumes, and evaporates quickly so that it must be reapplied for each layer of paint or coating to be removed. Additionally, paint and coating removal products formulated with methylene chloride tend to contain high concentrations of co-solvents that are flammable, reducing one perceived advantage of methylene chloride products.

Chemical products for paint and coating removal are used across several industries as well as by consumers or hobbyists, and products intended for one type of use—such as aircraft renovation—have been used in other situations, such as bathtub refinishing (Refs. 11, 32, and 33). Products intended for one specific type of paint removal project can be easily used in a different setting. Additionally, consumers can easily use products intended for or marketed to professional users since paint removal products are readily available at big box and local hardware stores, as well as paint specialty stores.

EPA has identified 59 different products for paint and coating removal that contain methylene chloride, formulated by 10 different firms. This is approximately 54% of the total number of paint and coating removal products EPA identified (109 products) (Ref. 34). Commercial uses of these products include automotive refinishing, furniture refinishing, art conservation and restoration, pleasure craft building and repair, aircraft paint removal, graffiti removal, bathtub refinishing, and renovations in residences or other buildings. Though the number of workers and consumers exposed to methylene chloride during paint and coating removal is uncertain, EPA has several estimates based on industry data and information gathered for rulemakings promulgated previously under other statutes, such as the Clean Air Act, intended to address different risks. As described in more detail in the Economic Analysis, EPA estimates that 32,600 workers annually are exposed to methylene chloride during paint and coating removal activities (Ref. 4). Of them, 15,000 are estimated to be exposed during furniture refinishing; 17,600 are estimated to be exposed during other commercial paint and coating removal processes (Ref. 4).

Consumer use of methylene chloride in paint and coating removal is similar to commercial use but is carried out by do-it-yourself (DIY) consumers and occurs in consumer settings, such as homes, workshops, basements, garages,

and outdoors. Paint and coating removal products containing methylene chloride are the same as those used in many commercial settings, and the process consumers use is similar to commercial methods of brushing or spraying on the paint and coating removal product, allowing time to pass for the product to penetrate the coating, and then scraping the loosened coating from the surface. Manufacturers and retailers of paint and coating removal products containing methylene chloride frequently sell them to consumers in small containers with marketing language or labeling that state they are easy to use and work on a variety of paints, coatings, and surfaces (Ref. 35). Products intended for consumers containing methylene chloride must meet minimum labeling requirements prescribed by CPSC that the product contains methylene chloride and that it may cause cancer (52 FR 34698, September 14, 1987). Information about risks of death as a result of acute exposure or methods to reduce exposure through personal protective equipment or ventilation are not required and frequently are not present on products containing methylene chloride (Refs. 35 and 36). Paint and coating removers containing methylene chloride are frequently sold at home improvement retailers or automotive supply stores that sell products to consumers as well as professional users. Additionally, due to the wide availability of products available on the Internet and through various additional suppliers that serve commercial and consumer customers, consumers may foreseeably purchase a variety of paint and coating removal products containing methylene chloride. EPA estimates that a large percentage of users of paint and coating removal products containing methylene chloride are consumers, rather than occupational users. EPA estimates that approximately 1.3 million consumers annually use paint removal products containing methylene chloride (Ref. 4).

C. Analysis of Regulatory Options

In this unit, EPA explains how it evaluated whether the regulatory options considered would address the risks presented by this use as necessary so that the risks are no longer unreasonable. First, EPA characterizes the unreasonable risks associated with the current use of methylene chloride in paint and coating removal. Then, EPA describes its initial analysis of which regulatory options have the potential to achieve standard non-cancer and cancer benchmarks. The levels of acute and chronic exposures estimated to present no risks of concern for non-cancer effects also result in no risks of concern for cancer. Lastly, this section evaluates how well those regulatory options would address the unreasonable risk in practice.

1. *Risks associated with the current use.*

a. General impacts. The methylene chloride risk assessment and supplemental analyses identified acute and chronic risks from inhalation of methylene chloride during paint and coating removal by consumers and bystanders in residences; and commercial users and occupational bystanders in workplaces (individuals not using the paint and coating remover but nearby a user) (Refs. 2 and 19). EPA estimates, having refined the numbers since the risk assessment, that, annually, there are approximately 17,600 direct users at 8,600 commercial operations conducting paint and coating removal with methylene chloride for the uses proposed for regulation that will potentially benefit from the risk reduction resulting from this proposed regulation. EPA estimates that approximately 1.3 million consumers who use paint and coating removal products containing methylene chloride each year that will also potentially benefit from risk reduction resulting from this proposal (Ref. 4).

b. Impacts on minority and other populations. While all consumers and workers using paint and coating removal products containing methylene chloride would benefit from risk reduction, some populations are currently at disproportionate risk for the health effects associated with use of methylene chloride in paint and coating removal. In the construction trades, Hispanic workers (of all races) and foreign-born workers are over-represented (Ref. 4). In the U.S. population, 16% of adults are Hispanic, whereas in the construction trades, 35% of workers are Hispanic (Ref. 4). Due to their overrepresentation in the construction trades, Hispanic workers are disproportionately at risk of exposure to methylene chloride when used in paint and coating removal.

Similarly, foreign-born workers are overrepresented in the construction trades. In the U.S. population overall, 17% of workers in all industries are foreign-born, whereas in the construction trades, 28% of workers are foreign-born (Ref. 4). As a result, they may primarily speak a language other than English and could be characterized as having limited English proficiency. Under Executive Order 13166, EPA and other agencies are charged with examining and identifying the needs of individuals with limited English proficiency (65 FR 50121, August 11, 2000). Like Hispanic workers, foreign-born workers are disproportionately at risk of exposure to methylene chloride when used in paint and coating removal in the construction trades.

EPA's identification of the current disproportionate risks of methylene chloride exposure faced by Hispanic and foreign-born workers in the construction trades is part of the analysis conducted as part of EPA's efforts towards environmental justice. Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice; EPA's compliance with this executive order is detailed in Unit XXIII.

c. Impacts on children. In the methylene chloride risk assessment, EPA examined acute risks for bystanders to consumer use of methylene chloride in paint and coating removal in residential settings. Although EPA expects that users of methylene chloride in paint and coating removal would be adult individuals (16 years old and older), bystanders could be individuals of any age group (*e.g.,* children, adults, and the elderly) who are elsewhere in the house during product application and in the hours following application (Ref. 2). In most scenarios, EPA found acute risks of concern for central nervous system effects for other residents of the house, including children, in which paint and coating removal with methylene chloride was conducted (Ref 2). EPA found risks of concern not only during the application of the product, but also for several hours following (Ref. 2).

Although EPA anticipates that most consumers conducting paint and coating removal with methylene chloride would likely exclude children from the room in which the project was being carried out, it is unclear if they would exclude them from the house overall during and after the product application. Additionally, if the project involved removing the coating from a bathtub, households with only one bathroom would present challenges for bystander exclusion for several hours. As a result, children present in homes where paint and coating removal is being conducted, by family members or by professionals, face acute risks of central nervous system impacts.

EPA was not able to model scenarios in which paint and coating removal was conducted in an apartment building, hotel, or other residence or place in which children may be present other than single-family homes. However, the findings related to bystander exposure suggest risks for children and other

residents of apartments or hotel rooms adjacent to units in which paint and coating removal is being conducted. In these situations, it is even less likely that children would be excluded from all affected areas in order to protect them from acute risks. As a result, methylene chloride is likely to present acute risks to children as bystanders to paint and coating removal with methylene chloride, even if they are excluded from the areas in which work is conducted (Ref. 2).

d. Exposures for this use. Exposures assessed for this use include acute exposures to methylene chloride in paint and coating removal by consumers and residential bystanders, and acute and chronic exposures by commercial workers and occupational bystanders, as described in the methylene chloride risk assessment (Ref. 2). In some cases where commercial paint and coating removal is conducted, such as in workshops or facilities that are within residences (for example, in the case of some small businesses) (Ref. 27), exposed bystanders may include family members, such as children. The exposures assessed included some commercial furniture refinishing, which is not proposed for regulation. Different exposure scenarios were evaluated for workers, occupational bystanders, consumers, and residential bystanders (Ref. 2)

For exposures in commercial settings, EPA assessed acute risks and chronic risks, including cancer risks. For acute risks, EPA assessed four occupational scenarios based on eight-hour TWA exposure concentrations and different variations in exposure conditions, such as presence or absence of respirators and the protection factor of any respirator used. For each commercial use evaluated in the assessment, EPA modeled scenarios using assumed parameters similar to typical use conditions within those industries, such as whether work was conducted indoors or outdoors and what quantity of methylene chloride was estimated to be used. For these acute workplace estimates, the acute methylene chloride exposure concentration evaluated for risk was the eight-hour TWA air concentration in milligrams per cubic meter reported for the various relevant industries. In the risk assessment, EPA assumed that some workers could be rotating tasks and not necessarily carrying out paint and coating removal tasks using methylene chloride on a daily basis. This type of exposure was characterized as acute in this assessment because the worker's body was estimated to have sufficient time to remove methylene chloride and its metabolites before the next encounter with methylene chloride during paint and coating removal (Ref. 2).

For chronic exposure scenarios, EPA varied not only the parameters described above, but also the number of working days exposed to methylene chloride during paint and coating removal (ranging from 125 to 250 days per year) and exposed working years (varying the number of years the worker was assumed to be exposed) (Ref. 2). Overall, EPA evaluated cancer and chronic non-cancer risks for 16 occupational scenarios.

Worker inhalation exposure data were taken from peer-reviewed literature sources, as cited in the risk assessment (Ref. 2). These data sources often did not indicate whether monitored exposure concentrations were for occupational users or bystanders. Therefore, EPA assumed that these exposure concentrations were for a combination of users and bystanders. EPA evaluated scenarios both with and without respirator use and a range of respirator assigned protection factors (APFs), but did not estimate the overall frequency of respirator use because supporting data on the prevalence of respirator use for these commercial uses was unavailable. Similarly, EPA made assumptions about the exposure frequencies and working years because data were not found to characterize these parameters, and estimated various exposure frequencies (125 and 250 days per year) and working years (20 and 40 years). Thus, EPA evaluated occupational risks by developing hypothetical scenarios under the varying exposure conditions described previously (Ref. 2).

It is important to note that EPA relied on monitoring data for these occupational exposure estimates. Many air concentrations reported and used in the risk assessment exceeded the current OSHA PEL of 25 ppm; in some industries where paint and coating removal was conducted by immersion in tanks or vats of methylene chloride, air concentrations were measured at above 7,000 milligrams per cubic meter, or 2,016 ppm. Even in industries with lower expected exposures, air concentrations frequently were reported in excess of 250 milligrams per cubic meter, or 72 ppm, such as during graffiti removal and automotive refinishing (Ref. 2). The risks associated with these dramatically high air concentrations are discussed in Unit VI.C.1.e.

For consumer and residential bystander exposures, EPA assessed exposure scenarios under which the individual user was presumed to work on one of several types of paint and coating removal projects (coffee table, chest of drawers, or bathtub). These scenarios take into account that consumers do not reliably use personal protective equipment (respirators) or have access to engineering controls (*e.g.,* exhaust ventilation), since these methods are costly, technically challenging, and not easily available to consumers (Ref. 2). EPA used product label information to establish the time durations (in minutes) that the user would require to complete each step of the paint or coating removal process. User breaks during wait periods were assumed; the scenarios varied the location of where the user rested (in the work space or elsewhere). In addition, back-to-back projects were modeled because it is likely that the user would take breaks during the wait periods specified on product labels. It was further assumed that the paint scrapings were removed from the house as soon as scraping was completed. In each scenario, the bystander was assumed to be somewhere else in the house, and exposed via inhalation to some of the methylene chloride from the workspace (Ref. 2).

EPA developed seven consumer exposure scenarios for the assessment. Similar to the worker exposure assessment, the following factors were considered in developing the exposure scenarios (Ref. 2):

- The type of application (*i.e.,* brush-on or spray-on), weight fraction of methylene chloride in the paint and coating removal product, application rate by the user, surface area of object from which the paint or coating was being removed, and emission rate of the chemical, which can affect the amount of methylene chloride that ultimately is released to the indoor environment;
- The location where the product is applied, which relates to exposure factors such as the room volume and its air exchange rate with outdoor air;
- The house volume and air exchange rate, for reasons similar to those for the product use location; and
- Precautionary behaviors such as opening windows in the application room, the user leaving the application room during the wait period, related changes to the air exchange rates, and the proximity of the user to the source of methylene chloride emissions.

In the absence of representative air monitoring data for consumer users and residential bystanders using paint and coating removal products containing methylene chloride, EPA used the Multi-Chamber Concentration and Exposure Model to estimate consumer and bystander inhalation exposure concentrations (Ref. 2).

EPA's estimates of the exposures during paint and coating removal with methylene chloride experienced by commercial users and bystanders and consumer users and bystanders were used to assess the risks of this use of methylene chloride. The full exposure estimates and risk findings are described in the methylene chloride risk assessment; risk findings are also summarized in Unit VI.C.1.e.

In addition to estimating likely exposures under current use patterns (baseline exposures), for both commercial and consumer users, EPA assessed a number of exposure scenarios associated with risk reduction options in order to identify variations in methylene chloride exposure during paint and coating removal. All variations in the scenarios were applied to industry-specific exposure inputs and evaluated with exposure parameters that were modified to reflect either a reasonable worst-case scenario (also called the baseline) or a scenario in which exposures were moderated by several factors (also called the central tendency scenario). The risk reduction options that varied between scenarios included engineering controls, use of PPE, and well as combinations of these options (Ref. 19).

- Under the PPE risk reduction option exposure scenarios, EPA evaluated respirators with APF 10 to 10,000 for acute and chronic risks, including cancer risks.
- For the engineering controls risk reduction option exposure scenarios, EPA evaluated exposures using local exhaust ventilation (LEV) to improve ventilation near the activity of workers (using furniture refinishing operations as a model), with an assumed 90% reduction in exposure levels.

Overall, EPA evaluated dozens of distinct exposure scenarios for commercial paint and coating removal with methylene chloride; exposure reductions for consumer users are expected to be similar to the acute risk evaluations for professional contractors or workers in furniture refinishing operations, since these commercial activities are most similar to the types of projects in which consumers would engage (Refs. 19 and 20).

e. Specific risks for this use. The acute inhalation risk assessment used central nervous system effects to evaluate the acute risks for occupational, consumer, and bystander exposure during paint and coating removal with methylene chloride. In the risk assessment, a risk of concern was identified if the MOE estimate was less than the benchmark MOE of 10 for acute central nervous system effects (Ref. 2).

EPA assessed acute risks for central nervous system effects from inhalation for all consumer, occupational, and bystander exposure scenarios of paint and coating removal with methylene chloride. For consumers, EPA identified risks of concern for all scenarios, with some consumer scenarios demonstrating risks within the first hour of product use when paint and coating removal was conducted indoors (such as in a workshop or bathroom), regardless of whether the product formulation was brush or spray. Risks for incapacitating nervous system effects were found in some indoor scenarios (such as in a bathroom) within four hours of product use. MOEs for consumer acute risks from exposures of one hour or less ranged from 1.6 to 0.2; this equates to estimated exposures that are between six and 50 times greater than those that are expected to produce no risks of concern (Ref. 2).

For residential bystanders, EPA identified risks of concern for all scenarios, even assuming that any bystander in the house was not in the room where the paint and coating removal occurred. Depending on the parameters of the scenario, MOEs for acute risks ranged from 2.9 to 0.5, or between three and 20 times greater than those that are expected to produce no risks of concern (Ref. 2).

For commercial users, the occupational scenarios in which acute risks for central nervous system effects were identified included nearly all occupational scenarios, irrespective of the absence or presence of respirators, and in both the central-tendency and worst-case assumed air concentrations of methylene chloride. Additionally, EPA found acute risks for incapacitating central nervous system effects for workers who had no respiratory protection in most industries, or with respirators with APFs of 10 or 25 in the industries with highest likely exposures, such as professional contractors, aircraft refinishers, and workers using immersion methods for paint and coating removal in several industries. MOEs for acute risks ranged from an average of 0.11 (automotive refinishing) to 0.037 (graffiti removal), with a lowest end of 0.0063 (workplaces engaged in paint and coating removal using immersion methods). In general, these workplaces are estimated to present exposure levels between 100 times to greater than 1,000 times more than those that are of concern. Not only workers, but also occupational bystanders, or workers engaged in tasks other than paint and coating removal, would be at acute risk for central nervous system effects (Ref. 2). Therefore, EPA's proposed determination is that acute methylene chloride exposures during paint and coating removal present unreasonable risks.

In the risk assessment, EPA also assessed risks of chronic exposure to methylene chloride during paint and coating removal by commercial users and occupational bystanders (Ref. 2). The methylene chloride risk assessment used liver toxicity as the critical endpoint for chronic exposure. EPA assessed risks for liver toxicity for occupational and bystander exposure scenarios of paint and coating removal with methylene chloride.

Workers and occupational bystanders in most industries evaluated were identified as at risk for non-cancer liver toxicity as a result of chronic exposure to methylene chloride during paint and coating removal under typical exposure scenarios. When workers were exposed repeatedly at facilities they were at risk, even for scenarios evaluated with workers wearing respiratory protection with APF 50 (Ref. 2). The concern is for workers engaging in long-term use of the product (*i.e.,* 250 days/year for 40 years) with no respiratory protection.

For commercial users and bystanders, EPA also assessed cancer risks as a result of chronic exposure to methylene chloride in paint and coating removal. Workers and occupational bystanders showed were estimated to have an excess cancer risk greater than 1 in 1,000,000 for all of the commercial scenarios evaluated if exposed to paint and coating removal with methylene chloride for 250 days per year for 40 years with no respiratory protection. Depending on industry, cancer risks ranged from 6 in 10,000 (graffiti removal) to 2.5 in 1,000 (aircraft refinishing), with a maximum of 4 in 1,000 (workplaces using immersion methods, such as dip tanks for miscellaneous metal items). Workers in all industries showed a relative reduction in cancer risks when estimated to be working for 125 days per year for 20 years with a respirator with APF 50, with cancer risks in some industries estimated to be below benchmark levels in these scenarios. Therefore, EPA's proposed determination is that chronic methylene chloride exposures during paint and coating removal present unreasonable risks.

The SBAR Panel convened in support of this action heard from several SERs who expressed concerns about the underlying methylene chloride risk assessment (Ref. 27). Many of the concerns expressed by these SERs were already expressed in the public comments and the peer review

comments on the methylene chloride risk assessment. The Summary of External Peer Review and Public Comments and Disposition document in the risk assessment docket (EPA–HQ–OPPT–2012–0725) explains how EPA responded to the comments received.

2. *Initial analysis of potential regulatory options.* Having determined that the risks from methylene chloride in paint and coating removal were unreasonable, EPA evaluated whether regulatory options under section 6(a) could reduce the risk (non-cancer and cancer) so that it is no longer unreasonable.

The results of EPA's assessment of consumer uses, exposures, and risks indicate that regulatory options for consumer uses such as reducing the concentration of methylene chloride or advising the use of respirators could not achieve the target MOE benchmarks for acute exposures (benchmark MOE is 10). Similarly, the results of EPA's evaluation indicate that regulatory options for occupational exposures such as reducing the concentration of methylene chloride in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks (benchmark MOE is 10) for non-cancer endpoints for acute and chronic exposures and common cancer risk benchmarks for chronic exposures (Refs. 19 and 20). The results also demonstrate that all risk reduction options meeting the benchmark MOEs and common cancer benchmarks for methylene chloride in paint and coating removal require the use of a respirator, whether used alone or in conjunction with additional levels of protection or the use of an air exposure limit. Therefore, EPA found the options of setting a maximum concentration of methylene chloride in products under TSCA section 6(a)(2) unable to reduce exposures to the risk benchmarks. Options found not to meet the risk benchmarks and, for the purposes of this proposal, found unable to address the unreasonable risk, are documented in EPA's supplemental technical reports on methylene chloride in paint and coating removal (Refs. 19 and 20).

3. *Assessment of whether regulatory options address the identified unreasonable risk so that methylene chloride in paint and coating removal no longer presents such risk.* As discussed earlier, EPA considered a number of regulatory options under TSCA section 6(a) for methylene chloride in paint and coating removal for the uses proposed for regulation. In assessing these options, EPA considered a wide range of exposure scenarios (Refs. 19, 20, and 38). These include both baseline and risk reduction scenarios involving varying factors such as exposure concentration percentiles, LEV use, respirator use, working lifetimes, etc. As part of this analysis, EPA considered the impacts of regulatory options on consumer users and commercial users separately. However, EPA is proposing to address paint and coating removal with methylene chloride for consumer uses together with many commercial uses, rather than as separate consumer and commercial uses. As described earlier, in Unit VI.B., paint and coating removal products containing methylene chloride frequently are available in the same distribution channels to consumers and professional users. Products are marketed for a variety of projects, and cannot be straightforwardly restricted to a single type of project or user. As highlighted in the investigation into recent deaths among bathtub refinishers using methylene chloride, ''ten different products were associated with the 13 deaths [from 2000–2011]. Six of the products were marketed for use in the aircraft industry, the rest for use on wood, metal, glass, and masonry. None of the product labels mentioned bathtub refinishing'' (Ref. 33).

The options that had the potential to address the unreasonable risks presented by methylene chloride when used for paint and coating removal by consumers, or within the commercial uses proposed for regulation, or for both consumer and these commercial uses included:

a. A supply-chain approach, which would include prohibiting the manufacturing (including import), processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for the consumer and commercial uses proposed for regulation; prohibiting the commercial use of methylene chloride in paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation; requiring that all paint and coating removers containing methylene chloride be distributed in volumes no less than 55-gallon containers under TSCA section 6(a)(2); requiring downstream notification when distributing methylene chloride under TSCA section 6(a)(3); and limited recordkeeping under TSCA section 6(a)(4);

b. Variations on such an approach, such as just prohibiting the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for consumer use and for the commercial uses proposed for regulation or just prohibiting the commercial use of methylene chloride for paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation;

c. Additional variations on such an approach, such as prohibiting the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for the consumer and commercial uses proposed for regulation and requiring downstream notification (*e.g.,* via a Safety Data Sheet (SDS)) when distributing methylene chloride for other uses under TSCA section 6(a)(3); and

d. Requiring a respiratory protection program, including PPE (a supplied-air respirator with APF 1,000 or 10,000) with an alternative air exposure limit of 1 part per million (ppm) achieved through engineering controls or ventilation alone or in combination with a supplied-air respirator at a lower APF, in commercial facilities where methylene chloride is used for paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation.

A discussion of the regulatory options that could potentially reach the risk benchmarks for consumer use, commercial uses proposed for regulation, or both is in this unit, along with EPA's evaluation of how well those regulatory options would address the unreasonable risks in practice.

a. Proposed approach. The proposed regulatory approach for methylene chloride in paint and coating removal for the uses proposed for regulation would prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for consumer uses and for the commercial uses proposed for regulation; would prohibit the commercial use of methylene chloride for paint and coating removal under TSCA section 6(a)(5) for the uses proposed for regulation; would require any remaining paint and coating removal products containing methylene chloride to be distributed in packaged volumes no less than 55-gallon containers, under TSCA section 6(a)(2); would require manufacturers, processors, and distributors to provide downstream notification of the prohibitions under TSCA section 6(a)(3), and would require recordkeeping relevant to these

prohibitions under TSCA section 6(a)(4).

As discussed in Unit VI.C.1., the risks for exposure to consumers, workers, and bystanders for methylene chloride in paint and coating removal vary. The MOEs for non-cancer endpoints range from 50 to 1,000 times below the benchmark MOEs for central nervous system effects (the acute health impact) or liver toxicity (the chronic health impact). Similarly, the increased risk of cancer (including brain, liver, and lung cancer) in some industries is 100 to nearly 1,000 times greater than common cancer benchmarks (Ref. 2). Under this proposed option, exposures to methylene chloride during paint and coating removal would be completely eliminated. As a result, non-cancer and cancer risks would be eliminated.

The proposed approach would reduce the risks to workers, consumers, and bystanders from methylene chloride in paint and coating removal for the uses proposed for regulation so that those risks are no longer unreasonable. Prohibiting the manufacturing, processing and distribution in commerce of methylene chloride for paint and coating removal for the uses proposed for regulation would minimize the overall availability of methylene chloride for paint and coating removal for these uses. Importantly, this proposed regulation is protective of consumer users. EPA cannot regulate consumer use under TSCA section 6(a)(5). The prohibition of the commercial use of methylene chloride for paint and coating removal in the uses proposed for regulation would reduce commercial demand for methylene chloride paint and coating removal products, reduce the likelihood that other types of products formulated with methylene chloride would be used for paint and coating removal, and significantly reduce the potential for consumer use of commercial paint and coating removal products containing methylene chloride. Workers and occupational bystanders would not be exposed to methylene chloride for paint and coating removal in the uses proposed for regulation, and the risk to consumers and residential bystanders would be minimized because commercial paint and coating removal products containing methylene chloride would not be available in volumes smaller than 55-gallon containers. This large volume requirement would ensure that consumers, who typically buy products in much smaller volumes, would not be able to easily divert products from the supply chain intended for commercial furniture refinishing or uses proposed to be critical to national security. EPA seeks comment on the impact to commercial furniture refinishers of a requirement that paint and coating removal products containing methylene chloride be sold only in 55-gallon containers for commercial paint and coating removal. This request for comment is one of the recommendations of the SBAR Panel, described earlier in Unit V.C. and in more detail in Unit XXIII.C. (Ref. 27). Based on the recommendations from the SBAR Panel, EPA is requesting comment on whether the rule should allow paint and coating removal products containing methylene chloride to be sold in 30-gallon containers, rather than limiting the volume to 55-gallon containers. EPA is also requesting comment on the feasibility of implementing appropriate industrial hygiene controls associated with 30- or 55-gallon containers in order to minimize potential disruptive impacts to those industrial processes where technically feasible substitutes are currently unavailable. The downstream notification of these restrictions ensures that processors and distributors are aware of the manufacturing, processing, distribution in commerce and use restrictions for methylene chloride in paint and coating removal, and enhances the likelihood that the risks associated with this use of methylene chloride are addressed throughout the supply chain. Downstream notification also streamlines compliance and enhances enforcement, since compliance is improved when rules are clearly and simply communicated (Ref. 39). This integrated supply chain proposed approach mitigates the risk to consumers and commercial workers and occupational bystanders in the uses proposed for regulation from methylene chloride in paint and coating removal.

b. Options that are variations of elements of the proposed approach. One variation of the proposed approach would be to prohibit manufacture, processing, and distribution in commerce of methylene chloride for consumer and commercial paint removal for the uses proposed for regulation without the prohibition on commercial use of methylene chloride for paint and coating removal and without the downstream notification of any prohibitions. Without the accompanying prohibition on commercial use and downstream notification that is included in the proposed supply chain approach, this option would leave open the likelihood that commercial users falling within the scope of this proposed rule and consumer users could obtain methylene chloride (which would continue to be available for other uses, such as degreasing or solvent purposes) and use it for paint and coating removal.

Without downstream notification, unsophisticated purchasers in particular are likely to be unfamiliar with the prohibitions regarding this use and mistakenly use methylene chloride for paint and coating removal, thereby exposing themselves and bystanders to unreasonable risks. Thus, under these variations, EPA anticipates that many users would not actually realize the risk benchmarks. Therefore, these variations fail to protect against the unreasonable risks.

Another regulatory option that EPA considered was to prohibit only the commercial use of methylene chloride for paint and coating removal in the uses proposed for regulation. This approach would reduce both non-cancer and cancer risks for commercial settings, but it would not reduce risks to consumers so that they are no longer unreasonable. By prohibiting use in the commercial sector alone, without a prohibition on the manufacture, processing, and distribution in commerce of paint and coating removal products containing methylene chloride for consumer and commercial use in the uses proposed for regulation, this approach would not address consumer risks as distributors of paint and coating removal products containing methylene chloride could continue to distribute to consumers methylene chloride marked as a paint and coating remover, including products labeled and marketed as ''professional strength'' or ''commercial grade'' products. Since it is foreseeable that consumers would continue to purchase products labeled and marketed in this fashion, and consumers would continue to be exposed far above the health benchmarks, they would not be protected from the unreasonable risks posed by methylene chloride.

c. Prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal under TSCA section 6(a)(2) or prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal under TSCA section 6(a)(2) and require downstream notification when distributing methylene chloride for other uses under TSCA section 6(a)(3). EPA considered prohibiting the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal including an option with a requirement for downstream

notification of such prohibition. If such a prohibition were effective, this option would mitigate the risks to consumers from methylene chloride in paint and coating removal. However, EPA recognizes that consumers can easily obtain products labeled for commercial use. Indeed, for many consumers, identifying a product as being for commercial use may imply greater efficacy. Coupled with the fact that many products identified as commercial or professional are readily obtainable in a variety of venues (*e.g.,* the Internet, general retailers, and specialty stores, such as automotive stores), EPA does not find that this option would protect consumers. In addition, this option alone would not address the risks to workers from methylene chloride in paint and coating removal.

d. Requiring a respiratory protection program, including PPE, air monitoring, and either a supplied-air respirator of APF 1,000 or 10,000 or an air exposure limit of 1 part per million (ppm) achieved through engineering controls or ventilation, in commercial facilities where methylene chloride is used for paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation. Another regulatory option that EPA considered for the commercial uses of methylene chloride for paint and coating removal proposed for regulation was to require risk reduction through an occupational respiratory protection program, which would include air monitoring, medical monitoring, and respiratory protection through use of a supplied-air respirator with an APF of 1,000 or 10,000, depending on the methods used for paint and coating removal with methylene chloride and other workplace characteristics, with a performance-based alternative of meeting an air concentration level of 1 ppm as an exposure limit for methylene chloride. A full-facepiece (or helmet/hood) self-contained breathing apparatus (SCBA) when used in the pressure demand mode or other positive pressure mode has an APF of 10,000. EPA's analysis showed that use of a SCBA with an APF of 10,000 would, in all scenarios evaluated, control the exposure of methylene chloride to levels that allow for meeting the benchmarks for non-cancer and cancer risks. Exposures in most workplaces proposed for regulation could be reduced with an APF of 1,000 to exposure levels that reduce risks to benchmark levels (Ref. 19). It is important to note that current OSHA requirements for dermal and eye protection when using methylene chloride in any way would be maintained under this approach, in addition to other requirements for work practices, training, and hazard communication put forth in OSHA's Methylene Chloride Standard (29 CFR 1910.1052). It is also important to note that any respirator used would need to be a supplied-air respirator, since methylene chloride can clog or damage filters or cartridges for air-purifying respirators, rendering them non-protective (Ref. 19).

Although respirators, specifically SCBAs, could reduce exposures to levels that are protective of non-cancer and cancer risks, not all workers may be able to wear respirators. Individuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for tight fitting full-face piece respirators to provide the required protection. Individuals with facial hair, like beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998). According to OSHA, ''improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health.'' (63 FR 1189–1190). Nonetheless, OSHA views respiratory protection as a backup method which is used to protect employees from toxic materials in those situations where feasible engineering controls and work practices are not available or are insufficient to protect employee health (63 FR 1156–1157). The OSHA respiratory protection standard (29 CFR 1910.134) requires employers to establish and implement a respiratory protection program to protect their respirator-wearing employees. This OSHA standard contains several requirements, *e.g.,* for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; respirator use; respirator cleaning, maintenance, and repair; and other provisions.

In addition, OSHA adopted a hierarchy of controls established by the industrial hygiene community and used to protect employees from hazardous airborne contaminants, such as methylene chloride (29 CFR 1910.1052). According to this hierarchy, substitution of less toxic substances, engineering controls, administrative controls, and work practice controls are the preferred method of compliance for protecting employees from airborne contaminants and are to be implemented first, before respiratory protection is used. OSHA permits respirators to be used where engineering controls are not feasible or during an interim period while such controls are being implemented.

Given equipment costs and the costs of establishing a respiratory protection program, which involves training, respirator fit testing, and the establishment of a medical monitoring program, EPA anticipates that most companies would choose to switch to substitutes instead of adopting a program for this type of PPE to continue using methylene chloride for paint and coating removal because this type of PPE program is not cost-effective. Further, even if cost were not an impediment, there are many limitations to the successful implementation of respirators with an APF of 1,000 or 10,000 in a workplace. As recommended by the SBAR panel, EPA is requesting comment on and information about workplace experience with respiratory protection programs and air monitoring for methylene chloride (Ref. 27). Specifically, EPA seeks comment on whether companies would opt to substitute an alternate chemical or process instead of implementing a worker protection program for PPE. EPA also requests comment on the scientific and technical support used for development of the 1 ppm air exposure limit (Ref. 21) for methylene chloride and the feasibility of implementing and enforcing this performance-based approach. Additionally, EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

EPA also considered requiring a combination of local exhaust ventilation and supplied-air respirators with APF of 1,000 or 50, with a performance-based alternative to the respirator of an air exposure limit of 1 ppm as an eight-hour TWA. When properly executed, this option would reduce risks to the health benchmarks for workers and bystanders (Refs. 19, 21, and 38). However, while this option has the benefit of incorporating engineering controls and the use of respirators with a lower APF, the limitations to successful implementation of the use of supplied-air respirators in the workplace discussed previously are still present. EPA is requesting comment on

whether this alternate option of allowing industrial use at specified exposure levels and with appropriate personal protective equipment should be adopted. Specifically, EPA seeks information on whether this alternative approach would incentivize industry to eliminate methylene chloride use in paint and coating removal wherever technically feasible while minimizing disruptive impacts to those processes where technically feasible substitutes are currently unavailable.

Furthermore, neither of the variations of relying upon respiratory protection for commercial paint and coating removal with methylene chloride addresses consumer risks. EPA does not have the authority to require that consumers change use practices or wear PPE. Even if this approach were coupled with a TSCA section 6(a)(2) prohibition on the manufacture, processing and distribution in commerce of methylene chloride for consumer use in paint and coating removal, this would not protect consumers because they would foreseeably continue to buy and use paint and coating removal products containing methylene chloride intended for commercial users, *e.g.,* via the Internet or home improvement or automotive supply retailers. Consumers would continue to be exposed far above the established health benchmarks when using methylene chloride for paint and coating removal (Ref. 20).

Therefore, considering the increased complexity of a respiratory protection program involving supplied-air respirators as well as the general inability to require that consumers adhere to a respiratory protection program resulting in little mitigation of risks to consumers, an option focusing on respiratory protection would not address the unreasonable risks presented by these uses.

D. Adverse Health Effects and Related Impacts That Would Be Prevented by the Proposed Option

The proposed option would prevent exposure to methylene chloride from paint and coating removal and thus would prevent the risks of adverse effects and associated impacts. As discussed in Unit II.C., the range of adverse health effects includes effects on the nervous system, liver, respiratory system, kidneys, and reproductive systems (Ref. 2). These health effects associated with exposure to methylene chloride are serious and can have impacts throughout a lifetime. The following is a discussion of the impacts of significant acute, chronic non-cancer, and cancer effects associated with methylene chloride exposure during paint and coating removal, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

1. Nervous system effects—acute exposures. The methylene chloride risk assessment and EPA's 2011 IRIS assessment identified nervous system effects as the critical effect of greatest concern for acute exposure to methylene chloride. Specifically, these assessments identified sensory impairment and incapacitation (loss of consciousness) as the critical effect of acute exposures (Refs. 2 and 5). Exposure to methylene chloride can rapidly cause death as a result of nervous system depression, but even exposures that may in some cases result only in dizziness or fainting can be fatal if the individual who is disoriented or has fainted is alone. Several individuals have died after becoming incapacitated during paint and coating removal with methylene chloride; after losing consciousness, their nervous system is overcome by the continued accumulation of volatile fumes. As described in a recent report on deaths caused by methylene chloride, ''. . . the danger posed by methylene chloride is its one-two punch when fumes accumulate. Because it turns into carbon monoxide in the body, it can starve the heart of oxygen and prompt an attack. The chemical also acts as an anesthetic at high doses: Its victims slump over, no longer breathing, because the respiratory centers of their brains switch off.'' (Ref. 7).

There are increased risks of death and nervous system effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated, as well as for the estimated 1.3 million consumers and residential bystanders who use or are exposed to paint and coating removers containing methylene chloride each year (Ref. 4).

Although the fact that deaths occur as a result of exposure to methylene chloride is well documented, the exact number of deaths specifically attributable to methylene exposure is unclear. In 2012, the Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report (MMWR) published results of an investigation into deaths among bathtub refinishers using methylene chloride. The authors of the investigation and the MMWR editors emphasized that the reported number of deaths due to methylene chloride is an underestimate and subject to at least three limitations: A lack of reporting to the OSHA incident database by self-employed individuals, no equivalent database to track consumer incidents and fatalities, and the likelihood that deaths due to methylene chloride exposures are misattributed to heart disease, since the pathology is similar (Ref. 33).

Based on data from OSHA, CPSC, state records, and publicly reported information, EPA has identified 49 fatalities since 1976 resulting from consumer or commercial worker exposure to methylene chloride during paint and coating removal, including for uses not proposed for regulation. However, as described earlier, this is likely an underestimate of the deaths that have occurred. As highlighted in the MMWR report from 2012 and OSHA alert from 2016, health effects from methylene chloride exposure are often misattributed to other causes (Refs. 32 and 33). For example, in several cases, workers were seen in hospital emergency rooms with symptoms of solvent exposure, were not properly diagnosed, and were sent back to the same work that ultimately killed them (Ref. 32).

Thus, EPA is unable to quantify the precise number or frequency of deaths that occur as a result of exposure to methylene chloride during paint and coating removal. However, the sporadically-occurring deaths outside of bathtub refinishing that have been documented as caused by methylene chloride, and the undocumented deaths that have been misattributed to heart disease should not be ignored merely because they cannot be monetized. Death following exposure to methylene chloride during paint and coating removal are characterized by family members as suddenly tragic, particularly when the deceased is young. In 1986 in Colorado, a worker died two hours into his first day on the job using methylene chloride to remove coatings from furniture (Ref. 40). In 2014 in New York, a 20-year old worker died while helping his father with a job refinishing a hotel bathtub (Ref. 41).

Fatalities have also occurred among more experienced workers. In 1990 in Georgia, a worker died while repairing a plastic-coated metal rack; he was found to have fainted and fallen into the tank of methylene chloride the company used to strip rack coatings (Ref. 7). In several instances, pairs of workers were killed while working on the same paint removal project with methylene chloride, such as renovating a squash court or the floor tile of a bathroom in a federal office building (Ref. 40).

In other cases, workers died when helping co-workers in distress. In South Carolina, in 1986, several workers were

killed or hospitalized in one incident: Two workers went to check on a colleague in a basement using a paint remover with methylene chloride; all three died. Five emergency responders arrived at the scene, and three were hospitalized due to inhalation of fumes (Ref. 7).

These sudden, unexpected deaths are not limited to commercial users or occupational bystanders exposed to methylene chloride during paint and coating removal. Consumer fatalities have been recorded, such as the woman who died in her house in 1990 in Ohio after removing paint from furniture with methylene chloride, as reported to the American Association of Poison Control Centers (Ref. 7). Consistent with the underreporting of commercial deaths, EPA estimates there are unreported consumer deaths due to exposure to methylene chloride during paint and coating removal.

These deaths clearly have a significant impact on families, workplaces, and communities, and yet not all of them can be monetized. Similarly, the serious health effects and lifetime impacts on workers who do not die but who are hospitalized with heart failure, coma, or other effects also cannot be quantified or monetized. However, the impacts of these effects should not be ignored. One example is a case in 2012 in California, where one man attempted to save a co-worker who had collapsed while cleaning a paint-mixing tank. The collapsed worker died, and the man attempting to rescue him was incapacitated within several seconds and lost consciousness. Though he survived, he required resuscitation, hospitalization for four days, and lengthy follow-up treatments (Ref. 7). The impacts on workers with severe but non-fatal nervous system impacts include monetary, personal health, and emotional suffering costs that cannot be quantified or monetized, but again, should not be ignored. These severe nervous system impacts can include coma and heart failure (Ref. 2).

Even when less severe, the nervous system effects of acute exposure to methylene chloride can have considerable adverse consequences on an individual, particularly if one is exposed as a bystander who is unaware of why these nervous system effects are occurring. Commercial and consumer users as well as bystanders in workplaces and residences are at risk of dizziness and sensory impairment during most uses of methylene chloride for paint and coating removal. Similarly, chronic exposure to methylene chloride presents risks to the nervous system of commercial users, consumer users, and bystanders exposed to methylene chloride in paint and coating removal.

2. Nervous system effects—chronic exposures. The methylene chloride risk assessment identified nervous system effects as adverse effects of chronic exposure to methylene chloride exposure in paint and coating removal. There are increased health risks for nervous system effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Chronic exposures in occupational settings put users and bystanders at risk of cognitive impairment (affecting eye-hand coordination, tracking tasks, auditory vigilance); adverse effects on autonomic, neuromuscular, and sensorimotor functions (Ref. 2); and long-term effects on specific cognitive-neurological measures (*i.e.,* attention and reaction time) (Ref. 5).

3. Liver toxicity. The methylene chloride risk assessment identified liver toxicity and liver cancer as adverse effects of chronic exposure to methylene chloride exposure in paint and coating removal. There are increased health risks for liver toxicity and liver cancer for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Specific effects to the liver include hepatic vacuolation and non-alcoholic fatty liver disease (NAFLD) (Ref. 2). Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans. Included in this number is at least 20% of those with NAFLD. NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors. The danger of NAFLD is that it can cause the liver to swell, which may result in cirrhosis over time and could even lead to liver cancer or failure (Ref. 42). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals such as methylene chloride.

Chronic exposure to methylene chloride can also lead to liver cancers including hepatocellular carcinomas (HCC), hepatocellular adenomas, and biliary tract cancer (Ref. 2). The monetizable benefits associated with reducing the risk of liver cancers associated with methylene chloride exposure are discussed in Unit VII.B. However, the impacts of these cancers should not be measured only as dollar valuations. For example, because HCC is frequently diagnosed only after an individual's health has deteriorated, survival is usually measured in months. As a result, ''HCC is responsible for a large proportion of cancer deaths worldwide . . . HCC classically arises and grows in silent fashion, making its discovery challenging prior to the development of later stage disease'' (Ref. 43). Recommended treatments are aggressive interventions such as the removal of the tumors or sections of the liver; the life expectancy of patients with HCC is a mean survival rate of 6 to 20 months. Advanced cases can metastasize to any organ system, and tends to spread to bones and lungs. Bone pain related to metastasis is frequently the initial presenting symptom of HCC (Ref. 43).

Additional medical and emotional costs are associated with cancer and non-cancer liver toxicity following chronic exposure to methylene chloride in paint and coating removal, although these costs cannot be quantified. These costs include medical visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to methylene chloride and other solvents; however, this may impact an individual's ability to continue to work. In severe cases, liver toxicity can lead to liver failure, which can result in the need for a liver transplant. Even if a donor is available, liver transplantation is expensive (with an estimated cost of $575,000) and there are countervailing risks for this type of treatment (Ref. 44). The mental and emotional toll on an individual and their family as they try to identify the cause of sickness and possibly experience an inability to work, as well as the potential monetary cost of medical treatment required to regain health, are significant.

4. *Hematopoietic cancers.* EPA's 2011 IRIS assessment for methylene chloride found that it is a likely human carcinogen. Chronic inhalation exposure to methylene chloride such as during paint and coating removal has been shown to result in increased risk for non-Hodgkin's lymphoma (NHL) or multiple myeloma in workers (Ref. 5). There are increased risks for NHL or

multiple myeloma for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

NHL is a form of cancer that originates in the lymphatic system. Approximately 19 new cases per 100,000 adults per year are diagnosed, with approximately 6.2 deaths per 100,000 adults annually (Ref. 45). NHL is the seventh most common form of cancer (Ref. 46). Other factors that may increase the risk of NHL are medications that suppress a person's immune system, infection with certain viruses and bacteria, or older age (Ref. 47).

Symptoms of NHL are swollen lymph nodes in the neck, armpits or groin, abdominal pain or swelling, chest pain, coughing or trouble breathing, fatigue, fever, night sweats, and weight loss. Depending on the rate at which the NHL advances, treatment may consist of monitoring, chemotherapy, radiation, stem cell transplant, medications that enhance the immune system's ability to fight cancer, or medications that deliver radiation directly to cancer cells (Ref. 47).

Multiple myeloma is a related hematopoietic cancer, formed by malignant plasma cells. Multiple myeloma is characterized by low blood counts, bone and calcium problems, infections, kidney problems, light chain amyloidosis, and various forms of abnormal plasma cell growth. Often, multiple myeloma has no clinical symptoms until it reaches an advanced stage (Ref. 48).

Treatments for NHL or multiple myeloma result in substantial costs for hospital and doctors' visits in order to treat the cancer. Treatments for NHL or multiple myeloma can also have countervailing risks and can lead to patients' higher susceptibility for secondary malignancies (Refs. 47 and 48). The emotional and mental toll from wondering whether a treatment will be successful, going through the actual treatment, and inability to do normal activities, or work will most likely be high (Ref. 49). This emotional and mental toll could extend to the person's family and friends as they struggle with the diagnosis and success and failure of a treatment regime.

5. Brain cancer. EPA's 2011 IRIS assessment for methylene chloride found that it is a likely human carcinogen. Chronic inhalation exposure to methylene chloride has been shown to result in brain cancer (Ref. 5). There are increased risks for brain cancer for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Researchers at the National Cancer Institute found that ''associations of astrocytic brain cancer were observed with likely exposure to carbon tetrachloride, methylene chloride, tetrachloroethylene, and trichloroethylene, but were strongest for methylene chloride. . . . Risk of astrocytic brain tumors increased with probability and average intensity of exposure, and with duration of employment in jobs considered exposed to methylene chloride . . . These trends could not be explained by exposures to the other solvents'' (Ref. 50).

Cancers that originate in the brain, which include astrocytic brain cancers, are relatively rare. Astrocytic brain cancers are estimated to have an incidence of approximately 10 cases per 1 million people per year, depending on how these types of cancers are defined (Ref. 51). Astrocytic tumors are characterized by varying degrees of growth potential and infiltration into nearby tissues. They include tumors that can spread quickly through the brain stem (brain stem gliomas); affect the pineal gland, which controls the sleeping and waking cycle (pineal astrocytic tumors); grow slowly and can be relatively easily cured (pilocytic astrocytoma); grow slowly but often spread into nearby tissues (diffuse astrocytoma); grow quickly and spread into nearby tissues (anaplastic astrocytoma); and grow quickly, spread quickly into nearby tissues, and usually cannot be cured (glioblastoma) (Ref. 51).

For astrocytic brain cancers, like other primary malignant brain tumors, initial clinical symptoms are frequently headaches and seizures. Lower-grade tumors may persist undetected for years, whereas the faster-growing or faster-spreading tumors may rapidly provoke neurological decline. Other symptoms may include nausea, vomiting, headache, and confusion as a result of increased intracranial pressure (Ref. 51).

Treatment for astrocytic brain cancers varies by the type and stage of the tumor; it can include pharmacological treatment (for many patients, this includes steroids and anti-convulsants if they are experiencing seizures), surgery (depending on location of the tumor, they may be removed or separated from the brain), chemotherapy, hormone modulation, or combinations of these treatments (Ref. 51). Like most cancer treatments, these can have countervailing risks. Additionally, the emotional and mental tolls described in earlier sections are relevant to these cancer treatments as well (Ref. 49).

6. Lung cancer. EPA's 2011 IRIS assessment for methylene chloride found that it is a likely human carcinogen. Chronic inhalation exposure to methylene chloride has been shown to result in bronchoalveolar carcinomas (BAC) or bronchoalveolar adenomas, which are forms of lung cancer (Ref. 5). There are increased risks for these lung cancers for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

BAC is a small percent of lung cancers (between 2% to 4%) and has unique characteristics. It is notable for its weak relationship with cigarette smoking; about one-third of patients in the United States with BAC were never smokers. Additionally, because it rarely spreads outside the lungs, it is often initially diagnosed as pneumonia or other lung inflammations (Ref. 52). Most patients do not present clinical symptoms (Ref. 52) and are only diagnosed following radiography or biopsy. Treatment requires surgery (Ref. 52). This has clear countervailing risks, and even if successful in removing any tumors present, the BAC may return.

7. Mammary tumors. Exposure to methylene has been shown to result in significant increases in the incidence of adenomas, fibroadenomas, or fibromas in or near the mammary gland (Refs. 2 and 5). These are largely benign tumors (Ref. 2). Though many benign tumors do not require invasive procedures, doctors recommend removing fibroadenomas. Patients need to undergo a biopsy to identify the carcinogenic risk of the tumor, and have the tumors removed if they continue to grow, change the shape of the breast, or are carcinogenic (Ref. 53). If removal is necessary, the procedure may also require the removal of nearby healthy mammary tissue, resulting in scarring and changed shape and texture of the breast (Ref. 53). Women with fibroadenomas and adenomas also have an increased risk of breast cancer, estimated to be approximately 1.5 to 2.0 times the risk of women with no breast changes (Ref. 54).

8. Reproductive effects. EPA's 2011 IRIS assessment for methylene chloride found that exposure can have reproductive effects that include testicular and ovarian atrophy (Ref. 5). At very high exposures, chronic inhalation of methylene chloride during paint and coating removal can result in these reproductive effects, which are related to decreased fertility (Ref. 55).

There are increased risks for these reproductive effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4). Similar to effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing exposure to methylene chloride or the total number of cases avoided can be estimated, EPA still considers their impact.

9. *Kidney toxicity.* EPA's 2011 IRIS assessment for methylene chloride identified kidney effects from exposure to methylene chloride; these effects include renal tubular degeneration (Ref. 5). At very high exposures, chronic inhalation exposure to methylene chloride during paint and coating removal can result in kidney toxicity. There are increased risks for these kidney effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Exposure to methylene chloride can lead to changes in the proximal tubules of the kidney. This damage may result in signs and symptoms of acute kidney failure that include; decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness; shortness of breath; fatigue; confusion; nausea; seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Kidney toxicity means the kidney has suffered damage that can result in a person being unable to rid their body of excess urine and wastes. In extreme cases where the kidney is impaired over a long period of time, the kidney could be damaged to the point that it no longer functions. When a kidney no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 56).

The monetary cost of kidney toxicity varies depending on the severity of the damage to the kidney. In less severe cases, doctor visits may be limited and hospital stays unnecessary. In more severe cases, a person may need serious medical interventions, such as dialysis or a kidney transplant if a donor is available, which can result in high medical expenses due to numerous hospital and doctor visits for regular dialysis and surgery if a transplant occurs. The costs for hemodialysis, as charged by hospitals, can be upwards of $100,000 per month (Ref. 57).

Depending on the severity of the kidney damage, kidney disease can impact a person's ability to work and live a normal life, which in turn takes a mental and emotional toll on the patient. In less severe cases, the impact on a person's quality of life may be limited while in instances where kidney damage is severe, a person's quality of life and ability to work would be affected. While neither the precise reduction in individual risk of developing kidney toxicity from reducing exposure to methylene chloride during paint or coating removal or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to methylene chloride.

10. Disproportionate impacts on environmental justice communities. An additional factor that cannot be monetized is the disproportionate impact on environmental justice communities. As described in Unit VI.C.1.b., Hispanic and foreign-born workers, who may have limited English proficiency, are disproportionately over-represented in construction trades (Ref. 4), in which methylene chloride is used for paint and coating removal. Because they are disproportionately over-represented in this industry, these populations are disproportionately exposed to methylene chloride during paint and coating removal, and are disproportionately at risk to the range of adverse health effects described in this unit.

E. Availability of Alternatives

For almost every situation in which methylene chloride is used to remove paints or coatings, EPA is aware of technically and economically feasible chemical substitutes or alternative methods that are reasonably available. The two situations for which EPA does not know of technically and economically feasible alternatives are the uses that EPA proposes are critical for national security, described in more detail in Unit VIII., and commercial furniture refinishing, discussed in more depth in Unit XI. With respect to the specific coating removal uses that EPA proposes are critical for national security, described in Unit VIII., EPA does not believe that technically and economically feasible alternatives are reasonably available at this time. With respect to the furniture refinishing uses described in Unit XI., EPA is still investigating whether economically feasible alternatives are reasonably available.

EPA considered chemical substitutes and alternative methods consistent with the requirements of TSCA section 6(c)(2)(C) and as similarly recommended by the SBAR panel (Ref. 27). A full industry profile characterizing manufacturers, processors and end users of methylene chloride for paint and coating removal and a use and substitutes analysis are included in sections 2 and 3 of EPA's economic assessment (Ref. 4). As described below, EPA proposes that alternatives are technologically feasible, economically feasible, reasonably available, and present fewer hazards to human health than methylene chloride in paint and coating removal. EPA requests comment on whether its conclusion that substitutes for methylene chloride identified are available and technically and economically feasible is accurate and whether its consideration of alternatives was sufficient to satisfy the requirements of TSCA section 6(c)(2)(C).

Research into the efficacy of chemical substitutes has identified products currently available for commercial and consumer users of methylene chloride for paint and coating removal, for a variety of coatings on numerous substrates (Refs. 58 and 59). Research by the European Association for Safer Coating Removal in 2006 found that for every use that was studied of methylene chloride in paint and coating removal, there was a suitable substitute (Ref. 60). Other non-chemical methods of paint removal are also available (Ref. 31). Additionally, in most commercial sectors, users have voluntarily adopted substitute chemicals or methods, either due to financial considerations, customer requests, concern for worker or individual health and safety, decreased discharges to air and water, reduced clean-up costs, or reduced cost of protective equipment and respiratory protection programs (Ref. 22).

Many producers of paint and coating removal products containing methylene chloride also produce paint and coating removal products with substitute chemicals (Ref. 4). This was emphasized by a small business who makes such products (Ref. 22); other small businesses separately described the limitations of many alternatives (Ref. 27). Thus, there is already precedent for producers reformulating products to meet demand from commercial or individual customers. Additionally, methylene chloride is prohibited from use in graffiti removal in California,

Connecticut, Delaware, the District of Columbia, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, New York, and Rhode Island (Ref. 12). The fact that 11 states and the District of Columbia have specifically prohibited the use of methylene chloride in graffiti removal supports a finding that it is not critical for this use and that there are efficacious substitutes.

Based on the frequent use of substitute chemicals or alternative methods for paint and coating removal in all industries discussed here, and the formulation and distribution of substitute chemicals for paint and coating removal by all formulators of products containing methylene chloride (Ref. 4), EPA finds that technically and economically feasible alternatives to methylene chloride are reasonably available for all uses proposed for regulation.

Primary chemical substitutes for methylene chloride in paint and coating removal include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (collectively ATM); and caustic chemicals. EPA evaluated these products for efficacy, toxicity, relative hazards compared to methylene chloride, and other hazards that might be introduced by use of these products (such as environmental toxicity, increased global warming potential, and increased flammability or other hazards to users). Overall, while the efficacies of the substitutes are comparable to the efficacy of methylene chloride, none of the substitute chemicals already available has the level of toxicity associated with methylene chloride.

Products based on benzyl alcohol formulations have been identified as efficacious paint and coating removers in various industry sectors (Refs. 22 and 27). Consumer products containing benzyl alcohol are available for sale (Refs. 22, 27, 35, 58, 59, and 61). There are fewer hazard concerns compared to methylene chloride-based products, and the levels at which benzyl alcohol causes toxicity are higher than for methylene chloride, suggesting lower toxicity (Ref. 34). The relative inhalation exposure potential is lower for benzyl alcohol than for methylene chloride. The relative dermal exposure potential of benzyl alcohol is similar to methylene chloride (Ref. 34). Benzyl alcohol-based paint removers are expected to result in lower risks than methylene chloride products, primarily due to lower toxicity (Ref. 29).

Dibasic ester products can include dimethyl succinate, dimethyl glutarate and dimethyl adipate. They are generally viewed as efficacious products by commercial users in several sectors, though, because they evaporate slowly, they require a longer dwell time than methylene chloride (Ref. 22, 27). In general, the hazards associated with dibasic esters are less severe and occur at concentrations higher than methylene chloride (Ref. 34). Regarding differential exposures between dibasic esters and methylene chloride, the relative inhalation exposure potential is lower for dibasic esters than for methylene chloride (Ref. 34). The relative dermal exposure potentials of dibasic esters are similar to methylene chloride. Taken together, dibasic ester-based paint removers are expected to result in lower risks than methylene chloride products, primarily due to lower toxicity (Ref. 34).

ATM products contain acetone, toluene, and methanol. Products containing these chemicals may remove coatings very quickly, but may not be effective on every type of coating (Refs. 22 and 27). Acetone, toluene, and methanol evaporate quickly and are very flammable (Ref. 62). However, it is important to note that acetone, toluene, and/or methanol are present in most paint removers that contain methylene chloride, as co-solvents (Ref. 34). As a result, the main difference between paint removers that contain methylene chloride (and typically also contain acetone, toluene, and/or methanol) and ATM products is the absence of methylene chloride. Acetone is readily absorbed via inhalation and the relative inhalation exposure potential is similar to methylene chloride (Ref. 34). Acetone in particular is significantly less toxic than methylene chloride. Toluene and methanol are readily absorbed via inhalation, but the relative inhalation exposure potential is lower than for methylene chloride (Ref. 34). Dermal exposure to acetone, toluene and methanol is slightly less than for methylene chloride (Ref. 34). Taken together, ATM-based paint removers are expected to result in lower cancer risks (Ref. 36).

Products with caustic chemicals typically include calcium hydroxide or magnesium hydroxide. In many uses, they can be effective products, particularly when multiple coatings are being removed from a substrate. Caustic products have been reported to remove up to 30 coats in 24 hours, and in some cases, they have no increased dwell time compared to methylene chloride (Ref. 23). In contrast to methylene chloride-based products, there are no cancer or other repeat dose endpoints of concern associated with caustic products (Ref. 34). Caustic products pose acute concerns due to their physical chemical properties and can cause chemical burns (Ref. 36). It is important to note that products containing methylene chloride may also cause chemical burns. Additionally, the risks associated with caustic-based products are entirely acute, and can be mitigated by appropriate protective equipment more easily than the acute and chronic risks presented by methylene chloride.

In summary, when NMP is excluded from consideration, the most likely chemical substitutes for methylene chloride in paint and coating removal do not pose a risk of cancer to users, generally have lower exposure potential than methylene chloride, and when acute risks are present, as in the case of caustic chemicals, those risks are self-limiting by the nature of the adverse effects (since a user experiencing those effects is likely to take immediate action to mitigate or cease the effect of the caustic chemical). The chemical formulations that seem to present some risks of concern are ATM products, since they contain toluene and methanol. However, these chemicals are also present in most paint removers that contain methylene chloride, as co-solvents. As a result, no additional risks would be introduced were users to substitute a typical methylene chloride product (which would likely contain acetone, toluene, and/or methanol as co-solvents) with ATM products.

In addition to examining toxicity to humans, EPA reviewed available data on the chemicals in the baseline and alternative products for aquatic toxicity, persistence and bioaccumulation data, as a basis for examining potential environmental toxicity. Only one chemical evaluated (citrus terpenes) may have significant impacts on aquatic toxicity, with concern for environmental persistence and/or bioaccumulation. This chemical is contained in NMP-based paint removal products (Ref. 34).

EPA is also mindful of the risks that may be introduced by substitute chemicals or methods to increase global warming, and has examined the global warming potential of the chemical components of likely chemical substitutes for methylene chloride in paint and coating removal. Methylene chloride presents concerns for global warming; it has a GWP of 8.7 (see Unit II.D.2.). The GWP values of likely substitute chemicals in paint and coating removal are: 0 GWP (benzyl alcohol, ATM) or not assessed (caustics, dibasic esters) (Ref. 23). As such, EPA has not identified any increased risk of global warming that would be introduced by use of chemical products

as substitutes for methylene chloride in paint and coating removal.

In addition to human and environmental toxicity, other hazards associated with chemical methods for paint and coating removal are risks of fire due to flammability of the chemical product, and poisoning or acute injury. Risks of fire are serious when using solvents such as paint and coating removal chemicals. The flammability of methylene chloride is lower than some of the substitute organic solvents. However, many paint and coating removal products containing methylene chloride also contain more flammable chemicals as part of the formulation (Ref. 34). Paint and coating removal products sold to consumers that contain methylene chloride frequently have flammability warnings prominently on them (Ref. 35). Other chemical paint and coating removal products, such as those based on benzyl alcohol and dibasic esters, have low flammability and do not present an increased risk of fire from products containing methylene chloride (Ref. 23). Even among products that fall within the same general product composition category, there is meaningful variability in the specific formulations of paint remover products, and thus in their flammability. Furthermore, it is impracticable for EPA to predict the specific product formulations for which use will increase as a result of prohibitions on methylene chloride in paint and coating removal. It is therefore impracticable for EPA to forecast whether the flammability of popular paint and coating removers would generally increase or decrease as a result of the proposed rule.

In addition to using substitute chemical products, non-chemical methods for paint and coating removal are frequently used. These include thermal removal, sanding, hydroblasting, abrasive blasting, and laser removal (Refs. 22 and 31). Acute and chronic physical hazards (*e.g.,* burns, injuries to bodily parts) to workers and consumers can occur, in addition to any lead-related risks that should be considered when using these methods with lead-based paint.

In this overview, when considering alternatives to methylene chloride that would be available, NMP generally was not considered because, under the first co-proposed option for NMP in this proposed rule, this chemical would also be prohibited from use in paint and coating removal. However, under the second co-proposed approach for reducing the risks of NMP in paint and coating removal, products containing NMP would be available for commercial and consumer paint and coating removal, with restrictions. Details of the two co-proposed options are in Unit XVI.3. EPA identified developmental risks following acute exposures for consumers and acute and chronic exposures for commercial users of paint and coating removal products containing NMP following exposure through dermal contact, inhalation, and vapor-through-skin. More information on the risks EPA identified related to NMP are in Unit XVI.B.1.

F. Impacts of the Proposed and Alternative Regulatory Options

This unit describes the estimated costs of the proposed and alternative regulatory actions that EPA considered for methylene chloride in paint and coating removal. More information on the benefits and costs of this proposal as a whole can be found in Unit XXIII.

1. Proposed approach for methylene chloride in paint and coating removal. The costs of the proposed approach are estimated to include product reformulation costs, downstream notification costs, recordkeeping costs, and Agency costs. The costs of paint and coating removal product reformulations are estimated to be approximately $10,000 to $20,000 per year (annualized at 3% over 20 years) and $14,000 to $24,000 (annualized at 7% over 20 years). The cost for reformulation includes a variety of factors such as identifying the appropriate substitute chemical for methylene chloride in the formulation, assessing the efficacy of the new formulation and determining shelf-life. Under the first co-proposed approach for NMP, where the manufacturing, processing, distribution, and commercial use of paint and coating removal products containing NMP would be prohibited, the costs to users of paint and coating removers containing methylene chloride are $4,217,000 to $23,436,000 using a 3% discount rate and $4,592,000 to $23,485,000 at the 7% discount rate (both rates annualized over 20 years). The costs of downstream notification and recordkeeping on an annualized basis over 20 years are $40 and $60 using 3% and 7% discount rates respectively (Ref. 4). Agency costs for enforcement are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively. The total cost of the proposed approach for paint and coating removers containing methylene chloride under the first co-proposed approach for NMP is estimated to be $4,247,000 to $23,446,000 and $4,612,000 to $23,495,000 annualized over 20 years at 3% and 7%, respectively (Ref. 4). Under the second co-proposed approach for NMP, where paint and coating removal products containing NMP would be available with some restrictions, the costs to users of paint and coating removers containing methylene chloride are $67,087,960 to $68,726,960 using a 3% discount rate and $67,369,940 to $69,006,940 at the 7% discount rate (both rates annualized over 20 years). The costs of downstream notification and recordkeeping on an annualized basis over 20 years are the same as under the first co-proposed approach for NMP. Agency costs for enforcement are estimated to be the same as under the first co-proposed approach for NMP. The total cost of the proposed approach for paint and coating removers containing methylene chloride under the second co-proposed approach for NMP is estimated to be $67,098,000 to $68,747,000 and $67,384,000 to $69,034,000 annualized over 20 years at 3% and 7%, respectively (Refs. 4 and 127).

2. Options that require personal protective equipment for methylene chloride in paint and coating removal. Given equipment costs and the requirements associated with establishing a respiratory protection program which involves training, respirator fit testing and the establishment and maintenance of a medical monitoring program, EPA considers the proposed approach more cost-effective than options that require person protective equipment. This is because EPA anticipates that companies would choose to switch to substitute chemicals instead of adopting a program for PPE, including with a performance-based option of meeting an air concentration level of 1 ppm as an exposure limit for methylene chloride in paint and coating removal. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 1,000 are $13,775,000 to $26,535,000 at 3% and $14,202,000 to $26,708,000 at 7% over 20 years (Ref. 4). In addition, there would be higher EPA administration and enforcement costs with a respiratory protection program under the proposed approach.

3. Options that exclude downstream notification. For those options that exclude downstream notification, the options are less effective and more to challenging to implement. The downstream notification (*e.g.,* via SDS) provides additional information on the prohibitions under the proposed option for processors and distributors of methylene chloride or products containing methylene chloride other than paint and coating removers, and

provides an efficient way for those entities to recognize themselves as affected by the regulation, which contributes to a more effective regulation (Ref. 63). In this way, the downstream notification component of the supply chain approach contributes to the use no longer presenting an unreasonable risk because it streamlines and aids in compliance and implementation (Ref. 64).

G. Summary

The proposed approach is necessary so that methylene chloride in paint and coating removal no longer presents an unreasonable risk. It is also more cost effective than other regulatory options the Agency identified as potentially reducing risks so that they are no longer unreasonable, because it achieves the benefits of reducing the unreasonable risks so they are no longer unreasonable for a lower cost than the primary alternative option. For more information, see section 6 in the Economic Analysis (Ref. 4).

As stated previously in this notice, the proposed approach includes:

- Prohibiting manufacturing (including import), processing, and distribution in commerce of methylene chloride for consumer paint and coating removal and commercial paint and coating removal for the uses proposed for regulation;
- Prohibiting commercial use of methylene chloride for paint and coating removal for the uses proposed for regulation;
- Requiring that any products containing methylene chloride intended or used for paint and coating removal be distributed in volumes no less than 55-gallon containers;
- Requiring downstream notification of the prohibition on manufacturing (including import) processing, and distribution of methylene chloride for paint and coating removal for the prohibited uses; and
- Requiring limited recordkeeping.

Technically and economically feasible substitutes to methylene chloride for paint and coating removal are reasonably available for the uses proposed to be regulated. The supply chain approach ensures protection of consumers from the unreasonable risk by precluding the off-label purchase of commercial products by consumers.

The proposed approach is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to the greatest extent the potential for methylene chloride products to be intentionally or unintentionally misdirected into the prohibited uses. Enforcement under the other options would be much more difficult since the key requirements are directly placed on the large number of product users. As described in a recent article on designing more effective rules and permits, ''the government can implement rules more effectively and efficiently when the universes of regulated sources are smaller and better-defined. This is because, other factors being equal, governments can more easily identify, monitor, and enforce against fewer, rather than more, entities'' (Ref. 63). Under other options, enforcement activities must target firms that might perform the activity where a use of methylene chloride is restricted or prohibited. Identifying which establishments might use paint and coating removers is difficult because paint and coating removal is not strictly specific to any industry (Ref. 4).

VII. Costs and Monetized Benefits of the Methylene Chloride Component of the Proposed Rule, the Alternatives EPA Considered, and Comparison of Costs and Benefits

EPA proposes that the identified risks from methylene chloride and in paint and coating removal are unreasonable risks. Apart from that proposed determination, EPA has evaluated the potential costs and benefits of the proposed approach and alternative approaches.

A. Costs

The details of the costs of the proposed approach for use of methylene chloride in paint and coating removal by consumers and in commercial uses proposed for regulation are discussed in Unit I.E. and in the Economic Analysis (Ref. 4). Under the proposed option for methylene chloride and the first co-proposed option for NMP, costs to users of paint and coating removal products containing methylene chloride are $4,217,000 to $23,436,000 annualized for 20 years at a discount rate of 3% and $4,592,000 to $23,485,000 at a discount rate of 7%. Costs of paint and coating removal product reformulations are estimated to be approximately $10,000 to $20,000 per year (annualized at 3% over 20 years) and $14,000 to $24,000 (annualized at 7% over 20 years). Costs of downstream notification and recordkeeping on an annualized basis over 20 years are $40 and $60 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively (Ref. 4).

Total costs of the proposed rule relevant to methylene chloride in paint and coating removal under the first co-proposed option for NMP are estimated to be $4,247,000 to $23,446,000 annualized over 20 years at 3% and $4,612,000 to $23,495,000 annualized over 20 years at 7% (Ref. 4).

Under the proposed option for methylene chloride and the second co-proposed option for NMP, costs to users of paint and coating removal products containing methylene chloride are $67,087,960 to $68,726,960 annualized for 20 years at a discount rate of 3% and $67,369,940 to $69,006,940 at a discount rate of 7%. Costs of paint and coating removal product reformulations, costs of downstream notification, and Agency costs for enforcement are estimated to be the same as under the first co-proposed option for NMP (Refs. 4 and 127).

Total costs of the proposed rule relevant to methylene chloride in paint and coating removal under the second co-proposed option for NMP are estimated to be $67,098,000 to $68,747,000 annualized over 20 years at 3% and $67,384,000 to $69,034,000 annualized over 20 years at 7% (Refs. 4 and 127).

Alternatives that EPA considered include the use of PPE as well as an option that would prohibit the use of methylene chloride in paint and coating removal for consumers and for the commercial uses proposed for regulation without the companion prohibition on manufacture, processing, or distribution in commerce for these uses or the downstream notification requirements. As discussed in Unit VI.C.3., EPA found that PPE options did not address the risks presented by methylene chloride in paint and coating removal so that the risks would no longer be unreasonable. This is because consumers could not be required to adopt PPE, resulting in a significant gap in protection for consumers. In addition, EPA also assumed that no commercial users would adopt PPE because the per-facility costs were prohibitively expensive.

EPA also found that a use prohibition alone without downstream notification requirements would not address the unreasonable risks. EPA estimated the costs of this option to be $4,239,000 to $23,442,000 annualized over 20 years at 3% and $4,604,000 to $23,491,000 annualized over 20 years at 7% (Ref. 4).

B. Benefits

EPA is not fully able to quantify the full monetary benefits that would accrue from preventing all deaths due to methylene chloride in paint and coating

removal. Similarly, EPA is not able to monetize the benefits that would accrue from preventing non-fatal and non-cancer effects from exposure to methylene chloride in paint and coating removal. The subset of benefits that can be monetized from mitigating the risks from methylene chloride in paint and coating removal for consumer uses and for the commercial uses proposed for regulation are estimated to be $14,363,000 to $14,565,000 (annualized at 3% over 20 years) and $13,796,000 to $13,921,000 (annualized at 7% over 20 years) (Ref. 4). Although the alternatives considered are unlikely to result in the same health benefits as the proposed option, EPA was unable to quantify the differences.

C. Comparison of Benefits and Costs

The monetized subset of benefits for preventing the risks resulting from methylene chloride in paint and coating removal by consumers and by commercial workers for the uses proposed for regulation do not outweigh the estimated monetary costs. EPA believes that the balance of costs and benefits cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects as well as cancer. As discussed previously, the multitude of potential adverse effects associated with methylene chloride in paint and coating removal can profoundly impact an individual's quality of life. Some of the adverse effects associated with methylene chloride exposure can be immediately experienced and can result in sudden death; others can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature. While the risk of non-cancer health effects associated with methylene chloride exposure during paint and coating removal cannot all be quantitatively estimated, the qualitative discussion highlights how some of these non-cancer effects may be as severe as cancer and thus just as life altering. These effects include not only medical costs but also personal costs such as emotional and mental stress that are impossible to accurately measure. Considering only monetized benefits would significantly underestimate the impacts of methylene chloride-induced non-cancer adverse outcomes on a person's quality of life.

Thus, considering costs; the subset of benefits that can be monetized (risk of cancer and risk of death in some sectors); and the remaining benefits that cannot be quantified and subsequently monetized (risk of nervous system effects, liver toxicity, reproductive effects, and kidney toxicity), including benefits related to the severity of the effects and the impacts on a person throughout a lifetime in terms of medical costs, effects on earning power and personal costs, emotional and psychological costs, and the disproportionate impacts on Hispanic communities and individuals with limited English proficiency; the benefits of preventing exposure to methylene chloride in paint and coating removal by an estimated 1.3 million consumers and estimated 17,600 commercial workers for the uses proposed for regulation outweigh the costs.

D. Impacts on the National Economy, Small Businesses, Technological Innovation, the Environment, and Public Health

As described in Unit V.B. and in the Economic Analysis, EPA considered the anticipated effects of this proposal on the national economy. While the impacts of this rule as a whole are described in Unit XXIII.C. and the impacts of the methylene chloride component of this proposal are described in more detail in Unit VII.A. and in Section 9.3 of the Economic Analysis (Ref. 4), EPA does not anticipate these impacts having an effect on the overall national economy. EPA anticipates that a majority of small businesses will have cost impacts of less than one percent of the annual revenue, and the majority of small business bathtub refinishing facilities and professional contractors will have cost impacts greater than one percent of annual revenue.

The proposed approach is anticipated to drive technological innovation by formulators of paint and coating removal products containing methylene chloride, as they continue to develop substitute products, and refine such products already available. It is also anticipated to drive technological innovation by formulators of chemical paint and coating removal products with different chemistries as well as manufacturers and retailers of alternative methods of paint and coating removal. See also section 9.3 in the Economic Analysis (Ref. 4).

The proposed approach is anticipated to have a positive impact on public health, as described in Unit VI.D. There is anticipated to be a positive impact on the environment, as a result of decreased use of methylene chloride, which is a hazardous air pollutant, as described in Unit III.A.

VIII. Uses of Methylene Chloride for Paint and Coating Removal Critical for National Security

As part of interagency collaboration with the Department of Defense (DOD) on this proposed rule, EPA is aware that there are specific military uses for which methylene chloride is essential for paint and coating removal and for which there are no technically feasible alternatives currently available. The military readiness of DOD's warfighting capability is paramount to ensuring national security, which includes ensuring the maintenance and preservation of DOD's warfighting assets. DOD has identified mission-critical uses for methylene chloride for ensuring military aviation and vessel readiness. These mission-critical items require the use of methylene chloride for the removal of coatings from mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components made of specialty metallic, nonmetallic, and composite materials. As described in this section, EPA proposes to exempt these uses from the regulations proposed on methylene chloride in paint and coating removal. This exemption is proposed for an initial ten-year period from the publication date of a final rule. EPA will engage with DOD to identify any potential extension that may need to be granted, by further rulemaking, after those ten years.

DOD has actively sought to reduce its use of methylene chloride in paint and coating removal since 1990. DOD has replaced most of its usage of methylene chloride for paint and coating removal with mechanical methods, benzyl alcohol products, other solvents, and laser ablation. For instance, the Navy's Fleet Readiness Center Southwest has undertaken a successful 20-year effort and eliminated all but a single use on safety-critical components. In an effort to reduce the use of all HAPs such as methylene chloride, the Army has conducted tests to identify and test the effectiveness of HAP-free paint and coating removers on military high-performance coatings (Ref. 61). In another example, the Air Force in December 2015 significantly reduced the use of methylene chloride for removing coatings on flight control parts and is now using substitute chemical products, primarily those with benzyl alcohol formulations (Ref. 65). This phase-out was driven by worker safety concerns and the destructive impact the methylene chloride product had on the installation's industrial wastewater treatment processes. The Air Force

sought alternatives for this use of methylene chloride for paint and coating removal in this industrial process and was successful at qualifying an alternative that met technical requirements (Ref. 65).

In light of these efforts to identify and adopt alternative chemicals or methods, it is unlikely that DOD has overlooked potential substitutes. DOD continues and will continue to pursue potential substitutes. However, for mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components, DOD has found that currently available substitute chemicals for paint and coating removal have one or more technical limitations. In these critical and essential applications, currently available substitute chemicals cannot completely remove specific military high performance or chemical resistant coatings, resulting in improperly applied, incompletely adhering replacement coatings. The impacts of this are early coating failure, corrosion of underlying critical parts, shortened service life for critical components (some of which are no longer manufactured), and reduced availability and mission readiness of military aircraft and vessels.

Substitute chemicals currently available are also incompatible with underlying metallic, nonmetallic and composite materials, resulting in material damage to critical components (*e.g.* hydrogen embrittlement) creating immediate damage or longer-term susceptibility to stress fracturing and corrosion. The impacts of this are shortened service life for critical components (some of which are no longer manufactured), reduced availability and mission readiness of military aircraft and vessels, and an increased risk of catastrophic failure of safety critical parts.

Additionally, substitute chemicals or methods currently available do not support the coating removal requirements of safety inspection, non-destructive inspection, material assessment, or field repair processes. This results in an inability to properly perform safety inspections for critical components, leading to undetected fractures and defects. The impacts of this are increased risk of catastrophic failure of safety critical parts.

Under TSCA section 6(g)(1)(B), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure. Based on discussions and information provided by DOD, EPA has analyzed the need for the exemption and concurs with DOD that compliance with the proposed regulations on the use of methylene chloride in paint and coating removal would significantly impact national security. DOD has demonstrated that the reduced mission availability of aircraft and vessels for military missions or, in the worst case, the loss of individual military aircraft and vessels, are potential impacts to military readiness that could result from the proposed prohibition of methylene chloride in paint and coating removal. Due to the importance of these military systems for national security, EPA has determined that these uses of methylene chloride for removal of specialized coatings from military aviation and vessel mission-critical corrosion-sensitive components, including safety-critical components, is critical for national security and the safety of personnel and assets. EPA includes in this exemption corrosion-sensitive military aviation and vessel mission-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the vessel or aircraft could be compromised.

EPA proposes to grant this exemption for a period of 10 years from the date of promulgation of a final rule, with a potential for extension, by further rulemaking, after review by EPA in consultation with DOD. The conditions for this exemption would be: (1) The use of methylene chloride for coating removal by DOD or its contractors performing this work only for DOD projects is limited to the mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components; and (2) this paint and coating removal must be conducted at DOD installations, at Federal industrial facilities, or at DOD contractor facilities performing this work only for DOD projects. This exemption granted under TSCA(6)(g)(1)(B) does not impact or lessen any requirements for compliance with other statutes under which the use, disposal, or emissions of methylene chloride is regulated.

As described in Unit VI.C.3., under the proposed approach, any paint and coating removal products containing methylene chloride would be required to be distributed in packaged volumes no less than 55-gallon containers. As part of the exemption for uses identified as critical for national security, for those formulations specifically manufactured for DOD, suppliers may provide paint and coating removal products containing methylene chloride to DOD in containers with a volume no less than 5 gallons. Allowing selective use for national security purposes does not disrupt the efficacy of the supply chain approach described in Unit VI.C.3.

In addition to the exemption described in this unit, EPA will consider granting additional time-limited exemptions, under the authority of TSCA section 6(g), for a specific condition of use for which EPA can obtain documentation: that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; that compliance with the proposed rule would significantly disrupt the national economy, national security, or critical infrastructure. To this end, EPA requests comment on a process for receiving and evaluating petitions and requesting EPA promulgate critical-use exemption rules. Under this process, entities who believe that their specific condition of use is a critical or essential use under TSCA section 6(g) would submit a petition for an exemption rulemaking with supporting documentation that they believe demonstrates that the use meets the statutory criteria. EPA would review the petition for completeness and, if the documentation warrants further action, respond to the petition by publishing a proposal in the **Federal Register** inviting comment on a proposed exemption. EPA would consider the comments received, along with any additional information reasonably available, and then take final action on the proposed exemption. EPA requests comment on the specific kinds of documentation that should be required from entities seeking an exemption rulemaking in order to facilitate EPA's and later, the public's review. EPA also requests comment on the appropriate timeframes for EPA action, given that the documentation for any given use could be technical and extensive, and that EPA may also need to develop additional information, such as economic estimates, in order to promulgate an exemption rule under TSCA section 6(g). Finally, members of

the potentially regulated community who believe that their operation is a critical or essential use should provide as much detail as possible to EPA about their operation during this comment period, including information on any evaluations of alternatives, the costs to transition to another chemical or process, and any other relevant information. This would assist EPA in reviewing the specific condition of use, as well as in establishing provisions for future exemption petitions.

IX. Overview of Uncertainties for Methylene Chloride in Paint and Coating Removal

A discussion of the uncertainties associated with this proposed rule can be found in the methylene chloride risk assessment (Ref. 2) and in the additional analyses for methylene chloride in commercial and consumer paint and coating removal (Refs. 19, 20, and 38). A summary of these uncertainties follows.

EPA used a number of assumptions in the methylene chloride risk assessment and supporting analysis to develop estimates for occupational and consumer exposure scenarios and to develop the hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include the likelihood that releases of and exposures to methylene chloride vary from one paint and coating removal project to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. In estimating the risk from methylene chloride in paint and coating removal, there are uncertainties in the number of workers, bystanders, and consumers exposed to methylene chloride and in the inputs to the models used to estimate exposures.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the benefits are most pronounced in estimating the benefits from preventing deaths due to methylene chloride that have been underreported in most commercial sectors. Additional significant uncertainties in benefits include the entirety of prevention of the non-cancer adverse effects, including underreported deaths (described in Unit VI.E.), because these benefits generally cannot be monetized due to the lack of concentration response functions in humans leading to the ability to estimate the number of population-level non-cancer cases and limitations in established economic methodologies. Additional uncertainties in benefit calculations arose from EPA's use of a forecast from an industry expert to estimate the categories of alternatives that users might choose to adopt and the potential risks for adverse health effects that the alternatives may pose. While there are no products or methods that have comparable cancer or lethal risks, these substitute products and alternative methods do present hazards. Without information on what alternative methods or chemicals users of methylene chloride for paint and coating removal are likely to switch to, and estimates of the exposures for those alternatives, EPA is unable to quantitatively estimate any change in non-cancer risks due to use of substitute chemicals or alternative methods instead of using methylene chloride for commercial or consumer paint and coating removal.

Additional uncertainties include any benefits accrued by commercial users of methylene chloride for paint and coating removal who would benefit from using substitute chemicals and alternative processes. These users would be able to reduce or eliminate costs incurred for emissions control, hazardous waste disposal, or wastewater treatment, which are all required for commercial users of methylene chloride for any purpose.

In addition to these uncertainties related to benefits, there are uncertainties related to the cost estimates. As noted earlier, there is uncertainty in EPA's estimates of which chemical substitutes or alternative methods users may adopt instead of methylene chloride for paint and coating removal, which in turn produces uncertainty as to the cost of those substitutes or methods. EPA has estimated the cost of substitute chemicals, and, in some sectors, some increase in costs due to increased labor required by some substitute methods, but is not able to fully characterize the total costs to all sectors for using substitute chemicals or alternative products. It is possible that some users with paint removal projects that require removing multiple layers of coatings may ultimately save time by switching to a substitute chemical that is more effective than methylene chloride for this particular use. However, changes in time gained or lost during paint and coating removal projects cannot be estimated for all users potentially affected by this proposed rule. In addition, under certain assumptions EPA's economic analysis estimates that some users of methylene chloride for paint and coating removal will see a cost savings when switching to substitutes. Standard economic theory suggests that financially rational companies would choose technologies that maximize profits so that regulatory outcomes would not typically result in a cost savings for the regulated facilities. There could be several reasons that cost savings might occur in the real world. Potential reasons include lack of complete information or barriers to obtaining information on the cost savings associated with alternatives as well as investment barriers or higher interest rates faced by firms. Additionally, there may be costs associated with these alternatives that are not adequately accounted for in the analysis. To evaluate the effect of this uncertainty, EPA has included a sensitivity analysis that sets the cost savings to zero for these compliance alternatives (Ref. 4 at Section 7). EPA also recognizes that these firms might experience positive costs of compliance rather than zero costs, so that the actual total costs could be higher than those in the sensitivity analysis. However, EPA has no current basis to estimate these potentially higher costs, since the available data appear to show that there are lower cost substitutes available. EPA requests comments on these assumptions.

Additionally, there are uncertainties due to the estimates of the number of affected commercial and consumer users, and for numbers of processors and distributors of methylene chloride-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records.

EPA will consider additional information received during the public comment period. This includes scientific publications and other input submitted to EPA during the comment period.

X. Major Provisions and Enforcement of the Proposed Rule for Methylene Chloride in Paint and Coating Removal

This proposal relies on general provisions in the proposed Part 751, Subpart A, which can be found at 81 FR 91592 (December 16, 2016).

A. Prohibitions and Requirements

The rule, when final, would (1) prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal for consumer uses and for all commercial uses excluding for commercial furniture refinishing (see Unit XI.) and exempting those defined as critical for national security (see Unit VIII.); (2) prohibit commercial use of methylene chloride for paint and coating removal except for commercial

furniture refinishing and for uses defined as critical for national security; (3) require any paint and coating removal products containing methylene chloride to be distributed in containers with a volume no less than 55-gallons, except for formulations manufactured specifically for the Department of Defense; (4) require manufacturers, processors, and distributors of methylene chloride and all products containing methylene chloride, excluding retailers, to provide downstream notification of the prohibitions; and (5) require recordkeeping relevant to these prohibitions. As described in Unit XI., EPA intends to issue separately a proposal to regulate the risks presented by methylene chloride in commercial furniture refinishing so that those risks are no longer unreasonable; EPA intends to finalize that separate proposal and this proposal together.

The prohibition on manufacturing, processing, and distributing in commerce methylene chloride for consumer paint and coating removal would take effect 180 days after publication of a final rule. Similarly, the prohibition on manufacturing, processing, and distributing in commerce methylene chloride for any non-prohibited paint and coating removal commercial uses in containers with volumes less than 55 gallons would take effect 180 days after publication of a final rule. The prohibition on commercial use of methylene chloride for paint and coating removal except in furniture refinishing or for critical national security uses would take effect 270 days after publication of a final rule. These are reasonable transition periods because, as noted in Unit VI.E. and by the small businesses participating in the SBAR process, many formulators of paint and coating removers containing methylene chloride also manufacture products for this use that do not contain methylene chloride (Ref. 27). In addition, alternative paint removal products exist at comparable expense for users to purchase. Six months from publication of the final rule is sufficient time to allow for existing stocks to move through the market place and to allow manufacturers, processers and distributors and users to plan for and implement product substitution strategies.

B. Downstream Notification

EPA has authority under TSCA section 6 to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. Many manufacturers and processors of methylene chloride are likely to manufacture or process methylene chloride or products containing methylene chloride for other uses that would not be regulated under this proposed rule. Other companies may be strictly engaged in distribution in commerce of methylene chloride, without any manufacturing or processing activities, to customers for uses that are not regulated. EPA is proposing a requirement for downstream notification by manufacturers, processors, and distributors of methylene chloride for any use to ensure compliance with the prohibition on manufacture, processing, distribution in commerce, and commercial use of methylene chloride for the uses proposed for regulation. Downstream notification is necessary for effective enforcement of the rule because it provides a record, in writing, of notification on use restrictions throughout the supply chain, likely via modifications to the Safety Data Sheet. Downstream notification also increases awareness of restrictions on the use of methylene chloride for paint and coating removal, which is likely to decrease unintentional uses of methylene chloride by these entities. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The estimated cost of downstream notification on an annualized basis over 20 years is $40 and $60 using 3% and 7% discount rates respectively (Ref. 4).

The effective date of the requirement for this notification would be 45 days after publication of the final rule. This is a reasonable transition period because regulated entities would only need to provide additional information on their SDS, which are routinely produced and updated.

C. Enforcement

Section 15 of TSCA makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA section 6. Therefore, any failure to comply with this proposed rule when it becomes effective would be a violation of section 15 of TSCA. In addition, section 15 of TSCA makes it unlawful for any person to: (1) Fail or refuse to establish and maintain records as required by this rule; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by section 11 of TSCA.

Violators may be subject to both civil and criminal liability. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty for each violation. Each day in violation of this proposed rule when it becomes effective could constitute a separate violation. Knowing or willful violations of this proposed rule when it becomes effective could lead to the imposition of criminal penalties for each day of violation and imprisonment. In addition, other remedies are available to EPA under TSCA.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to ''any person'' who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false information or cause it to be reported.

XI. Furniture Refinishing (Methylene Chloride)

At this time, following input from small entity representatives received during the SBAR process, and based on the SBAR panel recommendations, EPA is not proposing to regulate methylene chloride when used in paint and coating removal in commercial furniture refinishing, also referred to as professional furniture refinishing (Ref. 27). Although EPA proposes to determine that risks to workers using methylene chloride for commercial furniture refinishing are unreasonable, EPA is seeking additional information about this industry to inform development of future proposed restrictions on methylene chloride in commercial furniture refinishing.

A. Description of Commercial Furniture Refinishing

Commercial furniture refinishing consists of several processes, including but not limited to repair, reupholstery, repainting, and depainting or removing paints and coatings, sometimes referred to as furniture stripping. EPA has defined furniture stripping as paint and coating removal from furniture; it includes application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from wood, metal, or other types of furniture, doors, radiators, or cabinets. Furniture stripping can be conducted separately or as a part of furniture refinishing. EPA has defined commercial furniture stripping as furniture stripping conducted in a commercial facility performed by an

individual, government entity, or company for which an individual, government entity, or company receives remuneration or other form of payment.

As described in the methylene chloride risk assessment, to carry out furniture stripping, or to remove paint, lacquer, varnish, or other coatings from wood or metal furniture (or similar items such as doors, radiators, and cabinets), chemical paint and coating removal products may be applied to the furniture by either dipping the furniture in an open tank containing the chemicals, brushing or spraying the product onto the furniture surface, or manually applying the chemical product with a brush, rag, or aerosol spray. Larger furniture refinishing facilities conducting furniture stripping may pump the chemical product through a brush. The application method depends on the size and structure of the furniture as well as the capabilities of the facility (Ref. 2). Some firms may use alternative methods of paint and coating removal, such as sanding or heat/thermal guns, but EPA's information to date indicates that paint and coating removal on furniture is primarily conducted with chemical removers (Refs. 22, 27, 31, 66 and 27).

The area where furniture refinishing workers conducting furniture stripping apply paint and coating removal chemicals typically has a sloped surface to allow for collection and recycling of unused chemical product. Larger facilities use a flow tray to apply the paint and coating removal product or chemical to parts. The flow tray is a sloped, shallow tank with a drain at the lower end. Some facilities may use a dip tank to immerse whole pieces or parts of furniture in the chemical product (Refs. 2 and 22).

After a worker applies the chemical product or immerses the piece of furniture in it, the paint and coating remover is left to soak, or ''dwell,'' on the furniture surface to soften the paint, coating, or varnish. Once soaking is complete, a worker manually scrapes or brushes the unwanted coating from the furniture surface. The worker then transfers the furniture to a washing area where they wash the waste chemical and paint or coating sludge from the furniture. Workers can wash the treated furniture with low-pressure washing operations or high-pressure water jets or high-pressure wands. Wash water may contain oxalic acid to brighten the wood surface. Wash water is collected and either recycled or disposed of as waste. After washing, the worker transfers the furniture to a drying area where it is allowed to dry before being transferred to other refinishing processes (*e.g.,* sanding, painting, reupholstery) (Ref. 2).

Based on industry research and discussions with stakeholders, EPA is aware that most commercial furniture refinishing firms primarily use chemical methods for paint and coating removal, and that methylene chloride or methylene chloride-based products are the types of chemical paint removers primarily and, in some firms, exclusively, used. Some commercial furniture refinishers, including some small businesses participating in the SBAR process, have said that although they make limited use of acetone for some types of furniture, they have not found any workable substitutes for methylene chloride as a primary paint and coating removal method (Refs. 22 and 27). More information on the potential use of substitutes for furniture refinishing is provided in Unit XI.E.

B. Risks Associated With Furniture Refinishing

The methylene chloride risk assessment and additional supplemental analyses identified acute and chronic risks from inhalation of methylene chloride during paint and coating removal by consumers, commercial users, and bystanders in residences or workplaces (individuals not using the paint and coating remover but nearby a user) (Refs. 2, 19, 20, and 38). This includes an assessment of the risks from methylene chloride when used in commercial furniture refinishing. EPA estimates that, annually, there are approximately 15,000 workers at 4,900 commercial refinishing operations conducting paint and coating removal with methylene chloride (Ref. 4).

1. Exposures assessed to methylene chloride during commercial furniture refinishing and immersion stripping. Exposures assessed for workers in commercial furniture refinishing include acute and chronic exposures to methylene chloride for paint and coating removal, as described in the methylene chloride risk assessment (Ref. 2). The exposure pathways of interest included dermal contact and inhalation, but, due to limitations described in the risk assessment, the assessment was based only on the inhalation route of exposure. Different exposure scenarios were evaluated for workers, occupational bystanders, consumers, and residential bystanders (Ref. 2). Not included in the assessment but important to note are bystanders in commercial refinishing operations that are located in workshops or other parts of residences; here, the bystanders may include not only workers but also children and occupants of the home.

In addition to estimating likely exposures under current use patterns, for both commercial and consumer users, EPA assessed a number of exposure scenarios associated with risk reduction options in order to identify variations in methylene chloride exposure during paint and coating removal. All variations in the scenarios were applied to industry-specific exposure inputs and evaluated with exposure parameters that were modified to reflect either a reasonable worst-case scenario (also called the baseline) or a scenario in which exposures were moderated by several factors (also called the central tendency scenario). The risk reduction options varied between scenarios and included engineering controls and use of personal protective equipment (PPE), as well as combinations of these options (Ref. 19).

- Under the PPE risk reduction option exposure scenarios, EPA evaluated respirators with APF 10 to 10,000 for acute and chronic risks, including cancer risks.
- For the engineering controls risk reduction option exposure scenarios, EPA evaluated using local exhaust ventilation (LEV) to improve ventilation near the activity of workers in furniture refinishing operations, with an assumed 90% reduction in exposure levels.

Overall, EPA evaluated several distinct exposure scenarios for paint and coating removal with methylene chloride for commercial furniture refinishing. Additionally, EPA evaluated several distinct exposure scenarios for miscellaneous paint and coating removal conducted by immersion of the object in vats or tanks of methylene chloride (dip methods), since this has been reported as a method of paint and coating removal during furniture refinishing (Refs. 19 and 27).

The results of these evaluations of exposure scenarios demonstrate that the scenarios meeting all relevant health benchmarks for all scenarios of methylene chloride in paint and coating removal in commercial furniture refinishing requires: (1) A respiratory protection program using a supplied-air respirator with APF of 1,000 or 10,000, depending on type of method used for applying methylene chloride or workplace characteristics, such as the size of the facility; (2) reducing exposures with LEV that can achieve 90% efficiency in air flow plus worker respiratory protection with APF 1,000; or (3) elimination of exposure to methylene chloride by using an alternative method of paint and coating removal (Ref. 19). Although non-cancer risks and cancer risks were estimated using separate measures, exposure

reduction that is protective against non-cancer risks from methylene chloride is also protective against cancer risks.

2. Risks assessed from methylene chloride during commercial furniture refinishing and immersion methods. Exposure to methylene chloride is associated with death, neurotoxicity, liver toxicity, and cancer in humans and animals. To estimate non-cancer risks for acute and chronic exposures, the methylene chloride risk assessment used MOEs. Exposure scenarios with MOEs below the benchmark MOE have risks of concern, as explained in detail in the methylene chloride risk assessment. For acute and chronic exposure scenarios, the benchmark MOE is 10 (Ref. 2). The benchmark MOE identifies a risk of concern for a given endpoint; it is obtained by multiplying the total uncertainty factors associated with each health endpoint's point of departure. For more information on uncertainty factors, see Unit IV.B.

The acute inhalation risk assessment used central nervous system effects to evaluate the acute risks for occupational, consumer, and bystander exposure during paint and coating removal with methylene chloride. A risk of concern was identified if the MOE estimate was less than the benchmark MOE of 10 (Ref. 2).

EPA assessed acute risks for central nervous system effects from inhalation for workers using methylene chloride for commercial furniture refinishing and for immersion methods of paint and coating removal for various objects, including furniture. Acute risks were estimated in this sector, even in the presence of respirators with APF 10 or APF 25. MOEs for acute risks in commercial furniture refinishing ranged from a central tendency of 0.08 to 0.035, with a high end of 0.0063 (workplaces engaged in paint and coating removal using immersion methods). In general, these workplaces are estimated to present exposure levels between 125 times to greater than 1,500 times more than those that are expected to produce no risks of concern. Not only workers, but also occupational bystanders, or workers engaged in tasks other than paint and coating removal, would be at acute risk for central nervous system effects.

EPA also assessed risks of chronic exposure to workers using methylene chloride for commercial furniture refinishing. The methylene chloride risk assessment used liver toxicity as the critical endpoint for chronic exposure. The selected exposure scenarios represented inhalation exposures with a range of conservative assumptions. As described earlier, the assumptions were then varied, such as use of PPE (supplied-air or other respirator) and duration of time spent in contact with the product (days and years). EPA assessed risks for liver toxicity (with effects that include vacuolation and fatty liver) for occupational and bystander exposure scenarios of paint and coating removal with methylene chloride.

Workers and occupational bystanders in this industry were estimated to be at risk of non-cancer liver toxicity as a result of chronic exposure to methylene chloride during paint and coating removal under typical exposure scenarios. When workers' exposures were estimated at facilities repeatedly reporting moderate or high methylene chloride air concentration levels, EPA estimated that there were risks of concern for these workers, even for scenarios evaluated with workers wearing respiratory protection with APF 50. Among all of the occupational scenarios, the greatest risk of concern is for workers engaging in long-term use of the product (*i.e.,* 250 days/year for 40 years) with no respiratory protection. For those workers, MOEs for chronic exposures were 0.025, or reflective of risks 400 times greater than the benchmark. Even for workers assumed to have lower exposure, MOEs did not reach 10. In most workplaces engaged in commercial furniture refinishing, MOEs for chronic exposure ranged from a central tendency of 0.60 to 0.3. Additionally, in EPA's risk assessment scenarios, which are not necessarily reflective of industry-wide work practices, for workers and bystanders assumed to have the lowest exposure (respirator APF 50, limited exposure duration, and moderate air concentration), MOEs for chronic exposure were 5, or one-half of the benchmark (Ref. 2).

For commercial users and bystanders, EPA also assessed cancer risks as a result of chronic exposure to methylene chloride in paint and coating removal in commercial furniture refinishing. Methylene chloride is a likely human carcinogen; cancer risks determine the incremental increased probability of an individual in an exposed population developing cancer over a lifetime following exposure to the chemical under specified use scenarios. Common cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk of one in one million or one in ten thousand (*i.e.,* 1×10^{-6} or 1×10^{-4}). Estimates of cancer risk should be interpreted as the incremental increased probability of an individual in an exposed population developing cancer over a lifetime as a result of exposure to the potential carcinogen (*i.e.,* incremental or excess individual lifetime cancer risk) (Ref. 2).

In the methylene chloride risk assessment, when exposure for workers and occupational bystanders was estimated in facilities conducting commercial furniture refinishing, EPA identified excess cancer risks if these workers and bystanders were exposed to paint and coating removal with methylene chloride for 250 days per year for 40 years with no respiratory protection. Cancer risks ranged from 2 in 10,000 to 8 in 10,000, with a maximum of 5 in 1,000 (workplaces using immersion methods) (Ref. 2).

For commercial users and occupational bystanders in commercial furniture refinishing, acute and chronic risks were assessed based on the typical occupational exposure parameters, which may include several hours per day of exposure over several years of work. For these reasons, any risk mitigation measures must address not only acute risks, but also chronic risks, including both cancer and non-cancer effects. For these reasons, the most sensitive endpoint for risk mitigation must be considered, whether it derives from acute or chronic exposure.

3. Impacts of the exposures. As discussed for other commercial uses in Unit VI.E., exposure to methylene chloride in paint and coating removal, when conducted in commercial furniture refinishing and for other purposes, is associated with a range of adverse health effects, which include impacts on the nervous system, liver, respiratory system, kidneys, and reproductive systems. In some instances, these effects may appear relatively mild, such as dizziness, which occurs early in exposure and at low exposure levels. However, with increasing levels of exposure or increasing duration, these effects can take the form of generally irreversible health effects such as cognitive impairment, sensory impairment, coma, heart failure, liver toxicity, brain cancer, liver cancer, non-Hodgkin lymphoma, and multiple myeloma.

Acute exposure to methylene chloride during paint and coating removal can be fatal; since 1980, at least seven workers have died while using methylene chloride for commercial furniture refinishing. Data from OSHA indicate that the circumstances of death vary. For example, some workers collapse while conducting paint and coating removal over or near dip tanks, frequently falling into the tanks and subsequently dying. This was the case in 1985 in Pennsylvania, 1986 in Colorado, 1990 in Connecticut, and

2000 in Pennsylvania (Ref. 7). The worker in Connecticut earlier complained that the vapors were making him dizzy, and shortly after slumped into the dip tank and died; the worker in 2000 in Pennsylvania was found face-down in the dip tank next to the shutters from which he was attempting to remove paint (Ref. 7). Other workers in commercial furniture refinishing facilities lose consciousness at their workplace, but die sometime later, such as a worker in 1991 in Colorado, and in 1999 in Tennessee (Ref. 68).

These are likely not the only deaths in commercial furniture refinishing due to methylene chloride; as discussed in Unit VI.E., many deaths due to methylene chloride have not been recorded due to a lack of reporting to the OSHA incident database by self-employed individuals and the likelihood that deaths due to methylene chloride exposures are misattributed to heart disease, since the pathology is similar (Ref. 33).

In addition to fatalities, methylene chloride exposure during commercial wood refinishing has caused acute effects, such as the 1996 case of a cabinet manufacturer employee who experienced chronic headaches found to be due to methylene chloride exposure when the doors at his facility were closed in the winter months (Ref. 69).

In most commercial furniture refinishing facilities using methylene chloride for paint and coating removal, worker and occupational bystander exposure concentrations are orders of magnitude above what would be necessary to achieve the benchmark MOE of 10 for acute and chronic non-cancer effects. For acute health effects such as nervous system impacts, EPA estimated an MOE of 0.08 for workers in commercial furniture refinishing. For chronic non-cancer health effects such as liver toxicity, workers in this industry have an MOE of 0.6 to 0.3 (Ref. 2). For a description of MOEs and their use in risk assessment, see Unit IV.B.

In each case, workers in commercial furniture refinishing using methylene chloride for paint and coating removal are exposed at a level that is generally 125 to 1,500 times higher than what EPA has found to be a level that would not present acute or chronic non-cancer risks of concern. These risks of concern are for effects such as death, multiple adverse chronic health effects, and the subsequent lifetime impacts from these effects. Additionally, individuals occupationally exposed to methylene chloride in paint and coating removal may also be impacted by an increased risk for several types of cancer. The cancer risks to workers in commercial furniture refinishing using methylene chloride for paint and coating removal range from 8 cases in 10,000 people to 5 cases in 1,000 people (workplaces using immersion methods) (Ref. 2).

EPA's risk estimates are corroborated by research conducted independently investigating working conditions at commercial furniture refinishing and OSHA enforcement of their methylene chloride standard. In 1990, as a result of several cases of methylene chloride poisoning during paint and coating removal in commercial furniture refinishing in Colorado, occupational medicine specialists from the University of Colorado surveyed the 21 small shops in the Denver area engaged in commercial furniture refinishing. These researchers found that of the 21 shops, no workers wore respirators at all in seven shops, and in 14 facilities, workers occasionally wore half-face respirators with organic vapor cartridges (which do not provide respiratory or eye protection from methylene chloride). In ten of the 21 shops, workers experienced acute nervous system effects, such as dizziness or nausea while working to remove coatings from furniture. The researchers concluded that ''current safety practices in small-scale furniture-stripping shops may be inadequate to keep methylene chloride exposure levels in compliance with latest recommendations, and serious or fatal overexposure can occur'' (Ref. 70).

When considering the benefits of preventing exposure to methylene chloride in paint and coating removal in commercial furniture refinishing, EPA considered the type of effect, the severity of the effect, the duration of the effect, and costs and other impacts of the health endpoint. The health endpoints associated with exposure to methylene chloride are serious. Unit VI.E. presents a detailed discussion of the impacts of the most significant acute, chronic non-cancer, and cancer effects associated with methylene chloride exposure during paint and coating removal, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime. These effects include nervous system effects resulting from acute exposures, such as sensory impairment, incapacitation (loss of consciousness), and death; and effects resulting from chronic, occupational exposures including liver toxicity and liver cancer, hematopoietic cancers, brain cancer, lung cancer, reproductive effects, and kidney toxicity.

There are increased risks of death, nervous system effects, and liver, lung, brain, reproductive, and kidney effects for the approximately 15,000 workers in 4,900 commercial facilities or companies that use methylene chloride for paint and coating removal during commercial furniture refinishing each year (Ref. 4).

C. Approaches That Could Reduce the Risks of Methylene Chloride Used in Furniture Refinishing to Benchmark Levels

Although EPA is not proposing to regulate the use of methylene chloride in paint and coating removal for commercial furniture refinishing, EPA has identified potential requirements for methylene chloride in paint and coating removal for commercial furniture refinishing that could reduce exposures so that the risks presented would no longer be unreasonable. EPA is providing advanced notice of these potential approaches and is seeking comment on them.

1. Prohibition on manufacturing, processing, distribution, and use of methylene chloride in commercial furniture refinishing. Similar to the approach proposed for regulation of methylene chloride in other commercial paint and coating removal (see Unit V.), EPA has identified a prohibition on manufacturing, processing, distribution, and use of methylene chloride in commercial furniture refinishing as an option for reducing risks in this industry to benchmark levels, under TSCA sections 6(a)(2) and 6(a)(5). This approach could also require manufacturers, processors, and distributors to provide downstream notification of the prohibitions under TSCA section 6(a)(3), and could require recordkeeping relevant to these prohibitions under TSCA section 6(a)(4).

Under this approach, exposures to methylene chloride during paint and coating removal in commercial furniture refinishing would be completely eliminated. As a result, not only non-cancer risks, but also cancer risks would be eliminated.

2. Requiring a respiratory protection program, including PPE, air monitoring, and either a supplied-air respirator of APF 1,000 or 10,000 or an air exposure limit of 1 part per million (ppm) achieved through engineering controls or ventilation, in commercial facilities for furniture refinishing using methylene chloride for paint and coating removal under TSCA section 6(a)(5). Another regulatory approach that EPA has considered for the use of methylene chloride for paint and coating removal in commercial furniture refinishing would be to require risk reduction through an occupational respiratory

protection program, which would include air monitoring, medical monitoring, and respiratory protection through use of a supplied-air respirator with an APF of 1,000 or 10,000, depending on the methods used for paint and coating removal with methylene chloride and other workplace characteristics, with a performance-based option of meeting an air concentration level of 1 ppm as an exposure limit for methylene chloride.

A full-face (or helmet/hood) self-contained breathing apparatus (SCBA) when used in the pressure demand mode or other positive pressure mode has an APF of 10,000. EPA's analysis found that use of a SCBA with an APF of 10,000 would, in all scenarios evaluated, control the methylene chloride exposure to levels that allow for meeting the benchmarks for non-cancer and cancer risks. In some commercial furniture refinishing facilities using methylene chloride for paint and coating removal, workers with a supplied-air respirator with an APF of 1,000 would experience reduced exposures to methylene chloride such that their risks would be reduced to benchmark levels (Ref. 19). It is important to note that current OSHA requirements for dermal and eye protection when using methylene chloride in any way would be maintained under this approach, in addition to other requirements for work practices, training, and hazard communication put forth in OSHA's Methylene Chloride Standard (29 CFR 1910.1052).

EPA seeks comment on whether commercial furniture refinishing operations have these types of respiratory protection programs in place, any experiences in complying with the current OSHA methylene chloride standard, methods of reducing costs associated with these programs, and recommended approaches for small businesses considering a respiratory protection program that would include supplied-air respirators.

EPA also considered requiring a combination of local exhaust ventilation and respirators with APF of 1,000 or 50, with a performance-based option of an air exposure limit of 1 ppm as an eight-hour TWA. When properly executed, this option would reduce risks to the health benchmarks for workers and bystanders (Refs. 19 and 38). However, while this option has the benefit of incorporating engineering controls and the use respirators with a lower APF, the limitations to successful implementation of the use of supplied-air respirators in the workplace discussed previously are still present.

Further, this option would also require the use of prescriptive and expensive engineering controls to ensure that the exposures are below the benchmark cancer risks (Ref. 19). In an examination of the impacts of its methylene chloride standard, OSHA in 2010 found that furniture refinishing facilities in particular have not installed ventilation systems that would lower worker exposures to methylene chloride (Ref. 68). OSHA's assessment found that this is largely due the fact that most of these facilities are part of small businesses, and they tend to be less able to have sufficient capital to purchase the ventilation systems. Additionally, this type of ventilation requires make-up air systems, which have an additional cost and which, in cold climates, would need to heat the air and thus increase energy costs (Ref. 68).

Even if these engineering controls were installed, research conducted by the National Institutes of Occupational Safety and Health (NIOSH), as well as independent researchers, has indicated that ventilation alone is generally not able to reduce methylene chloride exposures below 25 ppm (Refs. 68 and 71), and there is no indication that a level close to 1 ppm (an acceptable exposure limit) could be reached.

3. Approaches that do not mitigate the risks of methylene chloride in commercial furniture refinishing to benchmark levels. As described in Units IV.B. and IV.C., EPA evaluated dozens of distinct exposure scenarios across consumer and commercial uses of methylene chloride for paint and coating removal, including in commercial furniture refinishing. The results of EPA's evaluation indicate that regulatory approaches for occupational exposures in commercial furniture refinishing such as reducing the concentration of methylene chloride in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures and standard cancer risk benchmarks for chronic exposures (Refs. 26 and 29). The results also demonstrate that all risk reduction options meeting the benchmark MOEs and cancer benchmarks for methylene chloride in paint and coating removal in commercial furniture refinishing require the use of a supplied-air respirator, whether used alone or in conjunction with additional levels of protection. Therefore, EPA found that setting a maximum concentration of methylene chloride in products under section 6(a)(2) could not reduce exposures so that risks from paint and coating removal with methylene chloride in commercial furniture refinishing would be reduced to benchmark levels. Options found not to meet the risk benchmarks are documented in EPA's supplemental technical reports on methylene chloride in paint and coating removal (Refs. 19, 20, 21, and 38).

D. Costs of EPA's Potential Approach for Regulation

EPA is at this time seeking additional information to inform its consideration of the reasonably ascertainable economic consequences of an action that would address the risks of commercial furniture refinishing so that they are no longer unreasonable, as required under TSCA section 6(c)(2)(A)(iv). This section presents the information EPA currently has and identifies the information that EPA is seeking. While the costs of potential risk management actions are not a legally permissible basis for EPA to reassess its proposed unreasonable risk determination, see TSCA section 6(b)(4)(A), costs are relevant to deciding among alternative risk management approaches that reduce risk so that a chemical substance no longer presents unreasonable risk and in establishing compliance dates for a risk management approach that is ultimately selected.

1. Information available to EPA. Based on industry research and information provided by stakeholders, including during informal discussions and more formally from small entity representatives participating in the SBAR process (described in more detail in Unit XXIII.), EPA has learned that there may not be any substitute chemicals or alternative practices frequently in use for paint and coating removal in commercial furniture refinishing other than chemical paint and coating removal with methylene chloride (Refs. 22 and 27).

Primary chemical substitutes for methylene chloride in commercial paint and coating removal more generally include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (ATM); and caustic chemicals. These substitute chemicals, their hazards, and their environmental impacts are described in more detail in Unit VI.E. EPA has learned that these chemicals are generally not suitable for paint and coating removal in furniture refinishing since they either are ineffective at removing particular coatings frequently found on furniture (such as varnish, lacquer, or older paint formulations in multiple layers); are formulated to include large amounts of water and thus

incompatible with wood objects that can become saturated and damaged (as is the case with many products containing benzyl alcohol); or are chemically incompatible with wood and can result in damage or raising the grain on the object (as is the case with caustic paint and coating removal products) (Refs. 22 and 27). Products that may be chemically compatible with wood substrates or the paints, varnishes, or lacquers to be removed were described by stakeholders as requiring too long a dwell time to be efficacious for their business and thus are not used (Refs. 22 and 27). Other than two commercial furniture refinishers who remove paints and coatings on some solid wood objects with either immersion in 100% acetone or an acetone-toluene-methanol blend, no commercial wood finishing firms reported using substitute chemicals routinely for paint and coating removal, and none felt they were able to completely eliminate use of methylene chloride, despite being aware of the worker health and environmental impacts (Refs. 22 and 27).

In addition to substitute chemical products, EPA has identified non-chemical methods for commercial paint and coating removal that can be used more generally as alternatives to methylene chloride. Frequently-used alternative methods to chemical paint and coating removal include thermal removal, sanding, hydroblasting, abrasive blasting, and laser removal (Refs. 22 and 27). These methods are already frequently in use in various industries for paint and coating removal (Refs. 22, 27, and 31); they and their acute and chronic hazards to workers are described in more detail in Unit VI.E.

For commercial furniture refinishing, EPA has learned that all firms engage in varying amounts of mechanical or hand-sanding but do not consider it a primary method of paint and coating removal (Refs. 22 and 27). Additionally, despite the hand scraping or brushing that is required to remove waste paint from furniture and other objects for which methylene chloride has been used to remove paint or coatings, most stakeholders described sanding as too time consuming or labor intensive to use routinely as a primary method of paint and coating removal. Additionally, though many other commercial sectors have adopted various soft media blasting techniques for delicate substrates, such as using soda blasting on fiberglass vehicle parts, EPA has not found this to be a practice used in commercial furniture refinishing (Refs. 22 and 27).

EPA is seeking additional information to inform its consideration of the impacts on commercial furniture refinishing if use of methylene chloride as a paint and coating remover were prohibited or restricted.

2. Information sought. To aid in identifying the economic impacts on commercial furniture refinishers of any potential prohibition or restriction on methylene chloride for paint and coating removal, EPA is seeking the following information related to the approach that would prohibit the use of methylene chloride for paint and coating removal in furniture refinishing:

- What percent of business for firms in this sector is paint and coating removal, versus furniture repair, reupholstery, or other furniture refinishing functions?
- How likely is it that firms in this sector would close if methylene chloride were prohibited from use in paint and coating removal in this sector?
- What would the impact be on this sector if all firms were prohibited from using methylene chloride for paint and coating removal, and thus any changes in work processes or dwell time would be universally experienced?
- Have firms had any success with substitute chemicals or alternative methods of paint and coating removal? If not, which aspects of the chemical or method renders the substitute or alternative ineffective?

Related to the approach that would require a respiratory protection program, including either a supplied-air respirator with either APF 1,000 or APF 10,000, or engineering controls or ventilation to reach an exposure limit of 1 ppm:

- What is the current experience of firms in this sector with supplied-air respirators and/or engineering controls?
- What is the current experience of firms in this sector with ventilation systems, makeup-air systems, and other engineering controls?
- What types of exposures do workers in firms in these sectors currently experience?

EPA has found that commercial furniture refinishing primarily uses methylene chloride for paint and coating removal and that no current chemical substitutes are seen as useful alternatives. However, in recent decades, substitute products have been developed for other types of paint and coating removal, and it is possible that new substitute chemicals or products could be developed to address the special coatings or substrates involved in commercial furniture refinishing. Several formulators and research organizations are exploring possibilities for efficacious and cost-effective substitute chemicals.

Additionally, outside of the United States, commercial furniture refinishers have adopted methods that are alternatives to chemical paint and coating removal. For example, most paint and coating removal in Sweden is conducted by thermal methods, such as heat guns or heat lamps, including for commercial furniture refinishing (Ref. 72). In Denmark, firms engaging in commercial furniture refinishing are reported to use large microwave furnaces, which can hold large pieces of furniture (Ref. 73).

These alternative methods and the research into substitute chemicals indicate that it is now and in the future may increasingly be possible to remove paint and coatings from furniture without methylene chloride. If that were the case, EPA would be able to more straightforwardly identify the costs and impacts of any proposed regulation of methylene chloride for paint and coating removal in commercial furniture refinishing. EPA is seeking additional information on the use and development of substitute chemicals and alternative methods that would be useful in commercial paint and coating removal on furniture, including information on:

- What are the current considerations when selecting a paint and coating removal chemical for furniture refinishing or refinishing of other wood objects or surfaces?
- What are the current considerations when selecting a paint and coating removal method for furniture refinishing or refinishing of other wood objects or surfaces?
- Are there substitute chemicals or alternative methods in use beyond what EPA has identified in this notice?
- Are any new paint and coating removal product formulations or chemistries under development?
- Are any new paint and coating removal methods in development for furniture refinishing, or refinishing of other wood objects or surfaces?

E. Public Engagement To Identify Impacts and Alternatives

To learn more about paint and coating removal in furniture refinishing, foreseeable impacts of any proposed regulations, and alternatives to methylene chloride, EPA plans to hold a series of stakeholder meetings. These meetings will focus on current practices related to methylene chloride for paint and coating removal in commercial furniture refinishing; any substitute chemicals or alternative methods currently in use or under development;

and current and best practices related to respiratory protection programs and exposure reduction.

EPA will announce dates and locations of these meetings in a future notice in the **Federal Register** as well as on EPA's Web site. EPA will provide some of these meetings electronically by Webinar to maximize public participation.

F. Next Steps

EPA views this section as an Advanced Notice of Proposed Rulemaking, and intends to issue a Notice of Proposed Rulemaking following the series of stakeholder meetings and further analysis on the cost impacts of regulatory action on this industry. Following that proposal and public comment period, EPA intends to finalize together the regulations proposed and the future proposal related methylene chloride in commercial furniture refinishing.

XII. Overview of NMP and Uses Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule would apply to N-methylpyrrolidone (Chemical Abstract Services Registry Number (CASRN) 872–50–4) when used in paint and coating removal.

B. What are the uses of NMP and how can people be exposed?

NMP is a solvent used in a variety of industrial, commercial and consumer use applications, including (Ref. 3):

- Petrochemical processing, acetylene recovery from cracked gas, extraction of aromatics and butadiene, gas purification, lube oil extraction;
- Plastics engineering, as a reaction medium for the production of high-temperature polymers such as polyethersulfones, polyamideimides and polyaramids;
- Use in coatings, as a solvent for acrylic and epoxy resins, polyurethane paints, waterborne paints or finishes, printing inks, synthesis/diluent of wire enamels, coalescing agent;
- Production of agricultural chemicals: Solvent and/or co-solvent for liquid formulations;
- Electronics cleaning: Cleaning agent for silicon wafers, photoresist stripper, auxiliary in printed circuit board technology; and
- Industrial and domestic cleaning, including as a component in degreasers and paint removers.

According to the 2012 CDR information, approximately 180 million pounds of NMP were produced or imported into the U.S. that year (Ref. 3).

Individuals, including workers, consumers, and the general population are exposed to NMP from industrial/commercial and consumer sources, in different settings such as homes and workplaces, and through multiple routes (inhalation, dermal, and vapor-through-skin).

According to data in the 2014 TRI, 386 facilities reported releases or transfers of NMP and the top 100 facilities disposed of or released a total of 10.2 million pounds of NMP (Ref. 6).

The use assessed by EPA that is the subject of this proposal, NMP in paint and coating removal, represents about 9% of total use of NMP (Ref. 3). Paint and coating removal is the application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from a substrate. Substrates can include objects, vehicles, architectural features, or structures. This use is discussed in detail in Unit XVI.A.

Although the TSCA Work Plan Chemical risk assessment for NMP focused on the chemical's use in paint and coating removal, EPA announced in December 2016 its designation of NMP as one of the ten chemical substances that will undergo risk evaluation pursuant to TSCA section 6(b)(2)(A) (81 FR 91927). The Agency is proceeding with this proposed rule addressing NMP in paint and coating removal in accordance with TSCA section 26(l) and asks for comment on its decision to pursue risk management for specific conditions of use of NMP while preparing to conduct a risk evaluation of remaining NMP conditions of use under TSCA section 6(b).

C. What are the potential health effects of NMP?

NMP is a developmental toxicant (Ref. 3). A broad set of relevant studies including animal bioassays in rats, mice, and rabbits show that maternal NMP exposure is associated with dose-dependent adverse developmental impacts on the fetus (including body weight reductions and fetal death). Developmental toxicity is the most sensitive endpoint. Other adverse impacts resulting from NMP exposure include effects on maternal body weight; alterations in blood cell counts; liver, kidney, splenic, thymus, and testicular effects; and neurotoxicity.

Nearly every study that evaluated developmental toxicity of NMP exposure identified some type of adverse effect depending on the route of exposure and the internal dose achieved. Moreover, a review of effect levels reveals that these effects are observed within a comparable dose range when administered doses are converted to internal doses for a series of gestational exposure studies in rats. The NOAELs for these comparable developmental studies typically ranged from 100 to 200 mg/kg/day for oral exposure, 237 mg/kg/day for dermal exposure, and 479 to 612 mg/m^3 for inhalation exposure. EPA applied a physiologically-based pharmacokinetic model to derive internal doses for these exposure scenarios to compare across routes and aggregate exposures. Specifically, EPA identified a number of biologically relevant, consistent, and sensitive effects, representing a continuum of reproductive and developmental effects for consideration in assessing human health risks, including decreased fetal and postnatal body weight, delayed ossification, skeletal malformations, and increased fetal and postnatal mortality. EPA identified a point of departure for decreased fetal body weight based on the average blood concentration of 411 mg/L. Studies have shown acute effects of NMP exposure to include fetal mortality and indications of fetal resorptions in rodents and a point of departure based on maximum blood concentration of 216 mg/L. Fetal and postnatal mortality have also been observed in oral and dermal studies (Ref. 3).

Chronic effects of NMP exposure include fetal body weight decreases. These effects were consistent among multiple studies with different dosing regimens and across exposure routes. Reduced fetal body weight is a sensitive endpoint that is considered a marker for fetal growth restriction, which is often assumed to be representative of chronic exposures. Decreases in fetal and postnatal body weights occur at similar dose levels (Ref. 3).

There is one case report of the fetus of a pregnant woman dying in utero at week 31 of pregnancy. The worker was exposed throughout pregnancy to NMP by inhalation and dermal exposure, but the exposure levels were unknown. The worker's tasks involved other chemicals, including acetone and methanol. During week 16 of the pregnancy, the worker cleaned up a spill of NMP using latex gloves that dissolved in the NMP. She was ill for the next 4 days and experienced malaise, headache, nausea and vomiting. While this study provides some evidence that NMP may be fetotoxic, the lack of quantitative exposure data precluded its use in the TSCA Work Plan Chemical Risk Assessment for NMP (Ref. 3).

Chronic effects of NMP exposure include systemic effects following

maternal exposure, which include body weight reductions, alterations in clinical chemistry and blood cell counts, liver and kidney toxicity, neurotoxicity and thymic atrophy, with highly variable dose levels where no observed adverse effects occurred (Ref. 3).

An additional effect of chronic NMP exposure is reproductive toxicity, though these findings are significantly less frequent or consistent than the occurrence of developmental effects. When observed, reproductive effects were variable in occurrence and dose effect range. Several rat studies identified some type of testicular effect, including testicular lesions, atrophy or smaller testes. Similarly, a small number of rat studies noted some effects related to developmental neurotoxicity in postnatal development and behavior following maternal exposure (Ref. 3).

In addition to developmental toxicity, exposure to NMP presents other acute and chronic toxicity concerns. Acute effects include skin, eye, and possible respiratory irritation. Human volunteer chamber studies revealed some discomfort during exposure. Prolonged exposures to neat (*i.e.,* pure) NMP increases the permeability of the skin (Ref. 3).

D. What are the environmental impacts of NMP?

Section 6(c) of TSCA requires that EPA state the effects of NMP on the environment and the magnitude of the exposure of the environment to NMP. The proposed unreasonable risk determination, however, is based solely on risks to human health since these risks are the most serious consequence of use of NMP and are sufficient to support this proposed action.

1. *Environmental effects and impacts.* Ecotoxicity studies for NMP have been conducted in fish, aquatic invertebrates, aquatic plants and birds. There were no acceptable studies identified for sediment or soil dwelling organisms. Based on available data in the NMP risk assessment, EPA concluded that NMP has low acute and chronic toxicity to aquatic organisms (including plants) and birds (Ref. 3). Based on NMP's low persistence, low bioaccumulation, and low hazard for environmental toxicity, the magnitude of potential environmental impacts on ecological receptors are judged to be low for the environmental releases associated with the use of NMP in paint and coating removal.

2. *What is the global warming potential of NMP?* Global warming potential (GWP) measures the potency of a greenhouse gas over a specific period of time, relative to carbon dioxide, which has a GWP of 1 regardless of the time period used. No GWP has been developed for NMP because of its very short atmospheric lifetime. Based on its very short half-life, its GWP is expected to be very low (Ref. 3).

3. *What is the ozone depletion potential of NMP?* NMP is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy (SNAP) program for degreasing and aerosols (Ref. 9).

4. *Is NMP a volatile organic compound (VOC)?* NMP is not a VOC as defined at 40 CFR 51.100(c). A VOC is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions.

5. *Does NMP persist in the environment and bioaccumulate?* NMP is not persistent or bioaccumulative. Biodegradation studies have consistently shown NMP to be readily biodegradable. Based on its vapor pressure, NMP released to the atmosphere is expected to exist solely in the vapor-phase. Vapor-phase NMP is degraded in air by reaction with photochemically-produced hydroxyl radicals. The half-life of this reaction is approximately 5.8 hours, assuming a hydroxyl radical concentration of 1.5×10^6 hydroxyl radicals/cm^3 air over a 12-hr day. NMP in the atmosphere can be expected to dissolve into water droplets, where it will be removed by condensation or further reactions with hydroxyl radicals (Ref. 3).

When released to water, NMP is not expected to adsorb to suspended solids or sediment in the water column based upon its Koc value. Based on its low soil organic carbon partitioning coefficient (log Koc = 0.9), NMP is expected to possess high mobility in soil; releases of NMP to soil may volatilize from soil surfaces or migrate through soil and contaminate groundwater (Ref. 3).

EPA was not able to locate measured bioconcentration studies for NMP; however, the estimated bioaccumulation factor of 0.9 and estimated bioconcentration factor of 3.16 suggest that bioaccumulation and bioconcentration in aquatic organisms is low. Based on the available environmental fate data, NMP is expected to have low bioaccumulation potential and low persistence (Ref. 3).

XIII. Regulatory Actions Pertaining to NMP

This section summarizes current state, federal, and international regulations and restrictions on NMP, with a focus on its use in paint and coating removal. None of these actions imposes requirements to the extent necessary so that NMP does not present the unreasonable risk described in this proposed rule.

A. Federal Actions Pertaining to NMP

While many of the statutes that EPA is charged with administering provide statutory authority to address specific sources and routes of NMP exposure, none of these can address the serious human health risks from NMP exposure that EPA is proposing to address under TSCA section 6(a).

- NMP is listed on the Toxics Release Inventory (TRI) and is therefore subject to reporting pursuant to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) (Ref. 6).
- NMP is on The Clean Air Act (CAA) Section 111, Standards of Performance for New Stationary Sources of Air Pollutants—Equipment Leaks Chemical List (40 CFR 68.130)
- NMP is currently approved for use by EPA as a solvent and co-solvent inert ingredient in pesticide formulations for both food and non-food uses and is exempt from the requirements of a tolerance limit (Ref. 74).

In 2013, the Consumer Product Safety Commission issued a fact sheet warning the public about hazards of paint sand coating removal products, including those containing NMP, and included recommendations for PPE when using products containing this chemical (Ref. 62).

B. State Actions Pertaining to NMP

Several states have taken actions to reduce or make the public aware of risks from NMP. California has set worker protection regulations that require workers to wear gloves when using NMP, and workplace to meet a permissible exposure limit of 1 ppm as an eight-hour time-weighted average (TWA) (Ref. 3). Additionally, NMP is listed as an informational candidate on California's Safer Consumer Products regulations candidate list of chemicals that exhibit a hazard trait and are on an authoritative list and is also listed on California's Proposition 65 list of chemicals known to cause cancer or birth defects or other reproductive harm (Ref. 3).

In Washington, NMP is listed as a chemical of high concern under the Children's Safe Product Act (Ref. 3). Minnesota classifies NMP as a chemical of high concern and several other states have placed NMP on similar chemical listings. Additional states have

recognized NMP as an air pollutant (Ref. 3).

C. International Actions Pertaining to NMP

NMP is currently on the candidate list of substances of very high concern for authorization in the European Union. In August 2013, the Dutch National Institute for Public Health and the Environment submitted a proposal for the restriction of NMP to the European Chemicals Agency under the Registration, Evaluation, Authorisation and Restriction regulation. The Risk Assessment Committee modified the restriction proposal and the combined opinion will be sent to the European Commission for final decision. The Risk Assessment Committee recommended using long-term exposure Derived No Effect Levels for pregnant workers (the most sensitive population) for both inhalation and dermal exposure (Ref. 3).

Other countries have also recognized the risks of NMP. When Canada conducted a categorization of the Domestic Substances List for its Chemicals Management Plan in 2006, NMP met Canada's human health categorization criteria. NMP has been the subject of a Tier II health risk assessment in Australia under that country's Inventory Multi-tiered Assessment and Prioritisation. It is currently subject to labeling and related requirements based on concern for skin, eye and respiratory irritation and for reproductive toxicity. These government assessments consider NMP to be of low environmental concern (Ref. 3). Australia concluded that further risk management is required and additional assessment (Tier III) is needed to determine if current exposure controls are adequate to protect workers and the public when NMP is used in domestic products (Ref. 3).

XIV. NMP Risk Assessment and Outreach

In 2013, EPA identified NMP in paint and coating removal as a priority for risk assessment under the TSCA Work Plan. This unit describes the development of the NMP risk assessment and supporting analysis and expert input on the uses that are the subject of this proposed rule. A more detailed discussion of the risks associated with NMP in paint and coating removal can be found in Units XVI.B.1. and XVI.D.

A. TSCA Work Plan for Chemical Assessments

Using the TSCA Work Plan chemical prioritization criteria, discussed in Unit IV.A., NMP ranked high for health hazards and exposure potential and was included on the initial list of TSCA Work Plan chemicals for assessment. NMP appeared in the 2012 TSCA Work Plan for Chemical Assessments and in the 2014 update of the TSCA Work Plan for Chemical Assessments.

B. NMP Risk Assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for NMP (NMP risk assessment) in 2015, following the 2013 peer review of the 2012 draft NMP risk assessment. All documents from the 2013 peer review of the draft NMP risk assessment are available in EPA Docket Number EPA–HQ–OPPT–2012–0725. The completed risk assessment is included in that docket.

The NMP risk assessment evaluated health risks to consumers, workers, and bystanders from dermal and inhalation exposures to NMP when used in paint and coating removal (Ref. 3). EPA assumes workers and consumers would be adults of both sexes 16 years and older, including pregnant women. EPA assumes bystanders in residential settings would be individuals of any age group (*e.g.,* children, adults, and the elderly) nearby during product application. During scoping and problem formulation for the risk assessment, EPA focused on occupational and consumer paint and coating removal because of high NMP content in products and potential high exposure to workers and consumers. EPA selected these uses for the NMP risk assessment because they were expected to involve frequent or routine use of NMP in high concentrations and/or have high potential for human exposure (Ref. 3). However, this does not mean that EPA determined that other uses not included in the NMP risk assessment present low risk.

The NMP risk assessment characterized human health effects associated with paint removal with NMP. Based on the physical-chemical properties of NMP and the paint stripping use scenarios described in the assessment, EPA views dermal exposure as the predominant route of exposure to NMP during paint removal, including absorption of vapor-through-skin.

The NMP risk assessment identified developmental risks of concern following acute (short-term) and chronic (repeated) exposures for workers conducting paint removal with NMP. Specifically, these developmental effects include increased fetal resorptions (fetal death) from acute exposures and decreased fetal body weight from chronic exposures (Ref. 3). EPA identified acute risks of concern for consumers using NMP for paint and coating removal in the more complete array of scenarios described in the supplemental analyses, which used the same modeling methods as the risk assessment (Refs. 75 and 76).

Margins of exposure (MOEs) were used in the risk assessment and supplemental analyses to estimate non-cancer risks for acute and chronic exposures. For an explanation of MOEs, see Unit IV.B. For NMP, EPA identified acute or chronic non-cancer risks of concern if the MOE estimates were less than the benchmark MOE of 30 (Ref. 3). The health endpoint used for the benchmark MOE for acute exposure to NMP is fetal death; the health endpoint used for the benchmark MOE for chronic exposure to NMP is decreased infant birth weight. These are the most sensitive adverse health effects from exposure to NMP.

The NMP risk assessment and supplemental analyses estimated acute risks of fetal death for consumers from the use of paint and coating removers containing NMP, and acute and chronic non-cancer risks of decreased infant birth weight for workers from the use of paint and coating removers containing NMP. Exposure scenarios with MOEs below the benchmark MOE present risks of concern. Typically, non-cancer adverse effects are more likely to result from exposure scenarios with MOEs multiple orders of magnitude below the benchmark MOE. For non-cancer effects, EPA estimated exposures that are significantly larger than the point of departure (Ref. 3). Specifically, the assessment identified risks of fetal death from acute exposures of:

- Four or fewer hours per day, when gloves were not used.
- Greater than 4 hours per day, and risks were not mitigated by personal protective equipment such as respirators or gloves.

The assessment identified risks of decreased infant birth weight from chronic (repeated) exposures of:

- Four or fewer hours per day, when gloves were not used.
- Greater than 4 hours per day, and risks were not mitigated by personal protective equipment such as respirators or gloves.
- Over the course of a work-week (5 days)

Given the risks identified in the NMP risk assessment, the agency undertook further analysis to consider whether that use of NMP in paint and coating removal poses an unreasonable risk.

C. Supplemental Analysis Consistent With the NMP Risk Assessment

Following the NMP risk assessment, EPA conducted supplemental analyses

to inform risk management and to expand on the consumer exposure scenarios. These analyses are consistent with the scope of the NMP risk assessment and were based on the peer-reviewed methodology used in the NMP risk assessment. They included identification of baseline and central tendency exposure scenarios, impacts of reduced NMP content in paint removers, addition of local exhaust ventilation (LEV), use of personally protective equipment (PPE), and methods of monitoring to ascertain workplace exposures. The results of EPA's analyses are available in this rulemaking docket (Refs. 37, 75, and 76). Prior to promulgation of the final rule, EPA will peer review the ''Recommendation for an Existing Chemical Exposure Limit (ECEL) for Occupational Use of NMP and Workplace Air Monitoring Methods for NMP,'' ''Respirator and Glove Specifications for Workers and Consumers Exposed to N-methylpyrrolidone (NMP) in Paint and Coating Removal and Estimated Fractions of Worker Population Vulnerable to the Acute Health Effect,'' and ''Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal'' (Refs. 37, 75, and 76).

D. Outreach

In addition to the consultations described in Unit XXIII., EPA initiated discussions with experts on and users of paint removers (Ref. 22). For more information on these discussions, see Unit IV.D.

XV. Regulatory Approach for NMP in Paint and Coating Removal

A. TSCA Section 6(a) Unreasonable Risk Analysis

Under TSCA section 6(a), if the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to EPA's risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

The TSCA section 6(a) requirements can include one or more, or a combination of, the following actions:

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).
- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration (§ 6(a)(2)).
- Require minimum warning labels and instructions (§ 6(a)(3)).
- Require recordkeeping or testing (§ 6(a)(4)).
- Prohibit or regulate any manner or method of commercial use (§ 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal (§ 6(a)(6)).
- Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances (§ 6(a)(7)).

EPA analyzed a wide range of regulatory options under section 6(a) for each use in order to select the proposed regulatory approach (Refs. 23 and 24). For each use, EPA considered whether a regulatory option (or combination of options) would address the unreasonable risk so that it no longer presents such risk. To do so, EPA initially analyzed whether the regulatory options could reduce risks to levels below those of concern, based on EPA's technical analysis of exposure scenarios.

After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered how reliably the regulatory options would actually reach these benchmarks. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In considering whether a regulatory option would ensure the chemical no longer presents the unreasonable risk, EPA considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks in relation to the benchmarks, as well as whether the option's protectiveness was impacted by environmental justice or children's health concerns.

B. TSCA Section 6(c)(2) Considerations

As noted previously, TSCA section 6(c)(2) requires EPA to consider and publish a statement based on reasonably available information with respect to the:

- Health effects of the chemical substance or mixture (in this case, NMP) and the magnitude of human exposure to NMP;
- Environmental effects of NMP and the magnitude of exposure of the environment to NMP;
- Benefits of NMP for various uses;
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost-effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

In addition, in selecting among prohibitions and other restrictions available under TSCA section 6(a), EPA must factor in, to the extent practicable, these considerations. Further, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's analysis of health effects and magnitude of exposure to NMP can be found in Units XIV.B., XVI.B. and XVI.C., which discuss the NMP risk assessment and EPA's regulatory assessment of the use of NMP in paint and coating removal. A discussion of the environmental effects of NMP is in Unit XII.D.

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the Economic Analysis (Ref. 4). The regulatory options and consideration of TSCA section 6(c)(2) factors are discussed in more detail in Unit V for methylene chloride in paint and coating removal and in Unit XV. for NMP in paint and coating removal.

To the extent information was reasonably available, EPA considered the benefits realized from risk reductions (including monetized benefits, non-monetized quantified benefits, and qualitative benefits), offsets to benefits from countervailing risks (*e.g.,* residual risk risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children and other potentially exposed or susceptible subpopulations (as compared to the general population), the cost of regulatory requirements for

the various options, and the cost effectiveness of the proposed action and the one or more primary alternate regulatory options. A discussion of the benefits EPA considered can be found in Units XVI.C. and XVII.B. as well as in the Economic Analysis (Ref. 4).

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. For example, an option that includes use of a respirator would include inspections to evaluate compliance with all elements of a respiratory protection program (Ref. 25). In understanding the burden, EPA took into account the reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives. Reasonably available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options. A discussion of the costs EPA considered and a discussion of the cost-effectiveness of the proposal and the primary alternate regulatory options that EPA considered is in Units XVI.E. and XVII.A. In addition, a discussion of the impacts on small businesses is in Unit XXIII. and in the Initial Regulatory Flexibility Analysis and Report from the Small Business Advocacy Review Panel (Refs. 26 and 27).

With respect to the anticipated effects of this proposal on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers. In addition, EPA considered the employment impacts of this proposal, as discussed in the Economic Analysis (Ref. 4). EPA found that the direction of change in employment is uncertain, but EPA expects the short term and longer-term employment effects to be small.

The benefits of NMP in paint and coating removal are discussed in Unit XVI.A., along with the availability of alternatives. The dates that the proposed restrictions would take effect are discussed in Unit XX. The availability of alternatives to methylene chloride in paint and coating removal on those dates is discussed in Unit XVI.D.

Finally, with respect to this proposal's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. An impending prohibition on this use of NMP is likely to increase demand for alternatives, which EPA expects would result in the development of new alternatives. See section 9.3 in the Economic Analysis (Ref. 4).

C. Regulatory Options Receiving Limited Evaluation

EPA analyzed a wide range of regulatory options under TSCA section 6(a). There are a range of regulatory options under TSCA; only those pertaining to these risks were evaluated in detail. An overview of the regulatory options not evaluated in detail follows.

First, EPA reasoned that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture, processing or distribution in commerce of NMP or limit the amount of NMP which may be manufactured, processed or distributed in commerce is not applicable because EPA is not proposing to ban or limit the manufacture, processing or distribution in commerce of NMP for uses other than paint and coating removal.

In addition, EPA reasoned that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not assess risks associated with NMP disposal.

Another option EPA evaluated would be to only require warning labels and instructions on paint and coating removal products containing NMP, pursuant to section 6(a)(3) (Ref. 30). EPA reasoned that warning labels and instructions alone could not mitigate the risks as necessary so that NMP no longer presents an unreasonable risk (either to users in the general population or to users who are women of childbearing age). For a further discussion of why EPA believes that labeling alone will not effectively mitigate the unreasonable risks, see Unit V.C. EPA's general observations about labeling, described in that unit, are also applicable in the case of NMP. Specifically regarding NMP, effective personal protection resulting in risk reduction would require not only the appropriate donning and doffing of specialized gloves that are not easily available to consumers, but also identification of which type of glove is protective against particular formulations of paint and coating removal products containing NMP (Ref. 75). Any labeling aiming to reduce risks to consumer or commercial users of these products would need to sufficiently and clearly explain this, and would still leave the user with the problem of obtaining and properly using the appropriate gloves and (in the case of commercial users or consumers using the product for several days at a time) the appropriate respirator. With respect to consumer risks in particular, a label on a product that is easily available to consumers, that directs the user to obtain and use safety equipment that is not easily available to consumers, is especially unlikely to be correctly followed.

A regulatory option receiving limited evaluation was a training and certification program for commercial paint and coating removers, similar to the certification process required under EPA's Lead Renovation, Repair, and Painting Rule (73 FR 21692, April 22, 2008). This option was recommended by the small entity representatives as part of the SBAR process (Ref. 27). EPA considered this option as an approach to reducing risks from NMP in paint and coating removal. However, unlike the process for training and certification of commercial workers required under the Lead Renovation, Repair, and Paint Rule, effective risk reduction from commercial use of NMP for paint and coating removal would require additional regulation of distributors of these products. When considering this approach, given the Agency's experience with the training and certification program under the Lead Renovation, Repair, and Paint Rule, EPA viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach. EPA seeks public comment on the feasibility of such a program and its potential to reduce risks of exposure to NMP for workers so that those risks are no longer unreasonable.

XVI. Regulatory Assessment of NMP in Paint and Coating Removal

This unit describes the current use of NMP in paint and coating removal, the unreasonable risks presented by this use, and how EPA identified which regulatory options reduce the risks so that they are no longer unreasonable.

A. NMP in Paint and Coating Removal

As described previously in Units I.A. and VI.B., paint and coating removal, also referred to as paint stripping, is the process of removing paint or other coatings from a surface of a substrate, such as an object or structure (Ref. 3). More information on specific techniques for paint removal in each industry and by consumers are in the NMP risk assessment and supplemental materials (Refs. 3, 75, and 76).

Chemical products for paint and coating removal are used across several industries as well as by consumers or hobbyists, and products intended for one type of use—such as aircraft renovation—have been used in other

situations, such as bathtub refinishing (Refs. 11, 32, and 33). There are no restrictions on using products intended for one specific type of paint removal project in a different setting. Additionally, consumers face no restrictions when using products intended for or marketed to professional users.

EPA has identified 64 different products for paint and coating removal that contain NMP, formulated by 21 different firms. This is approximately 59% of the total number of paint and coating removal products EPA identified (109 products) (Ref. 34). Though the number of workers and consumers exposed to NMP during paint and coating removal is uncertain, EPA has several estimates based on industry data. As described in Unit VI.B., commercial uses include automotive refinishing, furniture refinishing, art conservation and restoration, pleasure craft building and repair, aircraft paint removal, graffiti removal, bathtub refinishing, and renovations in residences or other buildings. As described in more detail in the Economic Analysis, EPA estimates that 30,300 workers annually are exposed to NMP during paint and coating removal activities (Ref. 4).

Consumer use of NMP in paint and coating removal is similar to commercial use, but occurs in consumer settings, such as homes, workshops, basements, garages, and outdoors. Paint and coating removal products containing NMP are the same as those used in many commercial settings, and the process consumers use is similar to commercial methods of brushing or spraying on the paint and coating removal product, allowing time to pass for the product to penetrate the coating, and then scraping the loosened coating from the surface.

When consumers interested in DIY paint and coating removal choose to use chemical paint removers (Ref. 77), they frequently receive advice to use products that contain NMP, without any reference to the risks presented by NMP or even solvents in general (Refs. 78 and 79). Manufacturers and retailers of paint and coating removal products containing NMP frequently sell them to consumers in small containers with marketing language or labeling that state they are biodegradable, 'plant-based', or contain 'no harsh fumes' and implies they are 'green' or 'safe' (Ref. 35). Products containing NMP are not required to be labeled with that information or any information about personal protection or risk reduction. These products are frequently sold at home improvement retailers or automotive supply stores that sell products to consumers as well as professional users (Ref. 35). Additionally, due to the wide availability of products available on the Internet and through various additional suppliers that serve commercial and consumer customers, consumers are able to purchase a variety of paint and coating removal products containing NMP. EPA estimates that the majority of users of paint and coating removal products containing NMP are consumers, rather than occupational users. EPA estimates that approximately 732,000 consumers annually use paint removal products containing NMP (Ref. 4).

B. Analysis of Regulatory Options

In this section, EPA explains how it evaluated whether the regulatory options considered would address the unreasonable risks presented by the use of NMP in paint and coating removal. First, EPA characterizes the unreasonable risks associated with the current use of NMP in paint and coating removal. Then, EPA describes its initial analysis of which regulatory options have the potential to achieve non-cancer benchmarks. Lastly, this section evaluates how well those regulatory options would address the unreasonable risk in practice.

1. Risks associated with the current use. a. General impacts. The NMP risk assessment and additional supplemental analyses identified acute and chronic risks for consumers and commercial users of paint and coating removal products containing NMP following exposure through dermal contact, inhalation, and vapor-through-skin (Refs. 3, 75, and 76). EPA did not find risks for occupational or residential bystanders (individuals not using the paint and coating remover, but near someone who is). EPA estimates, having refined the numbers since the risk assessment that, annually, there are approximately 30,300 workers at 4,300 commercial operations conducting paint and coating removal with NMP, and approximately 732,000 consumers who use paint and coating removal products containing NMP each year (Ref. 4).

b. Impacts on minority and other populations. While all consumers and workers using paint and coating removal products containing NMP would benefit from risk reduction, some populations are currently at disproportionate risk for the health effects associated with NMP in paint and coating removal. These are the same populations at disproportionate risk for the health effects associated with methylene chloride in paint and coating removal, and are described in Unit VI.C.1.b.

c. Impacts on children. EPA has concerns for effects on the developing fetus from acute and chronic worker and consumer maternal exposures to NMP. The risk estimates focus on the most susceptible life stages, which for NMP are women of childbearing age and their developing fetus. However, because women may not know that they are pregnant (Refs. 80 and 81) and short-term exposure to NMP may adversely impact fetal development during a single day or single week of exposure, the life stages of concern for risk assessment include all women of childbearing age (*i.e.,* women between the ages of 16 and 49 years) and the developing fetus. The impacts to children derive from the pre-natal or maternal exposure; these impacts include decreased fetal weight, decreased birth (post-natal) weight, and fetal death. Details on the impacts of these health effects are described in Unit XVI.C.

EPA assumed that consumer and commercial users would generally be adults of both sexes (16 years old and older, including women of childbearing age), although exposures by teenagers and even younger individuals may be possible in consumer settings. However, risk estimates focused on the most susceptible life stage, which are pregnant women and their developing fetus, because developmental toxicity is one of the most sensitive health effects associated with NMP exposure (Ref. 3).

d. Exposures for this use. Exposures assessed for this in the risk assessment and supplemental analyses use include acute and chronic (or repeat-dose) exposures by commercial workers and acute exposures by consumers engaging in paint and coating removal with NMP, as described in the NMP risk assessment and additional analyses (Refs. 3 and 76). The exposure pathways of interest included dermal contact, vapor-through-skin, and inhalation. Acute scenarios assumed one day, or up to eight hours, of exposure; chronic, or repeat-dose, scenarios assumed five days of exposure per week, or one work week, with up to eight hours per day of exposure (Refs. 3 and 76).

For exposures in commercial settings, EPA assessed exposure scenarios under which the worker was presumed to work on either an indoor project (such as work by professional contractors, furniture stripping and other settings) or an outdoor or semi-enclosed space (such as graffiti removal on the exterior of a building, outdoor escalator, or elevator).

In the NMP risk assessment, EPA developed six occupational user

exposure scenarios for assessment. The following factors were considered in developing the exposure scenarios (Ref. 3):

- The weight fraction of NMP in the paint and coating removal product;
- Skin surface area of the worker in contact with the paint removal product; and
- Duration of contact (in hours) with the paint removal product.

Within each of the six workplace scenarios, EPA evaluated five permutations, by modifying the parameters of the scenario to include different combinations of personal protective equipment (PPE). These permutations were (1) respirator with assigned protection factor (APF) of 10, and gloves; (2) respirator APF 10 only; (3) gloves only; (4) neither respirator nor gloves; and (5) not directly using the product (nearby worker) (Ref. 3).

EPA used air concentration data and estimates found in literature sources to serve as inhalation exposure concentration inputs to the physiologically-based pharmacokinetic modeling for occupational exposures to NMP. This modeling was used to derive internal dose estimates for acute and chronic occupational exposures, and predicted absorption of liquid or vapor by the individual in the scenario when using the paint and coating removal product containing NMP (Ref. 3).

For consumer exposures, EPA assessed exposure scenarios under which the individual was presumed to work on one of several types of paint and coating removal projects (table and chairs, chest of drawers, or bathtub), with inputs reflecting that consumers do not reliably use personal protective equipment (effective gloves) or have access to engineering controls (*e.g.,* ventilation fan). In each scenario, the consumer would be exposed via inhalation, dermal contact, and vapor-through-skin (Ref. 3).

EPA developed seven consumer exposure scenarios for the assessment. Similar to the worker exposure assessment, the following factors were considered in developing the exposure scenarios (Ref. 3):

- The type of application (*i.e.,* brush-on or spray-on), weight fraction of NMP in the paint and coating removal product, application rate by the user, surface area of object from which the paint or coating was being removed, and emission rate of the chemical, which can affect the amount of NMP that ultimately is released to the indoor environment;
- The location where the product is applied, which relates to exposure factors such as the room volume and its air exchange rate with outdoor air;
- The house volume and air exchange rate, for reasons similar to those for the product use location; and
- Precautionary behaviors such as opening windows in the application room, the user leaving the application room during the wait period, related changes to the air exchange rates, and the proximity of the user to the source of NMP emissions.

In the absence of representative air monitoring data for consumers using paint and coating removal products containing NMP, EPA used the Multi-Chamber Concentration and Exposure Model to estimate consumer inhalation exposure concentrations. The predicted air concentrations from the exposure modeling for users and non-users were inputs to the physiologically-based pharmacokinetic modeling software and used to define consumers' moment-by-moment air concentration inhaled and in contact with unobstructed skin. The parameters and data sources for the model are described in the NMP risk assessment (Ref. 3).

EPA's estimates of the exposures individuals experienced during the acute and chronic scenarios of commercial or consumer use of paint and coating removal products containing NMP were used to assess the risks of these uses of NMP. The full exposure estimates and risk findings are described in the NMP risk assessment; risk findings are also summarized in Unit XVI.B.1.a.

In addition to estimating likely exposures under current use patterns, for both commercial and consumer users, EPA assessed a number of exposure scenarios associated with risk reduction options in order to identify variations in NMP exposure. All variations in the scenarios were evaluated with exposure parameters that were modified to reflect either a reasonable worst-case scenario (also called the baseline) or a scenario in which exposures were moderated by several factors (also called the central tendency scenario). The risk reduction options that were varied between scenarios included material substitution, duration of use, engineering controls, and use of PPE, as well as combinations of these options (Refs. 37, 75, and 76), as follows:

- The material substitution scenarios involved reducing the concentration of NMP in the paint and coating removal product, with concentrations varying from 5, 10, 25, 30, 35, 40, 62.5 and 100% by weight in the product.
- The duration of use scenarios involved, for consumers, variations in the type of activity during which paint removal would be conducted (for example, 7 hours of exposure to NMP when removing paint from a table and 8 chairs; 0.5 hours of exposure to NMP when removing paint from a coffee table). For commercial users, duration of exposure to NMP in paint and coating removers was assessed as job time during a work day (1 to 8 hours).
- Under the PPE risk reduction option exposure scenarios, EPA evaluated consumers wearing specialized gloves, and workers wearing specialized gloves and/or respirators with APF 10.
- For the engineering controls risk reduction option exposure scenarios, EPA evaluated using LEV to improve ventilation near the activity of workers in furniture refinishing operations, with an assumed 90% reduction in exposure levels.

Additionally, EPA evaluated combinations of the options. For consumers, this included material substitution, duration of exposure, and PPE; for workers, this included material substitution, duration of exposure, PPE, and LEV. Engineering controls are not assumed to be practical for consumers as a method of exposure reduction. Overall, EPA evaluated dozens of distinct exposure scenarios for both consumer and commercial paint and coating removal with NMP.

e. Specific risks for this use. The assessment of acute risks used developmental toxicity data to evaluate the acute risks for paint and coating removal with NMP. EPA based its assessment of acute risks on the endpoint most protective of health (*i.e.,* fetal death (Ref. 3)), representing the most sensitive human life stage (*i.e.,* women of childbearing age (greater than 16 years) and the fetus). Because fetal effects were selected as key endpoints, risks were calculated for pregnant women and women of childbearing age who may become pregnant. As described in the risk assessment, exposures that do not result in risks of concern for these particular lifestages are also found to be protective of children and adult males. A risk of concern was identified if the MOE estimate was less than the benchmark MOE of 30 (Ref. 3).

In the risk assessment and supplemental analyses, EPA evaluated risks for fetal death from dermal contact, inhalation, and vapor-through-skin for all consumer, occupational, and bystander exposure scenarios of paint and coating removal with NMP. No risks were identified for occupational or residential bystanders. Acute risks of fetal death were identified for the

consumer and commercial users of NMP for paint and coating removal in several, although not all, scenarios. To identify what, if any, risks may be present for consumers in different scenarios, EPA conducted additional analyses consistent with the risk assessment to provide an expanded understanding of consumer exposures (Ref. 76). Additionally, it appears that consumers could engage in patterns of use comparable to worker exposures that present risk; for example, any consumers engaging in paint and coating removal with NMP for longer than four hours in one day could be subject to the acute occupational risks identified (Ref. 3).

For commercial users, the occupational scenarios in which acute risks were identified included four hours of paint removal in one day with no gloves, with or without a respirator, indoors or outdoors, assuming mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (MOEs range from 12 to 15); and four hours of paint removal in one day with or without a respirator and gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (MOEs range from 0.7 to 11.8) (Ref. 3). These risks are present whether the worker is indoors or outdoors, and may be present even in the presence of PPE or ventilation, depending on the duration of use and the concentration of NMP in the product. Therefore, EPA's proposed determination is that acute NMP exposures during paint and coating removal present unreasonable risks.

EPA also assessed risks of chronic exposure to NMP by commercial users, with a short-term chronic exposure that can be defined as a repeat-dose scenario in which the individual is exposed over the course of a work week, rather than over a lifetime. This chronic assessment used decreased fetal body weight as the critical endpoint. EPA assessed risks for decreased birth weight for occupational and bystander exposure scenarios of paint and coating removal with NMP. In the risk assessment, a risk of concern was identified if the MOE estimate was less than the benchmark MOE of 30 for decreased birth weight (Ref. 3).

Risk of decreased birth weight was identified for commercial users of NMP for paint and coating removal in several scenarios, including four hours of paint removal during each day in a work week without gloves, with or without a respirator, indoors or outdoors, assuming the mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (MOEs range from 5.4 to 6.1); and eight hours of paint removal during each day in a work week, with or without a respirator or gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (MOEs range from 0.1 to 3.2) (Ref. 3). Though no risks were identified for occupational bystanders, for workers, these risks are present whether the worker is indoors or outdoors, and may be present even if PPE or ventilation is used, depending on the duration of use and the concentration of NMP in the product (Ref. 3). In some scenarios, this equates to estimated exposures that are more than 10 times greater than those that would produce the benchmark MOE for this endpoint, which assesses risks for fetal death and decreased birth weight. Therefore, EPA's proposed determination is that chronic NMP exposures during paint and coating removal also present unreasonable risks.

The SBAR Panel convened in support of this action heard from several SERs who expressed concerns about the underlying NMP risk assessment (Ref. 27). Many of the concerns expressed by these SERs were already expressed in the public comments and the peer review comments on the NMP risk assessment. The Summary of External Peer Review and Public Comments and Disposition document in the risk assessment docket (EPA–HQ–OPPT–2012–0725) explains how EPA responded to the comments received.

2. Initial analysis of potential regulatory options. Having determined that the risks from NMP in paint and coating removal were unreasonable, EPA evaluated how regulatory options under section 6(a) might reduce the risks so that they are no longer unreasonable.

The results of EPA's assessment of consumer uses, exposures, and risks indicate that regulatory options for consumer uses such as reducing the concentration of NMP in a product or advising the use of specialized gloves or respirators individually could not achieve the target MOE benchmarks for acute exposures (Ref. 76). Similarly, the results of EPA's evaluation indicate that regulatory options for occupational exposures such as reducing the concentration of NMP in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures (Refs. 37 and 75). The results also demonstrate that all risk reduction options meeting the benchmark MOEs for NMP in paint and coating removal require the use of specialized gloves, whether used alone or in conjunction with additional levels of respiratory protection such as a respirator of APF 10 or the use of an air exposure limit, even when the concentration of NMP in a product was limited to 25 percent. Therefore, EPA found setting a maximum concentration of NMP in products under TSCA section 6(a)(2) alone would not reduce exposures to levels at which risks would be at or below the risk benchmarks. Further, EPA's analysis found that even with specialized gloves and a respirator, workers would be at risk of NMP exposure if they used products with more than 25 percent NMP. Additional exposure level estimates for various scenarios are available in the supplemental analyses, which also document options that did not meet the risk benchmarks and which do not, for purposes of this proposal, address the identified unreasonable risks (Refs. 37, 75, and 76).

3. Assessment of whether regulatory options address the identified unreasonable risks to the extent necessary so that NMP in paint and coating removal no longer presents such risk. As discussed earlier, EPA considered a number of regulatory options under TSCA section 6(a) for NMP in paint and coating removal, which are reflected in EPA's supporting analysis (Ref. 30). In assessing these options, EPA considered a wide range of exposure scenarios (Refs. 75 and 76). These include both baseline and risk reduction scenarios involving varying factors such as concentration of NMP in paint and coating removal products, LEV use, respirator and glove use, and duration of use. As part of this analysis, EPA considered the impacts of regulatory options on consumer users and commercial users separately. However, EPA is proposing to address the use of NMP in paint and coating removal as a whole rather than as separate consumer and commercial uses. As described earlier in Unit XVI.A., paint and coating removal products containing NMP frequently are available in the same distribution channels to consumers and professional users. Products are marketed for a variety of projects, and cannot be straightforwardly restricted to a single type of project or user.

The Agency examined two main alternative approaches to addressing the unreasonable risk from NMP in paint and coating removal under current conditions of use by consumers and commercial users. These two approaches are the supply chain approach (and its two primary variations) and the reformulation, labeling, and PPE approach. These

regulatory alternatives are the options that have the potential to address the unreasonable risks presented by NMP when used for paint and coating removal by consumers, commercial users, or for both. The two options and their variations are described below.

(a) The first co-proposed approach (option 1) is a supply-chain approach, which would include prohibiting the manufacturing, processing, and distribution in commerce of NMP for paint and coating removal under TSCA section 6(a)(2) except for certain uses critical to national security; prohibiting the commercial use of NMP in paint and coating removal under TSCA section 6(a)(5) except for certain uses critical to national security; requiring that all paint and coating removers containing NMP be distributed in containers with volumes no less than 5 gallons under TSCA section 6(a)(2); requiring downstream notification when distributing NMP for other uses under TSCA section 6(a)(3); and limited recordkeeping under TSCA section 6(a)(4);

(b) Variations on such a supply-chain approach, such as just prohibiting the manufacturing, processing, and distribution in commerce of NMP for paint and coating removal under TSCA section 6(a)(2) for consumer and commercial use or just prohibiting the commercial use of NMP for paint and coating removal under TSCA section 6(a)(5);

(c) Additional variations on such a supply-chain approach, such as prohibiting the manufacturing, processing, and distribution in commerce of NMP for paint and coating removal under TSCA section 6(a)(2) for consumer and commercial use and requiring downstream notification (*e.g.,* via SDS) when distributing NMP for other uses under TSCA section 6(a)(3); and

(d) The second co-proposed approach (option 2), a reformulation, PPE, and labeling approach, which would require (1) product reformulation to limit the concentration of NMP in paint and coating removal products under section 6(a)(2); (2) testing of product formulations to identify specialized gloves that provide protection for users and relevant recordkeeping under section 6(a)(4); (3) relabeling of products intended for consumer use to provide additional information to consumers under section 6(a)(3); (4) an occupational dermal and respiratory protection program for commercial use of NMP in paint and coating removal, including a requirement for hazard communication, specialized gloves and an air exposure limit or respirator under section 6(a)(5); (5) a prohibition on use of NMP above a concentration of 35 percent for commercial paint and coating removal under 6(a)(5); (6) downstream notification when distributing NMP for other uses under TSCA section 6(a)(3); and (7) limited recordkeeping under TSCA section 6(a)(4). Under this co-proposed approach, EPA is not proposing an exemption for coating removal uses identified as critical to national security because paint and coating removal products containing NMP would continue to be available for these national security uses under this option, even without establishing a national security exemption.

A discussion of the regulatory options that could reach the risk benchmarks for consumer use, commercial use, or both is in this unit, along with EPA's evaluation of how well those regulatory options would address the unreasonable risks EPA has identified. EPA requests comment on the two co-proposed regulatory options addressing the use of NMP in paint and coating removal, particularly with regard to the advantages and disadvantages of the different approaches, their potential associated benefits, and whether such approaches would be consistent with EPA's obligation under TSCA to address risks identified as unreasonable.

a. First co-proposed approach: Supply-chain (option 1). The proposed regulatory approach for NMP in consumer and commercial paint and coating removal would prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer and commercial paint and coating removal under TSCA section 6(a)(2), except for certain uses critical to national security; would prohibit the commercial use of NMP for paint and coating removal under TSCA section 6(a)(5), except for certain uses critical to national security; would require any remaining paint and coating removal products containing NMP to be distributed in containers with a volume no less than 5 gallons, under TSCA section 6(a)(2); would require manufacturers, processors, and distributors of NMP to provide downstream notification of the prohibitions under TSCA section 6(a)(3), and would require recordkeeping relevant to these prohibitions under TSCA section 6(a)(4).

As discussed earlier, a risk of concern was identified if the MOE estimate was less than the benchmark MOE of 30. As described in Unit XVI.B.1., the baseline risks for workers and consumers from paint and coating removal with NMP were identified as ranging from two to 10 times below the benchmark MOEs of 30 for fetal death (the acute health impact) or low birth weight (the chronic health impact). Under this proposed option, exposures to NMP during paint and coating removal would be eliminated for consumers and workers. As a result, acute and chronic risks would be eliminated.

The first co-proposed approach would ensure that workers and consumers from the general population (as well as workers and consumers who are women of childbearing age) are no longer exposed to unreasonable risks from NMP exposure during paint and coating removal. Prohibiting the manufacturing, processing and distribution in commerce of NMP for paint and coating removal would minimize the overall availability of NMP for paint and coating removal. Importantly, this proposed regulation is protective of consumer users. EPA cannot regulate consumer use under TSCA section 6(a)(5). The prohibition of the commercial use of NMP for paint and coating removal would reduce commercial demand for NMP paint and coating removal products, reduce the likelihood that other types of products formulated with NMP would be used for paint and coating removal, and significantly reduce the potential for consumer use of commercial paint and coating removal products containing NMP. Workers would not be exposed to NMP for paint and coating removal, except for those uses that are proposed to be exempt because they are critical to national security. The risk to consumers would be minimized because commercial paint and coating removal products containing NMP would not be available outside of those directly supplied to DOD for uses identified as critical to national security.

The downstream notification of these restrictions ensures that processors and distributors are aware of the manufacturing, processing, distribution in commerce and use restrictions for NMP in paint and coating removal, and enhances the likelihood that the risks associated with this use of NMP are addressed throughout the supply chain. Downstream notification also streamlines compliance and enhances enforcement, since compliance is improved when rules are clearly and simply communicated (Ref. 39). This integrated supply chain proposed approach completely mitigates the risk to consumers and workers from NMP in paint and coating removal.

b. Options that are variations of elements of the co-proposed supply-chain approach (option 2). One

variation of the proposed approach would be to prohibit manufacture, processing, and distribution in commerce of NMP for consumer and commercial paint removal for the uses proposed for regulation this without the prohibition on commercial use of NMP for paint and coating removal and without the downstream notification of any prohibitions. Without the accompanying prohibition on commercial use and downstream notification that is included in the proposed supply chain approach, this option would leave open the likelihood that commercial and consumer users could obtain NMP (which would continue to be available for other uses, such as degreasing or solvent purposes) and use it for paint and coating removal.

Without downstream notification, unsophisticated purchasers in particular are likely to be unfamiliar with the prohibitions regarding this use and mistakenly use NMP for paint and coating removal, thereby exposing themselves and bystanders to unreasonable risks. Thus, under these variations, EPA anticipates that many users would not actually realize the risk benchmarks. Therefore, these variations fail to protect against the unreasonable risks. EPA requests comment on its consideration of and conclusions regarding this option.

Another regulatory option that EPA considered was to prohibit only the commercial use of NMP for paint and coating removal. This approach would reduce risks for commercial settings, but it would not reduce risks to consumers so that they are no longer unreasonable. By prohibiting use in the commercial sector alone, without a prohibition on the manufacture, processing, and distribution in commerce of paint and coating removal products containing NMP for consumer and commercial use, this approach would not address consumer risks as distributors of paint and coating removal products containing NMP could continue to distribute to consumers NMP marked as a paint and coating remover, including products labeled and marketed as ''professional strength'' or ''commercial grade'' products. Since it is foreseeable that consumers would continue to purchase products labeled and marketed in this fashion, consumers would continue to be exposed far above the health benchmarks and would not be protected from the unreasonable risks posed by NMP. EPA requests comment on its consideration of and conclusions regarding this option.

c. Prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer paint and coating removal under TSCA section 6(a)(2) or prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer paint and coating removal under TSCA section 6(a)(2) and require downstream notification when distributing NMP for other uses under TSCA section 6(a)(3). EPA considered prohibiting the manufacturing, processing, and distribution in commerce of NMP only for consumer paint and coating removal, including an option with a requirement for downstream notification of such prohibition. If such a prohibition were effective, this option would mitigate the risks to consumers from NMP in paint and coating removal. However, consumers can easily obtain products labeled for commercial use. Indeed, for many consumers, identifying a product as being for commercial use may imply greater efficacy. Coupled with the fact that many products identified as commercial or professional are readily obtainable in a variety of venues (*e.g.,* the Internet, general retailers, and specialty stores, such as automotive stores), EPA does not find that this option would protect consumers. In addition, this option alone would not address the risks to workers from NMP in paint and coating removal. EPA requests comment on its consideration of and conclusions regarding this option.

d. Second co-proposed approach: Reformulation, labeling, and PPE approach. EPA is co-proposing two regulatory options for NMP. The second co-proposed option would involve product reformulation, glove testing, labeling, and worker protection. This approach has the potential to reduce the risks presented by NMP during paint and coating removal. EPA currently believes this potential is greater for workers than for consumers. potential is greater for workers than for consumers. EPA is considering this co-proposed regulatory option, and may adopt it in the final rule; the Agency therefore solicits comment on the option, as described below.

i. Description of second co-proposed approach. The second co-proposed approach for NMP in commercial and consumer paint and coating removal requires actions from commercial users and product formulators. Under this approach, under section 6(a)(5), commercial users of NMP for paint and coating removal would be required to establish a worker protection program for dermal and respiratory protection, including hazard communication, training, and requirements that workers wear clothing covering most of the body, *i.e.,* impervious long pants and shirts with long sleeves, use gloves specified by product formulators (described under formulator requirements below) and a respirator with APF 10, with an alternative air exposure limit of 5 ppm achieved through engineering controls or ventilation. Also under this approach, formulators of products for either commercial or consumer use would be required to (1) Reformulate products such that paint and coating removal products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations under section 6(a)(2) (except for product formulations destined to be used by DOD or its contractors performing work only for DOD projects identified in Unit XVIII.); (2) Test gloves for the product formulations being processed and distributed in commerce to identify specialized gloves that provide protection for users under section 6(a)(4); (3) Label products with information for consumers about reducing risks when using the products, including identifying which specialized gloves provide protection against their specific formulation; and (4) Provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication. Variations of more than 1% in any component of a paint and coating removal product containing NMP would be considered a separate formulation.

Specifically, for labeling targeted to consumers under section 6(a)(3) formulators would be required to provide the following information to consumers on product labels: A warning that irreversible health effects such as fetal death may occur as a result of using the product; instructions to not use the product without a new (*i.e.,* replaced each time the product is used) pair of the formulation-specific gloves identified on the label; instructions to either use the product outdoors or to adequately ventilate the workspace by opening windows and adding fans; instructions to not spray-apply the product; instructions to wear clothing that covers exposed skin; and instructions to use a respirator of APF 10, such as a NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100, R100, or P100 filters. The labeling requirement would also include appropriate placement and font size for the label information.

EPA requests comments on the components of this co-proposal, particularly on the maximum percent concentration that would be permitted

in paint and coating removal products containing NMP. EPA notes that the air exposure limit described earlier correlates with the concentration of NMP in the product, and would necessarily change with any corresponding change in NMP concentration (Ref. 37). EPA's calculations for the estimated exposures from products at various concentrations is in Ref. 75.

EPA also requests comment on the scientific and technical support used for development of the 5 ppm air exposure limit (Ref. 37) for NMP and the feasibility of implementing and enforcing this performance-based approach. Additionally, EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies. EPA is requesting comment on whether this alternate option of allowing industrial use at specified exposure levels and with appropriate personal protective equipment should be adopted. Specifically, EPA seeks information on whether this alternative approach would incentivize industry to eliminate NMP use in paint and coating removal wherever technically feasible while minimizing disruptive impacts to those processes where technically feasible substitutes are currently unavailable. EPA also requests comment on whether there should be a phase-in period, *e.g.,* 3 years for formulators to develop the new formulations of products containing NMP at 35 percent. This would also allow users to make the transition. EPA also requests comment on whether the 35% limit on the concentration of NMP in the formulation is appropriate; whether EPA should specify a higher, lower or no limit; and why. Finally, EPA requests comment on the specific regulatory requirements for glove testing and for personal protective equipment programs. EPA has identified two ASTM International standards that are pertinent to glove testing, ASTM F739, ''Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact,'' and ASTM F1194–99, ''Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials.'' EPA requests comment on whether these standards should govern the mandatory glove testing, or whether there are other standards or requirements that should be imposed. In addition, EPA is proposing to require employers whose employees are exposed to NMP in paint and coating removal products to develop and institute personal protective equipment programs. These programs must be in writing, specific to the affected workplace, and include provisions relating to the proper selection, use, and maintenance of equipment. EPA requests comment on whether the proposed requirements for personal protective equipment programs are appropriate and complete, whether less burdensome requirements would similarly allow risk to be reduced so that it is no longer unreasonable, or whether EPA should cross reference the OSHA regulations on personal protective equipment, specifically 29 CFR 1910.132–134 and 29 CFR 1910.138.

ii. Risk reduction of second co-proposed approach. Reducing risks to workers so that they would not be unreasonable requires a combination of a concentration limitation and worker protection programs that include PPE and hazard communication because concentration limits or a worker protection program alone would not be sufficient to reduce the risks to workers so that they are no longer unreasonable. For this reason, the second co-proposal aims to reduce the risks to workers by placing requirements on product formulators and commercial users.

Reducing exposure to NMP requires consideration of routes of exposure as well as user behaviors, such as wearing appropriate PPE (*i.e.,* specialized gloves that are effective for the specific formulation used, impervious clothing and a respirator). The dermal route is the primary contributor to exposures from NMP; however, vapor deposition and subsequent absorption through skin and inhalation are also important exposure pathways that must be considered in determining a person's exposure to NMP. Even when wearing specialized gloves, dermal absorption of NMP from the vapor phase typically contributes significantly to human exposure. EPA's calculations for dermal exposure are based on a person having up to 25 percent of exposed skin surface (*e.g.,* arms, head and neck), providing significant exposure to NMP even with impervious glove use (Ref. 3). Thus, the use of impervious long pants and shirts is needed to minimize the area of exposed skin and thus reduce the risk associated with using NMP for paint and coating removal. To address the exposures to NMP use in paint and coating removal via dermal exposure from both direct contact and vapor deposition, and via inhalation exposure, the following combination is required: Specialized gloves that are effective for the specific formulation used; a respirator with an APF of 10; and impervious clothing covering the body. This combination, as part of a worker protection program, will reduce occupational exposures so that the benchmark MOE is exceeded, provided that the concentration of NMP in the formulations used in paint and coating removals does not exceed 35 percent (Ref. 75). Therefore, EPA believes that any remaining occupational risks would not be unreasonable.

Specialized gloves are an important component of reducing exposure and, thus, must be effective. The presence of co-solvents in the paint and coating removal product containing NMP can result in inadvertent exposure to NMP. Most paint and coating removal products containing NMP contain co-solvents (Ref. 34). Gloves proven to resist permeation or breakthrough from pure NMP have been shown to experience degradation and permeation with these co-solvents especially those that are small-molecule, volatile solvents. For this reason, it is not possible to know which type of glove provides adequate protection from products containing NMP with any co-solvents without testing the formulation of each product for glove breakthrough and permeation. When working with formulated products, the chemical component with the shortest break-through time must be considered when selecting the appropriate glove type for protection against chemical hazards unless glove-specific test data are available (Ref. 82). Risks may not be reduced if the appropriate gloves are not identified through testing.

Consumers could have access to NMP formulations identical to those available to commercial users. This co-proposed approach would attempt to address the unreasonable risk to consumers through the combination of labeling and product reformulation. The product reformulation would be as discussed previously. If consumers using NMP formulations which did not exceed 35% of NMP were to consistently follow *all* the warnings on the label (specifically, if the consumer were to use a new pair of the formulation-specific gloves identified on the label each time the product is used; and were to adequately ventilate the workspace; and not spray-apply the product; and if they were to wear clothing that covers exposed skin; and properly fit and use a respirator of APF 10, such as a NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100, R100, or P100 filters) then the consumer exposures to NMP would be expected to result in MOEs that approach the benchmark MOE of 30 (Ref. 76).

Under real-world conditions, EPA expects that not all consumers will adequately follow the label to reduce risk to a level above the benchmark MOE. The Agency is requesting comment on whether incomplete adherence to the label might still suffice to reduce risks presented by NMP in paint and coating removal so that those risks are no longer unreasonable. EPA also requests comment on whether the voluntary nature of consumer use and the information provided on the label that would allow consumers to avoid risk below the benchmark MOE if label directions were followed should be a factor in determining whether any remaining risk associated with this exposure scenario is unreasonable, and if so, how.

EPA is also requesting comment on how labels may be constructed to effectively communicate risk and instructions on how to use the product, such as information on label content, placement of information, pictures, and font size and color; how to construct a label to effectively communicate and improve the user's understanding of risk and protective measures. EPA requests that this be supported by data demonstrating the effectiveness of a label approach, particularly as it pertains to susceptible sub-populations or individuals with limited English proficiency or low literacy in any language.

EPA requests comment on the efficacy of this co-proposed option, including on individual components.

iii. Concerns regarding second co-proposed approach. EPA has identified several concerns regarding this co-proposed option related to risk reduction for commercial users and for consumers. For commercial users, many of these concerns relate to the use of PPE. Although respirators in conjunction with the use of appropriate formulation-tested gloves could reduce exposures to levels that are protective of acute and chronic risks, respirators are not EPA's preferred approach to decrease exposures. Not all workers may be able to wear respirators, even those with a lower APF. For a discussion of the use of respirators and the associated respiratory protection program, see Unit VI.C. Given equipment costs and the costs of establishing a worker protection program, which involves training, respirator fit testing and the establishment of a medical monitoring program, EPA anticipates that most companies would choose to switch to substitutes instead of adopting a program for this type of PPE to continue using NMP in paint and coating removal. As recommended by the SBAR panel, EPA is requesting comment on and information about workplace experience with worker protection programs and air monitoring for NMP (Ref. 27). Specifically, EPA seeks comment on whether companies would opt to substitute an alternate chemical or process instead of implementing a worker protection program for PPE. Additionally, EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

Under this approach, risks to consumers are only addressed to the extent that consumers understand and follow the required label information. While the Agency expects that some number of consumers who read the labels of paint and coating removal products containing NMP would understand this information and take appropriate steps to reduce their risks based on label information, as noted in Unit V.C., studies have shown that consumers do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, often do not understand label information; consumers often base a decision to follow label information on previous experience and perceptions of risk; even if consumers have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers have varying behavioral responses to warning labels.

Even for those consumers who understand and follow the label, EPA expects some number will not follow the label instructions precisely or may be unable to readily locate the specialized gloves or the respirator indicated on the label (Ref. 28). Further, it is unlikely that consumers would have the fit of their respirator tested, which is important part of the proper use, and thus effectiveness, of a respirator, or that they would wear a new pair of specialized gloves for each use of the product containing NMP. EPA emphasizes that product labels are not equivalent to worker protection programs in which risks are reduced through, among other things, training programs, requirements that include proper testing and use of respirators, and requirements to use specialized gloves each time the product is used.

EPA is unable to determine how many consumers would read and take *all* appropriate action based on label information, and to what extent they could effectively carry out those actions such that their exposure would be reduced.

As under the first co-proposed approach, manufacturers, processors, and distributors would be required to provide downstream notification of these requirements under TSCA section 6(a)(3), and limited recordkeeping would be required under TSCA section 6(a)(4).

C. Adverse Health Effects and Related Impacts That Would Be Prevented by the Proposed Options

EPA is co-proposing these options to prevent exposure to NMP from paint and coating removal and thus prevent the risks of adverse effects and associated impacts. As discussed in Unit XII.C., the range of adverse health effects from NMP includes developmental toxicity resulting in decreased birth weight or fetal death, kidney toxicity, liver toxicity, immunotoxicity, and reproductive toxicity (Ref. 3). These health effects associated with exposure to NMP are serious and can have impacts throughout a lifetime. The following is a discussion of the impacts of significant acute and chronic non-cancer effects associated with NMP exposure during paint and coating removal, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

1. Developmental effects—acute exposures. The NMP risk assessment identified developmental effects as the most sensitive endpoint for acute exposure to NMP. Specifically, this assessment identified fetal death as the critical effect of acute exposures over the course of a day. Fetal death or fetal mortality includes miscarriage, spontaneous abortion, or stillbirth, depending on when in the pregnancy it occurs. Fetal death may result from a single maternal exposure to NMP at a developmentally critical period (Ref. 3). There are increased risks of fetal death for pregnant women who use NMP for paint and coating removal as consumers. EPA estimates that 732,000 consumers use NMP for paint and coating removal each year; of them, approximately 38,000 are estimated to be pregnant women. EPA estimates that approximately 11,300 of these pregnant women are estimated to experience acute exposure to NMP at levels that would result in an MOE below the benchmark of 30. Additionally, there are increased risks of fetal death for a subset of pregnant women among the approximately 8,800 female workers in 4,300 commercial facilities or companies that use NMP for paint and

coating removal. Of these female workers, approximately 500 are estimated to be pregnant, and, of them, approximately 160 are estimated to have acute exposure to NMP at levels that would result in an MOE below the benchmark of 30 for fetal death (Ref. 4). The basis for these calculations are shown in section 5.2.1 of the Economic Analysis (Ref. 4).

Researchers aiming to improve early childhood health outcomes have identified the most sensitive time in a pregnancy as the first few weeks following conception, before a woman may be aware she is pregnant. In the context of maternal welfare and risk reduction, ''women often delay assessing and improving their health until after confirmation of pregnancy, putting their baby at risk during the critical early developmental stages'' (Ref. 81). Approximately 35% of pregnancies in the United States are unplanned (Ref. 83); consequently, many women who are pregnant may not have taken or be prepared to take steps to reduce risks to the developing fetus during early stages of pregnancy. Maternal exposure to NMP in paint and coating removal may occur before a woman realizes she is pregnant. As such, even if she is aware of the risks of exposure to NMP, she may not take steps to reduce risks of fetal death.

Even if they are aware of their pregnancy, women may not wish to disclose this fact to their employers; although legal protections are in place, many women ''feel they may lose their job, may not be considered for a promotion, or may have a promotion taken away if they announce they are pregnant'' (Ref. 81). Similarly, the American College of Occupational and Environmental Medicine has found that ''while it is illegal for an employer to terminate a worker because of pregnancy, such fears may not be groundless for some workers'' (Ref. 83). Consequently, pregnant women may attempt to ''minimize their pregnancy'' (Ref. 81) and may not be vocal in their workplace about reducing risks to their pregnancy. This could increase chances of exposure to chemicals such as NMP that present a risk of fetal death.

Exposure to NMP in paint and coating removal during a single day (over 8 hours) was found to present risks of fetal death (Ref. 3). The impacts of fetal death, including miscarriage or stillbirth, include emotional impacts on the woman experiencing the death of a fetus, and also present significant emotional impacts for partners and spouses.

Emotional impacts and other mental health effects of miscarriage or stillbirth can include depression, anxiety, grief, and guilt. Mental health research has consistently identified both miscarriage (defined as fetal death occurring before the 20th week of gestation) and stillbirth (defined as fetal death occurring after the 20th week of gestation) as a significant emotional burden that can persist for more than a year and sometimes up to three years following the event of fetal death (Ref. 84). Compared with their peers, women who have experienced fetal death ''exhibit significantly elevated levels of depression and anxiety in the weeks and months following the loss, compared with samples of pregnant, community or postpartum women'' (Ref. 85). Psychologists see miscarriage and stillbirth as ''an unanticipated, often physically as well as psychologically traumatic event representing the death of a future child and disruption of reproductive plans. Physiologically, it marks the end of a pregnancy, and psychologically it may produce doubts about procreative competence'' (Ref. 86). Other descriptions of fetal death similarly characterize it as ''a significant psychosocial stressor that results in a high level of dysphoria and grief'' (Ref. 87). Consequently, women who experience the death of a fetus are at increased risk for depression, anxiety, and other psychiatric disorders (Ref. 86).

Major depressive disorder has been identified in between 10% to 50% of women after a miscarriage, depending on the measures used (Refs. 88 and 89). According to the National Institutes of Mental Health, persistent depressive disorder is a depressed mood that lasts for at least two years. Symptoms can include difficulty concentrating, sleep pattern disruptions, appetite or weight change, thoughts of suicide or suicide attempts, loss of interest in hobbies or activities, decreased energy, and aches, headaches, or digestive problems without a clear physical cause and that do not ease even with treatment (Ref. 90). Depression can affect an individual's physical health and their ability to work. Additionally, depression in one family member can also result in increased instance of illness or morbidity in other family members (Ref. 91). Treatment can require several types of attempted pharmaceutical or psychological therapies, and, in the case of depression following fetal death, can persist for years (Ref. 89).

Depression is not the only emotional impact of fetal death; many women also experience intense and persistent anxiety. Researchers have found that ''a significant percentage of women experience elevated levels of anxiety after a miscarriage up until about 6 months post-miscarriage, and they are at increased risk for obsessive-compulsive and posttraumatic stress disorder'' (Ref. 89).

In addition to depression and anxiety, a primary component of the emotional burdens presented by fetal death is guilt. As one researcher explained, women search for answers to what they perceive as an inexplicable trauma: ''They will spend enormous amounts of emotional energy trying to explain why it happened . . .. They often blame themselves, even when it is inaccurate, to help make sense of it. Women may torment themselves with guilt and blame, rewriting the story, so to speak: 'If I hadn't gone to the grocery store' or 'If I didn't stay up so late.' It's a way of coping with the loss'' (Ref. 92).

Related to these emotional impacts, one study found that ''the mean annual suicide rate within one year after miscarriage was significantly higher (18.1 per 100.000) than the suicide rates both for women who gave birth (5.9) and for women in the general population (11.3) in Finland between 1987 and 1994'' (Ref. 86).

Women experiencing miscarriages or stillbirths are not the only individuals affected by fetal death. Researchers have also documented the ways in which the woman's partners are affected by the loss (Ref. 86). Recent research has found that male partners experience more grief over miscarriages than previously assumed (Ref. 92) and that in 25% of the cases studied, the intensity of fathers' grief exceeded that of the mothers' (Ref. 93).

Additional burdens from fetal death can be felt throughout the affected family, including by subsequent children, since the depression, anxiety, and guilt initiated by fetal death may persist during and after any subsequent successful pregnancy (Ref. 92). As a result, future pregnancies and children can be adversely affected by fetal death during the mother's previous pregnancies due to persistent psychological impacts leading to maternal stress or depression that can last up to three years (Refs. 94 and 85). As a result of this stress or depression, complications during subsequent pregnancies can occur. Maternal anxiety or depression during pregnancy is associated with pre-term birth, decreased birth weight, and impacts on fetal brain development as a result of abnormal uterine blood flow and increased maternal cortisol levels (Ref. 94). Maternal anxiety and depression, including that initiated by fetal death during a previous pregnancy, is also

associated with a higher risk of maternal postpartum depression (Ref. 85), which can lead to poor infant care, and infant cognitive delay (Ref. 94). For some children born to women who previously experienced the death of a fetus, there may be disorganized or insecure maternal attachment or bonding (Ref. 95), and maternal perinatal mood symptoms that may alter a child's emotional or health outcomes (Refs. 85 and 86). For example, available data indicate that ''12-month-old infants born following prenatal loss were reported to show higher rates of disorganized attachment patterns to their mothers than children born into families without a loss history. Thus, even if there is no persistence of mood disturbance into the postnatal period, there may still be adverse effects of a previous prenatal loss on the parent-child relationship and child outcomes'' (Ref. 85). Similarly, maternal post-partum depression or anxiety has been found to have ''deleterious effects on maternal-child attachment, child behavior, and cognitive and neuroendocrine outcomes that persist into adolescence'' (Ref. 85). In this way, a single instance of fetal death may result in years of emotional impacts for the mother and may potentially affect the health and well-being of future children. In addition to depression and anxiety, emotional impacts can take the form of grief, envy, or isolation.

Similarly, a woman's attitude towards a pregnancy does not necessarily correlate with the emotional impact resulting from fetal death. Although ambivalence toward pregnancy was associated with different emotional impacts (greater association with depressive symptoms, rather than grief), they were found to be as intense as in women who were not ambivalent about their pregnancy (Ref. 86).

As a result, fetal death at any stage of a pregnancy, even when experienced by a woman who is ambivalent about that pregnancy, may result in intense emotional impacts and psychological morbidities, for both the mother and other family members; these impacts can include depression and anxiety and, in many cases, could persist and potentially impact future pregnancies and children.

Additionally, it is important to note that fetal death can present health risks to the woman; in some cases, maternal death can result. From 1981 to 1991, the Centers for Disease Control and Prevention (CDC) recorded 62 cases of maternal mortality following spontaneous abortion at or before 20 weeks of fetal gestational age (an overall case fatality rate of 0.7 per 100,000 spontaneous abortions) (Ref. 96). Leading causes of maternal mortality during these incidents of fetal death were infection, hemorrhage, or embolism (Ref. 96). The CDC has noted that this case fatality rate is likely the result of underreporting, and that ''the true number of deaths related to pregnancy might increase from 30% to 150% with active surveillance'' (Ref. 97).

Even when the effects of fetal death are less severe, a miscarriage or stillbirth can have considerable adverse consequences on an individual, family, or community. Commercial and consumer users of NMP in paint and coating removal are at risk of fetal death from typical use of products containing NMP; although EPA is unable to quantify the precise number or frequency of fetal deaths that may occur as a result of exposure to NMP during paint and coating removal, reducing the risks of exposure would benefit women, their families, and the public at large by reducing risks of fetal death in a population of approximately 12,000 pregnant individuals (consumers and workers) likely to experience acute exposures that present risks of fetal death. Details on how EPA estimated the number of individuals is in section 5.2.1 of the Economic Analysis (Ref. 4).

2. Developmental effects—chronic exposures. The NMP risk assessment identified developmental effects as the most sensitive endpoint for chronic exposure to NMP. Specifically, the assessment selected decreased birth weight as the critical effect resulting from repeated exposures to women of child-bearing age. It is not known if there is a window of exposure that may pose greater risks to the fetus; therefore, any repeated exposure to NMP could increase risks to the fetus for developmental effects.

Rather than accumulating over a lifetime, risks were found for workers exposed to NMP during paint and coating removal over the course of a workweek, or five days. Even when maternal exposure ceased, the decreased fetal body weight was found to be a persistent adverse effect (Ref. 3); consequently, a relatively brief period of maternal repeated exposure to NMP in typical paint and coating removal can cause fetal weight decreases, resulting in life-long impacts. There are increased risks of decreased fetal weight for the subset of pregnant women among the approximately 8,800 female workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal. EPA estimates that there are approximately 500 pregnant women working in these commercial facilities (Ref. 4). A subset of these 500 pregnant would have chronic exposure to NMP at levels that would result in an MOE below the benchmark of 30 for decreased fetal weight (Ref. 3).

Decreased fetal weight can lead to reduced or low birth weight, which can have lifelong effects on a person and their family. Most cases of reduced or low birth weight are pre-term or premature birth; as a result, until recently, health impacts of reduced or low birth weight have been difficult to separate from the effects due to premature birth or gestational age. However, epidemiological, social, and medical research in the past several decades has isolated several health effects of reduced or low birth weight separate from gestational age at birth. Full-term babies may be born at low or reduced birth weights as a result of fetal growth restriction; these infants are usually referred to as small for gestational age, and ''may have low birth weight because something slowed or stopped their growth in the womb'' (Ref. 98). Low birth weight is typically defined as birth weight of less than 5.5 pounds, or 2,500 grams. Very low birth weight is typically defined as less than 1,500 grams (Ref. 99).

Low birth weight can have significant impacts on childhood development and the incidence of future diseases (Ref. 100); reduced birth weight can cause serious health problems for some children (Ref. 98), as well as long-term impacts on their lives as adults (Ref. 101).

Health impacts of low or reduced birth weight can begin at birth. According to the CDC, low birth weight infants may be more at risk for many health problems as neonates (Ref. 99); other medical authorities report that health impacts for infants with low birth weight include low oxygen levels at birth, inability to maintain body temperature; difficulty feeding and gaining weight; infection; breathing problems such as respiratory distress syndrome; neurologic problems, such as intraventricular hemorrhage (bleeding inside the brain); gastrointestinal problems such as necrotizing enterocolitis (a serious disease of the intestine), and a greater risk of Sudden Infant Death Syndrome (Ref. 102). These effects and health impacts have clear implications for the infant's future health and survival, and can cause emotional stress and anguish for families of the infant.

Effects of reduced or low birth weight can persist beyond infancy. It can affect growth: Low birth weight has been found to be ''a major risk factor for children's physical growth in the early

years and there is no evidence of catch-up by age 2'' (Ref. 103). In populations that may already be at risk for poor health outcomes, children with reduced birth weight or who were small for gestational age continued to be significantly smaller in all measures (height, weight, and head circumference) than their normal birth weight counterparts at age 3 (Refs. 104 and 105), and generally smaller between ages 4 through 7 (although the differences were small) (Ref. 104).

A child's size is not the only potential effect of reduced or low birth weight. Many studies have identified increased risk of cognitive, behavioral, and neurological problems in children and adolescents who had low birth weight or who were small for gestational age (Refs. 106 and 107). A large cohort study that followed infants born at full term with reduced birth weight (small for gestational age) found that ''children of both genders who were born [small for gestational age] are at higher risk of learning difficulties'' (Ref. 106), with girls with the lowest birth weight experiencing an increased risk of attention problems (Ref. 106).

Other studies have confirmed the impact of reduced or low birth weight on academic success in childhood; researchers note that compared to their normal birth weight siblings, low birth weight children are less likely to be in excellent or very good health in childhood. They also score significantly lower on reading, passage comprehension, and math achievement tests. Low birth-weight children are roughly one-third more likely to drop out of high school relative to other children (Ref. 100).

After childhood, the health, social, and financial impacts of reduced or low birth weight can continue. In many cases, an individual's size may continue to be affected. The difference in growth during adolescence and early adulthood varies by sex. Female adults who were very low birth weight infants tend to be the same size as their peers of average birth weight by age 20, while male adults ''remain significantly shorter and lighter than controls'' (Ref. 109). However, this may have its own risks: ''Since catch-up growth may be associated with metabolic and cardiovascular risk later in life, these findings may have implications for the future adult health of [very low birth weight] survivors'' (Ref. 109).

In terms of health effects, low birth weight can continue to have significant negative effects on adults. Researchers have found that low birth weight increases the probability of being in fair or poor health as an adult. Specifically, ''low birth weight children are nearly twice as likely as their normal birth-weight siblings to be in problematic health by ages 37–52 (23% versus 12%) (Ref. 100). Specific risks associated with low birth weight (separate from pre-term birth or gestational age) include increased risk of renal disease (Ref. 110); increased risk of asthma, diabetes, stroke, heart attack, or heart disease by age 50 (compared to average weight siblings) (Ref. 100); and increased risk of clinically verified hyperkinetic disorder, including attention deficit hyperactivity disorder (Ref. 111). Adults who were low birth weight babies may be more likely to have certain health issues such as diabetes, heart disease, high blood pressure, metabolic syndrome, and obesity (Ref. 98).

Additionally, there are financial implications for adults who were low birth weight; low birth weight has been found to lower labor force participation and labor market earnings over an individual's lifetime (Ref. 100). Specifically, ''low birth weight is linked to a 10% reduction in hourly wages from ages 18–26, compared to the wages of normal birth-weight siblings, but a 22% reduction in wages from ages 37–52. Low birth-weight children, relative to their normal birth-weight siblings, work 7.4% fewer hours in adulthood'' (Ref. 100).

Decreased fetal weight and low birth weight are strongly associated with a number of adverse health effects in adults. The Barker Hypothesis (Ref. 112) was among the first to identify a pattern between neonatal health and cardiovascular disease. Subsequent research in laboratory animals and in human epidemiological studies confirmed this pattern and extended the observations to include the relationship between delayed fetal growth, low birth weight and metabolic syndrome, which encompasses a host of adverse outcomes, such as hypertension, insulin resistance, obesity and type 2 diabetes mellitus (Refs. 113, 114, and 115). Diseases such as cardiovascular disease, hypertension, obesity and diabetes mellitus have a tremendous impact on public health. For example, according to the CDC, heart disease remains the nation's leading cause of death (Ref. 116). In addition to causing premature mortality, the monetary costs of cardiovascular disease were estimated at $209.3 billion in direct costs and $142.5 billion in indirect costs, for a total of $351.8 billion (Ref. 116). A number of health disparities are associated with cardiovascular disease. Cardiovascular disease causes more deaths in women than men, and in black Americans, compared to white (Ref. 116). Years of potential life lost before age 75 from heart disease is nearly double for Black or African Americans relative to White, Non-Hispanic Americans (Ref. 116).

Several of these health effects associated with reduced fetal growth and low birth weight fall within the definition of metabolic syndrome, which is generally defined as the presence of 3 or more of the following: Abdominal obesity (waist circumference ≥88 cm in women or ≥102 cm in men); low HDL cholesterol (<50 mg/dL in women or <40 mg/dL in men); elevated triglycerides (≥150 mg/dL); elevated fasting blood glucose (≥100 mg/dL or use of oral hypoglycemic medication or insulin or both); or elevated blood pressure (at least 1 of the following: Systolic ≥130 mmHg, diastolic ≥85 mmHg, or use of antihypertensive medication). Epidemiological studies indicate a strong, consistent association between low birth weight and metabolic syndrome (Ref. 113). The symptoms associated with metabolic syndrome are in turn associated with increased risk of cardiovascular disease and diabetes (Ref. 117).

Collectively, the sign, symptoms and diseases associated with delayed fetal growth and small birth weight present an enormous burden on public health. The extent that the development of adult disease is rooted in reductions in fetal and neonatal growth could limit the success of adult lifestyle changes in modifying these effects. Therefore, prevention must be focused on assuring fetal and neonatal health and preventing adverse impacts on growth rates.

Researchers highlight the fact that low birth weight can occur in every demographic group, and that even though most babies with low birth weight have normal outcomes, as a whole, infants with low birth weight ''generally have higher rates of subnormal growth, illnesses, and neurodevelopmental problems. These problems increase as the child's birth weight decreases'' (Ref. 118). Additionally, by using sibling comparisons and cohort studies, the effects of low birth weight have been found to persist even when accounting for ''the independent effects of birth order, mother's age at birth, birth year cohort, race/ethnicity, family structure, parental income, and parental fertility timing'' (Ref. 100).

Though most research has focused on infants with low or very low birth weight, it is important to note that children with reduced, but clinically normal, birth weights (2,500 to 2,999 grams) are also at increased risk from the health, academic, social, and financial effects described.

In this way, reduced or low birth weight resulting from maternal exposure to NMP during paint and coating removal can have serious and life-long impacts on individuals and their families, including their future family members. Even when birth weight is not reduced to the clinical definition of low, the decrease in fetal weight can have significant impacts. Additionally, it is important to note that the impacts of low birth weight go beyond affected individuals and their families; reduced and low birth weight ''results in substantial costs to the health sector and imposes a significant burden on society as a whole'' (Ref. 101).

3. Body weight reductions—chronic exposures. While the impact of decreased body weights in adult animals may be minimal, decreased body weight gain in pregnant females, in particular, may contribute to negative developmental outcomes as well as impacts on adult health (Refs. 119 and 120).

4. Kidney toxicity—chronic exposures. There are increased health risks for liver toxicity for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal (Ref. 4). Exposure to NMP can cause kidney damage. This damage may result in signs and symptoms of acute kidney failure that include; decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness; shortness of breath; fatigue; confusion; nausea; seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Kidney toxicity means the kidney has suffered damage that can result in a person being unable to rid their body of excess urine and wastes. In extreme cases where the kidney is impaired over a long period of time, the kidney could be damaged to the point that it no longer functions. When a kidney no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 56).

The monetary cost of kidney toxicity varies depending on the severity of the damage to the kidney. In less severe cases, doctor visits may be limited and hospital stays unnecessary. In more severe cases, a person may need serious medical interventions, such as dialysis or a kidney transplant if a donor is available, which can result in high medical expenses due to numerous hospital and doctor visits for regular dialysis and surgery if a transplant occurs. The costs for hemodialysis, as charged by hospitals, can be upwards of $100,000 per month (Ref. 57).

Depending on the severity of the kidney damage, kidney disease can impact a person's ability to work and live a normal life, which in turn takes a mental and emotional toll on the patient. In less severe cases, the impact on a person's quality of life may be limited while in instances where kidney damage is severe, a person's quality of life and ability to work would be affected. While neither the precise reduction in individual risk of developing kidney toxicity from reducing exposure to NMP during paint or coating removal or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to NMP.

5. Liver toxicity—chronic exposures. There are increased health risks for liver toxicity for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal (Ref. 4).

Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans. Included in this number is at least 20% of those with NAFLD. NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors. The danger of NAFLD is that it can cause the liver to swell, which may result in cirrhosis over time and could even lead to liver cancer or failure (Ref. 42). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals such as NMP.

Additional medical and emotional costs are associated with liver toxicity following chronic exposure to NMP in paint and coating removal, although these costs cannot be quantified. These costs include medical visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to NMP and other solvents; however, this may impact an individual's ability to continue to work. In severe cases, liver toxicity can lead to liver failure, which can result in the need for a liver transplant. Even if a donor is available, liver transplantation is expensive (with an estimated cost of $575,000) and there are countervailing risks for this type of treatment (Ref. 44). The mental and emotional toll on an individual and their family as they try to identify the cause of sickness and possibly experience an inability to work, as well as the potential monetary cost of medical treatment required to regain health, are significant.

6. Reproductive toxicity. There are increased risks for these reproductive effects for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal (Ref. 4). Similar to effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing exposure to NMP or the total number of cases avoided can be estimated, EPA still considers their impact.

7. Disproportionate impacts on environmental justice communities. An additional factor that cannot be monetized is the disproportionate impact on environmental justice communities. As described in Units VI.C.1.b. and XVI.B.1.b, Hispanic and foreign-born workers, who may have limited English proficiency, are disproportionately over-represented in construction trades (Ref. 4), in which NMP is used for paint and coating removal. Because they are disproportionately over-represented in this industry, these populations are disproportionately exposed to NMP during paint and coating removal, and are disproportionately at risk to the range of adverse health effects described here.

D. Availability of Alternatives

For almost every situation in which NMP is used to remove paints or coatings, EPA is aware of a cost-effective, economically feasible chemical substitutes or alternative methods. The exception is for critical corrosion-sensitive components of military aviation and vessels, for which EPA proposes are critical for national security, and for which EPA proposes an exemption, described in more detail in Unit XVIII.

EPA considered chemical substitutes and alternative methods consistent with the requirements of TSCA Section 6(c)(2)(C) and as similarly recommended by the SBAR panel (Ref.

27). A full industry profile characterizing manufacturers, processors, and end users of NMP for paint and coating removal and a use and substitutes analysis are included in section 2 and 3 of EPA's economic assessment. (Ref. 4). As described below, EPA proposes that alternatives are technologically and economically feasible, reasonably available, and present fewer hazards to human health than NMP in paint and coating removal. EPA requests comment on whether its conclusion that substitutes for NMP are available and technically and economically feasible is accurate and whether its consideration of alternatives was sufficient to satisfy the requirements of TSCA section 6(c)(2)(C).

Research into the efficacy of chemical substitutes has identified products currently available for commercial and consumer users of NMP for paint and coating removal, for a variety of coatings on numerous substrates (Refs. 58 and 59). Additionally, in most commercial sectors, NMP is not in widespread use; most sectors use substitute chemicals or methods, either due to financial considerations, problems with the efficacy of products containing NMP, or concern for worker or individual health and safety (Ref. 22). This was emphasized by a small business that manufactures such products (Ref. 22).

Many producers of paint and coating removal products containing NMP also produce paint and coating removal products with substitute chemicals (Ref. 4). This was emphasized by small businesses participating in the SBAR process (Ref. 27). Thus, there is already precedent for producers reformulating products to meet demand from commercial or individual customers.

Based on the frequent use of substitute chemicals or alternative methods for paint and coating removal in all industries discussed here, and the formulation and distribution of substitute chemicals for paint and coating removal by all formulators of products containing NMP (Ref. 4), EPA found that economically feasible alternatives to NMP are reasonably available for all paint and coating removal uses. Primary chemical substitutes for NMP in paint and coating removal include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (ATM); and caustic chemicals. EPA evaluated these products for efficacy, toxicity, relative hazards compared to NMP, and other hazards that might be introduced by use of these products (such as environmental toxicity, increased global warming potential, and increased flammability or other hazards to users).

EPA's analysis compared the hazard and exposure characteristics of the chemical paint and coating removal chemicals and products presumed to be already in use to NMP, to aid in ascertaining the impact on users of moving to alternative products. EPA used authoritative sources to characterize efficacy, hazard endpoints and identify effect and no effect levels. Relative exposure potential was assessed based on physical chemical parameters and concentrations in formulations, and exposure potential was considered to be similar to NMP within an order of magnitude. Product composition was based on publicly available Safety Data Sheets for products advertised for paint and coating removal (Ref. 36).

Products based on benzyl alcohol formulations have been identified as efficacious paint and coating removers in various industry sectors (Refs. 22 and 27). Consumer products containing benzyl alcohol are available for sale (Refs. 22, 27, 35, 58, 59, and 61). Regarding differential hazards between benzyl alcohol and NMP, there are fewer hazard concerns compared to NMP-based products, and the benzyl alcohol NOAELs are higher than for NMP, suggesting lower toxicity (Ref. 34). Regarding differential exposures between benzyl alcohol and NMP, the relative inhalation and dermal exposure potentials are similar to NMP (Ref. 34). Taken together, benzyl alcohol-based paint removers are expected to result in lower risks, primarily due to lower toxicity.

Dibasic ester products can include dimethyl succinate, dimethyl glutarate and dimethyl adipate. Many NMP products contain dibasic esters, and given the efficacy of these products users of these products would not experience much inconvenience if switched to substitute products that contain solely formulations based on dibasic esters, without NMP (Ref. 34). Regarding differential hazards between dibasic esters and NMP, in general, the hazards associated with dibasic esters are less severe and occur at concentrations suggesting lower toxicity (Ref. 34). Regarding differential exposures between dibasic esters and NMP, the relative inhalation exposure potential is similar to NMP. The relative dermal exposure potential for dibasic esters is lower, but similar to, NMP (Ref. 34). Taken together, dibasic ester-based paint removers are expected to result in lower risks, primarily due to lower toxicity.

ATM products contain acetone, toluene, and methanol. Products containing these chemicals may remove coatings very quickly, but may not be effective on every type of coating (Ref. 27). ATM-based products are composed of chemicals that exhibit a range of hazard characteristics. Taken together, the components of ATM-based formulations have comparable hazard concerns to NMP. Regarding differential exposures between ATM and NMP, the relative inhalation exposure potentials for acetone, toluene and methanol are higher than NMP. The relative dermal exposure potentials for acetone, toluene and methanol are lower, but similar to, NMP (Ref. 34).

Products with caustic chemicals typically include calcium hydroxide or magnesium hydroxide. In many uses, they can be an effective product, particularly when multiple coatings are being removed from a substrate. In contrast to NMP-based products, there are no developmental or other repeat dose endpoints of concern associated with caustic products (Ref. 34). Caustic products pose acute concerns due to their physical chemical properties and can cause chemical burns (Ref. 34). The risks associated with caustic-based products are acute, and may be mitigated by appropriate and familiar protective equipment. The risks associated with NMP-based products are both acute and long term (Ref. 3).

In summary, when methylene chloride is excluded from consideration, the most likely chemical substitutes for NMP in paint and coating removal do not pose a risk of acute or chronic developmental effects, generally have lower or similar exposure potential than NMP, and when acute risks are present, as in the case of caustic chemicals, those risks are self-limiting by the nature of the adverse effects. The chemical formulations that seem to present some risks of concern contain toluene and methanol; however, risks from these chemicals can be mitigated by the user more easily than risks presented by NMP. Overall, exclusive use of substitute chemical products for paint and coating removal instead of NMP would remove the risks of chronic effects and acute developmental effects without introducing additional substantial risks to human health.

In addition to examining toxicity to humans, EPA reviewed available data on the chemicals in the baseline and alternative products for aquatic toxicity, persistence and bioaccumulation, as a basis for examining potential environmental toxicity. Only one chemical evaluated may have significant impacts on aquatic toxicity, with concern for environmental persistence and/or bioaccumulation. This chemical is contained in NMP-based paint

removal products and thus is not considered further.

EPA is also mindful of the risks that may be introduced by substitute chemicals or methods that increase global warming, and has examined the global warming potential of the chemical components of likely chemical substitutes for NMP in paint and coating removal. NMP does not present concerns for global warming and has a global warming potential (GWP) of 0 (Ref. 3). Similarly, the GWP values of likely substitute chemicals in paint and coating removal are: 0 GWP (benzyl alcohol, ATM) or not assessed (caustics, dibasic esters) (Ref. 24). As such, EPA has not identified any increased risk of global warming that would be introduced by use of chemical products as substitutes for NMP in paint and coating removal.

In addition to human and environmental toxicity, other hazards associated with chemical methods for paint and coating removal are risks of fire due to flammability of the chemical product, and poisoning or acute injury. Risks of fire are serious when using solvents such as paint and coating removal chemicals. Even among products that fall within the same general product composition category, there is meaningful variability in the specific formulations of paint remover products, and thus in their flammability. Furthermore, it is impracticable for EPA to predict the specific product formulations for which use will increase as a result of prohibitions on NMP in paint and coating removal. It is therefore impracticable for EPA to forecast whether the flammability of popular paint and coating removers would generally increase or decrease as a result of the proposed rule.

In addition to using substitute chemical products, EPA has identified non-chemical methods for paint and coating removal that can be used as alternatives to NMP. These methods are already frequently in use in various industries or by consumers for paint and coating removal, and are described in more detail in Unit VI.E.

EPA recognizes that all methods of paint and coating removal can present some hazards. Most of these alternative methods are already in frequent use, including by consumers and workers who currently use NMP or other chemicals for some paint and coating removal. The risks associated with each of these methods, while serious, are generally acute, related to injury, and can be mitigated through readily available and easy-to-implement standard safety practices; in contrast, the acute risks presented by NMP, such as fetal death, require specialized gloves and are not the type of hazard frequently encountered when using household products.

E. Impacts of the Proposed and Alternative Regulatory Options

1. First co-proposed approach: Supply-chain approach. The costs of the first co-proposed approach are estimated to include product reformulation costs, downstream notification costs, recordkeeping costs, and Agency costs. The costs of paint and coating removal product reformulations are estimated to be approximately $7,000 to $14,000 per year (annualized at 3% over 20 years) and $9,000 to $19,000 (annualized at 7% over 20 years). The cost for reformulation includes a variety of factors such as identifying the appropriate substitute chemical for NMP in the formulation, assessing the efficacy of the new formulation and determining shelf life. The costs to users of paint and coating removers containing NMP are (−$1,477,000) to $27,617,000 at a discount rate of 3% and (−$1,231,000) to $27,638,000 at a discount rate of 7% (Ref. 4). The costs of downstream notification and recordkeeping on an annualized basis over 20 years are $100 and $100 using 3% and 7% discount rates respectively (Ref. 4). Agency costs for enforcement are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively. The total cost of the proposed approach for paint and coating removers containing NMP is estimated to be (−$1,484,000) to $27,624,000 and (−$1,251,000) to $27,668,000 annualized over 20 years at 3% and 7%, respectively (Ref. 4).

2. Second co-proposed approach: Reformulation, labeling, and PPE approach. Reformulation costs are estimated to have less of an impact than those associated with adoption of worker protection programs. Given equipment costs and the requirements associated with establishing a dermal and respiratory protection program which involves training, purchase of specialized gloves, respirator fit testing and the establishment and maintenance of a medical monitoring program, EPA anticipates that companies would choose to switch to substitute chemicals instead of adopting a program for PPE, including with a performance-based option of meeting an air concentration level of 5 ppm as an exposure limit for NMP in paint and coating removal, when these products have a maximum concentration of 35% NMP by weight. The estimated annualized costs to commercial and consumer users of switching to this type of dermal and respiratory protection program are $47,076,900 to $56,130,900 at 3% and $47,245,900 to $56,383,900 at 7% over 20 years. In addition, there would be higher EPA administration and enforcement costs under the second co-proposed approach than there would be with an enforcement program under the first co-proposed approach. Finally, this option requires that formulators of paint and coating removal products containing NMP identify which gloves are non-penetrable by NMP if used for an eight-hour shift; this requires that the formulators or processors conduct testing, which can have costs of $15,786 per product (Refs. 4 and 127).

3. Options that exclude downstream notification. For those options that exclude downstream notification, the options are less effective and more to challenging to implement. The downstream notification (*e.g.,* via SDS) provides additional information on the prohibitions under the proposed option for processors and distributors of NMP or products containing NMP other than paint and coating removers, and provides an efficient way for those entities to recognize themselves as affected by the regulation, which contributes to a more effective regulation (Ref. 63). In this way, the downstream notification component of the supply chain approach contributes to the use no longer presenting an unreasonable risk because it streamlines and aids in compliance and implementation (Ref. 64).

F. Summary

EPA is co-proposing these two options because the Agency believes both deserve consideration by commenters. The first co-proposed approach is necessary so that NMP in paint and coating removal no longer presents an unreasonable risk to the general population or to women of childbearing age. It is more cost effective than other regulatory options EPA identified as potentially reducing risks so that they are no longer unreasonable, because the proposed option achieves the benefits of reducing the unreasonable risks so they are no longer unreasonable for a lower cost than the second co-proposed approach. For more information, see Section 6 in the Economic Analysis (Ref. 4). As stated previously in this notice, the first co-proposed approach includes:

- Prohibiting manufacturing (including import), processing, and distribution in commerce of NMP for use in consumer and commercial paint

and coating removal, except for specified uses critical to national security;

- Prohibiting commercial use of NMP for paint and coating removal, except for specified uses critical to national security;
- Requiring that any products containing NMP intended or used for paint and coating removal be distributed in containers with a volume no less than 5 gallons;
- Requiring downstream notification of the prohibition on manufacturing (including import), processing, and distribution of NMP for the prohibited uses; and
- Requiring limited recordkeeping.

Technically and economically feasible alternatives to NMP for paint and coating removal are reasonably available. The supply chain approach ensures protection of consumers from the unreasonable risk by precluding the off-label purchase of commercial products by consumers.

The first co-proposed approach is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to the greatest extent the potential for NMP products to be intentionally or unintentionally misdirected into the prohibited uses. Enforcement under the other options would be much more difficult since the key requirements are directly placed on the large number of product users. As described in a recent article on designing more effective rules and permits, ''the government can implement rules more effectively and efficiently when the universes of regulated sources are smaller and better-defined. This is because, other factors being equal, governments can more easily identify, monitor, and enforce against fewer, rather than more, entities'' (Ref. 63). Under other options, enforcement activities must target firms that might perform the activity where a use of NMP is restricted or prohibited. Identifying which establishments might use paint and coating removers is difficult because paint and coating removal is not strictly specific to any industry (Ref. 4).

The second co-proposed approach would allow the continued use of NMP in commercial and consumer paint and coating removal at up to 35 percent NMP by weight, except for exempt critical national security uses which can be at any concentration, provided that commercial users of NMP for paint and coating removal establish a worker protection program for dermal and respiratory protection.

In addition, the co-proposed approach would require formulators of products for either commercial or consumer uses other than critical national security uses to: Reformulate products such that paint and coating products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations; test gloves for the product formulations being processed and distributed in commerce to identify specialized gloves that provide protection for users; label products with information for consumers and provide information for commercial users about reducing risks when using the product. This approach would effectively reduce risk for workers. EPA is requesting comment on whether this co-proposed approach would be effective at reducing risks for consumers so that the risks are no longer unreasonable.

XVII. Costs and Monetized Benefits of the NMP Component of the Proposed Rule, the Alternatives EPA Considered, and Comparison of Costs and Benefits

EPA proposes that the identified risks from NMP in paint and coating removal are unreasonable. Apart from that proposed determination, EPA has evaluated the potential costs and benefits of the two co-proposed approach and their variations.

A. Costs of the First Co-Proposed Approach

The details of the costs of the first co-proposed approach for NMP in commercial and consumer paint and coating removal are discussed in Unit I.E. and in the Economic Analysis (Ref. 4). Under the first co-proposed option, costs to users of paint and coating removal products containing NMP are (−$1,477,000) to $27,617,000 at a discount rate of 3% and (−$1,231,000) to $27,638,000 at a discount rate of 7%. Costs of paint and coating removal product reformulations are estimated to be approximately $7,000 to $14,000 per year (annualized at 3% over 20 years) and $9,000 to $19,000 (annualized at 7% over 20 years). Costs of downstream notification and recordkeeping on an annualized basis over 20 years are $100 and $100 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $114,401 to $111,718 annualized over 20 years at 3% and 7%, respectively (Ref. 4). Under the first proposed approach, total costs of the proposed rule relevant to NMP in paint and coating removal are estimated to be (−$1,484,000) to $27,624,000 and (−$1,251,000) to $27,668,000 annualized over 20 years at 3% and 7% respectively (Ref. 4).

EPA also found that a use prohibition alone without downstream notification requirements would not address the unreasonable risks. EPA estimated the costs of this option to be $5,164,000 to $30,702,000 annualized over 20 years at 3% and $5,409,000 to $30,839,000 annualized over 20 years at 7% (Ref. 4).

B. Benefits of the First Co-Proposed Approach

As described in Unit XVII.B., there are no monetizable benefits from mitigating the risks from NMP in consumer and commercial paint and coating removal. Although the alternatives considered are unlikely to result in the same health benefits as the first co-proposed option, EPA was unable to quantify the differences.

C. Comparison of Benefits and Costs of the First Co-Proposed Approach

Based on the costs and benefits EPA can estimate, the monetized subset of benefits for preventing the risks resulting from NMP in consumer and commercial paint and coating removal do not outweigh the estimated monetary costs. However, EPA believes that the balance of costs and benefits of the proposed regulation of NMP cannot be fairly described without considering the additional, substantial, non-monetized benefits of mitigating the non-cancer adverse effects. As discussed previously, the multitude of potential adverse effects associated with NMP in paint and coating removal can profoundly impact an individual's quality of life. Some of the adverse effects associated with NMP exposure can be immediately experienced and can affect a person from childhood throughout a lifetime (*e.g.,* low birth weight and associated impacts). Other adverse effects (*e.g.,* adult immunotoxicity, kidney and liver failure, or fetal death) can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature.

While the benefits associated with avoiding the health effects associated with NMP exposure during paint and coating removal cannot be monetized or quantitatively estimated, the qualitative discussion highlights how some of these effects may be as severe as more traditionally monetizable effects and thus just as life-altering; therefore the benefits of avoiding these effects are substantial. These effects include not only medical costs but also personal costs such as emotional and mental stress that are impossible to accurately measure. Considering only monetized benefits would significantly underestimate the benefits of avoiding

NMP-induced adverse outcomes on a person's quality of life.

Thus, considering costs and the benefits that cannot be quantified and subsequently monetized (developmental effects, fetal death, adult body weight reductions, kidney toxicity, liver toxicity, and immunotoxicity), including benefits related to the severity of the effects and the impacts on a person throughout a lifetime in terms of medical costs, effects on earning power and personal costs, emotional and psychological costs, and the disproportionate impacts on Hispanic communities and individuals with limited English proficiency, the benefits of preventing exposure to NMP in paint and coating removal by an estimated 732,000 consumers and an estimated 30,300 commercial workers outweigh the costs.

D. Impacts on the National Economy, Small Businesses, Technological Innovation, the Environment, and Public Health of the First Co-Proposed Approach

As described in Unit V.B. and in the Economic Analysis, EPA considered the anticipated effects of this proposal on the national economy. While the impacts of this rule as a whole are described in Unit XXIII.C. and the impacts of the NMP component of this proposal are described in more detail in Unit XVII.A. and in Section 9.3 of the Economic Analysis (Ref. 4), EPA does not anticipate these impacts having an effect on the overall national economy. EPA anticipates that a majority of small businesses will have cost impacts of less than one percent of the annual revenue, and the majority of small business bathtub refinishing facilities and professional contractors will have cost impacts greater than one percent of annual revenue.

The first co-proposed approach is anticipated to drive technological innovation by formulators of paint and coating removal products containing NMP, as they continue to develop substitute products, and refine such products already available. It is also anticipated to drive technological innovation by formulators of chemical paint and coating removal products with different chemistries as well as manufacturers and retailers of alternative methods of paint and coating removal, particularly those with interest in appealing to the consumer uses. See section 9.3 in the Economic Analysis (Ref. 4).

The first co-proposed approach is anticipated to have a positive impact on public health, as described in Unit XVI.C. There is not anticipated to be a significant impact on the environment, for the reasons described in Unit XII.D.

E. Costs of the Second Co-Proposed Approach

The details of the costs of the second co-proposed approach for NMP in commercial and consumer paint and coating removal are discussed in Unit I.E. and in the supplement to the Economic Analysis (Ref. 127).

Under the second co-proposed option, costs to users of paint and coating removal products containing NMP are $47,076,900 to $56,130,900 (annualized at 3% over 20 years) and $47,245,900 to $56,383,900 (annualized at 7% over 20 years). Costs of paint and coating removal product reformulations are estimated to be approximately $15,100 to $21,100 per year (annualized at 3% over 20 years) and $20,100 to $28,100 (annualized at 7% over 20 years). Agency costs for enforcement are estimated to be approximately $1,024,144 and $998,711 annualized over 20 years at 3% and 7% respectively. Under the second proposed approach, total costs of the proposed rule relevant to NMP in paint and coating removal are estimated to be $47,098,000 to $56,146,000 and $47,274,000 to $56,404,000 annualized over 20 years at 3% and 7% respectively (Ref. 127).

F. Benefits of the Second Co-Proposed Approach

As described in Unit XVII.B., there are no monetizable benefits from mitigating the risks from NMP in consumer and commercial paint and coating removal. Although the second co-proposed option is unlikely to result in the same health benefits as the first co-proposed option, EPA was unable to quantify the differences.

G. Comparison of Benefits and Costs of the Second Co-Proposed Approach

Based on the costs and benefits EPA can estimate, the monetized subset of benefits for preventing the risks resulting from NMP in consumer and commercial paint and coating removal do not outweigh the estimated monetary costs. However, EPA believes that the balance of costs and benefits of the proposed regulation of NMP cannot be fairly described without considering the additional, substantial, non-monetized benefits of mitigating the non-cancer adverse effects. As discussed previously, the multitude of potential adverse effects associated with NMP in paint and coating removal can profoundly impact an individual's quality of life. Considering only monetized benefits would significantly underestimate the benefits of avoiding NMP-induced adverse outcomes on a person's quality of life.

H. Impacts on the National Economy, Small Businesses, Technological Innovation, the Environment, and Public Health of the Second Co-Proposed Approach

As described in Unit V.B. and in the Economic Analysis, EPA considered the anticipated effects of this proposal on the national economy. While the impacts of this rule as a whole are described in Unit XXIII.C. and the impacts of the NMP component of this proposal are described in more detail in Unit XVII.A. and in the supplement to the Economic Analysis (Ref. 127), EPA does not anticipate these impacts having an effect on the overall national economy.

The second co-proposed approach is anticipated to drive technological innovation by formulators of paint and coating removal products containing NMP, as they continue to develop substitute products, and refine such products already available. It is also anticipated to drive technological innovation by formulators of chemical paint and coating removal products with different chemistries as well as manufacturers and retailers of alternative methods of paint and coating removal, particularly those with interest in appealing to the consumer uses. See the supplement to the Economic Analysis (Ref. 127).

The second co-proposed approach is anticipated to have a positive impact on public health, as described in Unit XVI.C. There is not anticipated to be a significant impact on the environment, for the reasons described in Unit XII.D.

XVIII. Uses of NMP for Paint and Coating Removal Critical for National Security

As part of interagency collaboration with the Department of Defense (DOD) on this proposed rule, EPA is aware that there are specific military uses for which NMP is essential for paint and coating removal and for which there are no technically feasible alternatives currently available. The military readiness of DOD's warfighting capability is paramount to ensuring national security, which includes ensuring the maintenance and preservation of DOD's warfighting assets. DOD has identified mission-critical uses for NMP for ensuring military aviation and vessel readiness. These mission-critical items require the use of NMP for the removal of coatings from mission-critical corrosion-sensitive components on military aviation and

vessels, including safety-critical components made of specialty metallic, nonmetallic, and composite materials. As described in this section, EPA proposes to exempt these uses from the regulations proposed on NMP in paint and coating removal. This exemption is proposed for an initial ten-year period from the publication date of a final rule. EPA will engage with DOD to identify any potential extension that may need to be granted, by further rulemaking, after those ten years.

DOD continues and will continue to pursue potential substitutes for NMP in paint and coating removal. However, for mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components, DOD has found that currently available substitute chemicals for paint and coating removal have one or more technical limitations. These are the same technical limitations described in Unit VIII., which outlines the proposed exemption for methylene chloride for similar uses critical to national security.

Under TSCA section 6(g)(1)(B), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure. Based on discussions and information provided by DOD, EPA has analyzed the need for the exemption and concurs with DOD that compliance with the proposed regulations on the use of NMP in paint and coating removal would significantly impact national security. DOD has demonstrated that the reduced mission availability of aircraft and vessels for military missions or, in the worst case, the loss of individual military aircraft and vessels, are potential impacts to military readiness that could result from the proposed prohibition of NMP in paint and coating removal. Due to the importance of these military systems for national security, EPA has determined that these uses of NMP for removal of specialized coatings from military aviation and vessel mission-critical corrosion-sensitive components, including safety-critical components, is critical for national security and the safety of personnel and assets. EPA includes in this exemption corrosion-sensitive military aviation and vessel mission-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the vessel or aircraft could be compromised.

EPA proposes to grant this exemption for a period of ten years from the date of promulgation of a final rule, with a potential for extension, by further rulemaking, after review by EPA in consultation with DOD. The conditions for this exemption would be: (1) The use of NMP at any concentration for coating removal by DOD or its contractors performing this work only for DOD projects is limited to the mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components; (2) this paint and coating removal must be conducted at DOD installations, or at Federal industrial facilities, or at DOD contractor facilities performing this work only for DOD projects.

This exemption granted under TSCA(6)(g)(1)(B) does not impact or lessen any requirements for compliance with other statutes under which the use, disposal, or emissions of NMP is regulated.

As described in Unit XVI.B.3., under the proposed approach, any paint and coating removal products containing NMP would be required to be distributed in containers with a volume no less than 5 gallons, as part of the exemption for uses identified as critical for national security. Allowing selective use for national security purposes does not disrupt the efficacy of the supply chain approach described in Unit XVI.B.3.

In addition to the exemption described in this unit, EPA will consider granting additional time-limited exemptions, under the authority of TSCA section 6(g). Details of EPA's request for comment on such exemption are described in Unit VIII.

XIX. Overview of Uncertainties for NMP in Paint and Coating Removal

A discussion of the uncertainties associated with this proposed rule can be found in the NMP risk assessment (Ref. 3) and in the additional analyses for NMP in commercial and consumer paint and coating removal (Refs. 75 and 76). A summary of these uncertainties follows.

EPA used a number of assumptions in the NMP risk assessment and supporting analysis to develop estimates for occupational and consumer exposure scenarios and to develop the hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include the likelihood that exposures to NMP vary from one paint and coating removal project to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. In estimating the risk from NMP in paint and coating removal, there are uncertainties in the number of workers and consumers exposed to NMP and in the model inputs and algorithms used to estimate exposures.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the benefits are most pronounced in estimating the benefits from preventing the entirety of the adverse effects (described in Unit XIV.C.) because these non-cancer benefits generally cannot be monetized due to the lack of concentration response functions in humans leading to the ability to estimate the number of population-level non-cancer cases and limitations in established economic methodologies. Additional uncertainties in benefit calculations arose from EPA's use of a forecast from an industry expert to estimate the categories of alternatives that users might choose to adopt and the potential risks for adverse health effects that the alternatives may pose. While there are no products or methods that have comparable developmental or similar risks, these substitute products and alternative methods do present hazards. Without information on what alternative methods or chemicals users of NMP for paint and coating removal are likely to switch to, and estimates of the exposures for those alternatives. EPA is unable to quantitatively estimate any change in non-cancer risks due to use of substitute chemicals or alternative methods instead of using NMP for commercial or consumer paint and coating removal.

In addition to these uncertainties related to benefits, there are uncertainties related to the cost estimates. As noted earlier, there is uncertainty in EPA's estimates of which chemical substitutes or alternative methods users may adopt instead of NMP for paint and coating removal, which in turn produces uncertainty as to the cost of those substitutes or methods. EPA has estimated the cost of substitute chemicals, but is not able to fully characterize or quantify the total costs to all sectors for using substitute chemicals or alternative products. In addition, under certain assumptions EPA's economic analysis estimates that

some users of NMP for paint and coating removal will see a cost savings when switching to substitutes. Standard economic theory suggests that financially rational companies would choose technologies that maximize profits so that regulatory outcomes would not typically result in a cost savings for the regulated facilities. There could be several reasons that cost savings might occur in the real world. Potential reasons include lack of complete information or barriers to obtaining information on the cost savings associated with alternatives as well as investment barriers or higher interest rates faced by firms. Additionally, there may be costs associated with these alternatives that are not adequately accounted for in the analysis. To evaluate the effect of this uncertainty, EPA has included a sensitivity analysis that sets the cost savings to zero for these compliance alternatives (Ref. 4 at Section 7). EPA also recognizes that these firms might experience positive costs of compliance rather than zero costs, so that the actual total costs could be higher than those in the sensitivity analysis. However, EPA has no current basis to estimate these potentially higher costs, since the available data appear to show that there are lower cost substitutes available. EPA requests comments on these assumptions.

Additionally, there are uncertainties due to in the estimates of the number of affected commercial and consumer users, and for numbers of processors and distributors of NMP-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records.

EPA will consider additional information received during the public comment period. This includes scientific publications and other input submitted to EPA during the comment period.

XX. Major Provisions and Enforcement of the Proposed Rule for NMP in Paint and Coating Removal

This proposal relies on general provisions in the proposed Part 751, Subpart A, which can be found at 81 FR 91592 (December 16, 2016).

A. Prohibitions and Requirements

Under the first co-proposed approach, the rule, when final, would (1) prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer and commercial paint and coating removal, exempting uses defined as critical for national security (see Unit XVIII.); (2) prohibit the commercial use of NMP for paint and coating removal, exempting for uses defined as critical for national security; (3) require any paint and coating removal products containing NMP to be distributed in containers with a volume no less than 5 gallons; (4) require that any commercial use of NMP for paint and coating removal for uses critical to national security include specific worker protections; (5) require manufacturers, processors, and distributors of NMP and all products containing NMP, excluding retailers, to provide downstream notification of the prohibitions; (6) and require recordkeeping relevant to these prohibitions. The prohibition on manufacturing, processing, and distributing in commerce of NMP for all consumer paint and coating removal would take effect 180 days after publication of a final rule. Similarly, the prohibition on manufacturing, processing, and distributing in commerce of NMP for any paint and coating removal for uses other than those exempted as critical for national security in volumes less than 5-gallon containers would take effect 180 days after publication of a final rule. The prohibition on commercial use of NMP for paint and coating removal except for the exempted critical national security uses would take effect 270 days after publication of a final rule. These are reasonable transition periods because, as noted in Unit XVI.D. and by the small businesses participating in the SBAR process, many formulators of paint and coating removers containing NMP also manufacture products for this use that do not contain NMP (Ref. 27). In addition, alternative paint removal products exist at comparable expense for users to purchase. Six months from publication of the final rule is sufficient time to allow for existing stocks to move through the market place and to allow manufacturers, processers and distributors and users to plan for and implement product substitution strategies.

Under the second co-proposed approach, formulators of paint and coating removal products for either commercial or consumer use would be required to: (1) Ensure that their paint and coating removal products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations exempting products used for critical national security uses (see Unit XVIII.); (2) Test gloves for the product formulations being processed and distributed in commerce for other than exempt critical national security uses to identify specialized gloves that provide protection for users and keep records relevant to these tests; (3) Label products with information for consumers about the risks presented by products that contain NMP and how to reduce these risks when using the products, including identifying which specialized gloves provide protection against the specific formulation; and (4) Provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication. Variations of more than 1% in any component of a paint and coating removal product containing NMP would be considered a separate formulation.

Under this co-proposal, commercial users of NMP for paint and coating removal other than exempt critical national security uses would be prohibited from using paint and coating removal products or formulations that contain more than 35 percent by weight of NMP. They would also be required to establish a worker protection program for dermal and respiratory protection, including hazard communication, training, and requirements that workers wear clothing covering most of the body, *i.e.,* impervious long pants and shirts with long sleeves, use gloves specified by product formulators (described under formulator requirements below) and a respirator with APF 10, with an alternative air exposure limit of 5 ppm achieved through engineering controls or ventilation.

B. Downstream Notification

EPA has authority under TSCA section 6 of TSCA to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. Many manufacturers and processors of NMP are likely to manufacture or process NMP or products containing NMP for other uses that would not be regulated under this proposed rule. Other companies may be strictly engaged in distribution in commerce of NMP, without any manufacturing or processing activities, to customers for uses that are not regulated. Under both co-proposed approaches, EPA is proposing a requirement for downstream notification by manufacturers, processors, and distributors of NMP for any use to ensure compliance with the prohibition on manufacture, processing,

distribution in commerce, and commercial use of NMP for the uses proposed for regulation. Downstream notification is necessary for effective enforcement of the rule because it provides a record, in writing, of notification on use restrictions throughout the supply chain, likely via modifications to the Safety Data Sheet. Downstream notification also increases awareness of restrictions on the use of NMP for paint and coating removal, which is likely to decrease unintentional uses of NMP by these entities. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The estimated cost of downstream notification on an annualized basis over 20 years is $100 and $100 using 3% and 7% discount rates respectively (Ref. 4).

The effective date of the requirement for this notification would be 45 days after publication of the final rule. This is a reasonable transition period because regulated entities would only need to provide additional information on their SDS, which are routinely produced and updated.

C. Enforcement

Section 15 of TSCA makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA section 6. Therefore, any failure to comply with this proposed rule when it becomes effective would be a violation of section 15 of TSCA. In addition, section 15 of TSCA makes it unlawful for any person to: (1) Fail or refuse to establish and maintain records as required by this rule; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by section 11 of TSCA.

Violators may be subject to both civil and criminal liability. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty for each violation. Each day of operation in violation of this proposed rule when it becomes effective could constitute a separate violation. Knowing or willful violations of this proposed rule when it becomes effective could lead to the imposition of criminal penalties for each day of violation and imprisonment. In addition, other remedies are available to EPA under TSCA.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to ''any person'' who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false information or cause it to be reported.

XXI. Analysis for Methylene Chloride and NMP in Paint and Coating Removal under TSCA Section 9 and Section 26(h) Considerations

A. TSCA Section 9(a) Analysis

Section 9(a) of TSCA provides that, if the Administrator determines in her discretion that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. If the other agency responds by declaring that the activities described do not present an unreasonable risk or if that agency initiates action under its own law to protect against the risk within the timeframes specified by TSCA section 9(a), EPA is precluded from acting against the risk under sections 6(a) or 7 of TSCA.

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this proposed rule, EPA has consulted with OSHA and with CPSC. Both CPSC and OHSA have provided letters documenting this consultation (Refs. 121 and 122).

CPSC protects the public from unreasonable risks of injury or death associated with the use of consumer products under the agency's jurisdiction. Though CPSC has provided guidance to consumers when using products containing NMP, there are no CPSC regulations regarding NMP in paint and coating removal. CPSC currently requires that household products that can expose consumers to methylene chloride vapors must bear appropriate warning labels (52 FR 34698, September 14, 1987). In a letter regarding EPA's proposed rulemaking, CPSC stated that ''Some paint removers are distributed for sale to, and use by, consumers and thus would likely fall within CPSC's jurisdiction. However, because TSCA gives EPA the ability to reach both occupational and consumer uses, we recognize that EPA may address risks associated with these chemicals in a more cohesive and coordinated manner given that CPSC lacks authority to address occupational hazards'' (Ref. 121).

OSHA assures safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA's methylene chloride standard, 29 CFR 1910.1052, was issued in 1997 and applies to general industry, construction, and shipyard employment. It sets the PEL for airborne methylene chloride to an eight-hour TWA of 25 parts per ppm. OSHA has not set a standard for NMP. OSHA recently published a Request for Information on approaches to updating PELs and other strategies to managing chemicals in the workplace (79 FR 61384, October 10, 2014). OSHA's current regulatory agenda does not include revision to the methylene chloride PEL, establishment of a PEL for NMP, or other regulations addressing the risks EPA has identified when methylene chloride or NMP are used in paint and coating removal (Ref. 122).

This proposed rule addresses risk from exposure to methylene chloride and NMP during paint and coating removal in both workplace and consumer settings. With the exception of TSCA, there is no Federal law that provides authority to prevent or sufficiently reduce these cross-cutting exposures. No other Federal regulatory authority, when considering the exposures to the populations and within the situations in its purview, can evaluate and address the totality of the risk that EPA is addressing in this proposal and the prior proposal on TCE uses (Ref. 1). For example, OSHA may set exposure limits for workers but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals. Further, OSHA does not have direct authority over state and local employees, and it has no authority at all over the working conditions of state and local employees in states that have no OSHA-approved State Plan under 29 U.S.C. 667. Other Federal regulatory authorities, such as CPSC, have the authority to only regulate pieces of the risks posed by methylene chloride and NMP, such as when used in consumer products.

Moreover, recent amendments to TSCA, Public Law 114–182, alter both the manner of identifying unreasonable risk under TSCA and EPA's authority to address unreasonable risk under TSCA, such that risk management under TSCA is increasingly distinct from analogous provisions of the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), or the OSH Act. These changes to TSCA reduce the likelihood that an action under the CPSA, FHSA, or the OSH Act

would reduce the risk of methylene chloride and NMP in paint and coating removal so that the risks are no longer unreasonable under TSCA. Whereas (in a TSCA section 6 rule) an unreasonable risk determination sets the objective of the rule in a manner that excludes cost considerations, 15 U.S.C. 2605(a)(b)(4)(A), subject to time-limited conditional exemptions for critical chemical uses and the like, 15 U.S.C. 2605(g), a consumer product safety rule under the CPSA must include a finding that ''the benefits expected from the rule bear a reasonable relationship to its costs.'' 15 U.S.C. 2058(f)(3)(E). Additionally, recent amendments to TSCA reflect Congressional intent to ''delete the paralyzing 'least burdensome' requirement,'' 162 Cong. Rec. S3517 (June 7, 2016). However, a consumer product safety rule under the CPSA must impose ''the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated.'' 15 U.S.C. 2058(f)(3)(F). Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action under the FHSA relative to action under TSCA. 15 U.S.C. 1262. Gaps also exist between OSHA's authority to set workplace standards under the OSH Act and EPA's amended obligations to sufficiently address chemical risks under TSCA. To set PELs for chemical exposure, OSHA must first establish that the new standards are economically feasible and technologically feasible. 79 FR 61387 (2014). But under TSCA, EPA's substantive burden under TSCA section 6(a) is to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being determined without consideration of cost or other non-risk factors.

TSCA is the only regulatory authority able to prevent or reduce risks of methylene chloride or NMP exposure to a sufficient extent across the range of uses and exposures of concern. In addition, these risks can be addressed in a more coordinated, efficient and effective manner under TSCA than under two or more different laws implemented by different agencies. Furthermore, there are key differences between the newly amended finding requirements of TSCA and those of the OSH Act, CPSA, and the FHSA. For these reasons, in her discretion, the Administrator does not determine that unreasonable risks from the use of methylene chloride and NMP in paint and coating removal may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA. However, EPA is requesting public comment on this issue (*i.e.,* the sufficiency of an action taken under a Federal law not administered by EPA).

B. TSCA Section 9(b) Analysis

If EPA determines that actions under other Federal laws administered in whole or in part by EPA could eliminate or sufficiently reduce an unreasonable risk, section 9(b) of TSCA instructs EPA to use these other authorities unless the Administrator determines in the Administrator's discretion that it is in the public interest to protect against such risk under TSCA. In making such a public interest finding, TSCA section 9(b)(2) states: ''the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk . . . and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk.''

Although several EPA statutes have been used to limit methylene chloride or NMP exposure (Units III.A. and XII.A.), regulations under these EPA statutes have limitations because they largely regulate releases to the environment, rather than direct human exposure. SDWA only applies to drinking water. CAA does not apply directly to worker exposures or consumer settings where methylene chloride or NMP are used. Under RCRA, methylene chloride that is discarded may be considered a hazardous waste and subject to requirements designed to reduce exposure from the disposal of methylene chloride to air, land and water. RCRA does not address exposures during use of products containing methylene chloride or NMP. Only TSCA provides EPA the authority to regulate the manufacture (including import), processing, and distribution in commerce, and use of chemicals substances.

For these reasons, the Administrator does not determine that unreasonable risks from the use of methylene chloride and NMP in paint and coating removal could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

C. Section 26(h) Considerations

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. For example, EPA based its proposed determination of unreasonable risk presented by the use of methylene chloride and NMP in paint and coating removal on the completed risk assessments, which each followed a peer review and public comment process, as well as using best available science and methods (Refs. 2 and 3). Supplemental analyses were performed to better characterize the exposed populations and estimate the effects of various control options. These supplemental analyses were consistent with the methods and models used in the risk assessment. These analyses were developed for the purpose of supporting a future regulatory determination: To determine either that particular risks are not unreasonable or that those are risks are unreasonable. They were also developed to support risk reduction by regulation under section 6 of TSCA, to the extent risks were determined to be unreasonable. It is reasonable and consistent to consider these supplemental analyses in this rulemaking for such relevant purposes.

The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, can be found on EPA's Assessments for TSCA Work Plan Chemicals Web page at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals.*

XXII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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Paint Removers & TCE Rulemakings E.O. 13132: Federalism Consultation. May 13, 2015.
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127. EPA. Economic Analysis of Second Co-Proposal for N-Methylpyrrolidone. 2016.

XXIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 and Executive Order 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an economic analysis of the potential costs and benefits associated with this action, which is available in the docket and summarized in Units I.E., VII.B., and XVII.B. (Refs. 4 and 127).

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by the EPA has been assigned the EPA ICR number 2556.01. You can find a copy of the ICR in the docket for this proposed rule (Ref. 123), and it is briefly summarized here.

Under the proposed approach for methylene chloride and both co-proposed approaches for NMP, the information collection activities required under the proposed rule include a downstream notification requirement and a recordkeeping requirement. The downstream notification would require companies that ship methylene chloride or NMP to notify companies downstream in the supply chain of the prohibitions of methylene chloride or NMP in the proposed rule. The proposed rule does not require the regulated entities to submit information to EPA. The proposed rule also does not require confidential or sensitive information to be submitted to EPA or downstream companies. The recordkeeping requirement mandates companies that ship methylene chloride or NMP to retain certain information at the company headquarters for three years from the date of shipment. These information collection activities are necessary in order to enhance the prohibitions under the proposed rule by ensuring awareness of the prohibitions throughout the methylene chloride or NMP supply chain, and to provide EPA with information upon inspection of companies downstream who purchased methylene chloride or NMP. EPA believes that these information collection activities would not significantly impact the regulated entities.

Under the second co-proposed approach for NMP, processors of paint and coating removal products containing NMP must test gloves for permeability for each formulation they process. One type of gloves may not be appropriate for all NMP paint remover formulations because the permeability of the product will vary based on the other solvents and chemicals used in the formulation. The testing requirements for glove permeability and the labeling requirements mandate that processors paint removers containing perform glove permeability testing on each paint remover product containing NMP and update their current product labels to contain warnings and instructions for consumers on how to reduce exposures to NMP. Without the reporting requirements, processors of these products might not provide information about the specific types of protective gloves to users. Requiring that labels of paint and coating removal products containing NMP include information about which specific types of gloves provide dermal protection from the specific product formulation provides information that is essential for knowing how to reduce exposures while carrying out paint and coating removal with NMP. Requiring additional warnings and instructions to consumers provides information about the risks presented by the product and how those risks can be reduced. EPA believes that these information collection activities would not significantly impact the regulated entities.

Respondents/Affected Entities: Methylene chloride and NMP manufacturers, processors, and distributors; commercial users of NMP for paint and coating removal.

Respondent's Obligation to Respond: Respondents are not obligated to respond or report to EPA.

Estimated Number of Respondents for the Proposed Approach for Methylene Chloride and the First Co-Proposed Approach for NMP: 327.

Estimated Total Number of Potential Respondents for the Proposed Approach for Methylene Chloride and the Second Co-Proposed Approach for NMP: 327

Frequency of Response: On occasion to third parties as needed.

Total Estimated Burden for the Proposed Approach for Methylene Chloride and the First Co-Proposed Approach for NMP: 163.5

Estimated Total Annual Burden for the Proposed Approach for Methylene Chloride and the Second Co-Proposed Approach for NMP: 1,084 hours.

Total Estimated Cost for the Proposed Approach for Methylene Chloride and the First Co-Proposed Approach for NMP: $7,904 (per year).

Estimated Total Annual Costs for the Proposed Approach for Methylene Chloride and the Second Co-Proposed Approach for NMP: $924,890 (per year).

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 21, 2017. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq.,* EPA prepared an initial regulatory flexibility analysis (IRFA) (Ref. 26) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact. The complete IRFA is available for review in the docket and is summarized here.

1. Need for the rule. Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA

determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. Based on EPA's risk assessments of methylene chloride (Ref. 2) and NMP (Ref. 3), EPA proposes a determination that the use of methylene chloride and NMP in paint and coating removal presents an unreasonable risk of injury to human health. The provisions of this proposal are necessary to address the risk so that it is no longer unreasonable.

2. *Objectives and legal basis.* In part, the legal basis for this proposal is TSCA section 6(a), which provides authority for the Administrator to apply requirements to the extent necessary so that a chemical substance or mixture no longer presents an unreasonable risk of injury to health or the environment. Additional legal basis for the proposal is found at TSCA section 26(l)(4). With respect to chemical substances such as methylene chloride and NMP (which are listed in the 2014 update to the TSCA Work Plan for Chemical Assessments and for which completed risk assessments were published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) TSCA section 26(l)(4) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6.

3. *Small entities covered by this proposal.* EPA estimates that the proposal would affect approximately 10,300 small entities. The majority of these entities are commercial users of methylene chloride or NMP in paint and coating removal in a variety of occupational settings such as bathtub refinishing, graffiti removal, autobody repair, and residential renovations. This also includes a small number of formulators of paint and coating removal products that contain methylene chloride and NMP, for commercial or consumer uses (Refs. 4, 26, and 127).

4. *Compliance requirements and the professional skills needed.* For methylene chloride, EPA is proposing under TSCA section 6 to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer and many types or uses of commercial paint and coating removal, as described in the proposed rule. EPA is also proposing under TSCA section 6 to prohibit the use of methylene chloride for commercial paint and coating removal in these several specified sectors. Additionally, EPA is proposing to require that any paint or coating removal products containing methylene chloride that continue to be distributed be packaged in volumes no less than 55-gallon containers, except for formulations produced specifically for DOD. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of these requirements and prohibitions throughout the supply chain; and to require limited recordkeeping. More details on this supply chain approach are in Unit VI.C.3.

For NMP, EPA is co-proposing two approaches. Under the first co-proposed approach, EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal, exempting uses identified in the proposed rule as critical to national security; and to prohibit the commercial use of NMP for paint and coating removal, exempting uses identified as critical to national security. EPA is proposing to require that any paint or coating removal products containing NMP that continue to be distributed be packaged in no less than 5-gallon containers. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of NMP for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping. For the second co-proposed approach for NMP, commercial users would be required to implement and maintain a detailed program for worker protection, including dermal and respiratory protection. Additionally, product processors would be required to carry out testing to identify gloves that are protective against each product formulation, labeling product with that information, and provide additional information on the label to consumers regarding risks of using the product and instructions on how to reduce those risks. As in the first co-proposal, EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of NMP for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping. More details on these two co-proposals are in Unit XVI.B.3.

Under the proposed approach for methylene chloride and first co-proposed approach for NMP, complying with the prohibitions, the downstream notification, and the recordkeeping requirements involve no special skills. However, implementing the use of substitute chemicals or alternative paint and coating removal processes may involve special skills or expertise in the sector in which the paint and coating removal is conducted.

For the second co-proposed approach for NMP, commercial users would be required to implement and maintain a detailed program for worker protection, which would involve special skills or expertise in industrial hygiene. Similarly, product processors would be required to carry out testing to identify gloves that are protective against each product formulation, could involve special skills or expertise. Labeling products to comply with new requirements would not involve special skill, particularly since EPA proposes to identify specific information for labels of paint and coating removal products containing NMP. As in the first co-proposal for NMP, the downstream notification and the recordkeeping requirements require no special skills.

5. *Other Federal regulations.* Other Federal regulations that affect the use of methylene chloride or NMP in paint and coating removal are discussed in Units III.A. and XIII.A. While many of the statutes that EPA and other agencies are charged with administering provide statutory authority to address specific sources and routes of methylene chloride exposure, none of these can address the serious human health risks from methylene chloride exposure that EPA is proposing to address under TSCA section 6(a). Regarding methylene chloride, because the methylene chloride NESHAPs were developed only to regulate emissions from certain types of paint and coating removal operations, not to address worker or consumer exposures, they are not duplicative with this proposal. Similarly, regulations addressing methylene chloride disposal or water contamination do not address worker or consumer exposures when conducting paint and coating removal. This proposed rule does not conflict with the NESHAP (or regulations addressing methylene chloride disposal or water contamination): it neither prohibits any action required by such

rules, nor requires any action prohibited by such rules.

OSHA's methylene chloride standard, 29 CFR 1910.1052, was issued in 1997 and applies to general industry, construction, and shipyard employment. This proposal does not duplicate OSHA's methylene chloride standard. Nor does the proposed rule conflict with the OSHA standard: it would not prohibit actions required to meet OSHA's methylene chloride standard and it would not require actions in violation OSHA's methylene chloride standard.

CPSC requires that consumer products that contain methylene chloride be labeled with a statement regarding the cancer risks presented by inhalation of methylene chloride fumes. This proposal does not impose requirements that would duplicate or conflict with CPSC's labeling requirements for methylene chloride.

Regarding NMP, there are no OSHA or CPSC regulations. EPA's proposal is not duplicative of other Federal rules nor does it conflict with other Federal rules.

6. *Regulatory alternatives considered.* As described in Units V.C., VI.C., XV.C., and XVI.B., EPA considered a wide variety of risk reduction options. The Economic Analysis (Ref. 4) examined several alternative analytical options. However, most of the alternatives did not address the risks presented by methylene chloride and NMP in paint and coating removal as necessary so that they would no longer be unreasonable, either to the general population or (in the case of NMP) to women of childbearing age.

The primary alternative considered by EPA for methylene chloride in paint and coating removal was to allow the commercial use of methylene chloride in paint and coating removal and require a respiratory protection program, including PPE, air monitoring, and either a supplied-air respirator of APF 1,000 or 10,000 or an air exposure limit achieved through engineering controls or ventilation in commercial facilities where methylene chloride is used for paint and coating removal. Depending on air concentrations and proximity to the paint and coating removal, other employees in the area would also need to wear respiratory protection equipment. While this option would address the risks presented by methylene chloride in paint and coating removal, so that they would no longer be unreasonable, the Economic Analysis indicates that this option is more expensive than switching to a substitute chemical or alternative paint and coating removal method (Ref. 4). However, as recommended by the SBAR panel, EPA is seeking comment on and additional information about air monitoring and the use of supplied-air respirators in firms conducting paint and coating removal with methylene chloride (Ref. 27).

EPA is co-proposing two approaches to address risks presented by NMP in commercial and consumer paint and coating removal. Those approaches are described above. EPA considers both of these approaches to be primary regulatory alternatives.

As required by section 609(b) of the RFA, EPA also convened a SBAR Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an IRFA. A copy of the full SBAR Panel Report (Ref. 27) is available in the rulemaking docket.

The Panel recommended that EPA seek additional information in five specific areas: Exposure information, regulatory options, alternatives, cost information, and risk assessment. Specifically, the Panel recommendations were: (1) Exposure information: EPA should request workplace monitoring information during the comment period for worker exposure levels from companies for methylene chloride and NMP in paint and coating removal. EPA should request additional information regarding the frequency of use currently of PPE, and consider that information when weighing alternative options in the proposed rulemaking for methylene chloride and NMP in paint and coating removal. (2) Regulatory options: EPA should consider and seek public comments on enhanced labeling requirements for consumer paint removal products containing methylene chloride or NMP to reduce exposure to methylene chloride and NMP. EPA should consider and seek public comments on a control option such as a certification program similar to the Lead Renovation, Repair and Painting program with increased training and education for commercial users of paint removers. EPA should delay any proposed regulatory action on methylene chloride for the commercial furniture refinishing industry while it gathers additional information to characterize the impacts on this industry of restrictions on use of methylene chloride in paint and coating removal. EPA should request comment on current practices in the furniture refinishing industry on limiting exposure to methylene chloride used in paint and coating removal. EPA should request comment on the feasibility of methylene chloride only being sold in 30–55- gallon drums. EPA should address the proposed regulatory actions as distinctly as possible in the one proposed rulemaking addressing both methylene chloride and NMP in paint and coating removal. (3) Alternatives: EPA should ensure that its analysis of the available alternatives to methylene chloride and NMP in paint and coating removal comply with the requirements of TSCA section 6(c)(2)(C) and include consideration, to the extent legally permissible and practicable, of whether technically and economically feasible alternatives that benefit health or the environment, compared to the use being prohibited or restricted, will be reasonably available as a substitute when the proposed requirements would take effect. Specifically, EPA should evaluate the feasibility of using alternatives, including the cost, relative safety, and other barriers; and take into consideration the current and future planned regulation of compounds the agency has listed as alternatives. (4) Cost information: EPA should request additional information on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies. (5) Risk assessments: EPA should recognize the concerns that the SERs had on the risk assessments by referring readers to the risk assessments and the Agency's Summary of External Peer Review and Public Comments and Disposition document for each risk assessment, which addresses those concerns, in the preamble of the proposed rulemaking.

Throughout this preamble, EPA has requested information with respect to these and other topics.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The requirements of this action would primarily affect manufacturers, processors, and distributors of methylene chloride or NMP. The total estimated annualized cost of the proposed rule under the first co-proposed approach for NMP is $4,185,000 to $23,423,000 and $4,550,000 to $23,472,000 annualized over 20 years at 3% and 7%, respectively (Ref. 4). The total estimated annualized cost of the proposed rule under the second co-proposed approach for NMP is $114,196,000 to $125,893,000 and $114,658,000 to $125,438,000 annualized over 20 years

at 3% and 7%, respectively (Ref. 127), which does not exceed the inflation-adjusted unfunded mandate threshold of $154 million.

E. Executive Order 13132: Federalism

The EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt state law. EPA provides the following federalism summary impact statement. The Agency consulted with state and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. EPA invited the following national organizations representing state and local elected officials to a meeting on May 13, 2015, in Washington DC: National Governors Association; National Conference of State Legislatures, Council of State Governments, National League of Cities, U.S. Conference of Mayors, National Association of Counties, International City/County Management Association, National Association of Towns and Townships, County Executives of America, and Environmental Council of States. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 124). Although EPA provided these organizations an opportunity to provide follow-up comments in writing, EPA received no written follow-up.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rulemaking would not have substantial direct effects on tribal government because methylene chloride or NMP are not manufactured, processed, or distributed in commerce by tribes. Tribes do not regulate methylene chloride or NMP, and this rulemaking would not impose substantial direct compliance costs on tribal governments. Thus, EO 13175 does not apply to this action. EPA nevertheless consulted with tribal officials during the development of this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes.

EPA met with tribal officials in a national informational webinar held on May 12, 2015 concerning the prospective regulation of methylene chloride and NMP in paint and coating removal under TSCA section 6, and in another teleconference with tribal officials on May 27, 2015 (Ref. 125). EPA also met with the National Tribal Toxics Council (NTTC) in Washington, DC and via teleconference on April 22, 2015 (Ref. 125). In those meetings, EPA provided background information on the proposed rule and a summary of issues EPA explored. These officials expressed support for EPA regulation to reduce the risks presented by methylene chloride and NMP in paint and coating removal.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children, specifically on the developing fetus. Accordingly, we have evaluated the environmental health or safety effects of methylene chloride and NMP in paint and coating removal on children. This action's health and risk assessment of exposure by children to methylene chloride and NMP in paint and coating removal are contained in Units I.F., VI.C.1.c., and XVI.B.1.c. of this preamble. Supporting information on methylene chloride and NMP exposures and the health effects of methylene chloride or NMP exposure by children is available in the Toxicological Review of Methylene Chloride (Ref. 5), the NMP risk assessment (Ref. 3), and the methylene chloride risk assessment (Ref. 2).

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution in Commerce, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution in commerce, or use. This rulemaking is intended to protect against risks from methylene chloride and NMP in paint and coating removal, and does not affect the use of oil, coal, or electricity.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note. However, under one of the co-proposals for NMP discussed in Unit XVI, EPA is proposing to require processors of paint and coating removal products that contain NMP to identify, through testing, gloves that provide an impervious barrier to dermal exposure during normal and expected duration and conditions of exposure. EPA has identified two potentially-applicable voluntary consensus standards for this process: ASTM International Standard F739, ''Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact,'' and ASTM International F1194–99, ''Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials.'' EPA is not proposing specific provisions for conducting and documenting glove testing, nor is EPA proposing to incorporate these voluntary consensus standards by reference. EPA requests comment on whether the regulation should include additional requirements on glove testing for processors and, if so, how that should be accomplished.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the U.S. Units VI.C.1.b.,VI.D.10., XVI.B.1.b., and XVI.C.6. of this preamble address public health impacts from methylene chloride and NMP in paint and coating removal. This proposed rule would address the current disproportionate risk to Hispanic workers (of all races) and foreign-born workers in the construction trades, where these two populations are overrepresented compared to the general U.S. adult population (Ref. 4). Though this proposed rule would eliminate risks of exposure to NMP and methylene chloride when used in paint and coating removal in the construction trades, because workers in these two populations currently are overrepresented in this trade, these populations would disproportionately benefit from this risk reduction. The EPA places particular emphasis on the public health and environmental conditions affecting minority populations, low-income populations,

and indigenous peoples. In recognizing that these populations frequently bear a disproportionate burden of environmental harms and risks, EPA works to protect them from adverse public health and environmental effects (Ref. 126).

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Recordkeeping.

Dated: January 12, 2017.

Gina McCarthy,

Administrator.

Therefore, 40 CFR part 751, as proposed to be added at 81 FR 91592 (December 16, 2016), is proposed to be further amended as follows:

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

■ 1. The authority citation for part 751 is revised to read as follows:

Authority: 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4).

■ 2. Add Subpart B to read as follows:

Subpart B—Methylene Chloride

Sec.

Subpart B—Methylene Chloride

§ 751.101 General.

This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, and uses of methylene chloride (CASRN 75–09–2) to prevent unreasonable risks to health associated with human exposure to methylene chloride for the specified uses.

§ 751.103 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

Commercial furniture stripping means furniture stripping conducted in a commercial facility performed by an individual, government entity, or company for which an individual, government entity, or company receives remuneration or other form of payment.

Commercial paint and coating removal means paint and coating removal performed by an individual, government entity, or company, for which an individual, government entity, or company receives remuneration or other form of payment.

Critical corrosion-sensitive components of military aviation and vessels means parts that directly enable or support warfighting assets of the Department of Defense (DOD) and include ''safety critical items'' identified by DOD in accordance with DOD policies and requirements for ensuring safety and performance. These include corrosion-sensitive aviation and vessel safety-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of paint removal chemicals or methods other than methylene chloride that the safety of the system could be compromised.

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of § 751.109 and § 751.111.

Furniture stripping means paint and coating removal from furniture and includes application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from wood, metal, or other types of furniture, doors, radiators, or cabinets. Furniture stripping includes paint and coating removal from furniture that occurs separately from or as part of furniture refinishing.

Paint and coating removal means application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from a substrate, including objects, vehicles, architectural features, or structures.

Retailer means a person or business who distributes in commerce a chemical substance, mixture, or article to consumer end users.

§ 751.105 Consumer Paint and Coating Removal.

After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce methylene chloride for consumer paint and coating removal.

§ 751.107 Commercial Paint and Coating Removal in Specified Industries or for Specified Uses.

(a) After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce methylene chloride for commercial paint and coating removal except for commercial furniture stripping or for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.103. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce methylene chloride for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(b) After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from distributing in commerce methylene chloride for paint and coating removal in containers with a volume less than 55 gallons except for formulations specifically manufactured for the Department of Defense, which may be distributed in commerce in containers with a volume no less than 5 gallons.

(c) After [*date 270 calendar days after the date of publication of the final rule*], all persons are prohibited from commercial use of methylene chloride for paint and coating removal except for commercial furniture stripping or for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.103. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from commercial use of methylene chloride for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(d) Any paint and coating removal from critical corrosion-sensitive components of military aviation and vessels must be conducted under the following restrictions:

(1) All paint and coating removal from critical corrosion-sensitive components of military aviation and vessels using methylene chloride must be conducted at DOD installations, or at deployed locations under the control of DOD organizations, or at locations of DOD contractors performing coating removal work from corrosion-sensitive components of military aviation and vessels for DOD.

§ 751.109 Downstream Notification.

Each person who manufactures, processes, or distributes in commerce methylene chloride for any use after [*date 45 calendar days after the date of publication of the final rule*] must, prior to or concurrent with the shipment, notify companies to whom methylene chloride is shipped, in writing, of the restrictions described in this subpart.

§ 751.111 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any methylene chloride after [*date 45 calendar days after the date of publication of final rule*] must retain in one location at the headquarters of the company documentation showing:

(1) The name, address, contact, and telephone number of companies to whom methylene chloride was shipped;

(2) A copy of the notification provided under § 751.109; and

(3) The amount of methylene chloride shipped.

(b) The documentation in (a) must be retained for 3 years from the date of shipment.

■ 3. Add Subpart C as follows:

Subpart C—N-Methylpyrrolidone.

Sec.

Subpart C—N-Methylpyrrolidone

§ 751.201 General.

This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, and uses of N-methylpyrrolidone (NMP) (CASRN 872–50–4) to prevent unreasonable risks to health associated with human exposure to NMP for the specified uses.

§ 751.203 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

Commercial paint and coating removal means paint and coating removal performed by an individual, government entity, or company, for which an individual, government entity, or company receives remuneration or other form of payment.

Critical corrosion-sensitive components of military aviation and vessels means parts that directly enable or support warfighting assets of the Department of Defense (DOD) and include ''safety critical items'' identified by DOD in accordance with DOD policies and requirements for ensuring safety and performance. These include corrosion-sensitive aviation and vessel safety-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of paint removal chemicals or methods other than NMP that the safety of the system could be compromised.

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of § 751.209 and § 751.211.

Formulation is a mixture of active and other ingredients.

Paint and coating removal means application of a chemical or other method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coatings from a substrate, including objects, vehicles, architectural features, or structures.

Retailer means a person or business who distributes in commerce a chemical substance, mixture, or article to consumer end users.

[OPTION 1 PROPOSED REGULATORY TEXT FOR §§ 751.205, 751.207, 751.209, and 751.211: Co-Proposal 1: NMP—Banning the Manufacture, Processing, Distribution, and Use Except for a Critical Use Exemption]

§ 751.205 Manufacture, Processing, and Distribution of NMP for Consumer Paint and Coating Removal.

After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce NMP for consumer paint and coating removal.

§ 751.207 Manufacture, Processing, and Distribution of NMP for Commercial Paint and Coating Removal.

(a) After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce NMP for commercial paint and coating removal except for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce NMP for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(b) After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from distributing in commerce NMP for paint and coating removal in containers with a volume less than 55 gallons except for formulations specifically manufactured for the Department of Defense, which may be distributed in commerce in containers with a volume no less than 5 gallons.

(c) After [*date 270 calendar days after the date of publication of the final rule*], all persons are prohibited from commercial use of NMP for paint and coating removal except for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from commercial use of NMP for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(d) Any paint and coating removal from critical corrosion-sensitive components of military aviation and vessels must be conducted under the following restrictions:

(1) All paint and coating removal from critical corrosion-sensitive components of military aviation and vessels using NMP must be conducted at DOD installations; DOD owned, contractor operated locations; or contractor owned, contractor operated locations performing paint and coating removal from critical corrosion-sensitive components of military aviation and vessels for DOD.

(2) [Reserved].

§ 751.209 Downstream notification.

Each person who manufactures, processes, or distributes in commerce NMP for any use after [*date 45 calendar days after the date of publication of the final rule*] must, prior to or concurrent with the shipment, notify companies to whom NMP is shipped, in writing, of the restrictions described in this subpart.

§ 751.211 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any NMP after [*date 45 calendar days after the date of publication of final rule*] must retain in one location at the headquarters of the company documentation showing:

(1) The name, address, contact, and telephone number of companies to whom NMP was shipped;

(2) A copy of the notification provided under § 751.209; and

(3) The amount of NMP shipped.

(b) The documentation in (a) must be retained for 3 years from the date of shipment.

[OPTION 2 PROPOSED REGULATORY TEXT FOR §§ 751.205, 751.209, and 751.211: Co-Proposal 2: NMP—Continued Use with Requirements for Product Reformulation, Labeling, and PPE]

§ 751.205 Paint and Coating Removal for Specified Uses.

(a) *Processors.* (1) Formulations of NMP for paint and coating removal that contain more than 35 percent by weight of NMP must not be manufactured, processed, or distributed in commerce after [*date 180 calendar days after the date of publication of the final rule*], except for product formulations destined to be used by DOD or contractors performing work only on DOD projects for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203 and subsection (b)(1).

(2) Conduct glove testing for each separate formulation of NMP, with a variation of more than 1 percent in any component of a paint and coating removal product containing NMP considered a separate formulation.

(i) The processor must be able to demonstrate that the gloves provide an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure.

(ii) The processor must subject the gloves to the expected conditions of exposure, including the likely combinations of chemical substances to which the gloves may be exposed in the work area.

(3) Provide a label securely attached to each NMP paint and coating removal product and not in the form of a booklet or other pull off type labeling. Label information must be prominently displayed and in an easily readable font size. Each separate NMP paint and coating removal product must be labeled with the following information:

(i) A notice that 40 CFR 751.205 requires commercial users of NMP paint and coating removal products to establish an occupational dermal and respiratory protection program, including the use of specialized gloves and an air exposure limit or respirator.

(ii) A warning to consumers that fetal death and other irreversible health effects may occur as a result of using the NMP product;

(iii) An identification of the formulation-specific gloves that will provide protection from the NMP product and a direction to use a new pair of those gloves for each time the NMP product is used;

(iv) A direction for consumers to either use the product outdoors or adequately ventilate the workspace by opening windows and adding fans;

(v) A warning for consumers to not apply the product as a spray;

(vi) A direction to wear clothing that covers exposed skin;

(vii) A direction to use a respirator with an Assigned Protection Factor (APF) of 10. Refer to § 751.205(c)(3)(ii) for respirators having an APF of 10 or greater;

(b) *Commercial users.* Each person or company engaged in any commercial NMP paint and coating removal activities [*date 180 calendar days after the date of publication of the final rule*] is prohibited from using paint and coating removal products or formulations that contain more than 35 percent by weight of NMP and must institute a worker protection program that includes the requirements of § 751.205(c) and (e) except for product formulations destined to be used for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from using paint and coating removal products or formulations that contain more than 35 percent by weight of NMP and must institute a worker protection program that includes the requirements of § 751.205(c) and (e).

(1) Any paint and coating removal from critical corrosion-sensitive components of military aviation and vessels must be conducted under the following restrictions:

(i) All paint and coating removal from critical corrosion-sensitive components of military aviation and vessels using NMP must be conducted at DOD installations; or at government owned, contractor operated locations; or at contractor owned and contractor operated locations performing paint and coating removal from critical corrosion-sensitive components of military aviation and vessels for DOD.

(ii) [Reserved].

(2) [Reserved].

(c) *Personal protective equipment (PPE).*

(1) *General.* (i) Protective equipment that is of safe design and construction for the work to be performed must be provided, used, and maintained in a sanitary, reliable, and undamaged condition. The employer must select PPE that properly fits each affected employee and communicate PPE selections to each affected employee.

(ii) *Training.* The employer must provide training to each employee required to use PPE.

(A) Each affected employee must be trained to know at least the following:

(*1*) When PPE is necessary.

(*2*) What PPE is necessary.

(*3*) How to properly don, doff, adjust, and wear PPE.

(*4*) The limitations of the PPE.

(*5*) The proper care, maintenance, useful life and disposal of the PPE.

(B) Each affected employee must demonstrate an understanding of these elements and the ability to use PPE properly before being allowed to perform work requiring the use of PPE.

(C) Retraining is required when previous training is rendered obsolete, whether due to changes in the workplace or the type of PPE, or when the employer has reason to believe that a previously-trained employee does not have the understanding and skill required by this subparagraph.

(2) *Dermal protective equipment.* (i) *General.* Each person who is reasonably likely to be dermally exposed in the work area to an NMP paint and coating removal product through direct handling of the substance or through contact with equipment or materials on which the substance may exist, or because the substance becomes airborne must be provided with, and required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use.

(ii) *Specific dermal protective equipment.* The required dermal protective equipment includes, but is not limited to, the following items:

(A) Formulation-specific gloves as indicated on the NMP paint and coating removal product label. A new pair must be supplied and worn each time the NMP product is used.

(B) Impervious clothing covering the exposed areas of the body (*e.g.* long pants, long shirt).

(iii) *Demonstration of imperviousness.* The employer must demonstrate that each item of chemical protective clothing selected provides an impervious barrier to prevent dermal exposure during normal and expected

duration and conditions of exposure within the work area by any one or a combination of the following:

(A) Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

(B) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the chemical substance alone and in likely combination with other chemical substances in the work area.

(3) *Respiratory protection.* (i) *General.* Each person who is reasonably likely to be exposed in the workplace to the use of NMP in paint and coating removal products must be provided with and is required to wear, at a minimum, a NIOSH-certified respirator with an APF of 10. All respirators must be issued, used, and maintained in accordance with an appropriate written respiratory protection program that is specific to the workplace and that includes the following:

(A) Procedures for selecting respirators for use in the workplace.

(B) Medical evaluations of employees required to use respirators.

(C) Fit testing procedures.

(D) Procedures for proper use of respirators.

(E) Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators.

(F) Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators.

(G) Procedures for regularly evaluating the effectiveness of the program.

(H) Recordkeeping.

(ii) *Authorized respirators.* The following NIOSH-certified respirators meet the minimum requirements of this section:

(A) Any NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) Any appropriate NIOSH-certified N100 (if oil aerosols absent), R100, or P100 filtering facepiece respirator;

(C) Any NIOSH-certified air-purifying full facepiece respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. A full facepiece air-purifying respirator, although it has a higher APF of 50, is required to provide full face protection because the PMN substance presents significant exposure concern for mucous membranes, eyes, or skin;

(D) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask; or

(E) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half mask.

(d) *Alternative to respirator requirement.* Commercial users of NMP products for paint and coating removal may use an existing chemical exposure limit (ECEL) as a means of controlling inhalation exposures whenever practicable rather than respirators.

(1) *Existing Chemical Exposure Limit (ECEL).* The employer must ensure that no person is exposed to an airborne concentration of NMP in excess of 20 mg/m^3 (the ECEL) as an 8-hour time-weighted average (TWA) without using a respirator. For non-8-hour work-shifts, the ECEL for that work-shift (ECELn) must be determined by the following equation: ECELn = ECEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift.

(2) *Verification of method validity.* An independent accredited reference laboratory must verify the validity of the analytical method for NMP in paint and coating removal products. The sampling and analytical method, and all exposure monitoring data relied on by the employer, must be accurate to within 25% at a 95% confidence level for concentrations of NMP ranging from one half the ECEL to twice the ECEL.

(3) *Exposure monitoring.* The employer must collect samples that are representative of the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of NMP.

(i) *Initial monitoring.* Before the employer may deviate from the respirator requirements in subsection (d) of this section, the employer must conduct initial exposure monitoring to accurately determine the airborne concentration of NMP for each exposure group in which persons are reasonably likely to be exposed.

(ii) *Results.* (A) Employees whose exposures are represented by initial monitoring results below the ECEL need not wear the respirators required in subsection (d) of this section.

(B) Employees whose exposures are represented by initial monitoring results above the ECEL must continue to wear the respirators required in subsection (d) of this section until such time as two monitoring results below the ECEL, sampled at least 24 hours apart, are obtained.

(C) Within 15 days of the date exposure monitoring results are received, the employer must provide the results to each person whose exposure is represented by the monitoring. If the result is above the ECEL, the employer must also provide the employee with information on the actions the employer will take to reduce employee exposures to the ECEL or below.

(iii) *Periodic monitoring.* The employer must repeat exposure monitoring:

(A) Every 6 months for those employees whose initial monitoring results are between 0.5 ECEL and the ECEL, until such time as 2 results below 0.5 ECEL, from samples collected at least 24 hours apart, are obtained,

(B) Every 3 months for those employees whose initial monitoring results are at or above the ECEL. If 2 results below the ECEL, from samples collected at least 24 hours apart, are obtained, then frequency may be reduced to every 6 months. If 2 results below 0.5 ECEL, from samples collected at least 24 hours apart, are obtained, then exposure monitoring under this subsection need not be repeated unless there is a process, equipment, environment, or personnel change.

(C) At any time when process, equipment, environment, or personnel changes may reasonably cause new or additional exposures to NMP.

(e) *Hazard communication program.* Each employer that performs commercial NMP paint and coating removal activities must develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, SDSs, other forms of warning material, and employee information and training will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program that satisfies the requirements of this paragraph.

(1) *General.* The written program must include the following:

(i) A list of each NMP paint and coating removal product present in the work area. The list must be maintained in the work area and must use the identity provided on the appropriate

SDS. The list may be compiled for the workplace or for individual work areas.

(ii) The methods the employer will use to inform contractors of the presence of NMP paint and coating removal products in the employer's workplace and of the provisions of this part applicable to the NMP products if employees of the contractor work in the employer's workplace and are reasonably likely to be exposed to the NMP products while in the employer's workplace.

(2) *Employee information and training.* Each employer must ensure that employees are provided with information and training on NMP paint and coating removal products. This information and training must be provided at the time of each employee's initial assignment to using an NMP paint and coating removal product.

(i) Information provided to employees under this paragraph must include:

(A) The requirements of this section.

(B) The location and availability of the written hazard communication program.

(ii) Training provided to employees must include:

(A) The potential human health hazards of the NMP paint and coating removal products as specified on the label.

(B) The measures employees can take to protect themselves from the NMP paint and coating removal products, including specific procedures the employer has implemented to protect employees from exposure to the substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure.

(3) *Existing hazard communication program.* The employer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

§ 751.209 Downstream notification.

Each person who manufactures, processes, or distributes in commerce NMP for any use after [*date 45 calendar days after the date of publication of the final rule*] must, prior to or concurrent with the shipment, notify companies to whom NMP is shipped, in writing, of the restrictions described in this subpart.

§ 751.211 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any NMP after [*date 45 calendar days after the date of publication of final rule*] must retain in one location at the headquarters of the company documentation showing:

(1) The name, address, contact, and telephone number of companies to whom NMP was shipped;

(2) A copy of the notification provided under § 751.209; and

(3) The amount of NMP shipped.

(b) The documentation in (a) must be retained for 3 years from the date of shipment.

[FR Doc. 2017–01222 Filed 1–18–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2016–0163; FRL–9949–86]

RIN 2070–AK03

Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Trichloroethylene (TCE) is a volatile organic compound widely used in industrial and commercial processes and has some limited uses in consumer and commercial products. EPA identified significant health risks associated with TCE use in aerosol degreasing and for spot cleaning in dry cleaning facilities. EPA has preliminarily determined that these risks are unreasonable risks. To address these unreasonable risks, EPA is proposing under section 6 of the Toxic Substances Control Act (TSCA) to prohibit the manufacture, processing, and distribution in commerce of TCE for use in aerosol degreasing and for use in spot cleaning in dry cleaning facilities; to prohibit commercial use of TCE for aerosol degreasing and for spot cleaning in dry cleaning facilities; to require manufacturers, processors, and distributors, except for retailers of TCE for any use, to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping.

DATES: Comments must be received on or before February 14, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0163, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods (*e.g.,* mail or hand delivery), the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket. Docket number EPA–HQ–OPPT–2016–0163 contains supporting information used in developing the proposed rule, comments on the proposed rule, and additional supporting information. A public version of the docket is available for inspection and copying between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding federal holidays, at the U.S. Environmental Protection Agency, EPA Docket Center Reading Room, WJC West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Toni Krasnic, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–0984; email address: *krasnic.toni@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may potentially be affected by this proposed action if you manufacture (defined under TSCA to include import), process, or distribute in commerce TCE or commercially use TCE in aerosol degreasers or for spot cleaning in dry cleaning facilities. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- All Other Miscellaneous Textile Product Mills (NAICS code 314999).
- Petroleum Refineries (NAICS code 324110).
- Petroleum Lubricating Oil and Grease Manufacturing (NAICS code 324191).
- Petrochemical Manufacturing (NAICS code 325110).
- Industrial Gas Manufacturing (NAICS code 325120).
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180).
- All Other Basic Organic Chemical Manufacturing (NAICS code 325199).
- Plastics Material and Resin Manufacturing (NAICS code 325211).
- Synthetic Rubber Manufacturing (NAICS code 325212).
- Paint and Coating Manufacturing (NAICS code 325510).
- Adhesive Manufacturing (NAICS code 325520).
- Soap and Other Detergent Manufacturing (NAICS code 325611).
- Polish and Other Sanitation Good Manufacturing (NAICS code 325612).
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS code 325998).
- Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing (NAICS code 326113).
- All Other Plastics Product Manufacturing (NAICS code 326199).
- Rubber and Plastics Hoses and Belting Manufacturing (NAICS code 326220).
- All Other Rubber Product Manufacturing (NAICS code 326299).
- Cement Manufacturing (NAICS code 327310).
- Ground or Treated Mineral and Earth Manufacturing (NAICS code 327992).
- Iron and Steel Pipe and Tube Manufacturing from Purchased Steel (NAICS code 331210).
- Steel Wire Drawing (NAICS code 331222).
- Copper Rolling, Drawing, Extruding, and Alloying (NAICS code 331420)
- Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding (NAICS code 331491).
- Nonferrous Metal Die-Casting Foundries (NAICS code 331523).
- Powder Metallurgy Part Manufacturing (NAICS code 332117).
- Metal Crown, Closure, and Other Metal Stamping (except Automotive) (NAICS code 332119).
- Saw Blade and Hand Tool Manufacturing (NAICS code 332216).
- Metal Window and Door Manufacturing (NAICS code 332321).
- Power Boiler and Heat Exchanger Manufacturing (NAICS code 332410).
- Other Fabricated Wire Product Manufacturing (NAICS code 332618).
- Machine Shops (NAICS code 332710).
- Precision Turned Product Manufacturing (NAICS code 332721).
- Bolt, Nut, Screw, Rivet, and Washer Manufacturing (NAICS code 332722).
- Metal Heat Treating (NAICS code 332811).
- Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers (NAICS code 332812).

- Electroplating, Plating, Polishing, Anodizing, and Coloring (NAICS code 332813).
- Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132).
- Cutting Tool and Machine Tool Accessory Manufacturing (NAICS code 333515).
- Small Arms, Ordnance, and Ordnance Accessories Manufacturing (NAICS code 332994).
- Fluid Power Pump and Motor Manufacturing (NAICS code 333996).
- All Other Miscellaneous Fabricated Metal Product Manufacturing (NAICS code 332999).
- Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132).
- Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing (NAICS code 333413).
- Cutting Tool and Machine Tool Accessory Manufacturing (NAICS code 333515).
- Pump and Pumping Equipment Manufacturing (NAICS code 333911).
- Fluid Power Pump and Motor Manufacturing (NAICS code 333996).
- Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing (NAICS code 334511).
- Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use (NAICS code 334512).
- Motor and Generator Manufacturing (NAICS code 335312).
- Primary Battery Manufacturing (NAICS code 335912).
- Carbon and Graphite Product Manufacturing (NAICS code 335991).
- Motor Vehicle Brake System Manufacturing (NAICS code 336340).
- Aircraft Manufacturing (NAICS code 336411).
- Other Aircraft Parts and Auxiliary Equipment Manufacturing (NAICS code 336413).
- Guided Missile and Space Vehicle Manufacturing (NAICS code 336414).
- Ship Building and Repairing (NAICS code 336611).
- Dental Equipment and Supplies Manufacturing (NAICS code 339114).
- Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690).
- Petroleum Bulk Stations and Terminals (NAICS code 424710).
- Hazardous Waste Treatment and Disposal (NAICS code 562211).
- Solid Waste Combustors and Incinerators (NAICS code 562213).

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final section 6(a) rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Under section 6(a) of TSCA (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. Section 6(b)(4) (15 U.S.C. 2605(b)(4)) specifies that risk evaluations must be conducted without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use.

Since the original enactment of TSCA in 1976, EPA has addressed exposure to workers. For example, EPA routinely places restrictions on conditions of manufacturing, processing, distribution and use under the TSCA section 5 (15 U.S.C. 2604) new chemicals program. Further, as defined in TSCA, the term ''potentially exposed or susceptible subpopulation'' specifically includes workers. (15 U.S.C. 2602(12)). Thus, TSCA unambiguously provides EPA with the authority to address chemical risks to workers.

When issuing a rule under TSCA section 6(a), EPA must consider and publish a statement based on reasonably available information on the:

- Health effects of the chemical substance in question, TCE in this case, and the magnitude of human exposure to TCE;
- Environmental effects of TCE and the magnitude of exposure of the environment to TCE;
- Benefits of TCE for various uses; and the
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost-effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

For a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) expressly recognizes that EPA may issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6. TCE is such a chemical substance. It is listed in the 2014 update to the TSCA Work Plan and the completed risk assessment was published on June 25, 2014. The scope of the completed risk assessment includes aerosol degreasing and spot cleaning. The completed risk assessment also evaluated vapor degreasing, which EPA plans to address in a separate proposed rule.

C. What action is the Agency taking?

EPA has preliminarily determined that the use of TCE in aerosol degreasing and for spot cleaning in dry cleaning facilities presents an unreasonable risk of injury to health. Accordingly, EPA is proposing under section 6 of TSCA to prohibit the manufacture, processing, and distribution in commerce of TCE for use in aerosol degreasing and for use in spot cleaning in dry cleaning facilities; to prohibit commercial use of TCE for aerosol degreasing and for spot cleaning in dry cleaning facilities; and to require manufacturers, processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain (*e.g.,* via a Safety Data Sheet (SDS)) and to keep limited records. The application of this supply

chain approach is necessary so that the chemical substance no longer presents the identified unreasonable risks. EPA is requesting public comment on this proposal.

EPA's analysis of worker and consumer populations' exposures to TCE also preliminarily indicates that the use of TCE in vapor degreasing presents an unreasonable risk of injury to health. EPA intends to issue a separate proposed rule for TCE use in vapor degreasing, but plans to issue one final rule covering both today's proposal and the vapor degreasing proposal.

D. Why is the Agency taking this action?

Based on EPA's analysis of worker and consumer populations' exposures to TCE, EPA has preliminarily determined that the use of TCE in aerosol degreasing and as a spot cleaner in dry cleaning facilities presents an unreasonable risk to human health. More specifically, these uses result in significant non-cancer risks (acute and chronic exposure scenarios) and cancer risks. These adverse health effects include developmental toxicity (*e.g.,* cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to the kidney (kidney damage and kidney cancer), immunotoxicity (such as systemic autoimmune diseases, *e.g.,* scleroderma, and severe hypersensitivity skin disorder), non-Hodgkin's lymphoma, reproductive and endocrine effects (*e.g.,* decreased libido and potency), neurotoxicity (*e.g.,* trigeminal neuralgia), and toxicity to the liver (impaired functioning and liver cancer) (Ref. 1). TCE may cause fetal cardiac malformations that begin in utero. In addition, fetal death, possibly resulting from cardiac malformation, can be caused by exposure to TCE. Cardiac malformations can be irreversible and impact a person's health for a lifetime. In utero exposure to TCE may cause other effects, such as damage to the developing immune system, which manifest later in adult life and can have long-lasting health impacts. Certain effects that follow adult exposures, such as kidney and liver cancer, may develop many years after initial exposure.

As discussed in Unit I.C, EPA is not proposing to prohibit all manufacturing, processing, distribution in commerce, and use of TCE. The application of this supply chain approach tailored to specific uses that present unreasonable risk to human health is necessary so that the chemical substance no longer presents the identified unreasonable risks.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of multiple regulatory options, including the proposed approach of prohibiting the manufacture (including import), processing, and distribution in commerce of TCE for use in aerosol degreasing and for spot cleaning in dry cleaning facilities; prohibiting the commercial use of TCE for aerosol degreasing and for spot cleaning in dry cleaning facilities; and requiring manufacturers, processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain as well as associated recordkeeping requirements. This analysis, which is available in the docket, is discussed in Units VI and VII, and is briefly summarized here.

Costs of the proposed approach are discussed in Units VI.C.1 and VII.C.1. Alternatives to TCE are readily available at similar cost and performance. Blenders of TCE aerosol degreasers and spot cleaners are expected to reformulate their products. Reformulation costs are expected to be incurred during the first year and total $286,000 for reformulation of dry cleaning spot remover products and total $416,000 for aerosol degreasing products. Annualized costs of reformulation are approximately $32,000 per year (annualized at 3% over 15 years) and $41,000 (annualized at 7% over 15 years) for aerosol degreasing, and $22,000 per year (annualized at 3% over 15 years) and $28,000 (annualized at 7% over 15 years) for dry cleaning spot removers. Costs to users of aerosol degreasers and dry cleaning spotters are negligible as substitute products of similar performance are currently available on the market and are similarly priced (Ref. 2). Costs of downstream notification and recordkeeping are estimated to cost a total of $51,000 in the first year. On an annualized basis over 15 years are estimated to be approximately $3,900 and $5,000 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $112,000 and $109,000 annualized over 15 years at 3% and 7% respectively. Total costs of the proposed approach to prohibit manufacturing, processing, distribution in commerce for use of TCE in aerosol degreasing and for spot cleaning in dry cleaning facilities; commercial use of TCE in aerosol degreasing and spot cleaning in dry cleaning facilities; and require downstream notification and recordkeeping are estimated to be approximately $170,000 and $183,000 annualized over 15 years at 3% and 7% respectively. Total first-year costs to industry are estimated to be approximately $874,000 (Ref. 2).

Although TCE causes a wide range of non-cancer adverse effects and cancer, monetized benefits included only benefits associated with reducing cancer risks. The Agency does not have sufficient information to include a quantification or valuation estimate in the overall benefits at this time. The monetized benefits for the proposed approach range from approximately $9.3 million to $25.0 million on an annualized basis over 15 years at 3% and $4.5 million to $12.8 million at 7% (Ref. 2). There are also non-monetized benefits resulting from the prevention of the non-cancer adverse effects associated with TCE exposure from use in aerosol degreasing and spot cleaning for dry cleaning. These include developmental toxicity, toxicity to the kidney, immunotoxicity, reproductive and endocrine effects, neurotoxicity, and toxicity to the liver (Ref. 1). The adverse effects of TCE exposure as identified in the risk assessment include fetal cardiac malformations that begin in utero and fetal death. Cardiac malformations can be irreversible and impact a person's health for a lifetime. Other effects, such as damage to the developing immune system, may first manifest when a person is an adult and can have long-lasting health impacts. Certain effects that follow adult exposures, such as kidney and liver cancer, may develop many years after initial exposure. Also see Unit VIII.

Another alternative regulatory option considered was a respiratory protection program requiring an air-supplied respirator with an APF of 10,000. The costs of implementing a respiratory protection program, including a supplied-air respirator and related equipment, training, fit testing, monitoring, medical surveillance, and related requirements, would far exceed the costs of switching to alternatives, on a per facility basis. The estimated annualized costs of switching to a respiratory protection program requiring personal protective equipment (PPE) of 10,000 are $8,200 at 3% and $9,000 at 7% per dry cleaning facility and $8,300 at 3% and $9,100 at 7% per aerosol degreasing facility over 15 years. In addition, there would be higher EPA administration and enforcement costs with a respiratory protection program than there would be with an enforcement program under the proposed approach. The higher costs of this option render this option a less cost effective option than the proposed

approach at addressing the identified unreasonable risks so TCE no longer presents such risks.

F. Children's Environmental Health

This action is consistent with the 1995 EPA Policy on Evaluating Health Risks to Children (*http://www.epa.gov/children/epas-policy-evaluating-risk-children*). EPA has identified women of childbearing age and the developing fetus as a susceptible subpopulation relevant to its risk assessment for TCE. After evaluating the developmental toxicity literature for TCE, the TCE Integrated Risk Information System (IRIS) assessment concluded that fetal heart malformations are the most sensitive developmental toxicity endpoint associated with TCE inhalation exposure (Ref. 3). In its TSCA Chemical Work Plan Risk Assessment for TCE, EPA identified developmental toxicity as the most sensitive endpoint for TCE inhalation exposure (*i.e.,* fetal heart malformations; Ref. 1) for the most sensitive human life stage (*i.e.,* women of childbearing age between the ages of 16 and 49 years and the developing fetus) (Ref. 1). EPA used developmental toxicity endpoints for both the acute and chronic non-cancer risk assessments based on its developmental toxicity risk assessment policy that a single exposure of a chemical within a critical window of fetal development may produce adverse developmental effects (Ref. 33). While the proposed regulatory action is protective of the fetal heart malformation endpoint and is also protective of cancer risk from chronic exposure, the supporting non-cancer risk analysis of children and women of childbearing age conducted in the TSCA Chemical Work Plan Risk Assessment for TCE (Ref. 1) also meets the 1995 EPA Policy on Evaluating Health Risks to Children. Supporting information on TCE exposures and the health effects of TCE exposure on children are available in the Toxicological Review of Trichloroethylene (Ref. 3) and the TSCA Chemical Work Plan Risk Assessment on Trichloroethylene (Ref. 1), as well as Units VI.B.1.c and VII.B.1.c of this preamble.

II. Overview of TCE and Uses Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule would apply to TCE (Chemical Abstract Services Registry Number 79–01–6) for use in aerosol degreasing and for spot cleaning in dry cleaning facilities.

B. What are the uses of TCE and how can people be exposed?

In 2011, global consumption of TCE was 945 million pounds and consumption in the United States was 255 million pounds. TCE is produced within and imported into the United States. Nine companies, including domestic manufacturers and importers, reported a total production and import of 225 million pounds of TCE in 2011 to EPA pursuant to the Chemical Data Reporting CDR rule (Ref. 1).

Individuals, including workers, consumers and the general population, are exposed to TCE from industrial/commercial, consumer, and environmental sources, in different settings such as homes and workplaces, and through multiple exposure pathways (air, water, soil) and routes (inhalation, ingestion, dermal).

The majority (about 83.6%) of TCE is used as an intermediate chemical for manufacturing refrigerant HFC-134a. This use occurs in a closed system that has low potential for human exposure (Ref. 1). EPA did not assess this use and is not proposing to regulate this use of TCE under TSCA. Much of the remainder, about 14.7 percent, is used as a solvent for degreasing of metals. A relatively small percentage, about 1.7 percent, accounts for all other uses, including TCE use in products, such as aerosol degreasers and spot cleaners.

Based on the Toxics Release Inventory (TRI) data for 2012, 38 companies used TCE as a formulation component, 33 companies processed TCE by repackaging the chemical, 28 companies used TCE as a manufacturing aid, and 1,113 companies used TCE for ancillary uses, such as degreasing (Ref. 1). Based on the latest TRI data from 2014, the number of users of TCE has significantly decreased since 2012: 24 companies use TCE as a formulation component, 20 companies process TCE by repackaging the chemical, 20 companies use TCE as a manufacturing aid, and 97 companies use TCE for ancillary uses, such as degreasing.

The uses assessed by EPA that are the subject of this proposal, the use of TCE in aerosol degreasing and for spot cleaning in dry cleaning facilities, are estimated to represent up to 1.7 percent of total use of TCE. Aerosol degreasing is the use of TCE in aerosol spray products applied from a pressurized can to remove residual contaminants from fabricated parts. Spot cleaning is the use of TCE in dry cleaning facilities to clean stained areas on textiles or clothing. These uses are discussed in detail in Units VI and VII.

C. What are the potential health effects of TCE?

A broad set of relevant studies including epidemiologic studies, animal bioassays, metabolism studies, and mechanistic studies show that TCE exposure is associated with an array of adverse health effects. TCE has the potential to induce developmental toxicity, immunotoxicity, kidney toxicity, reproductive and endocrine effects, neurotoxicity, liver toxicity, and several forms of cancer (Ref. 1).

TCE is fat soluble (lipophilic) and easily crosses biological membranes. TCE has been found in human maternal and fetal blood and in the breast milk of lactating women (Ref. 1). EPA's Integrated Risk Information System (IRIS) assessment (Ref. 3) concluded that TCE poses a potential health hazard for non-cancer toxicity including fetal heart malformations and other developmental effects, immunotoxicity, kidney toxicity, reproductive and endocrine effects, neurotoxicity, and liver effects. The IRIS assessment also evaluated TCE and its metabolites. Based on the results of *in vitro* and *in vivo* tests, TCE metabolites have the potential to bind or induce damage to the structure of deoxyribonucleic acid (DNA) or chromosomes (Ref. 3).

An evaluation of the overall weight of the evidence of the human and animal developmental toxicity data suggests an association between pre- and/or post-natal TCE exposures and potential adverse developmental outcomes. TCE-induced heart malformations and immunotoxicity in animals have been identified as the most sensitive developmental toxicity endpoints for TCE. Human studies examined the possible association of TCE with various prenatal effects. These adverse effects of developmental TCE exposure may include: Fetal death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions); decreased growth (low birth weight, small for gestational age); congenital malformations, in particular heart defects; and postnatal effects such as growth, survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers. Some epidemiological studies reported an increased incidence of birth defects in TCE-exposed populations from exposure to contaminated water. As for human developmental neurotoxicity, studies collectively suggest that the developing brain is susceptible to TCE toxicity. These studies have reported an association with TCE exposure and central nervous system birth defects and postnatal effects such as delayed

newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit disorder (Ref. 1).

Immune-related effects following TCE exposures have been observed in adult animal and human studies. In general, these effects were associated with inducing enhanced immune responses as opposed to immunosuppressive effects. Human studies have reported a relationship between systemic autoimmune diseases, such as scleroderma, with occupational exposure to TCE. There have also been a large number of case reports in TCE-exposed workers developing a severe hypersensitivity skin disorder, often accompanied by systemic effects to the lymph nodes and other organs, such as hepatitis (Ref. 1).

Studies in both humans and animals have shown changes in the proximal tubules of the kidney following exposure to TCE (Ref. 1). The TCE IRIS assessment concluded that TCE is carcinogenic to humans based on convincing evidence of a causal relationship between TCE exposure in humans and kidney cancer (Ref. 3). A recent review of TCE by the International Agency for Research on Cancer (IARC) also supported this conclusion (Ref. 4). The 13th report on carcinogens (RoC) by the National Toxicology Program also concluded that TCE is reasonably anticipated to be a human carcinogen 2015 (Ref. 5). These additional recent peer reviews are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposure based upon strong epidemiological and animal evidence (Refs. 1 and 3).

TCE metabolites appear to be the causative agents that induce renal toxicity, including cancer. S-dichlorovinyl-L-cysteine (DCVC), and to a lesser extent other metabolites, appears to be responsible for kidney damage and kidney cancer following TCE exposure. Toxicokinetic data suggest that the TCE metabolites derived from glutathione conjugation (in particular DCVC) can be systemically delivered or formed in the kidney. Moreover, DCVC-treated animals showed the same type of kidney damage as those treated with TCE (Ref. 1). The toxicokinetic data and the genotoxicity of DCVC further suggest that a mutagenic mode of action is involved in TCE-induced kidney tumors, although cytotoxicity followed by compensatory cellular proliferation cannot be ruled out. As for the mutagenic mode of action, both genetic polymorphisms (Glutathione transferase (GST) pathway) and mutations to tumor suppressor genes have been hypothesized as possible mechanistic key events in the formation of kidney cancers in humans (Ref. 1).

The toxicological literature provides support for male and female reproductive effects following TCE exposure. Both the epidemiological and animal studies provide evidence of adverse effects to female reproductive outcomes. However, more extensive evidence exists in support of an association between TCE exposures and male reproductive toxicity. There is evidence that metabolism of TCE in male reproductive tract tissues is associated with adverse effects on sperm measures in both humans and animals. Furthermore, human studies support an association between TCE exposure and alterations in sperm density and quality, as well as changes in sexual drive or function and altered serum endocrine levels (Ref. 1).

Neurotoxicity has been demonstrated in animal and human studies under both acute and chronic exposure conditions. Evaluation of multiple human studies revealed TCE-induced neurotoxic effects including alterations in trigeminal nerve and vestibular function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. These studies in different populations have consistently reported vestibular system-related symptoms such as headaches, dizziness, and nausea following TCE exposure (Ref. 1).

Animals and humans exposed to TCE consistently experience liver toxicity. Specific effects include the following structural changes: Increased liver weight, increase in DNA synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation. Several human studies reported an association between TCE exposure and significant changes in serum liver function tests used in diagnosing liver disease, or changes in plasma or serum bile acids. There was also human evidence for hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure in TCE-exposed workers (Ref. 1).

TCE is characterized as carcinogenic to humans by all routes of exposure as documented in EPA's TCE IRIS assessment (Ref. 3). This conclusion is based on strong cancer epidemiological data that reported an association between TCE exposure and the onset of various cancers, primarily in the kidney, liver, and the immune system, *i.e.,* non-Hodgkin's lymphoma (NHL). Further support for TCE's characterization as a carcinogen comes from positive results in multiple rodent cancer bioassays in rats and mice of both sexes, similar toxicokinetics between rodents and humans, mechanistic data supporting a mutagenic mode of action for kidney tumors, and the lack of mechanistic data supporting the conclusion that any of the mode(s) of action for TCE-induced rodent tumors are irrelevant to humans. Additional support comes from the 2014 evaluation of TCE's carcinogenic effects by IARC, which classifies TCE as carcinogenic to humans (Ref. 4). The 13th Report on Carcinogens (RoC) by the National Toxicology Program also concluded that TCE exposure is reasonably anticipated to be a human carcinogen (Ref. 5). These additional recent peer reviewed documents are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposure based upon strong epidemiological and animal evidence (Refs. 1 and 3).

D. What are the environmental impacts of TCE?

Pursuant to Section 6(c) of TSCA, EPA in this section describes the effects of TCE on the environment and the magnitude of the exposure of the environment to TCE. The unreasonable risk preliminary determination of this proposal, however, is based solely on risks to human health since these risks are the most serious consequence of use of TCE and are sufficient to support this proposed action.

1. *Environmental effects and impacts.* TCE enters the environment as a result of emissions from metal degreasing facilities, and spills or accidental releases, and historic waste disposal activities. Because of its high vapor pressure and low affinity for organic matter in soil, TCE evaporates fairly rapidly when released to soil; however, where it is released onto land surface or directly into the subsurface, TCE can migrate from soil to groundwater (Ref. 1). Based on TCE's moderate persistence, low bioaccumulation, and low hazard for aquatic toxicity, the magnitude of potential environmental impacts on ecological receptors is judged to be low for the environmental releases associated with the use of TCE for spot cleaning in dry cleaning facilities and in aerosol degreasers. This should not be misinterpreted to mean that the fate and transport properties of TCE suggest that water and soil contamination is likely low or does not pose an environmental concern. EPA is addressing TCE contamination in

groundwater, drinking water, and contaminated soils at a large number of sites. While the primary concern with this contamination has been human health, there is potential for TCE exposures to ecological receptors in some cases (Ref. 1).

2. *What is the global warming potential of TCE?* Global warming potential (GWP) measures the potency of a greenhouse gas over a specific period of time, relative to carbon dioxide, which has a high GWP of 1 regardless of the time period used. Due to high variability in the atmospheric lifetime of greenhouse gases, the 100-year scale (GWP100) is typically used. TCE has relatively low global warming potential at a GWP100 of 140 and thus the impact is low (Ref. 1).

3. *What is the ozone depletion potential of TCE?* TCE is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy (SNAP) program for degreasing and aerosols. In 2007, TCE was identified as a substitute for two ozone depleting chemicals, methyl chloroform and CFC–113, for metals, electronics, and precision cleaning (72 FR 30142, May 30, 2007) (FRL–8316–8) (Ref. 6).

4. *Is TCE a volatile organic compound (VOC)?* TCE is a VOC as defined at 40 CFR 51.100(c). A VOC is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions.

5. *Does TCE persist in the environment and bioaccumulate?* TCE may be persistent, but it is not bioaccumulative. TCE is slowly degraded by sunlight and reactants when released to the atmosphere. Volatilization and microbial biodegradation influence the fate of TCE when released to water, sediment or soil. The biodegradation of TCE in the environment is dependent on a variety of factors and so a wide range of degradation rates have been reported (ranging from days to years). TCE is not expected to bioconcentrate in aquatic organisms based on measured bioconcentration factors of less than 1000 (Ref. 1).

III. Regulatory Actions Pertaining to TCE

Because of its potential health effects, TCE is subject to state, federal, and international regulations restricting and regulating its use, which are summarized in this section. None of these actions addresses the unreasonable risks under TSCA that EPA is seeking to address in this proposed rule.

A. Federal Actions Pertaining to TCE

Since 1979, EPA has issued numerous final rules and notices pertaining to TCE under its various authorities.

- *Safe Drinking Water Act:* EPA issued drinking water standards for TCE pursuant to section 1412 of the Safe Drinking Water Act. EPA promulgated the National Primary Drinking Water Regulation (NPDWR) for TCE in 1987 (52 FR 25690, July 8, 1987). The NPDWR established a non-enforceable maximum contaminant level (MCL) goal of zero mg/L based on classification as a probable human carcinogen. The NPDWR also established an enforceable MCL of 0.005 mg/L based on analytical feasibility. EPA is evaluating revising the TCE drinking water standard as part of a group of carcinogenic volatile organic compounds.
- *Clean Water Act:* EPA identified TCE as a toxic pollutant under section 307(a)(1) of the Clean Water Act (33 U.S.C. 1317(a)(1)) in 1979 (44 FR 44502, July 30, 1979) (FRL–1260–5). In addition, EPA developed recommended TCE ambient water quality criteria for the protection of human health pursuant to section 304(a) of the Clean Water Act.
- *Clean Air Act:* TCE is designated a hazardous air pollutant (HAP) under the Clean Air Act (42 U.S.C. 7412(b)(1)). EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) for TCE for several industrial source categories, including halogenated solvent cleaning, fabric printing, coating, and dyeing, and synthetic organic chemical manufacturing.
- *Resource Conservation and Recovery Act (RCRA):* EPA classifies certain wastes containing TCE as hazardous waste subject to Subtitle C of RCRA pursuant to the toxicity characteristics or as a listed waste. RCRA also provides authority to require cleanup of hazardous wastes containing TCE at RCRA facilities.
- *Comprehensive Environmental Response, Compensation and Liability Act (CERCLA):* EPA designated TCE as a hazardous substance with a reportable quantity pursuant to section 102(a) of CERCLA and EPA is actively overseeing cleanup of sites contaminated with TCE pursuant to the National Contingency Plan (NCP).

While many of the statutes that EPA is charged with administering provide statutory authority to address specific sources and routes of TCE exposure, none of these can address the serious human health risks from TCE exposure that EPA is proposing to address under TSCA section 6(a) today.

The Occupational Safety and Health Administration (OSHA) established a permissible exposure limit (PEL) for TCE in 1971. The PEL is an 8-hour time-weighted average (TWA) TCE concentration of 100 ppm. In addition, the TCE PEL requires that exposures to TCE not exceed 200 ppm (ceiling) at any time during an eight hour work shift with the following exception: Exposures may exceed 200 ppm, but not more than 300 ppm (peak), for a single time period up to 5 minutes in any 2 hours (Refs. 7 and 8). OSHA acknowledges that many of its PELs are not protective of worker health. OSHA has noted that ''with few exceptions, OSHA's PELs, which specify the amount of a particular chemical substance allowed in workplace air, have not been updated since they were established in 1971 under expedited procedures available in the short period after the OSH Act's adoption . . . Yet, in many instances, scientific evidence has accumulated suggesting that the current limits are not sufficiently protective.'' (Ref. 9 at p. 61386), including the PEL for TCE (Ref. 65).

To provide employers, workers, and other interested parties with a list of alternate occupational exposure limits that may serve to better protect workers, OSHA's Web page highlights selected occupational exposure limits derived by other organizations. For example, the National Institute for Occupational Safety and Health considers TCE a potential occupational carcinogen and recommended an exposure limit of 25 ppm as a 10-hour TWA in 2003 (Ref. 10). The American Conference of Governmental Industrial Hygienists recommended an 8-hour TWA of 10 ppm and acute, or short-term, exposure limit of 25 ppm in 2004 (Ref. 11).

B. State Actions Pertaining to TCE

Many states have taken actions to reduce risks from TCE use. TCE is listed on California's Safer Consumer Products regulations candidate list of chemicals that exhibit a hazard trait and are on an authoritative list, and is also listed on California's Proposition 65 list of chemicals known to cause cancer or birth defects or other reproductive harm. In addition, the California Code of Regulations, Title 17, Section 94509(a) lists standards for VOCs for consumer products sold, supplied, offered for sale, or manufactured for use in California (Ref. 12). As part of that regulation, use of consumer general purpose degreaser products that contain TCE are banned in California and safer substitutes are in use.

In Massachusetts, TCE is a designated high hazard substance, with an annual reporting threshold of 1,000 pounds (Ref. 13). Minnesota classifies TCE as a chemical of high concern. Many other states have considered TCE for similar chemical listings (Ref. 14). Several additional states have various TCE regulations that range from reporting requirements to product contamination limits to use reduction efforts aimed at limiting or prohibiting TCE content in products.

Most states have set PELs identical to the OSHA 100 ppm 8-hour TWA PEL (Ref. 15). Nine states have PELs of 50 ppm (Ref. 15). California's PEL of 25 ppm is the most stringent (Ref. 12). All of these PELs are significantly higher than the exposures at which EPA identified unreasonable risks for TCE use in aerosol degreasers and for spot cleaning in dry cleaning facilities and would not be protective.

C. International Actions Pertaining to TCE

TCE is also regulated internationally and the international industrial and commercial sectors have moved to alternatives. TCE is prohibited for use in the European Union (EU) as an aerosol degreaser and spotting agent at dry cleaning facilities based on its classification as a carcinogenic substance (Ref. 16). TCE was added to the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) restriction of substances classified as a carcinogen category 1B under the EU Classification and Labeling regulation in 2009 (Ref. 16). The restriction prohibits the placing on the market or use of TCE as a substance, as a constituent of other substances, or in mixtures for supply to the general public when the individual concentration of TCE in the substance or mixture is equal to or greater than 0.1% by weight (Ref. 16). In 2010, TCE was added to the Candidate List of substances for inclusion in Annex XIV of REACH, or the Authorisation List. Annex XIV includes Substances of Very High Concern that are subject to use authorization due to their hazardous properties. TCE meets the criteria for classification as a carcinogen. In 2011, TCE was recommended for inclusion in Annex XIV of REACH due to the very high volumes allocated to uses in the scope of authorization and because at least some of the described uses appeared to result in significant exposure of workers and professionals, and could be considered widely dispersive uses. In 2013, the Commission added TCE to Annex XIV of REACH, making it subject to authorization. As such, entities that wanted to use TCE were required to apply for authorization by October 2014, and those entities without an authorization were required to stop using TCE by April 2016. The European Chemicals Agency (ECHA) received 19 applications for authorization from entities interested in using TCE beyond April 2016. None of the applications were for use of TCE in aerosol degreasers or for spot cleaning in dry cleaning facilities (Ref. 16).

Canada conducted a hazard assessment of TCE in 1993 and concluded that ''trichloroethylene occurs at concentrations that may be harmful to the environment, and that may constitute a danger in Canada to human life or health. It has been concluded that trichloroethylene occurs at concentrations that do not constitute a danger to the environment on which human life depends'' (Ref. 17). In 2003, Canada issued the Solvent Degreasing Regulations (SOR/2003–283) to reduce releases of TCE into the environment from solvent degreasing facilities using more than 1,000 kilograms of TCE per year (Ref. 17). In 2013, Canada added TCE to the Toxic Substances List—Schedule 1 because TCE was found to be toxic under conditions (a) and (c) of Section 64(a) of the Canadian Environmental Protection Act (CEPA) because it ''is entering or may enter the environment in a quantity or concentration or under conditions that: (a) Have or may have an immediate or chronic harmful effect on the environment or its biological diversity, and (c) constitute or may constitute a danger in Canada to human life or health.'' (Ref. 18).

In Japan, the Chemical Substances Control Law considers TCE a Class II substance (substances that may pose a risk of long-term toxicity to humans or to flora and fauna in the human living environment, and that have been, or in the near future are reasonably likely to be, found in considerable amounts over a substantially extensive area of the environment) (Ref. 19). Japan also controls air emissions and water discharges containing TCE, as well as aerosol products for household use and household cleaners containing TCE.

TCE is listed in the Australian National Pollutant Inventory, a program run cooperatively by the Australian, State and Territory governments to monitor common pollutants and their levels of release to the environment. Australia classifies TCE as a health, physicochemical and/or ecotoxicological hazard, according to the Australian National Occupational Health and Safety Commission (Ref. 20).

IV. TCE Risk Assessment

In 2013, EPA identified TCE use as a solvent degreaser (aerosol degreasing and vapor degreasing) and spot remover in dry cleaning operations as a priority for risk assessment under the TSCA Work Plan. This Unit describes the development of the TCE risk assessment and supporting analysis and expert input on the uses that are the subject of this proposed rule. A more detailed discussion of the risks associated with each use subject to today's proposed rule can be found in Units VI and VII.

A. TSCA Work Plan for Chemical Assessments

In 2012, EPA released the TSCA Work Plan Chemicals: Methods Document in which EPA described the process the Agency intended to use to identify potential candidate chemicals for near-term review and assessment under TSCA (Ref. 21). EPA also released the initial list of TSCA Work Plan chemicals identified for further assessment under TSCA as part of its chemical safety program (Ref. 22).

The process for identifying these chemicals for further assessment under TSCA was based on a combination of hazard, exposure, and persistence and bioaccumulation characteristics, and is described in the TSCA Work Plan Chemicals Methods Document (Ref. 21). Using the TSCA Work Plan chemical prioritization criteria, TCE ranked high for health hazards and exposure potential and was included on the initial list of TSCA Work Plan chemicals for assessment.

B. TCE Risk Assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for TCE (TCE risk assessment) in June 2014, following the July 2013 peer review of the December 2012 draft TCE risk assessment. All documents from the July 2013 peer review of the draft TCE risk assessment are available in EPA Docket Number EPA–HQ–OPPT–2012–0723. TCE appears in the 2014 update of the TSCA Work Plan for Chemical Assessments and the completed risk assessment is noted therein. The draft TCE risk assessment evaluated commercial and consumer use of TCE as a solvent degreaser (aerosol degreasing and vapor degreasing) and consumer use of TCE as a spray-applied protective coating for arts and crafts (Ref. 1). In response to specific comments and information provided by the peer reviewers, the commercial use of TCE as a spotting agent at dry cleaning facilities was evaluated, using the near-field/far-field mass balance approach, for the

final risk assessment. The use of TCE in commercial/industrial vapor degreasing, and in arts and crafts, is not addressed in today's proposal. EPA intends to issue a separate proposed rule on TCE use in vapor degreasers at commercial/industrial facilities soon. EPA also published a final Significant New Use Rule (SNUR) that would require manufacturers (including importers) and processors of TCE to notify the Agency before starting or resuming any significant new uses of TCE in certain consumer products, including in spray fixatives used to finish arts and crafts (81 FR 20535; April 8, 2016).

The TCE risk assessment evaluated health risks to consumers and workers, including occupational bystanders, from inhalation exposures to TCE. A summary of the peer review and public comments, along with EPA's response, is available in the docket for the risk assessment and can be accessed electronically at *https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0723-0039.* While solvent degreasing (both aerosol and vapor) is within the scope of the TCE risk assessment, with respect to aerosol degreasing, the assessment targeted consumer use of specific products. Therefore, using the peer reviewed near-field/far-field mass balance approach that was used in the risk assessment, EPA performed supplemental analyses of worker and bystander inhalation risk from TCE aerosol degreaser use in occupational settings. The TCE risk assessment identified primary uses of TCE and selected uses including aerosol degreasing and spot cleaning in dry cleaning facilities as those that were expected to involve frequent or routine use of TCE in high concentrations and/or have high potential for human exposure (Refs. 1, 23, 24, and 25) and therefore were included in the scope of the risk assessment. However, this does not mean that EPA determined that other uses not included in the TCE risk assessments present low risk.

The TCE risk assessment identified acute non-cancer risks (*i.e.,* developmental effects) for most occupational and consumer exposure scenarios, including commercial vapor degreasing, spot cleaning, and consumer aerosol degreasing exposure scenarios (Ref. 1). For chronic non-cancer risks there is a range of human health effects in both the occupational vapor degreasing and spot cleaning exposure scenarios with the greatest concern for developmental effects (*i.e.,* fetal cardiac defects), as well as kidney effects and immunotoxicity. In addition, there are chronic non-cancer risks for adverse reproductive effects, neurotoxicity, and liver toxicity (Ref. 1).

Margins of exposure (MOEs) were used in this assessment to estimate non-cancer risks for acute and chronic exposures. The MOE is the health point of departure (an approximation of the no-observed adverse effect level (NOAEL) for a specific endpoint divided by the exposure concentration for the specific scenario of concern. The benchmark MOE accounts for the total uncertainty factor based on the following uncertainty factors: Intraspecies, interspecies, subchronic to chronic, and lowest observed adverse effect level (LOAEL) to NOAEL. Uncertainty factors are intended to account for (1) the variation in sensitivity among the members of the human population (*i.e.,* interhuman or intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (*i.e.,* interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (*i.e.,* extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a LOAEL rather than from a NOAEL (Ref. 26). MOEs provide a non-cancer risk profile by presenting a range of estimates for different non-cancer health effects for different exposure scenarios, and are a widely recognized method for evaluating a range of potential non-cancer health risks from exposure to a chemical.

The TCE risk assessment estimated acute non-cancer risks for consumers and residential bystanders from the use of TCE-containing aerosol degreasers and spray-applied protective coatings. Exposure scenarios with MOEs below the benchmark MOE have significant risks of concern and typically, non-cancer adverse effects are more likely to result from exposure scenarios with MOEs below the benchmark MOE. For non-cancer effects EPA estimated exposures that are significantly larger than the point of departure. The TCE risk assessment also estimated acute non-cancer risk for workers and occupational bystanders for uses including spot cleaning in dry cleaning facilities.

The TCE risk assessment also estimated chronic non-cancer risk for workers and occupational bystanders for uses including spot cleaning in dry cleaning facilities. These include developmental toxicity, toxicity to the kidney, immunotoxicity, reproductive and endocrine effects, neurotoxicity, and toxicity to the liver.

There are also cancer risks for persons occupationally exposed to TCE when using TCE-containing spot cleaners in dry cleaning facilities. For users of TCE-containing spot cleaning products, these cancer risks are 1.35×10^{-2} for spot cleaning. In the supplemental analysis following the TCE risk assessment, EPA also identified acute and chronic non-cancer and cancer risks for the commercial aerosol degreasing use scenario for workers and occupational bystanders using aerosol degreasers (Ref. 23).

The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also result in low risk for cancer.

Given the risks identified in the TCE risk assessment, the agency undertook further analysis to help determine whether the use of TCE for spot cleaning in dry cleaning facilities and in aerosol degreasers poses an unreasonable risk.

C. Supplemental Analysis Using the Methodology of the TCE Risk Assessment

Because the TCE risk assessment concentrated on consumer use of aerosol degreasers and because the aerosol degreaser products available to consumers are also available to commercial users, following release of the TCE risk assessment, EPA analyzed the risk to workers and occupational bystanders from commercial use of TCE-containing aerosol degreasers and identified short-term and long-term non-cancer and cancer risks for the commercial aerosol degreasing use scenario (Ref. 23). This analysis is consistent with the scope of the TCE risk assessment and was based on the peer-reviewed near-field/far-field mass balance approach that was used in the TCE risk assessment (Ref. 1). EPA also conducted supplemental analyses of various parameters of exposure scenarios, consistent with the methodology used in the risk assessment, on the use of TCE-containing aerosol degreasers by consumers and use of TCE for spot cleaning in dry cleaning facilities. Prior to promulgation of the final rule, EPA will peer review the ''Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Aerosol Degreasing'' (Ref. 25) and the exposure assessment for TCE use in spot cleaning in dry cleaning facilities in the ''TSCA Work Plan Chemical Risk Assessment. Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses'' (Ref. 1).

D. Expert Meeting on TCE

On July 29, 2014, EPA held a 2-day public workshop on TCE degreasing (Ref. 27). The purpose of the workshop was to collect information from users, academics, and other stakeholders on the use of TCE as a degreaser in various applications, *e.g.,* in degreasing metal parts, availability and efficacy of safer alternatives, safer engineering practices and technologies to reduce exposure to TCE, and to discuss possible risk reduction approaches. The workshop included presentations by experts, breakout sessions with case studies, and public comment opportunities (Ref. 27) and informed EPA's assessment of the alternatives to TCE considered in this proposed rule. All documents from the public workshop are available in EPA Docket Number EPA–HQ–OPPT–2014–0327. Informed in part by the workshop and other analysis, including discussion with Toxics Use Reduction Institute at the University of Massachusetts Lowell, EPA has concluded that TCE alternatives are available for all applications subject to this proposed rule (Ref. 2). The discussions of the meeting demonstrated that alternatives are available for aerosol uses that are being addressed in this proposed rulemaking.

V. Regulatory Approach

A. TSCA Section 6 Unreasonable Risk Analysis

Under section 6(a) of TSCA, if the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the Agency's risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

The section 6(a) requirements can include one or more, or a combination of, the following actions:

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).
- Prohibit or otherwise restrict manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration (§ 6(a)(2)).
- Require minimum warning labels and instructions (§ 6(a)(3)).
- Require record keeping or testing (§ 6(a)(4)).
- Prohibit or regulate any manner or method of commercial use (§ 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal (§ 6(a)(6)).
- Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances (§ 6(a)(7)).

EPA analyzed a wide range of regulatory options under section 6(a) for each use in order to determine the proposed regulatory approach (Refs. 28 and 29). For each use, EPA considered whether a regulatory option (or combination of options) would address the identified unreasonable risks so that it no longer presents such risks. To do so, EPA initially analyzed whether the regulatory options could reduce risks (non-cancer and cancer) so that TCE no longer presents unreasonable risks, based on EPA's technical analysis of exposure scenarios. For the non-cancer risks, EPA determined an option could be protective against the risk if it could achieve the benchmark MOE for the most sensitive non-cancer endpoint. EPA's assessments for these uses indicate that when exposures meet the benchmark MOE for the most sensitive endpoint, they also result in low risk for cancer.

After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered how reliably the regulatory options would actually reach these benchmarks. In determining whether a regulatory option would impose requirements to the extent necessary so that TCE no longer presents the identified unreasonable risks, the Agency considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks in relation to the benchmarks, as well as whether the option's protectiveness was impacted by environmental justice or children's health concerns.

B. Section 6(c)(2) considerations. As noted previously, TSCA section 6(c)(2) requires EPA to factor in, to the extent practicable, the following considerations in selecting regulatory requirements:

- Health effects of TCE and the magnitude of human exposure to TCE;
- Environmental effects of TCE and the magnitude of exposure of the environment to TCE;
- Benefits of TCE for various uses;
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost-effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

In deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's analysis of the regulatory options and consideration of the TSCA section 6(c)(2) factors are discussed in more detail in Unit VI for aerosol degreasing and in Unit VII for spot cleaning in dry cleaning facilities.

To the extent information was available, EPA considered the benefits realized from risk reductions (including monetized benefits, non-monetized quantified benefits, and qualitative benefits), offsets to benefits from countervailing risks (*e.g.,* residual risk risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children or other susceptible subpopulations (as compared to the general population), and the cost of regulatory requirements for the various options.

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. For example, an option that includes use of a respirator would include inspections to evaluate compliance with all elements of a respiratory protection program (Ref. 30). EPA took into account the available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives (*e.g.,* PPE). Available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options.

C. Regulatory Options Receiving Limited Evaluation

As discussed previously, EPA analyzed a wide range of regulatory options under TSCA section 6(a). Early in the process, EPA identified two

regulatory options under section 6(a) that do not pertain to this action and were therefore not evaluated for this proposed rulemaking. First, EPA determined that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture, processing or distribution in commerce of TCE or limit the amount of TCE which may be manufactured, processed or distributed in commerce is not applicable because the Agency is not proposing to ban or limit the manufacture, processing or distribution in commerce of TCE for uses other than in aerosol degreasing or for spot cleaning in dry cleaning facilities at this time. In addition, EPA determined that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not assess risks associated with TCE disposal.

Another option EPA evaluated would require warning labels and instructions on TCE-containing aerosol degreasers and for spot cleaning in dry cleaning facilities pursuant to section 6(a)(3) (Refs. 28 and 29). The Agency determined that warning labels and instructions alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users. The Agency based this determination on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies (Ref. 37).

These conclusions are based on the weight-of-evidence analysis that EPA conducted of the available literature on the efficacy of labeling and warnings. This analysis indicates that a label's effectiveness at changing user behavior to comply with instructions and warnings depends not only on attributes of the label and the user, but also on the multiple steps required in the processes of attention, comprehension, judgment, and action (Ref. 37).

Numerous studies have found that product labels and warnings are effective to some degree. However, the extent of the effectiveness has varied considerably across studies and some of the perceived effectiveness may not reflect real-world situations. This is because interactions among labels, users, the environment, and other factors greatly influence the degree of a label's effectiveness at changing user behavior (Ref. 37). In addition, while some studies have shown that different components of labels and warnings tend to have some influence, the evidence does not suggest that labels alone would be sufficient to ensure that users take the steps needed to protect themselves.

The Agency further determined that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user would need to read, understand, and act upon is extremely complex. When the precaution or information is simple or uncomplicated (*e.g.,* do not mix this cleaner with bleach or do not mix this cleaner with ammonia), it is more likely the user will successfully understand and follow the direction. In contrast, it would be challenging to most users to follow the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor, and window periods during pregnancy when the developing fetus is susceptible to adverse effects from acute exposures, as well as effects to bystanders. It is unlikely that label language changes will for this use result in widespread, consistent, and successful adoption of risk reduction measures by users.

Additionally, any use of labels to promote or regulate safe product use should be considered in the context of other potential risk reduction techniques. As highlighted by a 2014 expert report for the Consumer Product Safety Commission (CPSC), ''safety and warnings literature consistently identify warnings as a less effective hazard-control measure than either designing out a hazard or guarding the consumer from a hazard. Warnings are less effective primarily because they do not prevent consumer exposure to the hazard. Instead, they rely on persuading consumers to alter their behavior in some way to avoid the hazard'' (Ref. 38).

While this regulatory option alone does not address the risks, EPA recognizes that the section 6(a)(3) warnings and instruction requirement can be an important component to an approach for addressing unreasonable risks associated with TCE use in aerosol degreasers and for spot cleaning in dry cleaning facilities and has included a very simple downstream notification requirement as part of the proposed rulemaking.

VI. Regulatory Assessment of TCE Use in Aerosol Degreasing

This Unit describes the current use of TCE in aerosol degreasing, the unreasonable risks presented by this use, and how EPA preliminarily determined which regulatory options are necessary to address those unreasonable risks.

A. Description of the Current Use

Aerosol degreasing is a process that uses aerosol spray products, typically applied from a pressurized can, to remove residual contaminants from parts. The aerosol droplets bead up on the fabricated part and then drip off, carrying away any contaminants and leaving behind a clean surface. Components of an item can be cleaned in place or removed from the item for more thorough cleaning. Aerosol degreasers can also be sprayed onto a rag that is used to wipe components clean.

Aerosol degreasers are primarily used for niche industrial or manufacturing uses and some commercial service uses, such as degreasing of metals, degreasing of electrical motors, and electronic cleaners. One example of a commercial setting for the aerosol degreaser use is repair shops, where service items are cleaned to remove any contaminants that would otherwise compromise the item's operation. Internal components may be cleaned in place or removed from the item, cleaned, and then re-installed once dry. EPA identified 16 different aerosol spray degreaser products that contain TCE, blended by 6 different firms. EPA estimates that about 2,200 commercial facilities use TCE aerosol spray degreasers (Ref. 2). EPA requests comment on uses of TCE aerosol degreasers and TCE aerosol degreasing products that the agency did not identify.

Consumer use of TCE in aerosol degreasers is similar to commercial use but occurs in consumer settings. The aerosol products used in consumer settings are the same as those used in commercial settings. TCE use is very limited in products intended for consumers due to existing VOC regulations in California and in a number of northeast, mid-Atlantic, and Midwestern states. Consumer Specialty Products Association (CSPA) member

companies have consistently stated that they do not formulate TCE to be sold into consumer products, and the products are generally only sold in the commercial supply chains (Ref. 31). However, due to the wide availability of products available on the Internet and through various suppliers that serve commercial and consumer customers, consumers are able to purchase aerosol degreasing products containing TCE. As a result, EPA evaluated consumer exposures to aerosol degreasers containing TCE in its TCE risk assessment, and identified potential risks to consumers from aerosol degreasers.

There are currently TCE alternatives available on the market for all of the existing uses of aerosol degreasing that are similar in efficacy and cost (Refs. 2, 32). The most likely substitute products would be products with hydrocarbon/mineral spirits, products that are acetone or terpene based, and some that contain perchloroethylene or 1-bromopropane. All substitutes are expected to be less hazardous than TCE. Substitutes that are hazardous but at dose levels higher than the dose levels at which TCE causes adverse effects include perchloroethylene and 1-bromopropane. EPA does not advocate that perchloroethylene or 1-bromopropane be used as substitutes. EPA released a draft risk assessment for 1-bromopropane on March 3, 2016. The schedule for finalizing the assessment of 1-bromopropane and other chemicals is still under development. Many substitutes are expected to be significantly less hazardous than TCE, based on currently available information. These include formulations that may be categorized as acetone-, citrus terpene-, hydrocarbon-, and water-based degreasers. Several formulations are made with chemicals that are expected to have lower relative exposure potential, compared to TCE, based on currently available information. These include citrus terpenes and water-based degreasers. EPA has not developed risk estimates related to the use of substitutes, however, the benefits analysis incorporates the potential for certain alternatives to result in risks to users by assuming no benefits for TCE users that switch to perchloroethylene or 1-bromopropane alternatives in its lower estimate for benefits. EPA estimates that 25% of TCE users will substitute perchloroethylene or 1-bromopropane, 50% will substitute hydrocarbon/mineral spirits, and 25% will substitute acetone/terpene alternatives (Ref. 2). Although some substitutes, including perchloroethylene and 1-bromopropane, are hazardous, effects from these chemicals are generally seen at levels that are higher than the levels that are associated with TCE toxicity. Thus, considering similar exposure potentials for substitutes, the overall risk potential for the substitutes will be less than for TCE (Ref. 32).

B. Analysis of Regulatory Options

In this section, EPA explains how it determined whether the regulatory options considered would address the unreasonable risks presented by this use. First, EPA characterizes the unreasonable risks associated with the current use of TCE in aerosol degreasing. Then, the Agency describes its initial analysis of which regulatory options have the potential to reach the protective non-cancer and cancer benchmarks. The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also result in low risk for cancer. Lastly, this section evaluates how well those regulatory options would address the identified unreasonable risks in practice.

1. *Risks associated with the current use. a. General impacts.* The TCE risk assessment identified acute non-cancer risks for consumers and residential bystanders from the use of TCE-containing aerosol degreasers (Ref. 1). EPA performed supplemental analysis consistent with the methodology used for the consumer use scenario included in the TCE risk assessment (Ref. 24), and identified acute and chronic non-cancer risks and cancer risks for the commercial aerosol degreasing use scenario (Ref. 23). EPA estimates that there are approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations, and approximately 22,000 consumers and bystanders exposed to TCE during the consumer use of aerosol degreasers (Ref. 2).

b. Impacts on minority populations. There is no known disproportionate representation of minority populations in occupations using aerosol degreasers. All employees and consumers using aerosol degreasers would benefit from risk reduction.

c. Impacts on children. EPA has concerns for effects on the developing fetus from acute and chronic worker and consumer maternal exposures to TCE. The risk estimates are focused on pregnant women because one of the most sensitive health effects associated with TCE exposure from the use of consumer and commercial aerosol degreasers is adverse effects on the developing fetus. The potential for exposure is significant because approximately half of all pregnancies are unintended. If a pregnancy is not planned before conception, a woman may not be in optimal health for childbearing (Ref. 33). The pregnancy estimate includes women who have live births, induced abortions, and fetal losses (Ref. 2).

EPA also examined acute risks for consumer exposures in residential settings. EPA assumed that affected consumers would be individuals that intermittently use TCE aerosol degreasers in and around their homes, whereas bystanders would be individuals in close proximity to the use activity but not using the product. EPA assumed that consumer users would generally be adults of both sexes (16 years old and older, including women of childbearing age), although exposures to teenagers and even younger individuals may be possible in residential settings as bystanders. However, risk estimates focused on pregnant women. This is because one of the most sensitive health effects associated with TCE exposure is adverse effects on the developing fetus (Ref. 3).

d. Exposures for this use. For consumer exposures, EPA used the Exposure and Fate Assessment Screening Tool Version 2/Consumer Exposure Module to estimate TCE exposures for the consumer use scenarios (Ref. 1). This modeling approach was selected because emissions and monitoring data were not available for the aerosol degreasing TCE uses under consideration. The model used a two-zone representation of a house to calculate potential TCE exposure levels for consumers and bystanders. The modeling approach integrated assumptions and input parameters about exposure duration, the chemical emission rate over time, the volume of the house and the room of use, the air exchange rate and interzonal airflow rate. The model also considered the exposed individual's location as it relates to use, body weight, and inhalation rate during and after the product use (Ref. 1). No respirator scenarios were considered for use by consumers because EPA cannot require use of respirators by consumers under TSCA section 6(a). EPA used both an air exchange rate of 0.45 per hour based on the central tendency ventilation rate for a home in the United States and a higher ventilation rate (1.26 air exchanges per hour, representing the upper 10% of U.S. homes) to represent use of the TCE aerosol degreaser in a well-ventilated space (Refs. 1, 24). EPA also considered a range of concentrations of TCE in the aerosol

degreasers that the consumers used (5% to 90%) (Refs. 1, 24). In the modeling, TCE in the aerosol degreaser entered the room air through overspray of the product and evaporation from a thin film. The inhalation acute dose rates were computed iteratively by calculating the peak concentrations for each simulated 1-second interval and then summing the doses over 24 hours to form a 24-hour dose (Ref. 1).

The high-end inhalation exposure estimates for the consumer scenarios were 2 ppm for users of TCE-containing aerosol degreasers and 0.8 ppm for bystanders of TCE-containing solvent degreasers (Ref. 1).

For exposures in commercial settings, EPA determined baseline exposures using a near-field/far-field modeling approach to estimate airborne concentrations of TCE and Monte Carlo simulation to establish the range and likelihood of exposures (Ref. 23). The near-field/far-field model estimates airborne concentrations in a near field (a zone close to the source of exposure) and a far field (a zone farther from the source of exposure but within the occupational building). EPA used these estimated airborne concentrations to estimate 8-hour time weighted average exposures for workers (*i.e.,* in the near field) and occupational bystanders (*i.e.,* in the far field). A worker is defined as the person performing the task in which TCE is used. Occupational bystanders are defined as other people within the building who are not performing the TCE-based task. Details of the modeling and estimation method for calculating exposure levels during aerosol degreasing are available in the analysis document, *Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Aerosol Degreasing* (Ref. 23). As discussed in Unit IV.C, this analysis is based on the methodology used in the peer reviewed TCE risk assessment (Ref. 1).

EPA assumed that a worker applies aerosol degreasers 260 days a year, once per hour, and that no applications occur during the first hour of the 8-hour work day. EPA also assumed that aerosol degreasing facilities use 192.2 grams of degreaser per day and for 100% TCE degreaser this would be 27.5 grams of TCE per application. For degreasers with differing concentrations of TCE, the per-application quantity was adjusted accordingly (Refs. 1 and 23).

e. Risks for this use. As discussed in Unit IV.B, TCE is associated with a range of non-cancer adverse health effects in humans and animals and is carcinogenic to humans. MOEs were used in this assessment to estimate non-cancer risks for acute and chronic exposures. Exposure scenarios with MOEs below the benchmark MOE for the individual toxicity endpoints have risks of concern, as explained in detail in the TCE risk assessment (Ref. 1). Cancer risks express the incremental probability of an individual developing cancer over a lifetime as a result of exposure to TCE under specified use scenarios.

The acute inhalation risk assessment used developmental toxicity data to evaluate the acute risks for the TCE use scenarios. As indicated in the TSCA Work Plan Risk Assessment on TCE, EPA's policy supports the use of developmental studies to evaluate the risks of acute exposures. This science-based policy is based on the presumption that a single exposure of a chemical at a critical window of fetal development, as in the case of cardiac malformation, may produce adverse developmental effects (Ref. 34 and 35). EPA reviewed multiple studies for suitability for acute risk estimation including a number of developmental studies of TCE exposure and additional studies of TCE metabolites administered developmentally (Appendix N) (Ref. 1). EPA based its acute risk assessment on the most sensitive health endpoint (*i.e.,* fetal heart malformations; Ref. 1) representing the most sensitive human life stage (*i.e.,* the developing fetus). The acute risk assessment used the physiologically based pharmacokinetic (PBPK)-derived hazard values (HEC50, HEC95, or HEC99; HECXX is the Human Equivalent Concentration at a particular percentile) from the Johnson et al. (2003) (Ref. 36) developmental toxicity study for each aerosol degreaser use scenario. Note that the differences among these hazard values is small and no greater than 3-fold (*i.e.,* 2-fold for HEC50/HEC95 ratios; 3-fold for HEC50/HEC99 ratios; 1.4-fold for HEC95/HEC99 ratios). The TCE IRIS assessment preferred the HEC99 for the non-cancer dose-response derivations because the HEC99 was interpreted to be protective for a sensitive individual in the population. While the HEC99 was used to determine the level of risk to be used in making the preliminary section 6(a) determination, the small variation among HEC50, HEC95 and HEC99 would not result in a different risk determination.

Acute inhalation risks were estimated for all residential exposure scenarios of aerosol degreasing based on concerns for developmental effects. Risks of concern were identified for consumer users and bystanders, regardless of the type of exposure (typical vs. worst case scenario) and whether room ventilation was used. For acute consumer aerosol degreasing exposures, the high end MOE is 0.002 for fetal heart malformations. This means that exposures are estimated to be 5,000 times greater than exposures used to calculate the benchmark MOE of 10. All of the residential use scenarios resulted in MOE values significantly below the benchmark MOE of 10 irrespective of the percentile HEC value used to estimate the MOEs (Refs. 1, 24). Given this significant difference between the benchmark MOEs and the MOEs from the residential use scenarios, EPA has preliminarily determined that the risks TCE present for the consumer aerosol degreasing use are unreasonable risks.

For occupational aerosol degreasing exposures the MOE is 0.003 for fetal heart malformation and is also representative of MOEs for kidney toxicity and immunotoxicity. This equates to estimated exposures that are more than 3,000 times greater than those needed to achieve the benchmark MOE. For chronic occupational aerosol degreasing exposures the baseline cancer risk is 1.6×10^{-2} exceeding standard cancer benchmarks of 10^{-6} to 10^{-4} (Refs. 1, 23). EPA has preliminarily determined that TCE presents unreasonable risks for the occupational aerosol degreasing use.

2. Initial analysis of potential regulatory options. Having identified unreasonable risks from the use of TCE in aerosol degreasing, EPA evaluated whether regulatory options under section 6(a) could reach the risk (non-cancer and cancer) benchmarks.

EPA assessed a number of exposure scenarios associated with risk reduction options in order to determine variations in TCE exposure from aerosol degreasing, including: Material substitution, engineering controls, and use of PPE. EPA also assessed combinations of these options. The material substitution scenarios involved reducing the concentration of TCE in the degreasing formulation, with concentrations varying from 5 to 95 percent by weight in the product. For the engineering controls risk reduction option exposure scenarios, EPA evaluated using local exhaust ventilation to improve ventilation near the worker activity, with estimated 90% reduction in exposure levels. The PPE risk reduction option exposure scenarios evaluated workers and occupational bystanders wearing respirators with an assigned protection factor (APF) varying from 10 to 10,000. Additionally, EPA evaluated all combinations of the above three options: Material substitution plus PPE, material

substitution plus engineering controls such as local exhaust ventilation, PPE plus engineering controls such as local exhaust ventilation, and materials substitution plus PPE plus engineering controls such as local exhaust ventilation.

EPA's inhalation exposure modeling estimated exposures to characterize the range of workplace scenarios. Inhalation exposure level estimate for facilities without local exhaust ventilation ranged from 1.00 ppm to 14.36 ppm as 8-hour TWAs for workers and 0.21 ppm to 13.58 ppm for bystanders. For facilities with local exhaust ventilation which was estimated to have an effectiveness of 90%, EPA's inhalation exposure level estimates were 0.586 ppm for workers and 0.507 ppm for bystanders. This estimate was for the 99th percentile and assumed that the aerosol degreaser was 100% TCE and that no PPE was used. The exposure estimates for wearing PPE combined with facilities having local exhaust ventilation ranged from 0.0000586 ppm to 0.0586 ppm for workers and 0.0000507 ppm to 0.0507 ppm for bystanders. The range represents the 10 to 10,000 range of respirator APFs considered. The exposure estimates for material substitution plus local exhaust ventilation ranged from 0.0293 ppm to 0.556 ppm for workers and 0.0253 ppm to 0.482 ppm for bystanders. The range represents the various TCE concentrations (5% to 95%) considered for material substitution. Additional exposure level estimates for various scenarios are available in the analysis document *Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Aerosol Degreasing* (Ref. 23).

Overall, EPA evaluated dozens of distinct exposure scenarios. The results indicate that regulatory options such as reducing the concentration of TCE in aerosol degreasers and using local exhaust ventilation to improve ventilation near worker activity, in the absence of PPE could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures and standard cancer risk benchmarks for chronic exposures (Refs. 23 and 24). The results also demonstrate that all risk reduction options meeting the benchmark MOEs and cancer benchmarks for TCE aerosol degreasers require the use of a respirator, whether used alone or in conjunction with additional levels of protection. Therefore, EPA found options setting a maximum concentration in products under section 6(a)(2) to not be protective because the options failed—by orders of magnitude—to meet the risk benchmarks. Options found not to meet the risk benchmarks and, therefore, found not to address the identified unreasonable risks are documented in EPA's supplemental technical reports on aerosol degreasing (Refs. 23 and 24).

3. Assessment of regulatory options to determine whether they address the identified unreasonable risks to the extent necessary so that TCE no longer presents such risks. As discussed in Unit V, EPA considered a number of regulatory options under section 6(a) which are reflected in EPA's supporting analysis (Refs. 28 and 29). In assessing these options, EPA considered a wide range of exposure scenarios (Refs. 23, 24, 25). These include both baseline and risk reduction scenarios involving varying factors such as exposure concentration percentiles, local exhaust ventilation use, respirator use, working lifetimes, etc. As part of this analysis, EPA considered the impacts of regulatory options on consumer users and commercial users separately. However, EPA is proposing to address the aerosol degreasing use as a whole rather than as separate consumer and commercial uses given that the differences in the use itself between workers and consumers differ only in the degree of repetition and duration and, furthermore, that not addressing them jointly would facilitate products intended for one segment being intentionally or unintentionally acquired and misused by the other.

The options that had the potential to address the identified unreasonable risks for consumer use, commercial use, or both uses of TCE in aerosol degreasing included: (a) Prohibiting the manufacturing, processing, and distribution in commerce of TCE for use in aerosol degreasing under section 6(a)(2) plus prohibiting the use of TCE in commercial aerosol degreasing under section 6(a)(5) and requiring downstream notification when distributing TCE for other uses under section 6(a)(3); (b) variations on such a supply-chain approach (such as just prohibiting the manufacturing, processing, and distribution in commerce of TCE for use in aerosol degreasing products under section 6(a)(2) or just prohibiting the commercial use of TCE in aerosol degreasing under section 6(a)(5)); (c) prohibiting the manufacturing, processing, and distribution in commerce of TCE for use in consumer aerosol degreasing products under section 6(a)(2) and requiring downstream notification (*e.g.,* via a Safety Data Sheet (SDS)) when distributing TCE for other uses under section 6(a)(3); and (d) requiring the use of PPE in commercial aerosol degreasing operations in which TCE is used under section 6(a)(5) or requiring the use of PPE and engineering controls (local exhaust ventilation) in commercial aerosol degreasing operations in which TCE is used under section 6(a)(5).

The full range of regulatory options considered under section 6(a) is reflected in EPA's supporting analysis (Ref. 29). A discussion of those regulatory options that could reach the risk benchmarks for consumer use, commercial use, or both is provided in this Unit, along with the Agency's evaluation of how well those regulatory options would address the identified unreasonable risks in practice.

a. *Proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification.* As noted previously, the proposed regulatory approach for TCE use in aerosol degreasing would prohibit the manufacturing, processing, and distribution in commerce of TCE for aerosol degreasing under TSCA section 6(a)(2), prohibit the commercial use of TCE for aerosol degreasing under TSCA section 6(a)(5), and require manufacturers, processors, and distributors, except for retailers, to provide downstream notification, *e.g.,* via a Safety Data Sheet (SDS), of the prohibitions under TSCA section 6(a)(3).

As discussed in Unit VI.B.1, the baseline risk for exposure to workers and consumers for aerosol degreasing departs from non-cancer MOE benchmarks for all non-cancer effects (*e.g.,* developmental effects, kidney toxicity, and immunotoxicity) and standard cancer benchmarks. Under this proposed approach, exposures to TCE from use in aerosol degreasing would be completely eliminated. As a result, both non-cancer and cancer risks would be eliminated (Refs. 23 and 24).

The proposed approach would ensure that workers and consumers are no longer at risk from TCE exposure associated with this use. Prohibiting the manufacturing, processing and distribution in commerce of TCE for use in aerosol degreasing would minimize the availability of TCE for aerosol degreasing. The prohibition of the use of TCE in commercial aerosol degreasing would eliminate commercial demand for TCE aerosol degreasing products and significantly reduce the potential for consumer use of commercial products. These complementary provisions would protect both workers and consumers; workers would not be exposed to TCE and the risk to consumers would be

minimized because commercial aerosol degreasing products containing TCE would not be available, so consumers would not be able to divert commercial-use products from the supply chain. The downstream notification of these restrictions ensures that processors, distributors, and other purchasers are aware of the manufacturing, processing, distribution in commerce and use restrictions for TCE in aerosol degreasing, and helps to ensure that the rule is effectively implemented by avoiding off-label use as an aerosol degreaser of TCE manufactured for other uses. Downstream notification also streamlines and aids in compliance and enhances enforcement. Overall, downstream notification facilitates implementation of the rule. This integrated supply chain proposed approach minimizes the risk from TCE in aerosol degreasing. In addition, the proposed approach would provide staggered compliance dates for implementing the prohibition of manufacturing, processing, distribution in commerce, and commercial use in order to avoid undue impacts on the businesses involved.

b. Options that are variations of the proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification. One variation of the proposed approach would be to prohibit manufacture, processing, and distribution in commerce for the consumer and commercial aerosol degreasing uses alone. This option could reach the risk benchmarks for TCE. However, while this option could address the identified unreasonable risks, in practice given the continued availability of TCE for other uses, it would not do so. Without the accompanying prohibition on commercial use and downstream notification that is included in the proposed approach, this option would leave open the likelihood that commercial users or consumers could obtain off-label TCE for aerosol degreasing. For example, if only manufacturing, processing and distribution in commerce for the aerosol degreasing use were prohibited without also prohibiting the commercial use and providing the downstream notice, commercial users or consumers could more easily acquire TCE for degreasing from sources that make it available for other uses. This would be particularly easy for commercial users given that a company may buy a chemical substance for one use and also use it for another. Without downstream notification, unsophisticated purchasers, in particular, are likely to be unfamiliar with the prohibitions regarding this use and mistakenly use TCE for aerosol degreasing and thereby expose themselves and bystanders to unreasonable risks. Thus, under these variations, EPA anticipates that the risk benchmarks would not actually be realized by many users. Therefore, these variations fail to address the identified unreasonable risks, considering the practical limitations of the options.

Another regulatory option that EPA considered was to prohibit only the commercial use of TCE for aerosol degreasing. This approach would eliminate both non-cancer and cancer risks for commercial settings only, but would not eliminate risks to consumers. By prohibiting commercial use alone, without a prohibition on the manufacture, processing, and distribution in commerce for consumer and commercial use, this would not address consumer risks as consumers would still be able to purchase aerosol degreasing products containing TCE, including those products labeled and marketed as ''professional strength'' or ''commercial grade'' products. Consumers would continue to be exposed far above the health benchmarks and would not be protected from the unreasonable risks posed by TCE.

c. Prohibit the manufacturing, processing, and distribution in commerce of TCE for use in consumer aerosol degreasing products under section 6(a)(2) or prohibit the manufacturing, processing, and distribution in commerce of TCE for use in consumer aerosol degreasing products under section 6(a)(2) and require downstream notification when distributing TCE for other uses section 6(a)(3). EPA considered prohibiting the manufacturing, processing, and distribution in commerce of TCE for use in consumer aerosol degreasing products including an option with a requirement for downstream notification of such prohibition. If such a prohibition were effective, this option would mitigate the risks to consumers from TCE use in aerosol degreasing. However, EPA has determined that consumers can easily obtain products labeled for commercial use. Indeed, for many consumers, identifying a product as being for commercial use may imply greater efficacy. Coupled with the fact that many products identified as commercial or professional are readily obtainable in a variety of venues (*e.g.,* the Internet, general retailers, and specialty stores, such as automotive stores), EPA does not find that this option would protect consumers. In addition, this option alone would not address the risks to workers from commercial aerosol degreasing.

d. Require the use of personal protective equipment in commercial aerosol degreasing operations in which TCE is used under section 6(a)(5) or require the use of personal protective equipment and engineering controls in commercial aerosol degreasing operations in which TCE is used under section 6(a)(5). Another regulatory option that EPA considered was to require respiratory protection equipment at commercial aerosol degreasing operations in the form of a full face piece self-contained breathing apparatus (SCBA) in pressure demand mode or other positive pressure mode with an APF of 10,000. EPA's analysis determined that use of a SCBA with an APF of 10,000 for commercial aerosol degreasing uses could control TCE air concentration to levels that allow for meeting the benchmarks for non-cancer and cancer risks for the commercial uses addressed in this proposed rule.

Although respirators could reduce exposures to levels that are protective of non-cancer and cancer risks, there are many documented limitations to successful implementation of respirators with an APF of 10,000. Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirators to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, ''improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health.'' (63 FR 1189–1190). Nonetheless, it is sometimes necessary to use respiratory protection to control

exposure. The OSHA respiratory protection standard (29 CFR 1910.134) requires employers to establish and implement a respiratory protection program to protect their respirator wearing employees. This OSHA standard contains several requirements, *e.g.,* for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; respirator use; respirator cleaning, maintenance, and repair; and other provisions that would be difficult to fully implement in some small business settings where they are not already using respirators.

In addition, OSHA has adopted a hierarchy of industrial hygiene controls established by the industrial hygiene community to be used to protect employees from hazardous airborne contaminants, such as TCE (see, *e.g.,* 29 CFR 1910.134(a)(1); 29 CFR 1910.1000(e), and OSHA's substance-specific standards in 29 CFR 1910, subpart Z). According to the hierarchy, substitution of less toxic substances, engineering controls, administrative controls, and work practice controls are the preferred methods of compliance for protecting employees from airborne contaminants and are to be implemented first, before respiratory protection is used. OSHA permits respirators to be used only where engineering controls and effective work practices are not feasible or during an interim period while such controls are being implemented.

Also for commercial aerosol degreasing uses, EPA considered requiring a combination of local exhaust ventilation and a supplied-air respirator with an APF of 1,000, with a performance based option using an air exposure limit. This option could also reduce risks to the health benchmarks for workers when used properly (Ref. 23). However, while this option has the benefit of incorporating engineering controls and use of a respirator with a lower APF, there are still the limitations to successful implementation of the use of supplied-air respirators in the workplace as discussed previously. Further, this option would also require the use of prescriptive and expensive engineering controls to reach the risk benchmarks, unless the optional use of an air exposure limit is implemented (Ref. 39). Even if the performance-based option of meeting an air concentration level as an exposure limit for TCE were used, this would depend upon the use of both engineering controls and a respirator to meet the exposure limit for TCE.

Furthermore, neither of these variations of relying upon PPE for commercial aerosol degreasing use would do anything to reduce the risks to consumer users. Therefore, considering the practical limitations of PPE for this scenario as well as the unmitigated risks to consumers, this option would not address the unreasonable risks presented by these uses.

Even if either of these approaches were coupled with a section 6(a)(2) prohibition on the manufacture, processing and distribution in commerce of TCE for use in consumer aerosol degreasing products, this would not protect consumers because they would be able to buy and use commercial aerosol degreasing products, *e.g.,* via the Internet.

EPA could also require that TCE products be distributed with a respirator with an appropriate assigned protection factor to protect for the risks from TCE. EPA determined that this option would not address the identified unreasonable risks because simply packaging a respirator with a chemical (or any product) does not mean that a worker or consumer would actually use it properly or even understand how to use it (Refs. 28 and 29).

C. Availability of Substitutes and Impacts of the Proposed and Alternative Regulatory Options

This Unit examines the availability of substitutes for TCE in aerosol degreasing and describes the estimated costs of the proposed and alternative regulatory actions that EPA considered. More information on the benefits and costs of this proposal as a whole can be found in Unit VIII.

Overall, EPA notes that the cost of aerosol degreasing product reformulations are low. Total first-year reformulation costs are estimated to be $416,000 and annualized costs are estimated to be approximately $32,000 per year (annualized at 3% over 15 years) and $41,000 (annualized at 7% over 15 years). A wide variety of effective substitutes are available, as previously noted, and the current existence of non-TCE containing aerosol degreasers indicates that there are no specific aerosol degreasing uses for which TCE is critical. TCE use is limited in aerosol degreasing products intended for consumers due to existing VOC regulations in California and in a number of other states. New Hampshire and Virginia prohibit use of TCE in aerosol adhesives. Connecticut, Delaware, the District of Columbia, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, New York, and Rhode Island prohibit the use of TCE in aerosol adhesives, contact adhesives, electrical cleaners, footwear/leather care products, adhesive removers, general purpose degreasers, and graffiti removers (Ref. 15). New Jersey prohibits the use of TCE in all those products and also in brake cleaners, engine degreasers, and carburetor/fuel-injection air intake cleaners. In addition to prohibiting the use of TCE in all those products, California also prohibits the use of TCE in bathroom and tile cleaners, construction and panel/floor covering adhesives; carpet/upholstery cleaner, general purpose cleaners, fabric protectant, multi-purpose lubricant, penetrant, metal polish or cleanser, multi-purpose solvent, oven cleaners, paint thinner, pressurized gas duster, sealant or caulking compound, spot remover, and silicone-based multi-purpose lubricant (Ref. 12). The range of the State-mandated prohibitions demonstrate that other chemicals can be substituted for TCE for a wide range of uses because other chemicals or mixtures of chemicals can impart properties similar to those of TCE. Further, the fact that 10 states and the District of Columbia have specifically prohibited the use of TCE in general purpose degreasers and general purpose degreasers continue to be sold in those jurisdictions, demonstrates that TCE is not critical to the degreasing use and there are efficacious substitutes.

TCE is also prohibited in the European Union in aerosol degreasers (Ref. 16); TCE substitutes are used for aerosol degreasing. These regulations confirm that TCE is not a critical chemical for aerosol degreasing and that substituting alternate chemicals would not be overly difficult. Producers of aerosol degreasing products containing TCE also produce aerosol degreasing products with substitute chemicals. Thus, there is already precedent for producers reformulating products to meet demand in some states and countries. In addition, EPA expects that one effect of a ban on the use of TCE in aerosol degreasing products would be increased technological innovation, resulting in the development of additional alternatives.

1. Proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification. The costs of the proposed approach are estimated to include product reformulation costs, downstream notification costs, recordkeeping costs, and Agency costs. The total first-year costs of aerosol degreasing product reformulations are estimated to be $416,000 and annualized costs are estimated to be

approximately $32,000 per year (annualized at 3% over 15 years) and $41,000 (annualized at 7% over 15 years). The cost for reformulation includes a variety of factors such as identifying the substitute for TCE, assessing the efficacy of the new formulation and determining shelf-life. The costs to users of aerosol degreasers are negligible as substitute products are currently available on the market and are similarly priced. The first-year costs of downstream notification and recordkeeping are estimated to be $51,000 and on an annualized basis over 15 years are $3,900 and $5,000 using 3% and 7% discount rates respectively (Ref. 2). Agency costs for enforcement are estimated to be approximately $112,000 and $109,000 annualized over 15 years at 3% and 7%, respectively. Annual recurring costs to the Agency for enforcement are estimated to be $121,000 per year. The total cost of the proposed approach for aerosol degreasing use is estimated to be $37,000–$40,000 and $46,000–$49,000 annualized over 15 years at 3% and 7%, respectively.

2. Options that require personal protective equipment. Given equipment costs and the requirements associated with establishing a respiratory protection program which involves training, respirator fit testing and the establishment and maintenance of a medical monitoring program, EPA anticipates that companies would choose to switch to substitute chemicals instead of adopting a program for PPE, including with a performance based option of meeting an air concentration level as an exposure limit for TCE. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 10,000 are $8,300 at 3% and $9,100 at 7% per aerosol degreasing facility over 15 years. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 1,000 are $5,400 at 3% and $5,500 at 7% per facility over 15 years. In addition, there would be higher EPA administration and enforcement costs with a respiratory protection program than there would be with an enforcement program under the proposed approach. Further, even if cost were not an impediment, in addition to cost, there are many limitations to the successful implementation of respirators with an APF of 10,000 in a workplace.

3. Options that exclude downstream notification. EPA was unable to monetize the extent to which enforcement costs would vary by regulatory option so EPA assumed monetized enforcement costs to be the same under all options for the purpose of this proposed rulemaking. The proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to the greatest extent the potential for TCE products to be intentionally or unintentionally misdirected into the prohibited uses. Enforcement under the other options would be much more difficult since the key requirements are directly placed on the large number of product users (Ref. 40). Under these other options, enforcement activities must target firms that might perform the activity where a TCE use is restricted or prohibited. Identifying which establishments might use aerosol degreasers is difficult because aerosol degreasing is not strictly specific to any industry (Ref. 2). Therefore, while EPA considers downstream notification to be a critical component of this proposal, EPA also finds that incorporating downstream notification reduces the burden on society by easing implementation, compliance, and enforcement (Ref. 41).

D. Summary

The proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification is necessary to ensure that TCE no longer presents unreasonable risks for all users. This option does not pose an undue burden on industry because comparably effective and priced substitutes to TCE for aerosol degreasing are readily available. The supply chain approach ensures protection of consumers from the identified unreasonable risks by precluding the off-label purchase of commercial products by consumers. The downstream notification (*e.g.,* via SDS) component of the supply chain approach provides notice of the prohibition throughout the supply chain and, while slightly more costly to upstream entities, helps to ensure that the use no longer presents unreasonable risks because it streamlines and aids in compliance and enhances enforcement.

VII. Regulatory Assessment of TCE Use for Spot Cleaning in Dry Cleaning Facilities

This Unit describes the current use of TCE for spot cleaning in dry cleaning facilities, the unreasonable risks presented by this use, and how EPA preliminarily determined which regulatory options are necessary to address the identified unreasonable risks.

A. Description of the Current Use

TCE was first introduced as a dry cleaning solvent in the United States in the 1930s (Ref. 2). It was never widely used as a primary dry cleaning solvent; however, TCE is still used for spot cleaning in dry cleaning facilities to remove oily-type stains, including fats, waxes, grease, cosmetics, and paints. Stained fabrics are typically ''pre-spotted'' with spot treatment products, which are often solvent-based such as those containing TCE, prior to being placed in dry cleaning machines (Refs. 42, 43). TCE is one of many available spotting agents used in dry cleaning facilities. A range of alternative spotting agents are used in dry cleaning facilities including certain halogenated solvents, such as perchloroethylene, 1-bromopropane, and methylene chloride; water- and soy-based spotting agents; hydrocarbon/mineral spirits; glycol ethers; and others (Ref. 2). TCE is applied by a squirt bottle directly onto the stain on the garment (Ref. 1). Squirt bottles are hand filled from larger volume containers of the spotting agent. After application, the TCE-based spotting agent is patted with a brush to break up the stain without harming fabric and suction vacuumed from the garment, which is then placed in the dry cleaning machine. The TCE spotting agent from the vacuum is collected as hazardous waste. Concentrations of TCE in commercial spotting agents vary from 10% to 100% (Refs. 42, 43).

EPA estimates that there are approximately 61,000 dry cleaning facilities in the United States, with an estimated 210,000 workers. Approximately 32,000 to 52,000 of those dry cleaning facilities are estimated to be using TCE in spot cleaning, with an estimated 105,000 to 168,000 workers and occupational bystanders (Ref. 2). Less than 1% of the total 225 million pounds of TCE used in the United States is for dry cleaning with approximately 50% to 80% of dry cleaners estimated to be using TCE for spot cleaning in dry cleaning facilities (Ref. 2). A typical dry cleaning facility uses 0.84 to 8.4 gallons per year of TCE for spot cleaning operations (Ref. 1).

There are currently a wide variety of comparably effective substitutes on the market and in use in dry cleaning operations that are similarly priced to TCE (Ref. 2), including substitute water-based cleaners (Ref. 44), methyl esters (soy) cleaners, hydrocarbon/mineral spirits, glycol ethers, perchloroethylene, methylene chloride, and 1-bromopropane (Ref. 32). Chemical

substitutes that would most likely be used are water-based cleaners, methyl esters (soy) cleaners, hydrocarbon/mineral spirits, glycol ethers, perchloroethylene, 1-bromopropane, methylene chloride, and others. EPA estimates that 5% of users will switch to aqueous cleaners, 25% will switch to perchloroethylene and 1-bromopropane, and 70% will switch to other alternatives (Ref. 2). In general, substitutes are less toxic than TCE (Refs. 32, 44). Thus, considering similar exposure potentials for substitutes, the overall risk potential for the substitutes will be less than for TCE (Ref. 32).

B. Analysis of Regulatory Options

In this Unit, EPA explains how it determined whether the regulatory options considered would address the unreasonable risks presented by this use. First, EPA characterizes the unreasonable risks associated with the current use of TCE for spot cleaning in dry cleaning facilities. Then, the Agency describes its initial analysis of which regulatory options have the potential to achieve non-cancer and cancer benchmarks. The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also results in low risk for cancer. Lastly, this Unit evaluates how well those regulatory options would address the identified unreasonable risks in practice.

1. *Risks associated with the current use.* a. *General impacts.* The TCE risk assessment identified non-cancer risks and cancer risks for chronic exposures of workers and occupational bystanders in dry cleaning facilities that use TCE for spot cleaning (Ref. 1). EPA also identified acute non-cancer risks for workers and occupational bystanders (Ref. 1). The size of the potentially exposed population is approximately 105,000–168,000 workers and occupational bystanders in dry cleaning operations (Ref. 2).

b. *Impacts on minority populations.* In dry cleaning facilities, Asian and Hispanic populations are over-represented. 13% of dry cleaning workers are Asian, compared to 5% of the national population. Also, 30% of dry cleaning workers are Hispanic (of any race) compared to 16% of the national population (Ref. 2). Because minority populations are disproportionately over-represented in this industry they are disproportionately exposed; thus, there would be disproportionately positive benefits for these populations from the regulatory approach set forth in this proposal.

c. *Impacts on children.* EPA has concern for effects on the developing fetus from acute and chronic maternal exposures to TCE in dry cleaning facilities. The risk estimates are focused on pregnant women because adverse effects on the developing fetus is one of the most sensitive health effects associated with TCE exposure. Of the up to 168,000 workers and occupational bystanders in dry cleaning operations who make up the exposed population, 3.2% are estimated to be pregnant women. Thus, up to approximately 5,400 pregnant women are estimated to be exposed to TCE in spot cleaning in dry cleaning facilities each year. The pregnancy estimate includes women who have live births, induced abortions, and fetal losses (Ref. 2). The potential for exposure is significant because approximately half of all pregnancies are unintended. If a pregnancy is not planned before conception, a woman may not be in optimal health for childbearing (Ref. 33).

d. *Exposures for this use.* TCE exposures for this use are through the inhalation route. EPA used readily available information from a 2007 study on spotting chemicals, prepared for the California EPA and EPA, to estimate releases of TCE and associated inhalation exposures to workers from spot cleaning operations in dry cleaning facilities (Ref. 1). The near field/far field mass balance model, which has been extensively peer-reviewed, was used for this estimation of workplace exposure levels during spot cleaning (Ref. 1). The near-field/far-field model estimates airborne concentrations in a near field (a zone close to the source of exposure) and a far field (a zone farther from the source of exposure but within the occupational building). EPA used these estimated airborne concentrations to estimate exposures for the worker applying the spotting agent (*i.e.,* in the near field) and the occupational bystanders (*i.e.,* in the far field). A worker is defined as the person performing the task in which TCE is used. Occupational bystanders are defined as other persons within the dry cleaning facility who are not performing the TCE-based task. EPA assumed that dry cleaning facilities operated 260 days per year for 8 hours a day; that the concentration in the spotting agent ranged from 10 to 100% and that a typical dry cleaning facility used 0.84 to 8.4 gallons of TCE per year for spotting operations. Details of the modeling and estimation method for calculating exposure levels during spot cleaning are available in the TCE risk assessment (Ref. 1).

e. *Risks for this use.* As discussed in Unit IV.B, TCE is associated with a range of non-cancer health effects in humans and animals and is also carcinogenic to humans.

As discussed in Unit IV.B, MOEs were used in this assessment to estimate non-cancer risks for acute and chronic exposures. Exposure scenarios with MOEs below the benchmark MOE have risks of concern and typically, non-cancer adverse effects are more likely to result from exposure scenarios with MOEs below the benchmark MOE. For the use of TCE as a spot cleaner in dry cleaning facilities, the risk estimates for a range of non-cancer effects were below the benchmark MOE of 10 for developmental effects. The MOE for acute developmental effects is 0.002 for fetal heart malformation (Refs. 1, 25). For chronic occupational spot cleaning exposures, the MOE is 0.003 for fetal heart malformation and is similar to MOEs for kidney toxicity and immunotoxicity. In the baseline exposure scenarios, the MOEs are 3,000 times less than the benchmark MOEs (Refs. 1, 25). EPA has preliminarily determined that TCE presents unreasonable non-cancer risks from spot cleaning in dry cleaning facilities.

Cancer risks determine the incremental probability of an individual developing cancer over a lifetime as a result of exposure to TCE. For chronic occupational spot cleaning exposures the baseline cancer risk is 1×10^{-2} which exceeds the standard cancer benchmarks of 10^{-6} to 10^{-4} (Refs. 1 and 25). Accordingly, EPA has preliminarily determined that TCE presents unreasonable cancer risks from spot cleaning in dry cleaning facilities.

2. Initial analysis of potential regulatory options. Having identified unreasonable risks from the use of TCE in spot cleaning in dry cleaning facilities, EPA evaluated whether regulatory options under section 6(a) could reach the risk (non-cancer and cancer) benchmarks.

EPA assessed a number of exposure scenarios associated with risk reduction options in order to determine variations in TCE exposure when spot cleaning in dry cleaning facilities: Material substitution, engineering controls, and use of PPE, as well as combinations. The materials substitution scenarios involved reducing the concentration of TCE in the spot cleaning formulation, with concentrations varying from 5% to 95% total weight of the formulation. For the engineering control risk reduction option exposure scenarios, EPA evaluated using local exhaust ventilation to improve ventilation near the worker activity, with estimated 90% reduction in exposure levels. The PPE risk reduction option exposure scenarios evaluated workers and

occupational bystanders wearing respirators with APF varying from 10 to 10,000. Additionally, EPA evaluated all combinations of the above three options: Material substitution plus PPE; material substitution plus local exhaust ventilation; PPE plus local exhaust ventilation; and material substitution plus PPE plus local exhaust ventilation.

EPA's site-specific inhalation exposure level estimate for facilities without local exhaust ventilation ranged from 0.08 to 19 ppm as 8-hour TWAs. Although relevant exposure monitoring data were limited, EPA identified a study specific to spot cleaning with TCE (Ref. 42). In this study, TWA levels for worker exposure to TCE during spot cleaning (with no local exhaust ventilation) ranged from 2.37 to 3.11 ppm. This range of exposure levels falls within EPA's estimated exposure range of 0.08 to 19 ppm and is within a factor of 10 of EPA's high-end estimate of 19 ppm (Ref. 43).

For facilities with local exhaust ventilation, EPA's inhalation exposure level estimates were 5.0×10^{-1} ppm for workers and 4.2×10^{-1} for bystanders. The exposure estimates for wearing PPE combined with facilities having local exhaust ventilation ranged from 5.0×10^{-5} ppm to 5.0×10^{-2} ppm for workers and 4.2×10^{-5} ppm to 4.2×10^{-2} ppm for bystanders. The exposure estimates for material substitution plus local exhaust ventilation ranged from 2.5×10^{-2} ppm to 4.7×10^{-1} ppm for workers and 2.1×10^{-2} ppm to 4.0×10^{-1} ppm for bystanders. All exposure level estimates for the various scenarios considered are available in the TCE risk assessment (Ref. 1) and *Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Spot Cleaning* (Ref. 25).

The results indicate that alternate regulatory options such as reducing the concentration of TCE in spot cleaners for dry cleaning facilities and using local exhaust ventilation to improve ventilation near worker activity could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures and standard cancer risk benchmarks for chronic exposures. The results also demonstrate that all risk reduction options require the use of a respirator, whether used alone or in conjunction with additional levels of protection, in order to meet the non-cancer and cancer risk benchmarks (Ref. 25). Therefore, EPA found that options setting a maximum concentration in products under section 6(a)(2) did not address the identified unreasonable risks because the options failed—by orders of magnitude—to meet the risk benchmarks. Options found not to meet the risk benchmarks and which, therefore, do not address the identified unreasonable risks are documented in EPA's supplemental technical report on spot cleaning (Ref. 25).

3. Assessment of regulatory options to determine whether they address the identified unreasonable risks to the extent necessary so that TCE no longer presents such risks. As discussed in Unit V., EPA considered a number of regulatory options under section 6(a) to address TCE risks from spot cleaning in dry cleaning facilities which are reflected in EPA's supporting analysis (Ref. 29). In assessing these options, EPA considered a wide range of exposure scenarios (Ref. 25). These include both baseline and risk reduction scenarios involving varying factors such as reduction of TCE content in spot cleaners, exposure concentration percentiles, local exhaust ventilation use, respirator use, working lifetimes, etc. The options that could reduce the risks of TCE use to the benchmark MOE and standard cancer benchmarks for spot cleaning in dry cleaning include (a) prohibiting the manufacture, processing, and distribution in commerce of TCE for use as a spot cleaner in dry cleaning facilities (section 6(a)(2)) plus prohibiting the use of TCE as a spot cleaner in dry cleaning facilities (section 6(a)(5)) and requiring downstream notification when distributing TCE for other uses under section 6(a)(3); (b) variations on such a supply-chain approach (such as just prohibiting the manufacture, processing, distribution in commerce of TCE for use as a spot cleaner in dry cleaning facilities under section 6(a)(2) or just prohibiting the commercial use of TCE as a spot cleaner in dry cleaning facilities under section 6(a)(5)); (c) requiring the use of personal protective equipment in dry cleaning facilities in which TCE is used as a spot cleaner under section 6(a)(5) or requiring the use of personal protective equipment and engineering controls in dry cleaning facilities in which TCE is used as a spotting agent under section 6(a)(5).

The full range of regulatory options considered under section 6(a) is reflected in EPA's supporting analysis (Ref. 29). A discussion of the regulatory options that were determined to have the potential to address the identified unreasonable risks is provided in this Unit, along with the Agency's evaluation of how well those regulatory options would address the unreasonable risks in practice.

a. *Proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities and require downstream notification.* As noted previously, the proposed regulatory approach uses several elements of TSCA section 6(a) to address the risk of TCE use for spot cleaning in dry cleaning facilities throughout the supply chain. The proposed regulatory approach would prohibit the manufacturing, processing, and distribution in commerce of TCE for spot cleaning in dry cleaning facilities under TSCA § 6(a)(2), prohibit the commercial use of TCE for spot cleaning in dry cleaning facilities under TSCA § 6(a)(5), and require manufacturers, processors, and distributors, except for retailers, to provide downstream notification, *e.g.,* via a SDS, of the prohibitions under TSCA § 6(a)(3).

As discussed in Unit VII.B.1, the MOEs for occupational exposure for spot cleaning in dry cleaning facilities are below the non-cancer MOE benchmarks for all non-cancer effects (*e.g.,* developmental effects, kidney toxicity, and immunotoxicity) and standard cancer benchmarks. Under this proposed approach, exposures to TCE from this use would be completely eliminated. As a result, both non-cancer and cancer risks from exposure to TCE from this use would be eliminated (Ref. 39). All employees in dry cleaning facilities would benefit; and Asian and Hispanic populations, which are over-represented in dry cleaning facilities, would disproportionally benefit from the proposed approach.

The proposed approach would ensure that workers and occupational bystanders are no longer at risk from TCE exposure associated with this use throughout the supply chain. By proposing to prohibit the manufacture, processing and distribution in commerce of TCE for use as a spot cleaner in dry cleaning facilities, EPA would ensure that manufacturers, processors and distributors would not sell TCE for a use that EPA has determined presents an unreasonable risk of injury to health, and the intentional or unintentional availability of TCE for spot cleaning in dry cleaning facilities would be minimized. The proposal to prohibit commercial use of TCE as a spot cleaner in dry cleaning facilities would eliminate commercial demand for TCE-based spot cleaning products and would more effectively protect workers and bystanders than a prohibition only on manufacture, processing or distribution for this use under Section 6(a)(2). The prohibition on commercial use ensures that commercial users would not be able to divert TCE manufactured for other

allowable uses to this prohibited use without consequence. The downstream notification of these restrictions ensures that processors, distributors, and purchasers are aware of the manufacturing, processing, and distribution in commerce and use restrictions for TCE spot cleaner uses in dry cleaning facilities and helps to ensure that the rule is effectively implemented by avoiding off-label use as a spot cleaner of TCE manufactured for other uses. Downstream notification also streamlines and aids in compliance and enhances enforcement. Overall, downstream notification facilitates implementation of the rule. Collectively the proposed approach completely mitigates the risk from TCE in spot cleaners in dry cleaning facilities. In addition, the proposed approach would provide staggered compliance dates for implementing the prohibition of manufacturing, processing, distribution in commerce, and commercial use in order to avoid undue impacts on the businesses involved.

b. Options that are variations of the proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities and require downstream notification. Another regulatory option that EPA considered was to prohibit only the commercial use of TCE for spot cleaning in dry cleaning facilities under TSCA § 6(a)(5). This option could reach the risk benchmarks for TCE (Ref. 29). While this approach could eliminate non-cancer and cancer risks, in practice it would not address the identified unreasonable risks because users would easily be able to obtain TCE for use in dry cleaning facilities or would likely unknowingly purchase spot agents which contain TCE. If the Agency were to prohibit use alone, without the prohibition on manufacture, processing, and distribution in commerce for the use of TCE for spot cleaning in dry cleaning facilities, there is a greater likelihood that TCE manufactured for non-prohibited uses could be diverted to prohibited uses. Users would likely unknowingly purchase materials that they do not realize contain TCE because they would not be aware of the prohibition, which would result in unreasonable risks for those users. Taking the supply chain approach to addressing the risk of TCE in spot cleaning at commercial dry cleaning facilities helps to ensure that TCE manufactured for other allowed uses would not be used for this prohibited use.

Due to the large number of dry cleaning facilities in the United States (approximately 61,000), EPA is concerned that without the section 6(a)(3) downstream notification requirement, these entities might not become aware of the prohibition on TCE in spot cleaning because they may be unaware that certain products actually contain TCE. Thus, without downstream notification, EPA anticipates that the risk benchmarks would not actually be realized by many users. Therefore, such an option fails to address the identified unreasonable risks, considering the practical limitations.

Another regulatory option that EPA considered was to prohibit only the manufacturing, processing or distribution in commerce of TCE for spot cleaning in dry cleaning facilities under TSCA section 6(a)(2) or, a variation of this option: A prohibition of manufacturing, processing, or distribution in commerce of TCE for spot cleaning in dry cleaning facilities and require downstream notification when distributing TCE for other uses under section 6(a)(3). This option could reach the risk benchmarks for TCE (Ref. 29). However, this option introduces weaknesses, such as likelihood for users to obtain TCE for spot cleaning through other means, and thereby fails to address the identified unreasonable risks. For example, if only manufacturing, processing and distribution in commerce for the spot cleaning use in dry cleaners were prohibited without also prohibiting the use, dry cleaning facilities could go to other sources to acquire TCE for non-prohibited uses and divert those uses to the spot cleaning use without consequence. This would be the case even if the prohibition on manufacturing, processing and distribution in commerce were accompanied by the downstream notification requirement. A combined approach would ensure that the section 6(a) requirements address the identified unreasonable risks.

c. Require the use of personal protective equipment in commercial dry cleaning facilities in which TCE is used as a spot cleaner under section 6(a)(5) or require the use of personal protective equipment and engineering controls in commercial dry cleaning facilities in which TCE is used as a spot cleaner under section 6(a)(5). Another regulatory option that EPA considered was to require the use of respirators in the form of a supplied-air respirator with an APF of 10,000 for workers at risk of exposure to TCE with a performance based option using an air exposure limit. See Unit VI.B.3.d for a discussion of issues and drawbacks of requiring the use of a supplied-air respirator. In addition, while this option could mitigate the risk for workers, dry cleaning facilities are generally small shops and many are co-located in commercial shopping centers where the work goes on in plain view of customers or are co-located with residential buildings. It is highly unlikely that dry cleaning operations would undertake fitting all of their workers with the full face piece SCBA apparatus with accompanying supplied air breathing device necessary to mitigate risk. This approach could have separate economic impacts because consumers may not wish to enter an establishment in which workers are wearing supplied-air respirators. In addition, many dry cleaning establishments are located near residential areas. Local residents may react adversely to an establishment using chemicals which require a supplied-air respirator.

EPA also considered requiring the combination of the use of local exhaust ventilation which achieves 90% reduction in airborne concentrations to improve ventilation near the worker activity and a supplied-air respirator with an APF of 1,000 with a performance based option using an air exposure limit. EPA conducted a risk analysis for both baseline exposures and exposures after implementing risk management options, allowing for a direct comparison of the acute and chronic risks associated with the exposures following application of a risk reduction option. This option would also reduce risks to the health benchmarks for workers when used properly (Ref. 25). While this option has the benefit of incorporating engineering controls and use of a respirator with a lower APF, there are still the limitations to successful implementation of the use of supplied-air respirators in the workplace as discussed previously.

C. Availability of Substitutes and Impacts of the Proposed and Alternative Regulatory Options

This Unit examines the availability of substitutes for TCE as a spot cleaner in dry cleaning facilities and describes the estimated costs of the proposal and the alternatives that EPA considered. More information on the benefits and costs of this proposal as a whole can be found in Unit VIII.

Overall, EPA notes that the costs of dry cleaning spot cleaning product reformulation are low. Total first-year reformulation costs are estimated to be $286,000 and annualized costs are approximately $22,000 per year (annualized at 3% over 15 years) and $28,000 (annualized at 7% over 15 years). A wide variety of effective

substitutes for TCE in spot cleaning applications indicates that producers and users can readily shift from TCE to less hazardous chemical substitutes. Limitations on these or similar uses of TCE are already in place in many states in the United States and internationally. For example, TCE use is prohibited in California for aerosol and non-aerosol consumer spot removers. TCE is also prohibited in the European Union for spot cleaning use in dry cleaning facilities. In addition, according to the Drycleaning and Laundry Institute, a trade association representing more than 4,000 dry cleaning operations in the United States, not all dry cleaning facilities use TCE, and many other alternatives are available and equally effective (Refs. 42, 43). Further, prohibitions in California and the European Union indicate that the transition can be made to substitutes, demonstrating that switching to alternatives would not be overly difficult for users. Producers of spot cleaning products containing TCE also produce spot cleaning products with substitute chemicals. Thus, there is already precedent for producers reformulating products to meet demand in some states and countries. In addition, EPA expects that one effect of a ban on the use of TCE for spot cleaning at dry cleaning facilities would be increased technological innovation, resulting in the development of additional alternatives.

1. Proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities and require downstream notification. The costs of the proposed approach are estimated to include product reformulation costs, downstream notification and recordkeeping costs, and Agency costs. The total first-year costs of dry cleaning spot cleaning product reformulation are approximately $286,000 and annualized are estimated to be $22,000 per year (at 3% over 15 years) and $28,000 (at 7% over 15 years). The costs to users of dry cleaning spot cleaning products are negligible as substitute products are currently available on the market and are similarly priced. The costs of downstream notification and recordkeeping are estimated to be $51,000 and on an annualized basis over 15 years are $3,900 and $5,000 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $112,000 and $109,000 annualized over 15 years at 3% and 7%, respectively. Annual recurring costs to the Agency for enforcement are estimated to be $121,000 per year. The total cost of the proposed approach for the dry cleaning spot cleaning use is estimated to be $130,000 to $133,000 and $135,000 to $137,000 annualized at 3% and 7%, respectively, over 15 years.

2. Options that require personal protective equipment. The costs of implementing a respiratory protection program, including a supplied-air respirator and related equipment, training, fit testing, monitoring, medical surveillance, and related requirements, would far exceed the costs of switching to alternatives, on a per facility basis. The estimated annualized costs of switching to a respiratory protection program requiring PPE of 10,000 are $8,200 at 3% and $9,000 at 7% per dry cleaning facility over 15 years. The estimated annualized costs of switching to a respiratory protection program requiring PPE of 1,000 are $5,800 at 3% and $5,800 at 7% per dry cleaning facility over 15 years. In addition, there would be higher EPA administration and enforcement costs with respiratory protection program than there would be with an enforcement program under the proposed approach.

3. Options that exclude downstream notification. EPA was unable to monetize the extent to which enforcement costs would vary by regulatory option so EPA assumed monetized enforcement costs to be the same under all options for the purpose of this proposed rulemaking. The proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities and require downstream notification is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to the greatest extent the potential for TCE products to be intentionally or unintentionally misdirected into the prohibited uses. Enforcement under the other options would be much more difficult since the key requirements are directly placed on the large number of product users. Under these other options, enforcement activities must target firms that might perform the activity where a TCE use is restricted or prohibited. For the prohibition on TCE in dry cleaning spot removers, this would include all dry cleaning establishments. (Ref. 2). Therefore, while EPA considers downstream notification to be a critical component of this proposal, EPA also finds that incorporating downstream notification reduces the burden on society by easing implementation, compliance, and enforcement.

D. Summary

The proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities and require downstream notification is necessary to ensure that TCE no longer presents unreasonable risks for this use. This option does not pose an undue burden on industry because comparable substitutes to TCE for spot cleaning in dry cleaning facilities are readily available. This approach also protects workers and occupational bystanders from the identified unreasonable risks by providing downstream notification of the prohibition throughout the supply chain and avoiding off-label purchase and use of TCE for the prohibited use. Downstream notification streamlines compliance and aids in compliance and enhances enforcement.

VIII. Other Factors Considered

When issuing a rule under TSCA section 6(a), EPA must consider and publish a statement based on reasonably available information on the:

- Health effects of the chemical substance in question, TCE in this case, and the magnitude of human exposure to TCE;
- Environmental effects of TCE and the magnitude of exposure of the environment to TCE;
- Benefits of TCE for various uses; and the
- Reasonably ascertainable economic consequences of the rule, including the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health, the costs, benefits, and cost-effectiveness of the rule and of the one or more primary alternatives that EPA considered.

TSCA section 6(c)(2)(B) instructs EPA, when selecting among prohibitions and other restrictions under 6(a) to factor in, to the extent practicable, these considerations. This Unit provides more information on the benefits, costs, and cost-effectiveness of this proposal and the alternatives that EPA considered.

As discussed in Unit IV.B, TCE exposure is associated with a wide array of adverse health effects. These health effects include developmental toxicity (*e.g.,* cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to the kidney (kidney damage and kidney cancer), immunotoxicity (such as systemic autoimmune diseases *e.g.,* scleroderma) and severe hypersensitivity skin

disorder, non-Hodgkin's lymphoma, endocrine and reproductive effects (*e.g.,* decreased libido and potency), neurotoxicity (*e.g.,* trigeminal neuralgia), and toxicity to the liver (impaired functioning and liver cancer) (Ref. 1). TCE may cause fetal cardiac malformations that begin in utero. In addition, fetal death, possibly resulting from cardiac malformation, can be caused by exposure to TCE. Cardiac malformations can be irreversible and impact a person's health for a lifetime. Other effects, such as damage to the developing immune system, may first manifest when a person is an adult and can have long-lasting health impacts. Certain effects that follow adult exposures, such as kidney and liver cancer, may develop many years after initial exposure. The point during a lifetime when the effect manifests itself and the expected impacts to a person during her/his lifetime are important factors in determining the benefits of mitigating and preventing TCE exposure.

Based on EPA's analysis of worker and consumer populations' exposure to TCE, EPA has determined that there are significant cancer and non-cancer risks (acute and chronic) from TCE exposure, which can result in developmental effects, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity. These risks are unreasonable risks because the chemical exposures predicted for the various scenarios assessed are above what would be necessary to achieve the MOE benchmarks for cardiac defects, kidney toxicity, immunotoxicity, liver toxicity, neurotoxicity and endocrine and reproductive toxicity. For commercial use scenarios of aerosol degreasing and use of TCE for spot cleaning in dry cleaning facilities, as well as for all the residential use scenarios, exposures are far beyond what would be necessary to achieve the MOE benchmark for cardiac defects. For example, the 99th percentile of the upper end exposure use scenario for aerosol degreasing has a MOE of 0.003 for chronic exposures and 0.002 for acute exposures. Thus, for this aerosol degreasing use scenario, people are exposed at a level that is 3,000 times higher than what EPA determines is protective for the non-cancer health effect.

The number of people at risk for the developmental effects is estimated to be up to approximately 5,400 pregnant women in dry cleaning operations and approximately 900 pregnant women exposed to TCE during the use of aerosol degreasers. The potential for exposure is significant because approximately half of all pregnancies are unintended. If a pregnancy is not planned before conception, a woman may not be in optimal health for childbearing (Ref. 33).

Given the large differential between the benchmark MOE and the MOEs resulting from EPA's estimates of exposures, people exposed to TCE in aerosol degreasing and during dry cleaning operations are at significant risk for the multiple adverse non-cancer health effects caused by TCE and the impacts discussed below on many facets of their life that these adverse health effects cause. These risks are significant even when considered alone. However, workers may be also be impacted by the significant risks for several types of cancer. The cancer risks to workers using TCE in aerosol degreasing and for spot cleaning in dry cleaning facilities are 1.6×10^{-2} or more than one and one-half cases in one hundred for aerosol degreasing and 1.4×10^{-2} or more than one case in one hundred for use of TCE for spot cleaning in dry cleaning facilities.

The risk reduction from preventing TCE exposure cannot be comprehensively quantified or monetized even though the adverse effects are well-documented, the TCE risk assessment estimating these risks has been peer-reviewed, and the benefits of reducing the risk of these health endpoints can be described. It is relatively straightforward to monetize the benefits of reducing the risk of cancer (kidney cancer, liver cancer, non-Hodgkin's lymphoma) due to TCE exposure. The estimated value of the annualized benefit is estimated to be $9.3 million to $25.0 million at 3% and $4.5 million to $12.8 million at 7% over 15 years. It is currently not possible to monetize the benefits of reducing the risks of the costs of non-cancer effects (all developmental toxicity, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity) of TCE exposure. There are two reasons for this. First, dose response information and concentration response functions in humans are not available, which would allow EPA to estimate the number of population-level non-cancer cases that would be avoided by reducing exposures to levels corresponding with MOE benchmarks. Second, even it were possible to calculate the number of cases avoided, EPA may not be able to monetize the benefits of these avoided cases due to limitations in data needed to apply established economic methodologies. However, being unable to quantitatively assess individual risk and population-level non-cancer cases avoided from TCE exposure does not negate the impact of these effects. Similarly, the inability to monetize an adverse effect does not reflect the severity of the effect, the lifetime nature of the impact, or the magnitude of the benefit in preventing the adverse impact from TCE exposure, such as a cardiac malformation, on a person. In considering the benefits of preventing TCE exposure, EPA considered the type of effect, the severity of the effect, the duration of the effect, and costs and other monetary impacts of the health endpoint.

The health endpoints associated with TCE exposure are serious. The following is a discussion of the impacts of the most significant cancer and non-cancer effects associated with TCE exposure, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime. While TCE can cause a variety of adverse health effects, the general population incidences of these adverse health outcomes are not due solely to TCE.

A. Benefits of the Proposed Rule and the Alternatives That EPA Considered

1. *Developmental effects.* The TCE risk assessment (and EPA's 2011 IRIS Assessment) identified developmental effects as the critical effect of greatest concern for both acute and chronic non-cancer risks. There are increased health risks for developmental effects to the approximately 900 pregnant women exposed to TCE during the use of aerosol degreasers and approximately 5,400 pregnant women working in dry cleaning operations (Ref. 2). Specifically, these assessments identified fetal cardiac malformations in the offspring of mothers exposed to TCE during gestation as the critical effect. Although fetal cardiac defects is the most sensitive endpoint and is the focus of the discussion in this Unit, TCE exposures can result in other adverse developmental outcomes, including prenatal (*e.g.,* spontaneous abortion and perinatal death, decreased birth weight, and congenital malformations) and postnatal (*e.g.,* growth, survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers) effects. Developmental TCE exposure results in qualitatively different immunotoxicity effects than adult exposure. These effects influence the development of the immune system and result in impairment of the immune system to respond to infection whereas adult exposures result in more pronounced immune response related to autoimmune responses.

Cardiac defects, which can result from very low level exposure to TCE, affect

the structural development of a baby's heart and how it works. The defects impact how blood flows through the heart and out to the rest of the body. The impact can be mild (such as a small hole in the heart) or severe (such as missing or poorly formed septal wall and valves of the heart). While diagnosis for some cardiac defects can occur during pregnancy, for other cardiac defects, detection may not occur until after birth or later in life, during childhood or adulthood. These cardiac defects can be occult or life- threatening with the most severe cases causing early mortality and morbidity. While the incidences in the following paragraphs reflect adverse health outcomes beyond just exposure to TCE, the general population numbers provide a context for understanding the impact of the adverse health effects that TCE can cause.

Nearly 1% or about 40,000 births per year in the United States are affected by cardiac defects (Ref. 46). About 25% of those infants with a cardiac defect have a critical defect. Infants with critical cardiac defects generally need surgery or other procedures in their first year of life. Some estimates put the total number of individuals (infants, children, adolescents, and adults) living with cardiac defects at 2 million (Ref. 46). Cardiac defects can be caused by genetics, environmental exposure, or an unknown cause.

Infant deaths resulting from cardiac defects often occur during the neonatal period. One study indicated that cardiac defects accounted for 4.2% of all neonatal deaths. Of infants born with a non-critical cardiac defect, 97% are expected to survive to the age of one, with 95% expected to survive to 18 years of age. Of infants born with a critical cardiac defect, 75% are expected to survive to one year of age, with 69% expected to survive to 18 years of age (Ref. 47). A child with a cardiac defect is 50% more likely to receive special education services compared to a child without birth defects (Ref. 46).

Treatments for cardiac defects vary. Some affected infants and children might need one or more surgeries to repair the heart or blood vessels. In other instances, a heart defect cannot be fully repaired, although treatments have advanced such that infants are living longer and healthier lives. Many children are living into adulthood and lead independent lives with little or no difficulty. Others, however, may develop disability over time which is hard to predict and for which it is difficult to quantify impacts.

Even though a person's heart defect may be repaired, for many people this is not a cure. They can still develop other health problems over time, depending on their specific heart defect, the number of heart defects they have, and the severity of their heart defect. For example, some related health problems that might develop include irregular heart beat (arrhythmias), increased risk of infection in the heart muscle (infective endocarditis), or weakness in the heart (cardiomyopathy). In order to stay healthy, a person needs regular checkups with a cardiologist. They also might need further operations after initial childhood surgeries (Ref. 46).

Depending upon the severity of the defect, the costs for surgeries, hospital stays, and doctor's appointments to address a baby's cardiac defect can be significant. The costs for the defects may also continue throughout a person's lifetime. In 2004, hospital costs in the United States for individuals with a cardiac defect were approximately $1.4 billion (Ref. 46).

Beyond the monetary cost, the emotional and mental toll on parents who discover that their child has a heart defect while *in utero* or after birth will be high (Ref. 47). They may experience anxiety and worry over whether their child will have a normal life of playing with friends and participating in sports and other physical activities, or whether their child may be more susceptible to illness and be limited in the type of work and experiences they can have. In addition, parents can be expected to experience concerns over potential unknown medical costs that may be looming in the future, lifestyle changes, and being unable to return to work in order to care for their child.

The emotional and mental toll on a person throughout childhood and into adolescence with a heart defect also should be considered (Ref. 47). Cardiac patients who are children may feel excluded from activities and feel limited in making friends if they have to miss school due to additional surgeries, or may not be able to fully participate in sports or other physical exercise. Children may feel self-conscious of the scars left by multiple surgeries. This, in turn, adds emotional and mental stress to the parents as they observe their child's struggles.

As a person with a heart defect enters adulthood, the emotional or mental toll of a cardiac defect may continue or in other instances the problem may only surface as the person becomes an adult. If a cardiac defect impacts a person's ability to enter certain careers, this could take a monetary as well as emotional toll on that person and on their parents or families who may need to provide some form of financial support. The monetary, emotional, and mental costs of heart defects can be considerable, and even though neither the precise reduction in individual risk of developing a cardiac defect from reducing TCE exposure or the total number of cases avoided can be estimated, their impact should be considered.

2. *Kidney toxicity.* The TCE risk assessment identified kidney toxicity as a significant concern for non-cancer risk from TCE exposure with the risk being from chronic exposure. There are increased health risks for kidney toxicity to the approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 2).

Exposure to TCE can lead to changes in the proximate tubules of the kidney. This damage may result in signs and symptoms of acute kidney failure that include: Decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness, shortness of breath, fatigue, confusion, nausea, seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Kidney toxicity means the kidney(s) has suffered damage that can result in a person being unable to rid their body of excess urine and wastes. In extreme cases where the kidney(s) is impaired over a long period of time, the kidney(s) could be damaged to the point that it no longer functions. When a kidney(s) no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney(s) can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 48).

Approximately 31 million people, or 10% of the adult population, in the United States have chronic kidney disease. In the United States, it is the ninth leading cause of death. About 93% of chronic kidney disease is from known causes, including 44% from diabetes and 28.4% from high blood pressure. Unknown or missing causes account for about 6.5% of cases, or about 2 million people (Ref. 49).

The monetary cost of kidney toxicity varies depending on the severity of the damage to the kidney. In less severe cases, doctor visits may be limited and hospital stays unnecessary. In more

severe cases, a person may need serious medical interventions, such as dialysis or a kidney transplant if a donor is available, which can result in high medical expenses due to numerous hospital and doctor visits for regular dialysis and surgery if a transplant occurs. The costs for hemodialysis, as charged by hospitals, can be upwards of $100,000 per month (Ref. 50).

Depending on the severity of the kidney damage, kidney disease can impact a person's ability to work and live a normal life, which in turn takes a mental and emotional toll on the patient. In less severe cases, the impact on a person's quality of life may be limited while in instances where kidney damage is severe, a person's quality of life and ability to work would be affected. While neither the precise reduction in individual risk of developing kidney toxicity from reducing TCE exposure or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to TCE.

Chronic exposure to TCE can also lead to kidney cancer. The estimated value of the annualized benefit is $276,000 to $661,000 for aerosol degreasing and $1.4 million to $5.5 million for spot cleaning in dry cleaning facilities at 3% over 15 years; and $135,000 to $349,000 for aerosol degreasing and $677,000 to $2.9 million for spot cleaning in dry cleaning facilities at 7% over 15 years. Kidney cancer rarely shows signs or symptoms in its early stages. As kidney cancer progresses, the cancer may grow beyond the kidney spreading to lymph nodes or distant sites like the liver, lung or bladder increasing the impacts on a person and the costs to treat it. This metastasis is highly correlated with fatal outcomes. Impacts of kidney cancer that are not monetized include the emotional, psychological impacts and the impacts of treatment for the cancer on the well-being of the person.

3. *Immunotoxicity. a. Non-cancer chronic effects.* The TCE risk assessment identified immunotoxicity as a chronic non-cancer risk from TCE exposure. There are increased health risks for immunotoxicity to the approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 1).

Human studies have demonstrated that TCE exposed workers can suffer from systemic autoimmune diseases (*e.g.,* scleroderma) and severe hypersensitivity skin disorder. Scleroderma is a chronic connective tissue disease with autoimmune origins. The annual incidence is estimated to be 10 to 20 cases per 1 million persons (Ref. 51), and the prevalence is four to 253 cases per 1 million persons (Ref. 52). About 300,000 Americans are estimated to have scleroderma. About one third of those people have the systemic form of scleroderma. Since scleroderma presents with symptoms similar to other autoimmune diseases, diagnosis is difficult. There may be many misdiagnosed or undiagnosed cases (Ref. 52).

Localized scleroderma is more common in children, whereas systemic scleroderma is more common in adults. Overall, female patients outnumber male patients about 4-to-1. Factors other than a person's gender, such as race and ethnic background, may influence the risk of getting scleroderma, the age of onset, and the pattern or severity of internal organ involvement. The reasons for this susceptibility are not clear. Although scleroderma is not directly inherited, some scientists believe there is a slight predisposition to it in families with a history of rheumatic diseases (Ref. 53).

The symptoms of scleroderma vary greatly from person-to-person with the effects ranging from very mild to life threatening. If not properly treated, a mild case can become much more serious. Relatively mild symptoms are localized scleroderma, which results in hardened waxy patches on the skin of varying sizes, shapes and color. The more life threatening symptoms are from systemic scleroderma, which can involve the skin, esophagus, gastrointestinal tract (stomach and bowels), lungs, kidneys, heart and other internal organs. It can also affect blood vessels, muscles and joints. The tissues of involved organs become hard and fibrous, causing them to function less efficiently.

Severe hypersensitivity skin disorder includes exfoliative dermatitis, mucous membrane erosions, eosinophilia, and hepatitis. Exfoliative dermatitis is a scaly dermatitis involving most, if not all, of the skin. Eosinophilia on the other hand is a chronic disorder resulting from excessive production of a particular type of white blood cells. If diagnosed and treated early a person can lead a relatively normal life (Ref. 51).

The monetary costs for treating these various immunotoxicity disorders will vary depending upon whether the symptoms lead to early diagnosis and early diagnosis can influence whether symptoms progress to mild or life threatening outcomes. For mild symptoms, doctors' visits and outpatient treatment could be appropriate while more severe immunotoxicity disorders, may require hospital visits. Treatments for these conditions with immune modulating drugs also have countervailing risks.

These disorders also take an emotional and mental toll on the person as well as on their families. Their quality of life may be impacted because they no longer have the ability to do certain activities that may affect or highlight their skin disorder, such as swimming. Concerns over doctor and hospital bills, particularly if a person's ability to work is impacted, may further contribute to a person's emotional and mental stress. While neither the precise reduction in individual risk of developing this disorder from TCE exposure or the total number of cases avoided can be estimated, this should be considered.

b. *Non-Hodgkin's Lymphoma.* EPA's 2011 IRIS assessment for TCE found that TCE is carcinogenic. Chronic exposure to TCE, by all routes of exposure, can result in non-Hodgkin's lymphoma (NHL), one of the three cancers for which the EPA TCE IRIS assessment based its cancer findings. There are increased health risks for NHL for the approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 2).

NHL is a form of cancer that originates in a person's lymphatic system. For NHL, there are approximately 19.7 new cases per 100,000 men and women per year with 6.2 deaths per 100,000 men and women per year. NHL is the seventh most common form of cancer (Ref. 53). Some studies suggest that exposure to chemicals may be linked to an increased risk of NHL. Other factors that may increase the risk of NHL are medications that suppress a person's immune system, infection with certain viruses and bacteria, or older age (Ref. 54).

Symptoms are painless, swollen lymph nodes in the neck, armpits or groin, abdominal pain or swelling, chest pain, coughing or trouble breathing, fatigue, fever, night sweats, and weight loss. Depending on the rate at which the NHL is advancing, the approach may be to monitor the condition, while more aggressive NHL could require chemotherapy, radiation, stem cell transplant, medications that enhance a person's immune system's ability to fight cancer, or medications that deliver radiation directly to cancer cells.

Treatment for NHL will result in substantial costs for hospital and doctors' visits in order to treat the cancer. The treatments for NHL can also have countervailing risks and can lead to higher susceptibility of patients for secondary malignancies (Ref. 55). The emotional and mental toll from wondering whether a treatment will be successful, going through the actual treatment, and inability to do normal activities or work will most likely be high. This emotional and mental toll will extend to the person's family and friends as they struggle with the diagnosis and success and failure of a treatment regime. If a person has children, this could affect their mental and emotional well-being and may impact their success in school. A discussion of the monetized benefits associated with reducing risk of NHL is located in Unit VIII.B. The estimated value of the annualized benefit is $759,000 to $1.2 million for aerosol degreasing and $3.9 million to $10.1 million for spot cleaning in dry cleaning facilities at 3% over 15 years; and $355,000 to $601,000 for aerosol degreasing and $1.8 million to $5.0 million for spot cleaning in dry cleaning facilities at 7% over 15 years.

4. Reproductive and endocrine effects. The TCE risk assessment identified chronic non-cancer risks for reproductive effects for workers and bystanders exposed to TCE. There are increased health risks for reproductive effects for the approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 2).

The reproductive effect for both females and males can be altered libido. The prevalence of infertility is estimated at about 10–15% of couples with a decreased libido among the factors of infertility (Ref. 56). For females, there can be reduced incidence of fecundability (6.7 million women ages 15 to 44 or 10.9% affected) (Ref. 57), increase in abnormal menstrual cycle, and amenorrhea (the absence of menstruation). Reproductive effects on males can be decreased potency, gynaecomastia, impotence, and decreased testosterone levels, or low T levels. Approximately 2.4 million men age 40 to 49 have low T levels, with a new diagnosis of about 481,000 androgen deficiency cases a year. Other estimates propose a hypogonadism prevalence of about 13 million American men (Ref. 58). Low T levels are associated with aging; an estimated 39% of men 45 or older have hypogonadism, resulting in low T levels (Ref. 59). Hormone therapy and endocrine monitoring may be required in the most severe cases. Low T levels are associated with aging; an estimated 39% of men 45 or older have hypogonadism, resulting in low T levels (Ref. 59). Hormone therapy and endocrine monitoring may be required in the most severe cases.

The monetary costs of these potential reproductive effects involve doctor's visits in order to try to determine why there is a change. In some instances, a person or couple may need to visit a fertility doctor.

The impact of a reduced sex drive can take an emotional and mental toll on single people as well as couples. For people trying to get pregnant, decreased fertility can add stress to a relationship as the cause is determined and avenues explored to try to resolve the difficulties in conceiving. A person or couples' quality of life can also be affected as they struggle with a reduced sex drive. Similar to effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing TCE exposure or the total number of cases avoided can be estimated, the Agency still considers their impact.

5. Neurotoxicity. The TCE risk assessment identified chronic risks for neurotoxicity for workers and bystanders. There are increased health risks for neurotoxicity to the approximately 10,800 workers and bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and bystanders in dry cleaning operations (Ref. 2).

Studies have also demonstrated neurotoxicity for acute exposure. Neurotoxic effects observed are alterations in trigeminal nerve and vestibular function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. Developmental neurotoxicity effects are delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit (Ref. 3).

The impacts of neurotoxic effects due to TCE exposure can last a person's entire lifetime. Changes in vision may impact a person's ability to drive, which can create difficulties for daily life. Impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit can impact a child's educational progression and adolescent's schooling and ability to make friends, which in turn can impact the type of work or ability get work later in life.

Neurotoxicity in adults can affect the trigeminal nerve, the largest and most complex of the 12 cranial nerves, which supplies sensations to the face, mucous membranes, and other structures of the head. Onset of trigeminal neuralgia generally occurs in mid-life and known causes include multiple sclerosis, sarcoidosis and Lyme disease. There is also a co-morbidity with scleroderma and systemic lupus. Some data show that the prevalence of trigeminal neuralgia could be between 0.01% and 0.3% (Ref. 60). Alterations to this nerve function might cause sporadic and sudden burning or shock-like facial pain to a person. One way to relieve the burning or shock-like facial pain is to undergo a procedure where the nerve fibers are damaged in order to block the pain. This treatment can have lasting impact on sensation which may also be deleterious for normal pain sensation. The potential side effects of this procedure includes facial numbness and some sensory loss.

The monetary health costs can range from doctor's visits and medication to surgeries and hospital stays. Depending upon when the neurotoxic effect occurred, the monetary costs may encompass a person's entire lifetime or just a portion.

The personal costs (emotional, mental, and impacts to a person's quality of life) cannot be discounted. Parents of a child with impaired learning, memory, or some other developmental neurotoxic effect may suffer emotional and mental stress related to worries about the child's performance in school, ability to make friends, and quality of the child's life because early disabilities can have compounding effects as they grow into adulthood. The parent may need to take off work unexpectedly and have the additional cost of doctor visits and/or medication.

For a person whose trigeminal nerve is affected there is an emotional and mental toll as they wonder what is wrong and visit doctors in order to determine what is wrong. Depending on the severity of the impact to the nerve they may be unable to work. Doctor visits and any inability to work will have a monetary impact to the person. There are varying costs (emotional, monetary, and impacts to a person's quality of life) from the neurotoxicity effects due to TCE exposure. However, while neither the precise reduction in

individual risk of developing this disorder from reducing TCE exposure or the total number of cases avoided can be estimated, this is not a reason to disregard their impact.

6. Liver toxicity. The TCE risk assessment identified liver toxicity as an adverse effect of chronic TCE exposure. There are increased health risks for liver toxicity to the approximately 10,800 workers occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 1).

Specific effects to the liver can include increased liver weight, increase in DNA synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation (Ref. 1). In addition, workers exposed to TCE have shown hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure (Ref. 1).

Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans (Ref. 61). Included in this number is at least 20% of those with nonalcoholic fatty liver disease (NAFLD) (Ref. 61). NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors (Ref. 61). The danger of NAFLD is that it can cause the liver to swell, which may result in cirrhosis over time and could even lead to liver cancer or failure (Ref. 61). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. In 2013, there were 1,781 reported acute cases of viral hepatitis A and the estimated actual cases were 3,500 (Ref. 62). For hepatitis B in 2013 there were 3,050 reported acute cases, while the estimated actual incidence was 19,800, and the estimated chronic cases in the United States is between 700,000 to 1.4 million (Ref. 62). For hepatitis C, in 2013 there were 2,138 reported cases; however, the estimated incidence was 29,700 and the estimated number of chronic cases is between 2.7 to 3.9 million (Ref. 62). These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals.

Effects from TCE exposure to the liver can occur quickly. Liver weight increase has occurred in mice after as little as 2 days of inhalation exposure (Ref. 3). Human case reports from eight countries indicated symptoms of hepatitis, hepatomegaly and elevated liver function enzymes, and in rare cases, acute liver failure developed within as little as 2–5 weeks of initial exposure to TCE (Ref. 3).

Chronic exposure to TCE can also lead to liver cancer. There is strong epidemiological data that reported an association between TCE exposure and the onset of various cancers, including liver cancer. The estimated value of the annualized benefit is $493,000 to $811,000 for aerosol degreasing and $2.5 million to $6.7 million for spot cleaning in dry cleaning facilities at 3% over 15 years; and $252,000 to $436,000 for aerosol degreasing and $1.3 million to $3.6 million for spot cleaning in dry cleaning facilities at 7% over 15 years.

Additional medical and emotional costs are associated with non-cancer liver toxicity from TCE exposure, although they cannot be quantified. These costs include doctor and hospital visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper ongoing medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease. Symptoms of jaundice include yellow or itchy skin and a yellowing of the whites of the eye, and a pale stool and dark urine. These symptoms can create a heightened emotional state as a person tries to determine what is wrong with them.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to the TCE; however, this may impact a person's ability to continue to work. In severe cases, the liver toxicity can lead to liver failure, which can result in the need for a liver transplant, if a donor is available. Liver transplantation is expensive (with an estimated cost of $575,000) and there are countervailing risks for this type of treatment (Ref. 63). The mental and emotional toll on an individual and their family as they try to determine the cause of sickness and possibly experience an inability to work, as well as the potential monetary cost of medical treatment required to regain health are significant.

7. Disproportionate impacts on environmental justice communities. An additional factor that cannot be monetized is the disproportionate impact on environmental justice communities. Asian and Hispanic populations are disproportionately represented in dry cleaning facilities. 13% of dry cleaning workers are Asian, compared to 5% of the national population, and 30% of dry cleaning workers are Hispanic (of any race), compared to 16% of the national population, indicating that these two populations are over-represented. Because they are disproportionately over-represented in the dry cleaning industry, these populations are disproportionately exposed to TCE during spot cleaning in dry cleaning facilities and disproportionately at risk to the range of adverse non-cancer effects and cancer.

B. Monetized Benefits of the Proposed Rule and the Alternatives That EPA Considered

The benefits that can be monetized from risk reductions due to the proposed prohibitions on manufacture, processing, and distribution in commerce of TCE for aerosol degreasing, and the prohibition on commercial use of TCE in aerosol degreasing are estimated to be $1.5 million to $2.7 million (annualized at 3% over 15 years) and $700,000 to $1.4 million (annualized at 7% over 15 years). The monetized benefits from similar prohibitions to mitigate the risks from TCE for spot cleaning in dry cleaning facilities are estimated to be $7.8 million to $22.3 million (annualized at 3% over 15 years) and $3.7 million to $11.4 million (annualized at 7% over 15 years). The total monetized benefits for the proposed rule range from approximately $9.2 million to $24.8 million on an annualized basis over 15 years at 3% and $4.4 million to $12.6 million at 7%. The alternatives considered are unlikely to result in the same health benefits as the proposed rule for the reasons discussed in Units VI and VII. However, EPA was unable to quantify the differences in benefits that would result from the alternatives.

C. Costs of the Proposed Rule and the Alternatives That EPA Considered

The details of the costs of the proposed approach for use of TCE in aerosol degreasing are discussed in Unit VI.C.1 and the details of the costs of the proposed approach for spot cleaning in dry cleaning facilities are discussed in Unit VII.C.1. Under the proposed option, costs to users of aerosol degreasers are negligible as substitute products are currently available on the market and are similarly priced. Total costs of aerosol degreasing product reformulations are estimated to be approximately $416,000 in the first year and $32,000 per year (annualized at 3% over 15 years) and $41,000 (annualized at 7% over 15 years). Costs of downstream notification and recordkeeping are estimated to be $51,000 in the first year and on an

annualized basis over 15 years are $3,900 and $5,000 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $112,000 and $109,000 annualized over 15 years at 3% and 7%, respectively. The total cost of the proposed approach for the aerosol degreasing use is estimated to be $37,000 to $40,000 and $46,000 to $49,000 annualized over 15 years at 3% and 7%, respectively. Annual recurring costs to the Agency for enforcement are estimated to be $121,000 per year.

Under the proposed approach, dry cleaners are expected to switch to alternatives because they are readily available at similar cost and performance. Blenders of TCE spot cleaners are expected to reformulate their products. Total costs of reformulation are estimated to be $286,000 in the first year and annualized costs are approximately $22,000 per year (annualized at 3% over 15 years) and $28,000 (annualized at 7% over 15 years). Costs of downstream notification and recordkeeping are estimated to be $51,000 in the first-year and on an annualized basis over 15 years are $3,900 and $5,000 using 3 and 7 percent discount rates respectively. Agency costs for enforcement are estimated to be approximately $112,000 to $109,000 annualized over 15 years at 3% and 7%. Annual recurring costs to the Agency for enforcement are estimated to be $121,000 per year. The total cost of the proposed approach for the dry cleaning spotting use is estimated to be $130,000–$133,000 and $135,000–$137,000 annualized over 15 years at 3% and 7%, respectively.

Total costs of the proposed rule for both uses are estimated to be $170,000 annualized over 15 years at 3% and $183,000 annualized over 15 years at 7%.

Alternatives that EPA considered include the use of PPE as well as an option that would prohibit the use of TCE in aerosol degreasing and as a spot cleaner at dry cleaning facilities, without the companion prohibition on manufacture, processing, or distribution in commerce for these uses or the downstream notification requirements. As discussed in Unit VI., EPA assumed that no users would adopt PPE because the per-facility costs were prohibitively expensive. The estimated annualized costs of switching to a respiratory protection program requiring PPE of 10,000 are $8,200 at 3% and $9,000 at 7% per dry cleaning facility and $8,300 at 3% and $9,100 at 7% per aerosol degreasing facility over 15 years. EPA also found that a use prohibition alone without downstream notification requirements would not address the identified unreasonable risks. EPA estimated the costs of this option to be $166,000 annualized over 15 years at 3% and $178,000 annualized over 15 years at 7%.

D. Comparison of Benefits and Costs

The monetized benefits for preventing the risks resulting from TCE exposure from both these uses significantly outweigh the estimated costs. Even though simply comparing the costs and monetized benefits of prohibiting the manufacture, processing, and distribution in commerce of TCE as an aerosol degreaser; prohibiting its use as an aerosol degreaser; and requiring downstream notification demonstrates that the monetized benefits of this proposed action outweigh the costs, EPA believes that the balance of costs and benefits cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects as well as cancer. As discussed previously, the multitude of potential adverse effects associated with TCE exposure can profoundly impact an individual's quality of life. Some of the adverse effects associated with TCE exposure can be immediately experienced and can affect a person from childhood throughout a lifetime (*e.g.,* cardiac malformations, developmental neurotoxicity, and developmental immunotoxicity). Others (*e.g.,* adult immunotoxicity, kidney and liver failure or cancers) can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature.

While the risk of non-cancer health effects associated with TCE exposure cannot be quantitatively estimated, the qualitative discussion highlights how some of these non-cancer effects occurring much earlier in life from TCE exposure may be as severe as cancer's mortality and morbidity and thus just as life-altering. These effects include not only medical costs but also personal costs such as emotional and mental stress that are impossible to accurately measure.

While the impacts of non-cancer effects cannot be monetized, EPA considered the impacts of these effects in making its determination about how best to address the unreasonable risks presented by TCE use in aerosol degreasing and as a spot cleaner in dry cleaning facilities. Considering only monetized benefits would significantly underestimate the impacts of TCE-induced non-cancer adverse outcomes on a person's quality of life to perform basic skills of daily living, including the ability to earn a living, the ability to participate in sports and other activities, and the impacts on a person's family and relationships.

Thus, considering costs, benefits that can be monetized (risk of cancer), and benefits that cannot be quantified and subsequently monetized (risk of developmental toxicity, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity), including benefits related to the severity of the effects and the impacts on a person throughout her/his lifetime in terms of medical costs, effects on earning power and personal costs, emotional and psychological costs, and the disproportionate impacts on Asian and Hispanic communities, the benefits of preventing TCE exposure outweigh the costs. Further, if EPA were to consider only the benefits that can be monetized in comparison to the cost, the monetized benefits from preventing kidney and liver cancer and non-Hodgkin's lymphoma from the use of TCE in aerosol degreasing (the annualized monetized benefits on a 15 year basis range from approximately $1.5 million to $2.7 million at 3% and $700,000 to $1.4 million at 7%) and the use of TCE in spot cleaners in dry cleaning facilities (the annualized monetized benefits on a 15 year basis range from approximately $7.8 million to $22.3 million at 7% and $3.7 million to $11.4 million at 3%) far outweigh the costs of the proposed approaches for use of TCE in aerosol degreasing (the annualized costs on a 15 year basis range from approximately $37,000 to $40,000 at 3% and $46,000 to $49,000 at 7%) and for use of TCE in spot cleaners in dry cleaning facilities (the annualized costs on a 15 year basis range from approximately $130,000 to $133,000 at 3% and $135,000 to $137,000 at 7%).

IX. Overview of Uncertainties

A discussion of the uncertainties associated with this proposed rule can be found in the TCE risk assessment (Ref. 1) and in the supplemental analysis (Refs. 23, 24, 25) for use of TCE in aerosol degreasing and use of TCE for spot cleaning in dry cleaning facilities. A summary of these uncertainties follows.

EPA used a number of assumptions in the TCE risk assessment and supporting analysis to develop estimates for occupational and consumer exposure scenarios and to develop the hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include: (1) Releases of and exposures to

TCE can vary from one aerosol degreasing activity to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. In estimating the risk from aerosol degreasing, there are uncertainties in the number of workers exposed to TCE and in the inputs to the models used to estimate exposures. (2) Although EPA found information about TCE products intended for consumer use, there is some general uncertainty regarding the nature and extent of the consumer use of aerosol products containing TCE. (3) Releases of and exposures to TCE can vary from one dry cleaning facility to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. There is also uncertainty in the number of workers exposed to TCE for spot cleaning in dry cleaning facilities. There are uncertainties in the model and inputs used to model the exposures to TCE from these uses.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the benefits are most pronounced in estimating the benefits from preventing the non-cancer adverse effects because these benefits generally cannot be monetized due to the lack of concentration response functions in humans leading to the ability to estimate the number of population-level non-cancer cases and limitations in established economic methodologies. Additional uncertainties in benefit calculations include the reliance on professional judgment to estimate the alternatives that users might choose to adopt and the potential risks for adverse health effects that the alternatives may pose. While there are some products that have comparable risks, there are a number of alternatives that are likely to be of lower risk, although EPA is unable to estimate the incremental change in the risk. To account for this uncertainty, EPA includes a lower and a higher estimate for the benefits from eliminating exposure to TCE. The lower benefits estimate does not include any benefits for firms that switch to anything other than water-based, methyl ester (soy-based) cleaners, or acetone degreasers. The higher benefits estimate includes the benefit from entirely eliminating TCE exposure for all alternative compliance strategies and assumes that no risks are introduced by alternatives. This inability to adequately account for adverse health effects of alternatives in the benefits analysis is expected to contribute most to the uncertainty in the estimates.

There are also uncertainties in the estimates of the number of affected facilities, particularly those for the aerosol degreasing use and for numbers of processors and distributors of TCE-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records. The estimate for number of facilities using TCE-containing aerosol degreasers is based on EPA calculations using data derived from the California Air Resources Board Initial Statement of Reasons for the Proposed Airborne Toxic Control Measure for Emissions of Chlorinated Toxic Air Contaminants from Automotive Maintenance and Repair Activities (Ref. 2). To estimate the number of processors, EPA relied on public 2012 CDR data. The number of sites is reported in the CDR data as a range. The midpoint of the reported ranges was used to estimate the total number of sites using the chemical. Furthermore, the CDR data only include processors immediately downstream of those reporting to CDR. Finally, EPA estimated the number of wholesaler firms distributing products containing TCE by taking a ratio of the number of Chemical and Allied Products Merchant Wholesaler firms to Basic Chemical Manufacturing firms and applying it to the estimated number of manufacturers and processors of TCE (Ref. 2).

Another uncertainty concerns the estimate for the cost of reblending products and the time required to reblend those products. EPA used a study on the automotive aftermarket parts products industry that provided a range of costs for product reformulation and used the mean value of $26,000 from that study. EPA contacted both dry cleaners and blenders of aerosol degreasing products for additional information and received a few estimates from the aerosol degreasing product blenders which ranged from $15,000 to $30,000. However, EPA received no information from dry cleaning spot cleaning product blenders, so there is some uncertainty as to how representative the estimate is for that industry.

EPA also assumes that companies are generally able to reblend products within 6 months following publication of the final rule; however, it is not certain whether they may experience additional costs if they are not able have a product available to market at that time.

EPA will consider additional information received during the public comment period, including comments on implementation timeframes. This includes public comments, scientific publications, and other input submitted to EPA during the comment period.

X. Analysis Under Section 9 of TSCA (Other Authorities) for Aerosol Degreasing and Spot Cleaning in Dry Cleaning Facilities and TSCA Section 26(h) Considerations

A. Section 9 Analysis

1. Section 9(a) analysis. Section 9(a) of TSCA provides that, if the Administrator determines in her discretion that unreasonable risks may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. If the other agency responds by declaring that the activities described do not present unreasonable risks or if that agency initiates action under its own law to protect against the risk, EPA is precluded from acting against the risk under sections 6 or 7 of TSCA.

Section 9(d) of TSCA instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For today's proposed rule, EPA has consulted with CPSC and OSHA.

CPSC protects the public from unreasonable risks of injury or death associated with the use of consumer products under the agency's jurisdiction. There are no CPSC regulations on use of TCE in aerosol degreasers and for spot cleaning at dry cleaning facilities (Ref. 64).

OSHA assures safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA adopted an eight-hour time weighted average PEL of 100 ppm along with a ceiling limit in 1971 shortly after the agency was formed. It was based on the American Conference of Governmental Industrial Hygienists (ACGIH) recommended occupational exposure limit that was in place at that time. OSHA recognizes that the TCE PEL and many other PELs issued shortly after adoption of the OSHA Act in 1970 are outdated and inadequate for ensuring protection of worker health. OSHA recently published a Request for Information on approaches to updating PELs and other strategies to managing chemicals in the workplace (Ref. 9).

OSHA's current regulatory agenda does not include revision to the TCE PEL or other regulations addressing the risks EPA has identified when TCE is used in aerosol degreasing or for spot cleaning in dry cleaning facilities (Ref. 9).

EPA has determined that risks from the use of TCE in aerosol spray degreasers and as a spot cleaner in dry cleaning facilities are best managed by regulation under TSCA rather than by referral to other agencies. Today's proposed rule addresses risk from TCE exposure to populations in both workplaces and consumer settings. With the exception of TSCA, there is no Federal law that provides authority to prevent or sufficiently reduce these cross-cutting exposures. No other Federal regulatory authority, when considering the exposures to the populations and within the situations in its purview, can evaluate and address the totality of the risk that EPA is addressing in this proposed rulemaking under TSCA. For example, OSHA may set exposure limits for workers but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals. Further, OSHA does not have direct authority over state and local employees, and it has no authority at all over the working conditions of state and local employees in states that have no OSHA-approved State Plan under 29 U.S.C. 667. Other Federal regulatory authorities, such as CPSC, have the authority to only regulate pieces of the TCE risk, such as consumer products. And neither agency has authority to bar the manufacture, processing or distribution for these uses and require downstream notification of restrictions like EPA proposes to do.

Moreover, recent amendments to TSCA, Public Law 114–182, alter both the manner of identifying unreasonable risk under TSCA and EPA's authority to address unreasonable risk under TSCA, such that risk management under TSCA is increasingly distinct from analogous provisions of the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), or the OSH Act. These changes to TSCA reduce the likelihood that an action under the CPSA, FHSA, or the OSH Act would reduce the risk of these uses of TCE so that the risks are no longer unreasonable under TSCA. Whereas (in a TSCA section 6 rule) an unreasonable risk determination sets the objective of the rule in a manner that excludes cost considerations, 15 U.S.C. 2605(b)(4)(A), subject to time-limited conditional exemptions for critical chemical uses and the like, 15 U.S.C. 2605(g), a consumer product safety rule under the CPSA must include a finding that ''the benefits expected from the rule bear a reasonable relationship to its costs.'' 15 U.S.C. 2058(f)(3)(E). Additionally, recent amendments to TSCA reflect Congressional intent to ''delete the paralyzing 'least burdensome' requirement,'' 162 Cong. Rec. S3517 (June 7, 2016). However, a consumer product safety rule under the CPSA must impose ''the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated.'' 15 U.S.C. 2058(f)(3)(F). Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action under the FHSA relative to action under TSCA. 15 U.S.C. 1262. Gaps also exist between OSHA's authority to set workplace standards under the OSH Act and EPA's amended obligations to sufficiently address chemical risks under TSCA. To set PELs for chemical exposure, OSHA must first establish that the new standards are economically feasible and technologically feasible. (79 FR 61387, October 10, 2014). But under TSCA, EPA's substantive burden under TSCA section 6(a) is to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being determined without consideration of cost or other non-risk factors.

TSCA is the only regulatory authority able to prevent or reduce risk from these uses of TCE to a sufficient extent across the range of uses and exposures of concern. In addition, these risks can be addressed in a more coordinated, efficient and effective manner under TSCA than under two or more different laws implemented by different agencies. Accordingly, EPA determines that referral to other Federal authorities for risk management would not necessarily address the unreasonable risk. As noted previously, there are key differences between the newly amended finding requirements of TSCA and those of the OSH Act, CPSA, and the FHSA. For these reasons, in her discretion, the Administrator does not determine that unreasonable risks from these uses of TCE may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

2. Section 9(b) analysis. If EPA determines that actions under other Federal authorities administered in whole or in part by EPA may eliminate or sufficiently reduce unreasonable risks, section 9(b) of TSCA instructs EPA to use these other statutes unless the Administrator determines in the Administrator's discretion that it is in the public interest to protect against such risk under TSCA. In making such a public interest determination, section 9(b)(2) of TSCA states: ''the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk . . . and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk.''

Although several EPA statutes have been used to limit TCE exposure, as discussed in Unit III.A, regulations under these EPA statutes have limitations because they largely regulate releases to the environment, rather than direct human exposure. SDWA only applies to drinking water. CAA does not apply directly to worker exposures or consumer settings where TCE is used. Under RCRA, TCE that is discarded may be considered a hazardous waste and subject to requirements designed to reduce exposure from the disposal of TCE to air, land and water. RCRA does not address exposures during use of products containing TCE. Only TSCA provides EPA the authority to regulate the manufacture (including import), processing, and distribution in commerce, and use of chemicals substances.

B. Section 26(h) Considerations

In proposing this rule under section 6 of TSCA, the EPA has made a decision based on science. EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. Specifically, EPA based its preliminary determination of unreasonable risk presented by the use of TCE in aerosol degreasing products and as a spot cleaner in dry cleaning facilities on the completed risk assessment, which followed a peer review and public comment process, as well as using best available science and methods (Ref. 1). Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, can be found on EPA's Assessments for TSCA Work Plan Chemicals Web page at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals.*

The scientific information and technical measures and models used in the risk assessment and supplemental analyses are consistent with the intended use for risk reduction by regulation under section 6 of TSCA. The degree of clarity and completeness of

the science used in the risk assessment and supplemental analyses are described in the risk assessment (Ref. 1) and Unit IX. Similarly, the variability and uncertainty in the information or models and methods used are described in the risk assessment (Ref. 1) and Unit IX.

XI. Major Provisions of the Proposed Rule

A. Prohibitions on TCE Manufacturing, Processing, Distribution in Commerce, and Commercial Use

The rule would prohibit (1) the manufacture, processing, distribution in commerce, and commercial use of TCE in aerosol degreasers; and (2) the manufacture, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities.

B. Downstream Notification

EPA has authority under section 6 of TSCA to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. Many TCE manufacturers and processors are likely to manufacture or process TCE or TCE containing products for other uses that would not be regulated under this proposed rule. Other companies may be strictly engaged in distribution in commerce of TCE, without any manufacturing or processing activities, to customers for uses that are not regulated. EPA is proposing a requirement for downstream notification by manufacturers, processors, and distributors of TCE for any use to ensure compliance with the prohibition on manufacture, processing, distribution in commerce, and commercial use of TCE for spot cleaning in dry cleaning facilities and in aerosol degreasers. Downstream notification is necessary for effective enforcement of the rule because it provides a record, in writing, of notification on use restrictions throughout the supply chain, likely via modifications to the Safety Data Sheet. Downstream notification also increases awareness of restrictions on the use of TCE for spot cleaning in dry cleaning facilities and in aerosol degreasers, which is likely to decrease unintentional uses of TCE by these entities. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The estimated cost of downstream notification is $51,000 in the first year and $3,900 and $5,000 on an annualized basis over 15 years using 3 and 7 percent discount rates respectively.

C. Enforcement

Section 15 of TSCA makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under section 6 of TSCA. Therefore, any failure to comply with this proposed rule when it becomes effective would be a violation of section 15 of TSCA. In addition, section 15 of TSCA makes it unlawful for any person to: (1) Fail or refuse to establish and maintain records as required by this rule; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by section 11 of TSCA.

Violators may be subject to both civil and criminal liability. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty for each violation. Each day of operation in violation of this proposed rule when it becomes effective could constitute a separate violation. Knowing or willful violations of this proposed rule when it becomes effective could lead to the imposition of criminal penalties for each day of violation and imprisonment. In addition, other remedies are available to EPA under TSCA.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to ''any person'' who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false information or cause it to be reported.

XII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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67. EPA. Notification of Consultation and Coordination on Proposed Rulemakings under the Toxic Substances Control Act for (1) Methylene Chloride and n-Methylpyrrolidone in Paint Removers and (2) Trichloroethylene in Certain Uses. April 8, 2015.

XIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action because it may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, EPA submitted the action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and Executive Order 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an economic analysis of the potential costs and benefits associated with this action, which is available in the docket and summarized in Unit VIII. (Ref. 2).

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted to OMB for review and comment under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by the EPA has been assigned the EPA ICR number 2541.01. You can find a copy of the ICR in the docket for this proposed rule, and it is briefly summarized here.

The information collection activities required under the proposed rule include a downstream notification requirement and a recordkeeping requirement. The downstream notification would require companies that ship TCE to notify companies downstream in the supply chain of the prohibitions of TCE in the proposed rule. The proposed rule does not require the regulated entities to submit information to EPA. The proposed rule also does not require confidential or sensitive information to be submitted to EPA or downstream companies. The recordkeeping requirement mandates companies that ship TCE to retain certain information at the company headquarters for two years from the date of shipment. These information collection activities are necessary in order to enhance the prohibitions under the proposed rule by ensuring awareness of the prohibitions throughout the TCE supply chain, and to provide EPA with information upon inspection of companies downstream who purchased TCE. EPA believes that these information collection activities would not significantly impact the regulated entities.

Respondents/affected entities: TCE manufacturers, processors, and distributors.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 697.

Frequency of response: On occasion.

Total estimated burden: 348.5 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $16,848 (per year).

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than January 17, 2017. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are blenders of TCE-containing dry cleaning spot removers and aerosol degreasers, users of dry cleaning spot removers and aerosol degreasers, and manufacturers, processors, and distributors of non-prohibited TCE-containing products. Users of these products are not expected to experience costs as there are currently a number of alternatives available that are similar in performance and cost. There are no small governmental jurisdictions or non-profits expected to be affected by the proposed rule. Overall, EPA estimates there are approximately 51,000 small entities affected by the proposed rule.

Comparing the total annualized compliance cost for companies to their revenue, the Agency has estimated that all companies are expected to have cost impacts of less than one percent of their revenues, ranging from an estimated high of 0.3 percent of revenues to a low of 0.01 percent of revenues. Details of this analysis are presented in the Economic Analysis for this proposed rule (Ref. 2).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The requirements of this action would primarily affect manufacturers, processors, and distributors of TCE. The total estimated annualized cost of the proposed rule is approximately

$170,000 at 3% and $183,000 at 7% (Ref. 2).

E. Executive Order 13132: Federalism

The EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt state law. EPA provides the following preliminary federalism summary impact statement. The Agency consulted with state and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. EPA invited the following national organizations representing state and local elected officials to a meeting on May 13, 2015, in Washington DC: National Governors Association; National Conference of State Legislatures, Council of State Governments, National League of Cities, U.S. Conference of Mayors, National Association of Counties, International City/County Management Association, National Association of Towns and Townships, County Executives of America, and Environmental Council of States. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 65). Although EPA provided these organizations an opportunity to provide follow-up comments in writing, no written follow-up was received by the Agency.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rulemaking would not have substantial direct effects on tribal government because TCE is not manufactured, processed, or distributed in commerce by tribes. TCE is not regulated by tribes, and this rulemaking would not impose substantial direct compliance costs on tribal governments. Thus, E.O. 13175 does not apply to this action. EPA nevertheless consulted with tribal officials during the development of this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes.

EPA met with tribal officials in a national informational webinar held on May 12, 2015 concerning the prospective regulation of TCE under TSCA section 6, and in another teleconference with tribal officials on May 27, 2015 (Ref. 66). EPA also met with the National Tribal Toxics Council (NTTC) in Washington, DC and via teleconference on April 22, 2015 (Ref. 66). In those meetings, EPA provided background information on the proposed rule and a summary of issues being explored by the Agency. These officials expressed concern for TCE contamination on tribal lands and supported additional regulation of TCE.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. This action's health and risk assessment of TCE exposure on children are contained in Units VI.B.1.c and VII.B.1.c of this preamble. Supporting information on the exposures and health effects of TCE exposure on children is also available in the Toxicological Review of Trichloroethylene (Ref. 3) and the TCE risk assessment (Ref. 1).

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution in Commerce, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution in commerce, or use. This rulemaking is intended to protect against risks from TCE, and does not affect the use of oil, coal, or electricity.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the U.S. Units VI.B., VII.B, and VIII. of this preamble address public health impacts from TCE. EPA has determined that there would not be a disproportionately high and adverse health or environmental effects on minority, low income, or indigenous populations from this proposed rule.

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Trichloroethylene, Recordkeeping.

Dated: December 6, 2016,

Gina McCarthy,

Administrator.

■ Therefore, it is that 40 CFR chapter I, subchapter R, is proposed to be amended by adding a new part 751 to read as follows:

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

Subpart A—General Provisions

Sec.

Subpart B—[Reserved]

Subpart C—[Reserved]

Subpart D—Trichloroethylene

Authority: 15 U.S.C. 2605.

Subpart A—General Provisions

§ 751.1 Purpose.

This part sets forth requirements, such as prohibitions concerning the manufacture (including import), processing, distribution in commerce, uses, and/or disposal of certain chemical substances and mixtures under section 6(a) of the Toxic Substances Control Act, 15 U.S.C. 2605(a).

§ 751.5 Definitions.

The definitions in section 3 of the Toxic Substances Control Act, 15 U.S.C. 2602, apply to this part except as otherwise established in any subpart under this part.

Act or TSCA means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

CASRN means Chemical Abstracts Service Registry Number.

EPA means the U.S. Environmental Protection Agency.

Person means any natural person, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity; any State or political

subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal Government.

§ 751.7 Exports and imports.

(a) *Exports.* Persons who intend to export a chemical substance identified in any subpart under this part, or in any proposed rule which would amend any subpart under this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at 40 CFR part 707, subpart D.

(b) *Imports.* Persons who import a substance identified in any subpart under this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR 12.118 through 12.127. See also 19 CFR 127.28.

§ 751.9 Enforcement and Inspections.

(a) *Enforcement.* (1) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit entry or inspection as required by section 11 of the Act (15 U.S.C. 2610) is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(b) *Inspections.* EPA will conduct inspections under section 11 of the Act (15 U.S.C. 2610) to ensure compliance with this part.

Subpart B—[Reserved]

Subpart C—[Reserved]

Subpart D—Trichloroethylene

§ 751.301 General.

This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, and uses of trichloroethylene (TCE) (CASRN 79–01–6) to prevent unreasonable risks to health associated with human exposure to TCE for the specified uses.

§ 751.303 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

Aerosol degreasing means the use of a chemical in aerosol spray products applied from a pressurized can to remove contaminants.

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of § 751.311 and § 751.313.

Dry cleaning facility means an establishment with one or more dry cleaning systems.

Dry cleaning system means a dry-to-dry machine and its ancillary equipment or a transfer machine system and its ancillary equipment.

Retailer means a person who distributes in commerce a chemical substance, mixture, or article to consumer end users.

Spot cleaning means use of a chemical to clean stained areas on materials such as textiles or clothing.

§ 751.305 Aerosol Degreasing.

(a) After [*Date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce TCE in aerosol degreasing products and TCE for use in aerosol degreasing products.

(b) After [*Date 270 calendar days after the date of publication of the final rule*], all persons are prohibited from commercial use of TCE in aerosol degreasing products.

§ 751.307 Spot Cleaning at Dry Cleaning Facilities.

(a) After [*Date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce TCE for spot cleaning at dry cleaning facilities.

(b) After [*Date 270 calendar days after the date of publication of the final rule*], all persons are prohibited from commercial use of TCE for spot cleaning at dry cleaning facilities.

§ 751.309 [Reserved]

§ 751.311 Downstream Notification.

Each person who manufactures, processes, or distributes in commerce TCE for any use after [*Date 45 calendar days after the date of publication of the final rule*] must, prior to or concurrent with the shipment, notify companies to whom TCE is shipped, in writing, of the restrictions described in this subpart.

§ 751.313 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any TCE after [*Date 45 calendar days after the date of publication of final rule*] must retain in one location at the headquarters of the company documentation of:

(1) The name, address, point of contact, and telephone number of companies to whom TCE was shipped; and

(2) The amount of TCE shipped.

(3) Downstream notification.

(b) The documentation in (a) must be retained for 2 years from the date of shipment.

[FR Doc. 2016–30063 Filed 12–15–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2016–0387; FRL–9950–08]

RIN 2070–AK11

Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Trichloroethylene (TCE) is a volatile organic compound widely used in industrial and commercial processes and has some limited uses in consumer and commercial products. EPA identified significant health risks associated with TCE use in vapor degreasing and EPA's proposed determination is that these risks are unreasonable risks. To address these unreasonable risks, EPA is proposing under section 6 of the Toxic Substances Control Act (TSCA) to prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; to prohibit commercial use of TCE in vapor degreasing; to require manufacturers, processors, and distributors, except for retailers of TCE for any use, to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping.

DATES: Comments must be received on or before March 20, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0387, at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods (*e.g.,* mail or hand delivery), the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

Docket. Docket ID No. EPA–HQ–OPPT–2016–0387 contains supporting information used in developing the proposed rule, comments on the proposed rule, and additional supporting information. In addition to being available online at *http://www.regulations.gov,* the docket is available for inspection and copying between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding federal holidays, at the U.S. Environmental Protection Agency, EPA Docket Center Reading Room, WJC West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Cindy Wheeler, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 566–0484; email address: *wheeler.cindy@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this proposed action if you manufacture (defined under TSCA to include import), process, or distribute in commerce TCE or commercially use TCE in vapor degreasers. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Petroleum Refineries (NAICS code 324110).
- Petroleum Lubricating Oil and Grease Manufacturing (NAICS code 324191).
- Petrochemical Manufacturing (NAICS code 325110).
- Industrial Gas Manufacturing (NAICS code 325120).
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180).
- All Other Basic Organic Chemical Manufacturing (NAICS code 325199).
- Plastics Material and Resin Manufacturing (NAICS code 325211).
- Synthetic Rubber Manufacturing (NAICS code 325212).
- Paint and Coating Manufacturing (NAICS code 325510).
- Adhesive Manufacturing (NAICS code 325520).
- Soap and Other Detergent Manufacturing (NAICS code 325611).
- Polish and Other Sanitation Good Manufacturing (NAICS code 325612).
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS code 325998).
- Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing (NAICS code 326113).
- All Other Plastics Product Manufacturing (NAICS code 326199).
- Rubber and Plastics Hoses and Belting Manufacturing (NAICS code 326220).
- All Other Rubber Product Manufacturing (NAICS code 326299).
- Cement Manufacturing (NAICS code 327310).
- Ground or Treated Mineral and Earth Manufacturing (NAICS code 327992).
- Iron and Steel Pipe and Tube Manufacturing from Purchased Steel (NAICS code 331210).
- Steel Wire Drawing (NAICS code 331222).
- Copper Rolling, Drawing, Extruding, and Alloying (NAICS code 331420)
- Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding (NAICS code 331491).
- Nonferrous Metal Die-Casting Foundries (NAICS code 331523).
- Powder Metallurgy Part Manufacturing (NAICS code 332117).
- Metal Crown, Closure, and Other Metal Stamping (except Automotive) (NAICS code 332119).
- Saw Blade and Hand Tool Manufacturing (NAICS code 332216).
- Metal Window and Door Manufacturing (NAICS code 332321).
- Power Boiler and Heat Exchanger Manufacturing (NAICS code 332410).
- Other Fabricated Wire Product Manufacturing (NAICS code 332618).
- Machine Shops (NAICS code 332710).
- Precision Turned Product Manufacturing (NAICS code 332721).
- Bolt, Nut, Screw, Rivet, and Washer Manufacturing (NAICS code 332722).
- Metal Heat Treating (NAICS code 332811).
- Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers (NAICS code 332812).

- Electroplating, Plating, Polishing, Anodizing, and Coloring (NAICS code 332813).
- Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132).
- Cutting Tool and Machine Tool Accessory Manufacturing (NAICS code 333515).
- Small Arms, Ordnance, and Ordnance Accessories Manufacturing (NAICS code 332994).
- Fluid Power Pump and Motor Manufacturing (NAICS code 333996).
- All Other Miscellaneous Fabricated Metal Product Manufacturing (NAICS code 332999).
- Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132).
- Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing (NAICS code 333413).
- Cutting Tool and Machine Tool Accessory Manufacturing (NAICS code 333515).
- Pump and Pumping Equipment Manufacturing (NAICS code 333911).
- Fluid Power Pump and Motor Manufacturing (NAICS code 333996).
- Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing (NAICS code 334511).
- Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use (NAICS code 334512).
- Motor and Generator Manufacturing (NAICS code 335312).
- Primary Battery Manufacturing (NAICS code 335912).
- Carbon and Graphite Product Manufacturing (NAICS code 335991).
- Motor Vehicle Brake System Manufacturing (NAICS code 336340).
- Aircraft Manufacturing (NAICS code 336411).
- Other Aircraft Parts and Auxiliary Equipment Manufacturing (NAICS code 336413).
- Guided Missile and Space Vehicle Manufacturing (NAICS code 336414).
- Ship Building and Repairing (NAICS code 336611).
- Dental Equipment and Supplies Manufacturing (NAICS code 339114).
- Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690).
- Petroleum Bulk Stations and Terminals (NAICS code 424710).
- Hazardous Waste Treatment and Disposal (NAICS code 562211).
- Solid Waste Combustors and Incinerators (NAICS code 562213).

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final TSCA section 6(a) rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

For a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6. TCE is such a chemical substance. It is listed in the 2014 update to the TSCA Work Plan and the completed risk assessment was published on June 25, 2014. The scope of the completed risk assessment includes vapor degreasing.

C. What action is the Agency taking?

EPA's proposed determination is that the use of TCE in vapor degreasing presents an unreasonable risk of injury to health. Accordingly, EPA is proposing under TSCA section 6 to prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; to prohibit commercial use of TCE in vapor degreasing; and to require manufacturers, processors, and distributors, except for retailers, to provide downstream notification of this prohibition throughout the supply chain (*e.g.,* via a Safety Data Sheet (SDS)), and to keep records. The application of this supply chain approach is necessary so that TCE no longer presents the identified unreasonable risks. EPA is requesting public comment on this proposal.

This proposal is related to the proposed rule on TCE aerosol degreasing and spot cleaning in dry cleaning facilities that published in the **Federal Register** on December 16, 2016 (81 FR 91592) (FRL–9949–86) (Ref. 1). This proposal and the earlier proposal together address risks for workers and consumers associated with exposure to TCE through inhalation that were identified in the 2014 TCE risk assessment and EPA intends to finalize both actions together.

D. Why is the Agency taking this action?

Based on EPA's analysis of worker exposures to TCE, EPA's proposed determination is that the use of TCE in vapor degreasing presents an unreasonable risk to human health. More specifically, this use results in significant non-cancer risks under both acute and chronic exposure scenarios and significant cancer risks from chronic exposures. These adverse health effects include those resulting from developmental toxicity (*e.g.,* cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to the kidney (kidney damage and kidney cancer), immunotoxicity (such as systemic autoimmune diseases, *e.g.,* scleroderma, and severe hypersensitivity skin disorder), non-Hodgkin's lymphoma, reproductive and endocrine effects (*e.g.,* decreased libido and potency), neurotoxicity (*e.g.,* trigeminal neuralgia), and toxicity to the liver (impaired functioning and liver cancer) (Ref. 2). TCE may cause fetal cardiac malformations that begin in utero. Cardiac malformations can be irreversible and impact a person's health for a lifetime. In addition, fetal death, possibly resulting from cardiac malformation, can be caused by exposure to TCE. In utero exposure to TCE may cause other effects, such as damage to the developing immune system, which manifest later in adult

life and can have long-lasting health impacts. Certain effects that follow adult exposures, such as kidney and liver cancer, may develop many years after initial exposure.

As discussed in Unit I.C., EPA is not proposing to prohibit all manufacturing, processing, distribution in commerce, and use of TCE. As such, the application of this proposal's supply chain approach tailored to specific uses that present unreasonable risks to human health is necessary so that the chemical substance no longer presents the identified unreasonable risks.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of multiple regulatory options, including the proposed approach of prohibiting the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; prohibiting the commercial use of TCE in vapor degreasing; and requiring manufacturers, processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain as well as associated recordkeeping requirements. This analysis (Ref. 3), which is available in the docket, is discussed in Unit VI., and is briefly summarized here.

Alternatives to TCE with similar performance characteristics are readily available. Most of the costs of the rule would be borne by commercial users of TCE in vapor degreasing equipment, because they would have to switch solvents and likely equipment as well. EPA has estimated that the costs to users range from $30M to $45M when annualized over 20 years at a 3% discount rate, and from $32M to $46M over 20 years at a 7% discount rate. These are the total estimated costs of this proposal. The costs of the downstream notification and recordkeeping requirements to manufacturers, processors, and distributors of TCE, estimated to be approximately $3,200 and $4,400 annualized over 20 years using 3% and 7% discount rates respectively. For additional information see Unit 5.1.3 of the Economic Analysis. (Ref. 3) However, because these notification and recordkeeping costs were already accounted for in the economic analysis accompanying the earlier TCE proposal (Ref. 1), they are not included in the total costs for this proposal. EPA accounted for these costs in the prior proposal because it believes the universe of entities distributing TCE for both sets of uses are the same. EPA is taking comment on whether the same firms distribute TCE for these two sets of uses.

Although TCE causes a wide range of non-cancer adverse effects and cancer, monetized benefits included only benefits associated with reducing cancer risks. The Agency does not have sufficient information to include a quantification or valuation estimate for non-cancer benefits in the overall benefits at this time. The monetized benefits for the proposed approach range from approximately $65 to $443 million on an annualized basis over 20 years at 3% and $31 million to $225 million at 7% (Ref. 3). The non-monetized benefits resulting from the prevention of the non-cancer adverse effects associated with TCE exposure from use in vapor degreasers include developmental toxicity, toxicity to the kidney, immunotoxicity, reproductive and endocrine effects, neurotoxicity, and toxicity to the liver (Ref. 2). Some of the effects that can be caused by exposure to TCE, such as cardiac malformations and fetal death, occur in utero and can impact a person for a lifetime; other effects, such as damage to the developing immune system, may first manifest when a person is an adult and can have long lasting impacts. Also see Unit VI.D.

F. Children's Environmental Health

This action is consistent with the 1995 EPA Policy on Evaluating Health Risks to Children (*http://www.epa.gov/children/epas-policy-evaluating-risk-children*). EPA has identified women of childbearing age and the developing fetus as a susceptible subpopulation relevant to its risk assessment for TCE. After evaluating the developmental toxicity literature for TCE, the Integrated Risk Information System (IRIS) TCE assessment concluded that fetal heart malformations are the most sensitive developmental toxicity endpoint associated with TCE inhalation exposure (Ref. 4). In its TSCA Chemical Work Plan Risk Assessment for TCE, EPA identified developmental toxicity as the most sensitive endpoint for TCE inhalation exposure (*i.e.,* fetal heart malformations) for the most sensitive human life stage (*i.e.,* women of childbearing age between the ages of 16 and 49 years and the developing fetus) (Ref. 2). EPA used developmental toxicity endpoints for both the acute and chronic non-cancer risk assessments based on its developmental toxicity risk assessment policy that a single exposure of a chemical within a critical window of fetal development may produce adverse developmental effects (Ref. 5). For the identified susceptible subpopulations, the proposed regulatory action is protective of the fetal heart malformation endpoint and, for the exposed population as a whole, the proposal is also protective of cancer risk. In addition, the supporting non-cancer risk analysis of children and women of childbearing age conducted in the TSCA Chemical Work Plan Risk Assessment for TCE (Ref. 2) also meets the 1995 EPA Policy on Evaluating Health Risks to Children (Ref. 6). Supporting information on TCE exposures and the health effects of TCE exposure on children are also available in the IRIS Toxicological Review of Trichloroethylene (Ref. 4) and the TSCA Chemical Work Plan Risk Assessment on Trichloroethylene (Ref. 2), as well as Unit VI of this preamble.

II. Overview of TCE and the Use Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule applies to TCE (Chemical Abstract Services Registry Number 79–01–6) for use in vapor degreasing.

B. What are the uses of TCE?

In 2011, global consumption of TCE was 945 million pounds and consumption in the United States was 255 million pounds. TCE is produced within and imported into the United States. Nine companies, including domestic manufacturers and importers, reported a total production and import of 225 million pounds of TCE in 2011 to EPA pursuant to the Chemical Data Reporting (CDR) rule (Ref. 2).

The majority (about 83.6%) of TCE is used as an intermediate chemical for manufacturing refrigerant HFC-134a. This use occurs in a closed system that has low potential for human exposure (Ref. 2). EPA did not assess this use and is not proposing to regulate this use of TCE under TSCA at this time. However, this does not mean that EPA found that this use or other uses not included in the TCE risk assessment present low risk. Much of the remainder, about 14.7%, is used as a solvent for degreasing of metals. A relatively small percentage, about 1.7%, accounts for all other uses, including TCE use in products, such as aerosol degreasers.

Based on the Toxics Release Inventory (TRI) data for 2012, 38 companies used TCE as a formulation component, 33 companies processed TCE by repackaging the chemical, 28 companies used TCE as a manufacturing aid, and 1,113 companies used TCE for ancillary uses, such as degreasing (Ref. 2). Based on the latest TRI data from 2014, the number of users of TCE has significantly

decreased since 2012: 24 companies use TCE as a formulation component, 20 companies process TCE by repackaging the chemical, 20 companies use TCE as a manufacturing aid, and 97 companies use TCE for ancillary uses, such as degreasing. The TRI data does not represent all of the facilities manufacturing, processing, and/or using TCE because only certain industries and types of facilities are required to report. EPA estimates that there are 2,632 to 6,232 firms using TCE for vapor degreasing in the U.S. (Ref. 3).

The use assessed by EPA that is the subject of this proposal, commercial use of TCE in vapor degreasing, is estimated to represent up to 14.7% of total use of TCE. This use is discussed in detail in Unit VI.

C. What are the potential health effects of TCE?

A broad set of relevant studies including epidemiologic studies, animal bioassays, metabolism studies, and mechanistic studies show that TCE exposure is associated with an array of adverse health effects. TCE has the potential to induce developmental toxicity, immunotoxicity, kidney toxicity, reproductive and endocrine effects, neurotoxicity, liver toxicity, and several forms of cancer (Ref. 2).

TCE is fat soluble (lipophilic) and easily crosses biological membranes. TCE has been found in human maternal and fetal blood and in the breast milk of lactating women (Ref. 2). EPA's IRIS assessment (Ref. 4) concluded that TCE poses a potential health hazard for non-cancer toxicity including fetal heart malformations and other developmental effects, immunotoxicity, kidney toxicity, reproductive and endocrine effects, neurotoxicity, and liver effects. The IRIS assessment also evaluated TCE and its metabolites. Based on the results of *in vitro* and *in vivo* tests, TCE metabolites have the potential to bind or induce damage to the structure of deoxyribonucleic acid (DNA) or chromosomes (Ref. 4).

An evaluation of the overall weight of the evidence of the human and animal developmental toxicity data suggests an association between pre- and/or post-natal TCE exposures and potential adverse developmental outcomes. TCE-induced heart malformations and immunotoxicity in animals have been identified as the most sensitive developmental toxicity endpoints for TCE. Human studies examined the possible association of TCE with various prenatal effects. These adverse effects of developmental TCE exposure may include: Death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions); decreased growth (low birth weight, small for gestational age); congenital malformations, in particular heart defects; and postnatal effects such as reduced growth, decreased survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers. Some epidemiological studies reported an increased incidence of birth defects in TCE-exposed populations from exposure to contaminated water. As for human developmental neurotoxicity, studies collectively suggest that the developing brain is susceptible to TCE toxicity. These studies have reported an association with TCE exposure and central nervous system birth defects and postnatal effects such as delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit disorder (Ref. 2).

Immune-related effects following TCE exposures have been observed in adult animal and human studies. In general, these effects were associated with enhanced immune response as opposed to immunosuppressive effects. Human studies have reported a relationship between systemic autoimmune diseases, such as scleroderma, with occupational exposure to TCE. There have also been a large number of case reports in TCE-exposed workers developing a severe hypersensitivity skin disorder, often accompanied by systemic effects to the lymph nodes and other organs, such as hepatitis (Ref. 2).

Studies in both humans and animals have shown changes in the proximal tubules of the kidney following exposure to TCE (Ref. 2). The IRIS TCE assessment concluded that TCE is carcinogenic to humans based on convincing evidence of a causal relationship between TCE exposure in humans and kidney cancer (Ref. 4). A recent review of TCE by the International Agency for Research on Cancer (IARC) also supported this conclusion (Ref. 7). The 12th report on carcinogens (RoC) by the National Toxicology Program also concluded that TCE is reasonably anticipated to be a human carcinogen 2015 (Ref. 8). These additional recent peer reviews are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposures based upon strong epidemiological and animal evidence (Refs. 2, 4).

TCE metabolites appear to be the causative agents that induce renal toxicity, including cancer. S-dichlorovinyl-L-cysteine (DCVC), and to a lesser extent other metabolites, appears to be responsible for kidney damage and kidney cancer following TCE exposure. Toxicokinetic data suggest that the TCE metabolites derived from glutathione conjugation (in particular DCVC) can be systemically delivered or formed in the kidney. Moreover, DCVC-treated animals showed the same type of kidney damage as those treated with TCE (Ref. 2). The toxicokinetic data and the genotoxicity of DCVC further suggest that a mutagenic mode of action is involved in TCE-induced kidney tumors, although cytotoxicity followed by compensatory cellular proliferation cannot be ruled out. As for the mutagenic mode of action, both genetic polymorphisms (Glutathione transferase (GST) pathway) and mutations to tumor suppressor genes have been hypothesized as possible mechanistic key events in the formation of kidney cancers in humans (Ref. 2).

The toxicological literature provides support for male and female reproductive effects following TCE exposure. Both the epidemiological and animal studies provide evidence of adverse effects to female reproductive outcomes. However, more extensive evidence exists in support of an association between TCE exposures and male reproductive toxicity. There is evidence that metabolism of TCE in male reproductive tract tissues is associated with adverse effects on sperm measures in both humans and animals. Furthermore, human studies support an association between TCE exposure and alterations in sperm density and quality, as well as changes in sexual drive or function and altered serum endocrine levels (Ref. 2).

Neurotoxicity has been demonstrated in animal and human studies under both acute and chronic exposure conditions. Evaluation of multiple human studies revealed TCE-induced neurotoxic effects including alterations in trigeminal nerve and vestibular function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. These studies in different populations have consistently reported vestibular system-related symptoms such as headaches, dizziness, and nausea following TCE exposure (Ref. 2).

Animals and humans exposed to TCE consistently experience liver toxicity. Specific effects include the following structural changes: Increased liver weight, increased DNA synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation. Several human studies

reported an association between TCE exposure and significant changes in serum liver function tests used in diagnosing liver disease, or changes in plasma or serum bile acids. There was also human evidence for hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure in TCE-exposed workers (Ref. 2).

TCE is characterized as carcinogenic to humans by all routes of exposure as documented in EPA's IRIS TCE assessment (Ref. 4). This conclusion is based on strong cancer epidemiological data that reported an association between TCE exposure and the onset of various cancers, primarily in the kidney, liver, and the immune system, *i.e.,* non-Hodgkin's lymphoma (NHL). Further support for TCE's characterization as a carcinogen comes from positive results in multiple rodent cancer bioassays in rats and mice of both sexes, similar toxicokinetics between rodents and humans, mechanistic data supporting a mutagenic mode of action for kidney tumors, and the lack of mechanistic data supporting the conclusion that any of the mode(s) of action for TCE-induced rodent tumors are irrelevant to humans. Additional support comes from the 2014 evaluation of TCE's carcinogenic effects by IARC, which classifies TCE as carcinogenic to humans (Ref. 7). The 12th NTP RoC also concluded that TCE exposure is reasonably anticipated to be a human carcinogen (Ref. 8). These additional recent peer reviewed documents are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposures based upon strong epidemiological and animal evidence (Refs. 2, 4).

D. What are the environmental impacts of TCE?

Pursuant to TSCA section 6(c), this unit describes the effects of TCE on the environment and the magnitude of the exposure of the environment to TCE. The unreasonable risk determination of this proposal is based solely on risks to human health since those risks are the most serious consequence of use of TCE and are sufficient to support this proposed action. The following is a discussion of the environmental impacts of TCE.

1. Environmental effects and impacts. TCE enters the environment as a result of emissions from metal degreasing facilities, and spills or accidental releases, and historic waste disposal activities. Because of its high vapor pressure and low affinity for organic matter in soil, TCE evaporates fairly rapidly when released to soil; however, where it is released onto land surface or directly into the subsurface, TCE can migrate from soil to groundwater. Based on TCE's moderate persistence, low bioaccumulation, and low hazard for aquatic toxicity, the magnitude of potential environmental impacts on ecological receptors is judged to be low for the environmental releases associated with the use of TCE for vapor degreasing. This should not be misinterpreted to mean that the fate and transport properties of TCE suggest that water and soil contamination is likely low or does not pose an environmental concern. EPA is addressing TCE contamination in groundwater, drinking water, and contaminated soils at a large number of sites. While the primary concern with this contamination has been human health, there is potential for TCE exposures to ecological receptors in some cases (Ref. 2).

2. What is the global warming potential of TCE? Global warming potential (GWP) measures the potency of a greenhouse gas over a specific period of time, relative to carbon dioxide, which has a high GWP of 1 regardless of the time period used. Due to high variability in the atmospheric lifetime of greenhouse gases, the 100-year scale (GWP100) is typically used. TCE has relatively low global warming potential at a GWP100 of 140 and thus the impact is low (Ref. 2).

3. What is the ozone depletion potential of TCE? TCE is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy (SNAP) program for degreasing and aerosols. In 2007, TCE was identified as a substitute for two ozone depleting chemicals, methyl chloroform and CFC–113, for metals, electronics, and precision cleaning (72 FR 30142, May 30, 2007) (FRL–8316–8) (Ref. 9).

4. Is TCE a volatile organic compound (VOC)? TCE is a VOC as defined at 40 CFR 51.100(c). A VOC is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions.

5. Does TCE persist in the environment and bioaccumulate? TCE may be persistent, but it is not bioaccumulative. TCE is slowly degraded by sunlight and reactants when released to the atmosphere. Volatilization and microbial biodegradation influence the fate of TCE when released to water, sediment or soil. The biodegradation of TCE in the environment is dependent on a variety of factors and so a wide range of degradation rates have been reported (ranging from days to years). TCE is not expected to bioconcentrate in aquatic organisms based on measured bioconcentration factors of less than 1000 (Ref. 2).

III. Regulatory Actions Pertaining to TCE

Because of its potential health effects, TCE is subject to state, federal, and international regulations restricting and regulating its use, which are summarized in this unit. None of these actions addresses the unreasonable risks under TSCA that EPA is seeking to address in this proposed rule.

A. Federal Actions Pertaining to TCE

Since 1979, EPA has issued numerous rules and notices pertaining to TCE under its various authorities.

- *Toxic Substances Control Act:* On December 16, 2016, EPA issued a proposed rule under TSCA section 6 to prohibit the manufacture (including import), processing, distribution in commerce and commercial use of TCE in aerosol degreasers and as a spot removal agent in dry cleaning facilities (Ref. 1). In addition, EPA published a final Significant New Use Rule (SNUR) that would require manufacturers (including importers) and processors of TCE to notify the Agency before starting or resuming any significant new uses of TCE in certain consumer products, including in spray fixatives used to finish arts and crafts (81 FR 20535, April 8, 2016) (Ref. 10).
- *Safe Drinking Water Act:* EPA has issued drinking water standards for TCE pursuant to section 1412 of the Safe Drinking Water Act. EPA promulgated the National Primary Drinking Water Regulation (NPDWR) for TCE in 1987 (52 FR 25690, July 8, 1987). The NPDWR established a non-enforceable maximum contaminant level (MCL) goal of zero milligrams per liter (mg/L) based on classification as a probable human carcinogen. The NPDWR also established an enforceable MCL of 0.005 mg/L. EPA is evaluating revising the TCE drinking water standard as part of a group of carcinogenic volatile organic compounds.
- *Clean Water Act:* EPA identified TCE as a toxic pollutant under section 307(a)(1) of the Clean Water Act (33 U.S.C. 1317(a)(1)) in 1979 (44 FR 44502, July 30, 1979) (FRL–1260–5). In addition, EPA developed recommended TCE ambient water quality criteria for the protection of human health pursuant to section 304(a) of the Clean Water Act.
- *Clean Air Act:* TCE is a hazardous air pollutant (HAP) under the Clean Air Act (42 U.S.C. 7412(b)(1). EPA

promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) for TCE for several industrial source categories, including halogenated solvent cleaning, fabric printing, coating, and dyeing, and synthetic organic chemical manufacturing. The halogenated solvent cleaning NESHAP, controls emissions of several halogenated solvents, including TCE, from halogenated solvent cleaning machines (40 CFR subpart T). The NESHAP includes multiple compliance alternatives to allow maximum compliance flexibility. In 2007, EPA promulgated the Halogenated Solvent Cleaning NESHAP RTR (Risk and Technology Review) Rule (72 FR 25138, May 3, 2007) (FRL–8303–6), in which EPA evaluated the health and environmental risks remaining after promulgation of the original NESHAP and established revised standards that further limit emissions of TCE (and other solvents) in halogenated solvent cleaning. Specifically, EPA promulgated a facility-wide emission limit of 60,000 kilograms per year (kg/year) methylene chloride equivalent, a unit which combines emissions of methylene chloride, trichloroethylene, and perchloroethylene. The facility-wide emission limit applied to all halogenated solvent cleaning machines with the exception of halogenated solvent cleaning machines used by the following industries: Facilities that manufacture narrow tubing, facilities that use continuous web cleaning machines, aerospace manufacturing and maintenance facilities, and military maintenance and depot facilities. EPA also promulgated a facility-wide emission limit of 100,000 kg/year methylene chloride equivalent for halogenated solvent cleaning machines used at military maintenance and depot facilities. TCE is also regulated under the NESHAP rule for synthetic organic chemical manufacturing. This rule consists of four subparts in 40 CFR part 63. In 2003, EPA issued a final NESHAP rule to reduce toxic air pollutant emissions from fabric and other textile coating, printing, and dyeing facilities. The final rule applied to new and existing facilities that emit 10 tons per year or more of a single toxic air pollutant listed in the Clean Air Act or 25 tons per year or more of a combination of those pollutants, including TCE. In addition, EPA has established VOC standards for consumer products under section 183(e) of the Clean Air Act.

- *Resource Conservation and Recovery Act (RCRA):* EPA classifies certain wastes containing TCE as hazardous waste subject to Subtitle C of RCRA pursuant to the toxicity characteristics or as a listed waste. RCRA also provides authority to require cleanup of hazardous wastes containing TCE at RCRA facilities.
- *Comprehensive Environmental Response, Compensation and Liability Act (CERCLA):* EPA designated TCE as a hazardous substance with a reportable quantity pursuant to section 102(a) of CERCLA and EPA is actively overseeing cleanup of sites contaminated with TCE pursuant to the National Contingency Plan (NCP). While many of the statutes that EPA is charged with administering provide statutory authority to address specific sources and routes of TCE exposure, none of these can address the serious human health risks from TCE exposure that EPA is proposing to address under TSCA section 6(a) with this proposed rule.

The Occupational Safety and Health Administration (OSHA) established a permissible exposure limit (PEL) for TCE in 1971. The PEL is an 8-hour time-weighted average (TWA) TCE concentration of 100 ppm. In addition, the TCE PEL requires that exposure to TCE not exceed 200 ppm (ceiling) at any time during an eight hour work shift with the following exception: Exposures may exceed 200 ppm, but not more than 300 ppm (peak), for a single time period up to 5 minutes in any 2 hours (Ref. 11). OSHA acknowledges that many of its PELs are not sufficiently protective of worker health. OSHA has noted that ''with few exceptions, OSHA's PELs, which specify the amount of a particular chemical substance allowed in workplace air, have not been updated since they were established in 1971 under expedited procedures available in the short period after the OSH Act's adoption . . . Yet, in many instances, scientific evidence has accumulated suggesting that the current limits are not sufficiently protective'' (Ref. 12 at p. 61386), including the PEL for TCE.

To provide employers, workers, and other interested parties with a list of alternate occupational exposure limits that may serve to better protect workers, OSHA's Web page highlights selected occupational exposure limits derived by other organizations. For example, the National Institute for Occupational Safety and Health considers TCE a potential occupational carcinogen and recommended an exposure limit of 25 ppm as a 10-hour TWA in 2003 (Ref. 13). The American Conference of Governmental Industrial Hygienists recommended an 8-hour TWA of 10 ppm and an acute, or short term, exposure limit of 25 ppm in 2004 (Ref. 14).

B. State Actions Pertaining to TCE

Many states have taken actions to reduce risks from TCE use. TCE is listed on California's Safer Consumer Products regulations candidate list of chemicals that exhibit a hazard trait and are on an authoritative list and is also listed on California's Proposition 65 list of chemicals known to cause cancer or birth defects or other reproductive harm. In addition, the California Code of Regulations, Title 17, Section 94509(a) lists standards for VOCs for consumer products sold, supplied, offered for sale, or manufactured for use in California (Ref. 15). As part of that regulation, use of consumer general purpose degreaser products that contain TCE are banned in California and safer substitutes are in use.

In Massachusetts, TCE is a designated high hazard substance, with an annual reporting threshold of 1,000 pounds (Ref. 16). Minnesota classifies TCE as a chemical of high concern (Ref. 17). Many other states have considered TCE for similar chemical listings (Ref. 18). Several additional states have various TCE regulations that range from reporting requirements to product contamination limits to use reduction efforts aimed at limiting or prohibiting TCE content in products.

Most states have set PELs identical to the OSHA 100 ppm 8-hour TWA PEL (Ref. 18). Nine states have PELs of 50 ppm (Ref. 18). California's PEL of 25 ppm is the most stringent (Ref. 15). All of these PELs are significantly higher than the exposure levels at which EPA identified unreasonable risks for TCE use for vapor degreasing and would not be protective.

C. International Actions Pertaining to TCE

TCE is also regulated internationally and the international industrial and commercial sectors have moved to alternatives. TCE was added to the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) restriction of substances classified as a carcinogen category 1B under the EU Classification and Labeling regulation in 2009 (Ref. 19). The restriction prohibits the placing on the market or use of TCE as a substance, as a constituent of other substances, or in mixtures for supply to the general public when the individual concentration of TCE in the substance or mixture is equal to or greater than 0.1% by weight (Ref. 19). In 2010, TCE was added to the Candidate List of substances for inclusion in Annex XIV of REACH, or the Authorisation List. Annex XIV includes substances of very high concern that are subject to use

authorization due to their hazardous properties. TCE meets the criteria for classification as a carcinogen. In 2011, TCE was recommended for inclusion in Annex XIV of REACH due to the very high volumes allocated to uses in the scope of authorization and because at least some of the described uses appeared to result in significant exposure of workers and professionals, and could be considered widely dispersive uses.

In 2013, the Commission added TCE to Annex XIV of REACH, making it subject to authorization. As such, entities that wanted to use TCE were required to apply for authorization by October 2014, and those entities without an authorization were required to stop using TCE by April 2016. The European Chemicals Agency (ECHA) received 19 applications for authorization from entities interested in using TCE beyond April 2016. Two of those were for vapor degreasing applications (Refs. 20, 21). In each case, the opinion of the Committee for Risk Assessment was that it was not possible to determine a derived no-effect level (DNEL) for the carcinogenicity properties of the substance in accordance with REACH and that the operational conditions and risk management measures in the applications appeared not to limit the risk. Those measures included use in a specific type of closed vapor degreasing system with personal protective equipment (PPE). Final decisions have not yet been made on the applications.

Canada conducted a hazard assessment of TCE in 1993 and concluded that ''trichloroethylene occurs at concentrations that may be harmful to the environment, and that may constitute a danger in Canada to human life or health. It has been concluded that trichloroethylene occurs at concentrations that do not constitute a danger to the environment on which human life depends'' (Ref. 22). In 2003, Canada issued the Solvent Degreasing Regulations (SOR/2003–283) to reduce releases of TCE into the environment from solvent degreasing facilities using more than 1,000 kilograms of TCE per year (Ref. 23). In 2013, Canada added TCE to the Toxic Substances List—Schedule 1 because TCE ''is entering or may enter the environment in a quantity or concentration or under conditions that: (a) Have or may have an immediate or chronic harmful effect on the environment or its biological diversity, and (c) constitute or may constitute a danger in Canada to human life or health.'' (Ref. 23).

In Japan, the Chemical Substances Control Law considers TCE a Class II substance (substances that may pose a risk of long-term toxicity to humans or to flora and fauna in the human living environment, and that have been, or in the near future are reasonably likely to be, found in considerable amounts over a substantially extensive area of the environment) (Ref. 24). Japan also controls air emissions and water discharges containing TCE, as well as aerosol products for household use and household cleaners containing TCE.

TCE is listed in the Australian National Pollutant Inventory, a program run cooperatively by the Australian, State and Territory governments to monitor common pollutants and their levels of release to the environment. Australia classifies TCE as a health, physicochemical and/or ecotoxicological hazard, according to the Australian National Occupational Health and Safety Commission (Ref. 25).

IV. TCE Risk Assessment

In 2013, EPA identified TCE use as a solvent degreaser (aerosol degreasing and vapor degreasing) and spot remover in dry cleaning operations as a priority for risk assessment under the TSCA Work Plan. This Unit describes the development of the TCE risk assessment and supporting analysis and expert input on vapor degreasing, the use that is the subject of this proposed rule. A more detailed discussion of the risks associated with TCE use in vapor degreasing can be found in Unit VI.

A. TSCA Work Plan for Chemical Assessments

In 2012, EPA released the TSCA Work Plan Chemicals: Methods Document in which EPA described the process the Agency intended to use to identify potential candidate chemicals for near-term review and assessment under TSCA (Ref. 26). EPA also released the initial list of TSCA Work Plan chemicals identified for further assessment under TSCA as part of its chemical safety program (Ref. 27).

The process for identifying these chemicals for further assessment under TSCA was based on a combination of hazard, exposure, and persistence and bioaccumulation characteristics, and is described in the TSCA Work Plan Chemicals Methods Document (Ref. 26). Using the TSCA Work Plan chemical prioritization criteria, TCE ranked high for health hazards and exposure potential and was included on the initial list of TSCA Work Plan chemicals for assessment.

B. TCE Risk Assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for TCE (TCE risk assessment) in June 2014, following the July 2013 peer review of the December 2012 draft TCE risk assessment. All documents from the July 2013 peer review of the draft TCE risk assessment are available in EPA Docket Number EPA–HQ–OPPT–2012–0723. TCE appears in the 2014 update of the TSCA Work Plan for Chemical Assessments and the completed risk assessment is noted therein. The TCE risk assessment evaluated commercial and consumer use of TCE as a solvent degreaser (aerosol degreasing and vapor degreasing), commercial use of TCE as a spotting agent at dry cleaning facilities, and consumer use of TCE as a spray-applied protective coating for arts and crafts (Ref. 2).

The uses selected for the TCE risk assessment were chosen because they were expected to involve frequent or routine use of TCE in high concentrations and/or have high potential for human exposure (Ref. 2). However, this does not mean that EPA found that other uses not included in the TCE risk assessment present low risk.

As described in the TCE risk assessment, solvent cleaning or degreasing is widely used to remove grease, oils, waxes, carbon deposits, fluxes, and tars from metal, glass, or plastic surfaces. With respect to vapor degreasing, there are two general types of degreasing machines: Batch and in-line. Batch cleaning machines are the most common type, while in-line cleaners are typically used in large-scale industrial operations. There are a number of variations of each general type of machine. Emissions from degreasing machines typically result from:

- Evaporation of the solvent from the interface between the solvent and the air,
- ''Carry out'' of excess solvent on cleaned parts, and
- Evaporative losses of the solvent during filling and draining of the degreasing machine.

In its assessment of vapor degreasing, the TCE risk assessment concentrated on open top vapor degreasing machines because they are the most prevalent, particularly for smaller operations. The risk assessment identified acute and chronic non-cancer risks for workers who conduct TCE-based solvent vapor degreasing at small degreasing facilities, as well as occupational bystanders to those activities. More specifically, the TCE risk assessment identified risks for non-cancer developmental effects resulting from acute exposure. The risk assessment also identified risks for a range of non-cancer health effects resulting from chronic exposure. Within

this range of effects, the greatest risk is for developmental effects (*i.e.,* fetal cardiac defects), although there also are risks for kidney effects and immunotoxicity. In addition, there are risks for adverse reproductive effects, neurotoxicity, and liver toxicity associated with chronic exposures (Ref. 2).

Margins of exposure (MOEs) were used in this assessment to estimate non-cancer risks for acute and chronic exposures. The MOE is the health point of departure (an approximation of the no-observed adverse effect level) for a specific endpoint divided by the exposure concentration for the specific scenario of concern. The benchmark MOE accounts for the total uncertainty factor based on the following uncertainty factors: Intraspecies, interspecies, subchronic to chronic, and lowest observed adverse effect level (LOAEL) to no-observed adverse effect level (NOAEL). Uncertainty factors are intended to account for (1) the variation in sensitivity among the members of the human population (*i.e.,* interhuman or intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (*i.e.,* interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (*i.e.,* extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a LOAEL rather than from a NOAEL (Ref. 28). MOEs provide a non-cancer risk profile by presenting a range of estimates for different non-cancer health effects for different exposure scenarios, and are a widely recognized method for evaluating a range of potential non-cancer health risks from exposure to a chemical.

The acute inhalation risk assessment used developmental toxicity data to evaluate the acute risks for the TCE use scenarios. As indicated in the TCE risk assessment, EPA's policy supports the use of developmental studies to evaluate the risks of acute exposures. This science-based policy presumes that a single exposure of a chemical at a critical window of fetal development may produce adverse developmental effects (Ref. 5). This is the case with cardiac malformation. EPA reviewed multiple studies for suitability for acute risk estimation including a number of developmental studies of TCE exposure and additional developmental studies of TCE metabolites (Appendix N) (Ref. 2). EPA based its acute risk assessment on the most sensitive health endpoint (*i.e.,* fetal heart malformations) representing the most sensitive human life stage (*i.e.,* the developing fetus) (Ref. 2). The acute risk assessment used the physiologically-based pharmacokinetic (PBPK)-derived hazard values (HEC50, HEC95, or HEC99; HECXX is the Human Equivalent Concentration at a particular percentile) from the Johnson et al. (2003) (Ref. 29) developmental toxicity study for each vapor degreaser use scenario. Note that the differences among these hazard values is small and no greater than 3-fold (*i.e.,* 2-fold for HEC50/HEC95 ratios; 3-fold for HEC50/HEC99 ratios; 1.4-fold for HEC95/HEC99 ratios). The IRIS TCE assessment used the HEC99 for the non-cancer dose-response derivations because the HEC99 was interpreted to be protective for a sensitive individual in the population (Ref. 4). While the HEC99 was used to find the level of risk to be used in making the proposed TSCA section 6(a) determination, the small variation among HEC50, HEC95 and HEC99 would not result in a different risk determination.

For non-cancer effects, EPA estimated exposures that are significantly greater than the point of departure. The baseline cancer risk is estimated to be 3.66×10^{-1} for users of open top vapor degreasing systems.

The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also result in low risk for cancer.

Given these identified risks, EPA conducted an additional analysis consistent with the scope of the TCE risk assessment to better characterize the risk to workers and occupational bystanders from the use of TCE in batch vapor degreasing machines as well as in two different types of in-line systems (conveyor and continuous web cleaning machines) (Ref. 30). This analysis also evaluated the exposure reductions that would result from switching from an open-top vapor degreasing system to a closed-loop vapor degreasing system. More information on the different types of vapor degreasing machines can be found in Unit VI.A.1. In the supplemental analysis, EPA identified short-term and long-term non-cancer and cancer risks for all types of vapor degreasing machines, although the risks for closed-loop machines are estimated to be lower than for any of the other types (Ref. 30).

C. Stakeholder Input on TCE and Vapor Degreasing

On July 29, 2014, EPA held a 2-day public workshop on TCE degreasing (Ref. 31). The purpose of the workshop was to collect information from users, academics, and other stakeholders on the use of TCE as a degreaser in various applications, *e.g.,* in degreasing metal parts, availability and efficacy of safer alternatives, safer engineering practices and technologies to reduce exposure to TCE, and to discuss possible risk reduction approaches. The workshop included presentations by experts, breakout sessions with case studies, and public comment opportunities (Ref. 31) and informed EPA's assessment of the alternatives to TCE considered in this proposed rule. All documents from the public workshop are available in EPA Docket Number EPA–HQ–OPPT–2014–0327. Informed in part by the workshop and other analysis, including discussion with the Toxics Use Reduction Institute at the University of Massachusetts Lowell, EPA has concluded that TCE alternatives are available for all applications subject to this proposed rule as well as EPA's earlier proposal (Ref. 1). The discussions at the public workshop demonstrated that alternatives are available for the vapor degreasing uses that are being addressed in this proposed rulemaking.

On June 1, 2016, EPA convened a Small Business Advocacy Review (SBAR) Panel on TCE in vapor degreasing. The Panel solicited input from eighteen Small Entity Representatives (SERs) and made several recommendations on aspects of this rulemaking. The Panel process, including the final report of the Panel (Ref. 32), is discussed in Unit XII.

V. Regulatory Approach

A. TSCA Section 6 Unreasonable Risk Analysis

Under TSCA section 6(a), if the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the Agency's risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

The TSCA section 6(a) requirements can include one or more, or a combination of, the following actions:

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).
- Prohibit or otherwise restrict manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration (§ 6(a)(2)).

- Require minimum warning labels and instructions (§ 6(a)(3)).
- Require record keeping or testing (§ 6(a)(4)).
- Prohibit or regulate any manner or method of commercial use (§ 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal (§ 6(a)(6)).
- Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances (§ 6(a)(7)).

EPA analyzed a wide range of regulatory options under TSCA section 6(a) in order to select the proposed regulatory approach. EPA considered whether a regulatory option (or combination of options) would address the identified unreasonable risks so that the chemical substance no longer presents such risks. To do so, EPA initially analyzed whether the regulatory options could reduce risks (non-cancer and cancer) to levels below those of concern, based on EPA's technical analysis of exposure scenarios. For the non-cancer risks, EPA found an option could be protective against the risk if it could achieve the benchmark MOE for the most sensitive non-cancer endpoint. EPA's assessments for these uses indicate that when exposures meet the benchmark MOE for the most sensitive endpoint, they also result in low risk for cancer.

After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered how reliably the regulatory options would actually reach these benchmarks. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In evaluating whether a regulatory option would ensure that the chemical substance no longer presents the identified unreasonable risks, the Agency considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks in relation to the benchmarks, as well as whether the option's protectiveness was impacted by environmental justice or children's health concerns.

B. TSCA Section 6(c)(2) Considerations

TSCA section 6(c)(2) requires EPA to consider and publish a statement based on reasonably available information with respect to the:

- Health effects of the chemical substance or mixture (in this case, TCE) and the magnitude of human exposure to TCE;
- Environmental effects of TCE and the magnitude of exposure of the environment to TCE;
- Benefits of TCE for various uses;
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

In addition, in selecting among prohibitions and other restrictions available under TSCA section 6(a), EPA must factor in, to the extent practicable, these considerations. Further, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's analysis of the health effects of and magnitude of exposure to TCE can be found in Units IV and VI, which discuss the TCE risk assessment and EPA's regulatory assessment of the use of TCE in vapor degreasing. A discussion of the environmental effects of TCE can be found in Unit II.D.

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the economic analysis document (Ref. 3) To the extent information was available, EPA considered the benefits realized from risk reductions (including monetized benefits, non-monetized quantified benefits, and qualitative benefits), offsets to benefits from countervailing risks (*e.g.,* risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children and other potentially exposed or susceptible subpopulations (as compared to the general population), and the cost of regulatory requirements for the various options. A discussion of the benefits EPA considered can be found in Units VI.C. and VII.

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. For example, an option that includes use of a respirator would include inspections to evaluate compliance with all elements of a respiratory protection program. EPA took into account reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives (*e.g.,* PPE). Reasonably available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options. A discussion of the costs EPA considered can be found in Units VI.E. and VII, along with a discussion of the cost effectiveness of the proposal and the alternatives that EPA considered. In addition, a discussion of the impacts on small businesses can be found in Unit XII.C.

With respect to the anticipated effects of this proposal on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers. In addition, EPA considered the employment impacts of this proposal, as discussed in the economic analysis for this proposal (Ref. 3). EPA found that the direction of change in employment is uncertain, but the expected short term and longer term employment effects are expected to be small.

The benefits of TCE in vapor degreasing are discussed in Unit VI.D., along with the availability of alternatives. The dates that the proposed restrictions would take effect are discussed in Unit X.D., as is the availability of alternatives to TCE vapor degreasing on those dates.

Finally, with respect to this proposal's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. (Ref. 3) An impending ban on the use of TCE in vapor degreasing is likely to increase demand for alternatives, which would be expected to result in the development of new alternatives.

C. Regulatory Options Receiving Limited Evaluation

As discussed previously, EPA analyzed a wide range of regulatory options under TSCA section 6(a). One of the options EPA evaluated involved a TSCA section 6(a)(3) requirement for warning labels or instructions on containers of TCE or on vapor degreasing equipment. However, EPA

reasoned that warning labels and instructions alone could not mitigate the identified unreasonable risks presented by TCE to workers operating vapor degreasing equipment. In making this finding, EPA considered several factors including the fact that, in many cases, the workers being exposed are not in a position to influence their employer's decisions about the type of solvent or the type of degreasing equipment that will be used, or ensure that their employer provides appropriate PPE and an adequate respiratory protection program. EPA also considered the analysis of relevant studies that was discussed in the prior proposal on TCE (Ref. 33). This analysis found that even professional users do not consistently pay attention to labels; they often do not understand label information; and they often base a decision to follow label information on previous experience and perceptions of risk (Ref. 33).

EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user or owner would need to read, understand, act upon, convey, and ensure adherence to is extremely complex. It would be challenging to most users or owners to follow or convey the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders. It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.

While labeling alone would not address the identified unreasonable risks so that TCE used in vapor degreasing no longer presents such risks, EPA recognizes that the TSCA section 6(a)(3) warnings and instruction requirement can be an important component of an approach that addresses identified unreasonable risks with a specific use prohibition. EPA has included a simple downstream notification requirement as part of this proposed rule to ensure that users would be made aware of the ban on the use of TCE in vapor degreasing.

In addition, early in the process, EPA identified two regulatory options under TSCA section 6(a) that do not pertain to this action and were therefore not evaluated for this proposed rulemaking. First, EPA reasoned that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture (including import), processing or distribution in commerce of TCE or limit the amount of TCE which may be manufactured (including imports), processed or distributed in commerce is not germane because the Agency is not proposing to ban or limit the manufacture (including import), processing or distribution in commerce of TCE for uses other than in vapor degreasing, aerosol degreasing or for spot cleaning in dry cleaning facilities at this time. In addition, EPA reasoned that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not evaluate the risks associated with ongoing TCE disposal.

VI. Regulatory Assessment of TCE Use in Vapor Degreasing

This Unit describes the current use of TCE in vapor degreasing, the unreasonable risks presented by this use, and how EPA identified which regulatory options address those unreasonable risks so that TCE in vapor degreasing no longer presents such unreasonable risks.

A. Description of the Current Use

Vapor degreasing is a cleaning process that uses a solvent vapor to remove contaminants such as grease, oils, dust, and dirt from fabricated parts. Solvents such as TCE are boiled in a degreasing unit to produce a hot vapor. When parts are placed into the degreaser, the hot vapor within the unit condenses onto the parts, causing beading and dripping. The dripping action carries the contaminants away from the fabricated part, leaving behind a clean surface. After vapor degreasing, the parts are suspended on a rack in order to drain the solvent (Ref. 30). Vapor degreasing is used in a variety of occupational settings such as metal plating, electronics assembly, metal or composite part fabrication, and repair shops.

Vapor degreasing may take place in batches or as part of an in-line (*i.e.,* continuous) system. In batch machines, each load (parts or baskets of parts) is loaded into the machine after the previous load is completed. With in-line systems, parts are continuously loaded into and through the vapor degreasing equipment as well as the subsequent drying steps.

The five basic types of batch vapor degreasers are described in the following paragraphs (Ref. 30):

As the name suggests, open-top vapor degreasers are open at the top to allow introduction of the parts to be cleaned. Heating elements at the bottom of the cleaner heat the liquid solvent to above its boiling point. Solvent vapor rises in the machine to the height of chilled condensing coils on the inside walls of the cleaner. The condensing coils cool the vapor, causing it to condense and return to the bottom of the cleaner. Cleaning occurs in the vapor zone above the liquid solvent and below the condensing coils, as the hot vapor solvent condenses on the cooler work surface. The workload or a parts basket is lowered into the heated vapor zone with a mechanical hoist. While the condensing coils reduce the amount of solvent that escapes the vapor zone, they do not eliminate emissions, and throughout the degreasing process, significant vapor emissions of the solvent can occur. These vapor emissions are hazardous to workers operating the machine, as well as nearby workers. In addition, replacing solvent lost to emissions can be costly. In assessing the use of TCE in vapor degreasers, the TCE risk assessment focused on the use of open top vapor degreasing systems.

Vapor emissions of solvent can be reduced by enclosing the vapor degreasing machine. Open top vapor degreasing systems with enclosures operate in the same manner as standard open top vapor degreasing systems, except that the machine is enclosed on all sides during degreasing. The enclosure is opened and closed when adding or removing parts, and solvent is exposed to the air when the cover is open. Nearly all open top vapor degreasing systems regulated by the NESHAP have a cover because that is a more common compliance strategy than complying with the overall emission limit. A variety of additional controls may be needed to comply with the NESHAP, including two-part covers, extended freeboard (the area above the vapor zone), freeboard refrigeration devices, and holding cleaned parts in the freeboard to allow draining. Enclosed vapor degreasing systems may be vented directly to the atmosphere or first vented to an external carbon filter and then to the atmosphere.

Solvent emissions can be further reduced by using a sealed, closed-loop degreasing system. In airtight closed-loop systems, parts are placed into a basket, which is then placed into an airtight work chamber. The door is closed and solvent vapors are sprayed

onto the parts. When cleaning is complete, vapors are exhausted from the work chamber and circulated over a cooling coil to condense and recover the solvent. The parts are dried by forced hot air. Air is circulated through the chamber and residual solvent vapors are captured by carbon adsorption. The door is opened when the residual solvent vapor concentration has reached a specified level.

A refinement of the airtight closed-loop degreasing system is the airless degreasing system. An airless system removes air at some point during the degreasing process. Typically, this takes the form of drawing vacuum, but some machines purge the air with nitrogen. In airless degreasing systems with vacuum drying, a vacuum is generated, typically below 5 torr, which dries the parts. A vapor recovery system recovers the solvent.

The greatest solvent emission reductions are achieved with the airless vacuum-to-vacuum degreasing system. These systems are referred to as airless because the entire cycle is operated under vacuum. Typically, parts are placed into the chamber, the chamber sealed, and then vacuum drawn within the chamber. The parts are then sprayed with hot solvent vapor, which raises the pressure in the chamber. The parts are dried by again drawing vacuum in the chamber. Solvent vapors are recovered through compression and cooling. An air purge then removes residual vapors which can be routed to an optional carbon adsorber and then out a vent. Finally, air is introduced to return the chamber to atmospheric pressure so that the chamber can be opened. These systems have the added benefit of generating vapor at a much lower temperature than open-top degreasing systems because the boiling point of TCE is lower at the lower pressure of these systems.

In contrast to batch degreasers, in-line vapor degreasing systems use an automated parts handling system, often a conveyor, to automatically provide a continuous supply of parts to be cleaned (Ref. 30). Conveyorized vapor degreasing systems are usually fully enclosed except for the conveyor inlet and outlet portals. Conveyorized degreasers are likely used in the same applications as batch vapor degreasers, except that they would be used in larger operations, where the number of parts being cleaned is large enough to warrant the use of a conveyorized system. Conveyorized degreasers use different methods for transporting the parts through the cleaning zone. For example, monorail degreasers use a straight-line conveyor to transport parts into and out of the cleaning zone; these systems are typically used when parts are already being transported through manufacturing areas by a conveyor. Cross-rod degreasers use two parallel chains connected by a rod to support the parts, which are typically loaded manually into perforated baskets or cylinders. Ferris wheel degreasing systems, generally the smallest of the conveyorized degreasers, rotate manually-loaded baskets or cylinders of parts vertically through the cleaning zone and back out. Belt degreasers are used for simple and rapid loading and unloading of parts; the parts are loaded onto a mesh conveyor belt that transports them through the cleaning zone and out the other side.

There are also continuous web cleaning machines (Ref. 30). These in-line degreasers differ from typical conveyorized degreasers in that they are specifically designed for cleaning parts that are coiled or on spools such as films, wires, metal strips, and metal sheets. In continuous web degreasers, parts are uncoiled and loaded onto rollers that transport the parts through the cleaning and drying zones at speeds typically greater than 11 feet per minute. The parts are then recoiled or cut after exiting the machine.

B. Analysis of Regulatory Options

In this unit, EPA explains how it evaluated whether the regulatory options considered would address the unreasonable risks presented by the current use so that TCE in vapor degreasing no longer presents such unreasonable risks. First, EPA characterizes the unreasonable risks associated with the current use of TCE in vapor degreasers. Then, the Agency describes its initial analysis of which regulatory options have the potential to reach the protective non-cancer and cancer benchmarks. The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also result in low risk for cancer. Lastly, this unit evaluates how well those regulatory options would address the identified unreasonable risks in practice.

1. Risks associated with the current use. a. General impacts. The TCE risk assessment identified cancer and non-cancer risks from acute and chronic exposure for workers operating vapor degreasers and for occupational bystanders, nearby workers who have the potential to be exposed to TCE but are not directly involved with degreasing operations (Ref. 2). Because the TCE risk assessment focused on open top vapor degreasing systems, EPA performed supplemental analysis consistent with the methodology used in the risk assessment for closed-loop, conveyorized, and continuous web degreasers and identified cancer and non-cancer risks from acute and chronic exposure for each of the scenarios (Ref. 30). EPA estimates that there are approximately 2,600 to 6,000 open top vapor degreasing systems currently using TCE, 120 closed-loop systems currently using TCE, and 150 in-line (either conveyorized or continuous web) systems currently using TCE, with an estimated 17 workers and occupational bystanders per machine (Ref. 3). This means that there are an estimated 40,800 to 102,000 persons exposed to TCE from open top vapor degreasing systems, 2,040 persons exposed to TCE from closed-loop systems, and 2,550 persons exposed to TCE from in-line systems.

b. Impacts on minority and low income populations. There is no known disproportionate representation of minority or low income populations in these occupations.

c. Impacts on children. EPA has concerns for effects on the developing fetus from acute and chronic worker and occupational bystander exposures to TCE used in vapor degreasers. The risk estimates are focused on pregnant women because one of the most sensitive health effects associated with TCE exposure from vapor degreasing is adverse effects on the developing fetus. The potential risk due to exposure during pregnancy is significant. Approximately half of all pregnancies are unintended. If a pregnancy is not planned before conception, a woman may not be in optimal health for childbearing (Ref. 34). More specifically, in this case, a woman who is not planning a pregnancy may not take steps to avoid exposure to TCE in vapor degreasing. EPA estimates that there are over 1,000 pregnant women exposed to TCE as a result of vapor degreasers.

d. Specific vapor degreaser exposure information. In the supplemental analysis (Ref. 30), EPA estimated baseline exposures for all batch vapor degreasing machines, regardless of facility size, and for in-line vapor degreasing machines (both conveyorized and continuous web). Baseline exposures for in-line machines were not specifically calculated in the TCE risk assessment. For the supplemental analysis, estimating the baseline exposures involved using a near-field/far-field modeling approach to estimate airborne concentrations of TCE and Monte Carlo simulation to establish the range and likelihood of exposures. The near-field/far-field model estimates airborne concentrations in a near field (a

zone close to the source of exposure) and a far field (a zone farther from the source of exposure but within the occupational building). Controls required by the 2007 NESHAP were accounted for in the estimations. (Ref. 30) EPA used these estimated airborne concentrations to estimate 8-hour time weighted average (TWA) exposures for workers (*i.e.,* in the near field) and occupational bystanders (*i.e.,* in the far field). Details of the modeling and estimation method for calculating exposure levels during vapor degreasing are available in the supplemental analysis document (Ref. 30). This analysis is based on the methodology used in the peer reviewed TCE risk assessment (Ref. 2). Prior to promulgation of the final rule, EPA will peer review the ''supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Vapor Degreasing'' (Ref. 30).

The estimated 8-hour TWA exposure levels for open top vapor degreasing systems ranged from 2.74 ppm to 491.36 ppm for workers, with the 50th percentile at 55.16 ppm and the 99th percentile at 190.17 ppm. For occupational bystanders, the exposure levels ranged from 0.33 ppm to 440.61 ppm, with the 50th percentile at 20.45 ppm and the 99th percentile at 144.93 ppm. The estimated 8-hour TWA exposure levels for conveyorized degreasers were even higher, ranging from 5.14 ppm to 32,722 ppm for workers, with the 50th percentile and 99th percentile being 180.74 ppm and 1162.6 ppm, respectively. For bystanders, the levels ranged from 0.63 ppm to 29,410 ppm, with the 50th percentile and 99th percentile being 80.93 ppm and 745.11 ppm, respectively. The estimated 8-hour TWA exposure levels for continuous web degreasers were lower overall than for open top vapor degreasing systems or conveyorized degreasers. These estimates ranged from 4.18 ppm to 50.61 ppm for workers, with the 50th percentile and 99th percentile being 8.18 ppm and 22.42 ppm, respectively. For bystanders, the levels ranged from 0.52 ppm to 45.49 ppm, with the 50th percentile and 99th percentile being 3.70 ppm and 17.49 ppm, respectively.

As part of this supplemental analysis, EPA also evaluated the exposure reductions that would result from switching from an open top vapor degreasing system to a closed-loop vapor degreasing system. The data available on TCE emissions from closed-loop systems was not sufficient to enable EPA to distinguish between the three types of closed-loop systems (airtight, airless, and airless vacuum-to-vacuum) with respect to employee exposures. As a result, for the purpose of assessing exposure, EPA assumed that all of the closed-loop systems achieve a 98% reduction in exposure compared to open top vapor degreasing systems (Ref. 30). This assumption leads to exposure estimates of 0.05 ppm to 9.8 ppm for workers.

However, the assumption of a 98% reduction in exposures compared to open top vapor degreasing systems may be an overestimate for airtight systems, and an underestimate for airless vacuum-to-vacuum systems. EPA requests information and data on TCE emissions from all vapor degreasing systems, particularly information and data that would enable EPA to better distinguish between the different types of closed-loop systems.

The SBAR Panel convened in support of this action heard from several SERs who disagreed with EPA's exposure estimates. These SERs indicated that fewer employees were involved in the degreasing operation, or that the machines were operated for fewer hours per day than EPA estimated. However, another SER stated that his degreasing machines run ten hours a day during the week and six hours on Saturdays, which exceeds EPA's estimate. In addition, most SERs thought that EPA's estimated TWAs were too high, and EPA received some monitoring data indicating lower exposures, but several SERs stated that they complied with the recommended exposure limit of the American Conference of Governmental Industrial Hygienists (ACGIH) of 10 ppm, which is within the exposure ranges estimated by EPA. However, EPA specifically requests exposure data, especially data involving employee exposure monitoring.

e. Specific risks for TCE use in vapor degreasers. Inhalation risks were estimated for all acute exposure scenarios and risks were identified for all types of machines, regardless of the type of exposure (typical vs. reasonable worst case scenario). For acute exposures associated with open top vapor degreasing systems, the MOE is 0.00006 for fetal heart malformations. This equates to exposures that are many times greater than the benchmark MOE of 10. The MOE for fetal heart malformations from acute exposures associated with conveyorized systems is 0.00001, while for continuous web systems, the MOE is 0.0005. Even for acute exposures with closed-loop systems, which we assume reduce TCE emissions as much as 98% from open top vapor degreasing systems, the MOE for fetal heart malformations is 0.003. The MOEs for every vapor degreasing scenario are below the benchmark MOE. Based on this assessment, EPA's proposed determination is that acute TCE exposures from vapor degreasing present unreasonable risks.

Chronic exposures from TCE use in vapor degreasing also present risks. For non-cancer effects, the most sensitive of which are developmental, the benchmark MOE is also 10. For chronic exposures associated with open top vapor degreasing systems, conveyorized systems, continuous web systems, and closed-loop systems, the MOEs are 0.00008, 0.00001, 0.00007, and 0.004, respectively. With respect to cancer, the risk posed to workers ranges from 5.16×10^{-1} for open top vapor degreasing systems to 1×10^{-2} for closed-loop systems, exceeding common cancer benchmarks of 10^{-6} to 10^{-4} (Refs. 2, 30). Therefore, EPA's proposed determination is that chronic TCE exposures due to vapor degreasing also present unreasonable risks.

The SBAR Panel convened in support of this action heard from several SERs who expressed concerns about the underlying TCE risk assessment. Many of the concerns expressed by these SERs were already expressed in the public comments and the peer review comments on the risk assessment. The Summary of External Peer Review and Public Comments and Disposition document explains how EPA responded to the comments received (Ref. 35).

2. Initial analysis of potential regulatory options. Having identified unreasonable risks from the use of TCE in vapor degreasing, EPA evaluated whether regulatory options under TSCA section 6(a) could reach the risk (non-cancer and cancer) benchmarks.

EPA assessed a number of exposure scenarios associated with risk reduction options in order to find variations in TCE exposure from vapor degreasing, including: Reducing the amount of TCE in the degreasing formulation, with concentrations varying from 5% to 95% by weight in the product, engineering controls, equipment substitution, and use of PPE. EPA also assessed combinations of these options.

For the engineering controls risk reduction option exposure scenarios, EPA evaluated using local exhaust ventilation to improve ventilation near the vapor degreaser, with an assumed 90% reduction in exposure over baseline levels. The equipment substitution risk reduction option was only evaluated with respect to open top vapor degreasing systems, the evaluation assumed substitution of a closed-loop system for the open top

vapor degreasing system. EPA did not identify any equipment substitution options for either conveyorized or continuous web systems; it is likely that a closed-loop system, being a batch-process system, would not meet the specialized production requirements of facilities currently using conveyorized or continuous web systems. EPA requests comment, information, and data on potential equipment substitution options for these systems, including both emissions and cost information. The PPE risk reduction option exposure scenarios evaluated workers and occupational bystanders wearing respirators with an assigned protection factor (APF) varying from 10 to 10,000. Additionally, EPA evaluated various combinations of these options, including PPE with each of the other three options and reducing the amount of TCE in the solvent solution with each of the other three options. The way that closed-loop systems operate may render local exhaust ventilation redundant, because ventilation is being done as part of the closed system, so EPA did not evaluate local exhaust ventilation and equipment substitution together. EPA requests comment on the accuracy of EPA's assumption that these control options are mutually exclusive.

EPA has estimated that, in order to avoid cancer and non-cancer unreasonable risks, the 8-hour TWA exposure should be approximately 1 ppb (Ref. 36). However, EPA's inhalation exposure level estimates for all types of vapor degreasing machines exceed that figure by several orders of magnitude.

Of the control options evaluated by EPA in its supplemental analysis (Ref. 30), which did not include a ban on the use of TCE in vapor degreasing, the only control options that achieved the necessary exposure reductions for workers operating the degreaser involved PPE in addition to other measures. Even switching from an open top vapor degreasing system to a closed-loop system did not achieve the necessary reductions without the addition of PPE with an APF of 10,000. For that control option, equipment substitution plus PPE, EPA estimated that worker exposure levels would be 0.4 ppb. Other combinations of control options, such as reducing the amount of TCE in the solvent solution and PPE with an APF of 10,000, or reducing the amount of TCE in the solvent solution and engineering controls and PPE, achieved exposure reductions of approximately the same magnitude. However, EPA found that these combinations are unlikely to be practical for users because the exposure reductions needed would only be achieved by a reduction in the concentration of TCE in the degreasing solution to 5%. At 5% TCE, the effectiveness of the solution would be greatly reduced. Additional exposure level estimates for various scenarios are available in the supplemental analysis document, which also documents options that did not meet the risk benchmarks and which do not, for purposes of this proposal, address the identified unreasonable risks (Ref. 30).

3. Assessment of whether regulatory options address the identified unreasonable risks to the extent necessary so that TCE no longer presents such unreasonable risks. After excluding the unrealistic options involving reductions in the amount of TCE in the solvent solution, only two options were left that had the potential to address the identified unreasonable risks. These options were: (a) Prohibiting under TSCA section 6(a)(2) the manufacturing (including import), processing, and distribution in commerce of TCE for use in vapor degreasing, prohibiting the commercial use of TCE in vapor degreasing under TSCA section 6(a)(5), and requiring downstream notification under TSCA section 6(a)(3) when distributing TCE; and (b) prohibiting under TSCA section 6(a)(2) the manufacturing (including import), processing, and distribution in commerce of TCE for use in vapor degreasing except in closed-loop vapor degreasing machines, prohibiting under TSCA section 6(a)(5) the commercial use of TCE in vapor degreasing except in closed-loop vapor degreasing machines, requiring downstream notification under TSCA section 6(a)(3) when distributing TCE, and requiring, under TSCA section 6(a)(5), appropriate PPE (or an exposure limit alternative) for both workers operating closed-loop vapor degreasing machines containing TCE and for occupational bystanders.

a. *Proposed approach to prohibit manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing and require downstream notification.* As noted previously, the proposed regulatory approach is to prohibit the manufacturing (including import), processing, and distribution in commerce of TCE for vapor degreasing under TSCA section 6(a)(2), prohibit the commercial use of TCE in vapor degreasing under TSCA section 6(a)(5), and require manufacturers, processors, and distributors, except for retailers, to provide downstream notification, *e.g.,* via a Safety Data Sheet (SDS), of the prohibition under TSCA section 6(a)(3).

As discussed in Unit IV, the baseline risk for exposure to workers and occupational bystanders for vapor degreasing does not achieve the non-cancer MOE benchmarks for all non-cancer effects (*e.g.,* developmental effects, kidney toxicity, and immunotoxicity) or the common cancer benchmarks. Under this proposed approach, exposures to TCE from use in vapor degreasing would be completely eliminated. As a result, both non-cancer and cancer risks from this use of TCE would be eliminated.

The proposed approach would ensure that employees are no longer at risk from TCE exposure associated with vapor degreasing. Prohibiting the manufacturing (including import), processing and distribution in commerce of TCE for use in vapor degreasing would minimize the availability of TCE for vapor degreasing. The downstream notification of these restrictions ensures that processors, distributors, and other purchasers are aware of the manufacturing (including import), processing, distribution in commerce and use restrictions for TCE in vapor degreasing, and helps to ensure that the rule is effectively implemented by discouraging off-label use of TCE manufactured for other uses. Downstream notification is important because EPA is not proposing to prohibit manufacturing, processing and all uses of TCE, just those activities associated with vapor degreasing. This integrated supply chain approach is necessary to address the identified unreasonable risks presented by the use of TCE in vapor degreasing. In addition, the proposed approach would provide staggered compliance dates for implementing the prohibition on manufacturing (including import), processing, distribution in commerce, and commercial use in order to avoid undue impacts on the businesses involved.

b. Variation of the proposed approach that would allow the use of TCE in closed-loop vapor degreasing systems and require under TSCA section 6(a)(5) the use of personal protective equipment in vapor degreasing operations in which TCE is used. Another regulatory option that EPA considered was to allow the use of TCE in closed-loop vapor degreasing systems and require respiratory protection equipment for workers operating the equipment in the form of a full face piece self-contained breathing apparatus (SCBA) in pressure demand mode or other positive pressure mode with an APF of 10,000 with an alternative to the specified APF respirator of an air exposure limit. EPA's analysis found

that use of a SCBA with an APF of 10,000 for workers operating closed-loop vapor degreasing systems that contain TCE could control TCE air concentration to levels that ensure that TCE no longer presents the identified unreasonable risks. Depending on air concentrations and proximity to the vapor degreasing equipment, other employees in the area would also need to wear respiratory protection equipment.

Although respirators could reduce exposures to levels that are protective of non-cancer and cancer risks, there are many documented limitations to successful implementation of respirators with an APF of 10,000. Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-facepiece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good facepiece fit, including those individuals whose beards or sideburns interfere with the facepiece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems and vision problems, increase worker fatigue, and reduce work efficiency (Ref. 37). According to OSHA, ''improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health.'' (Ref. 37, at 1189–1190). Nonetheless, it is sometimes necessary to use respiratory protection to control exposure. The OSHA respiratory protection standard requires employers to establish and implement a respiratory protection program to protect their respirator-wearing employees (Ref. 38). This OSHA standard contains a number of implementation requirements, *e.g.,* for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; respirator use; respirator cleaning, maintenance, and repair; and other provisions that would be difficult to fully implement in some small business settings where they are not already using respirators.

In addition, OSHA adopted a hierarchy of controls established by the industrial hygiene community used to protect employees from hazardous airborne contaminants, such as TCE (see, *e.g.,* 29 CFR 1910.134(a)(1), 29 CFR 1910.1000(e), and OSHA's substance specific standards in 29 CFR 1910 subpart Z). According to the hierarchy, substitution of less toxic substances, engineering controls, administrative controls, and work practice controls are the preferred method of compliance for protecting employees from airborne contaminants and are to be implemented first, before respiratory protection is used. OSHA permits respirators to be used where engineering controls are not feasible or during an interim period while such controls are being implemented.

Under this approach, a company could choose to use a closed-loop system coupled with an air exposure limit. In order to reach the health benchmarks, the air exposure limit would have to be 1 ppb as an 8-hour TWA. Based on EPA's analysis, the only way to achieve an air exposure limit of 1 ppb is with a combination of a closed-loop vapor degreaser and a respirator with an APF of 10,000. However, as previously discussed, EPA acknowledges that available data is limited, particularly with respect to the different types of closed-loop vapor degreasers. It is possible that the more sophisticated airless vacuum-to-vacuum closed-loop systems have lower emissions than EPA estimated, and, therefore, respiratory protection with an APF of 10,000 may not be necessary for operators. As part of this approach, EPA believes it would be necessary to establish employee exposure monitoring requirements to ensure that employee exposures are measured accurately and that employees are not exposed to the identified unreasonable risks associated with TCE use in vapor degreasing. EPA would require upfront monitoring representative of each exposed employee's exposures and would model the requirements on comparable OSHA requirements as well as on the New Chemical Exposure Limit (NCEL) requirements that EPA has long used in addressing employee exposure to chemicals undergoing review under TSCA section 5 (Refs. 38–39). The requirements would specify how and when sampling must be performed and how the samples would have to be analyzed.

EPA is not proposing this option because substitutes for TCE are commercially available and implementation of a respiratory protection program is likely to be difficult for many vapor degreasing facilities. In addition, EPA's economic analysis indicates that this option is more expensive than switching to a different solvent or cleaning system. However, EPA requests comment, information, and data on the utility and feasibility of this option and whether, if it were adopted, it should be implemented by specifying the vapor degreasing technology and either requiring specific PPE or compliance with an air exposure limit. If EPA were to specify both the vapor degreasing technology and the required PPE with the alternative air exposure limit in the final rule, EPA would require the vapor degreasing system to be an airless vacuum-to-vacuum closed-loop system and the PPE to have an APF of 10,000 or otherwise meet the air exposure limit of 1 ppb as an 8-hour TWA. As previously discussed, EPA's assessment of worker exposure from closed-loop systems relies on an assumption that emissions from each closed-loop system are 98% less than the emissions from an open top vapor degreasing system. EPA is requesting information on whether releases from the use of TCE in an airless vacuum-to-vacuum closed-loop system would result in air levels that are at or below the air exposure limit of 1 ppb. To the extent that EPA receives information that indicates that this is the case, EPA would consider finalizing this rule to exclude airless vacuum-to-vacuum closed-loop systems. In contrast, this assumption of a 98% reduction may be overly generous for the most basic of the closed-loop systems, and operators of such systems, even when wearing PPE with an APF of 10,000, would continue to be exposed to the identified unreasonable risks. Under the optional approach, companies choosing to keep using TCE would have to comply with all of OSHA's requirements for respiratory protection programs, including fit-testing and medical monitoring.

C. Adverse Health Effects and Related Impacts That Would Be Prevented by the Proposed Option

The proposed option would prevent exposure to TCE from vapor degreasing and thus would prevent the risks of adverse effects and associated impacts. As discussed in Unit IV., TCE exposure is associated with a wide array of adverse health effects. These health effects include those resulting from developmental toxicity (*e.g.,* cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to

the kidney (kidney damage and kidney cancer), immunotoxicity (systemic autoimmune diseases such as scleroderma) and severe hypersensitivity skin disorder, non-Hodgkin's lymphoma, endocrine and reproductive effects (*e.g.,* decreased libido and potency), neurotoxicity (*e.g.,* trigeminal neuralgia), and toxicity to the liver (impaired functioning and liver cancer) (Ref. 2). These health effects associated with exposure to TCE are serious and can have impacts throughout a lifetime. The following is a discussion of the impacts of significant acute, chronic non-cancer, and cancer effects associated with TCE exposure during vapor degreasing, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

1. Developmental effects. The TCE risk assessment (and EPA's 2011 IRIS Assessment) identified developmental effects as the critical effect of greatest concern for both acute and chronic non-cancer risks. There are increased health risks for developmental effects to the estimated 454 to 1,066 pregnant women exposed to TCE during the use of vapor degreasers (Ref. 3). Specifically, these assessments identified fetal cardiac malformations in the offspring of mothers exposed to TCE during gestation as the critical effect. Although fetal cardiac defects are the effect of greatest concern and are the focus of the discussion in this Unit, TCE exposures can result in other adverse developmental outcomes, including prenatal (*e.g.,* spontaneous abortion and perinatal death, decreased birth weight, and congenital malformations) and postnatal (*e.g.,* reduced growth, decreased survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers) effects. TCE exposure during development results in qualitatively different immunotoxic effects than when exposure occurs during adulthood. TCE exposure during development can influence the development of the immune system and result in impairment of the immune system's ability to respond to infection, whereas TCE exposures during adulthood result in a more pronounced immune effect related to autoimmune responses.

Cardiac defects, which can result from low-level exposure to TCE, affect the structural development of a baby's heart and how it works. The defects impact how blood flows through the heart and out to the rest of the body. The impact can be mild (such as a small hole in the heart) or severe (such as missing or poorly formed septal wall and valves of the heart). While diagnosis for some cardiac defects can occur during pregnancy, for other cardiac defects, detection may not occur until after birth or later in life, during childhood or adulthood. These cardiac defects can be occult or life- threatening with the most severe cases causing early mortality and morbidity. While the incidences in the following paragraphs reflect adverse health outcomes beyond just exposure to TCE, the general population numbers provide a context for understanding the impact of the adverse health effects TCE can cause.

Nearly 1% or about 40,000 births per year in the United States are affected by cardiac defects (Ref. 40). About 25% of those infants with a cardiac defect have a critical defect. Infants with critical cardiac defects generally need surgery or other procedures in their first year of life. Some estimates put the total number of individuals (infants, children, adolescents, and adults) living with cardiac defects at 2 million (Ref. 40). Cardiac defects can be caused by genetics, environmental exposure, or an unknown cause.

Infant deaths resulting from cardiac defects often occur during the neonatal period. One study indicated that cardiac defects accounted for 4.2% of all neonatal deaths. Of infants born with a non-critical cardiac defect, 97% are expected to survive to the age of one, with 95% expected to survive to 18 years of age. Of infants born with a critical cardiac defect, 75% are expected to survive to one year of age, with 69% expected to survive to 18 years of age (Ref. 41). A child with a cardiac defect is 50% more likely to receive special education services compared to a child without birth defects (Ref. 40).

Treatments for cardiac defects vary. Some affected infants and children might need one or more surgeries to repair the heart or blood vessels. In other instances, a heart defect cannot be fully repaired, although treatments have advanced such that infants are living longer and healthier lives. Many children are living into adulthood and lead independent lives with little or no difficulty. Others, however, may develop disability over time, making it difficult to predict and quantify impacts.

Even though a person's heart defect may be repaired, for many people this is not a cure. They can still develop other health problems over time, depending on their specific heart defect, the number of heart defects they have, and the severity of their heart defect. For example, some related health problems that might develop include irregular heart beat (arrhythmias), increased risk of infection in the heart muscle (infective endocarditis), or weakness in the heart (cardiomyopathy). In order to stay healthy, a person needs regular checkups with a cardiologist. They also might need further operations after initial childhood surgeries (Ref. 40).

Depending upon the severity of the defect, the costs for surgeries, hospital stays, and doctor's appointments to address a baby's cardiac defect can be significant. The costs for the defects may also continue throughout a person's lifetime. In 2004, hospital costs in the United States for individuals with a cardiac defect were approximately $1.4 billion (Ref. 40).

Beyond the monetary cost, the emotional and mental toll on parents who discover that their child has a heart defect while *in utero* or after birth will be high (Ref. 41). They may experience anxiety and worry over whether their child will have a normal life of playing with friends and participating in sports and other physical activities, or whether their child may be more susceptible to illness and be limited in the type of work and experiences they can have. In addition, parents can be expected to experience concerns over potential unknown medical costs that may be looming in the future, lifestyle changes, and being unable to return to work in order to care for their child.

The emotional and mental toll on a person throughout childhood and into adolescence with a heart defect also should be considered (Ref. 41). Cardiac patients who are children may feel excluded from activities and feel limited in making friends if they have to miss school due to additional surgeries, or may not be able to fully participate in sports or other physical exercise. Children may feel self-conscious of the scars left by multiple surgeries. This, in turn, adds emotional and mental stress to the parents as they observe their child's struggles.

As a person with a heart defect enters adulthood, the emotional or mental toll of a cardiac defect may continue or in other instances the problem may only surface as an adult. If a cardiac defect impacts a person's ability to enter certain careers, this could take a monetary as well as emotional toll on that person and on their parents or families who may need to provide some form of financial support. The monetary, emotional, and mental costs of heart defects can be considerable, and even though neither the precise reduction in individual risk of developing a cardiac defect from reducing TCE exposure or the total

number of cases avoided can be estimated, their impact should be considered.

2. Kidney toxicity. a. Non-cancer chronic effects. The TCE risk assessment identified kidney toxicity as a significant concern from TCE exposure with the risk from this non-cancer effect being from chronic exposure. There are increased health risks for kidney toxicity to the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders in facilities that use TCE for vapor degreasing, where exposure to TCE is a result of vapor degreasing operations (Ref. 3).

Exposure to TCE can lead to changes in the proximate tubules of the kidney. This damage may result in signs and symptoms of acute kidney failure that include; decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness; shortness of breath, fatigue, confusion, nausea, seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Kidney toxicity means the kidney(s) has suffered damage that can result in a person being unable to rid their body of excess urine and wastes. In extreme cases where the kidney(s) is impaired over a long period of time, the kidney(s) could be damaged to the point that it no longer functions. When a kidney(s) no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney(s) can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 42).

Approximately 31 million people, or 10% of the adult population, in the United States have chronic kidney disease. In the United States, it is the ninth leading cause of death. About 93% of chronic kidney disease is from known causes, including 44% from diabetes and 28.4% from high blood pressure. Unknown or missing causes account for about 6.5% of cases, or about 2 million people (Ref. 43).

The monetary cost of kidney toxicity varies depending on the severity of the damage to the kidney. In less severe cases, doctor visits may be limited and hospital stays unnecessary. In more severe cases, a person may need serious medical interventions, such as dialysis or a kidney transplant if a donor is available, which can result in high medical expenses due to numerous hospital and doctor visits for regular dialysis and surgery if a transplant occurs. The costs for hemodialysis, as charged by hospitals, can be upwards of $100,000 per month (Ref. 44).

Depending on the severity of the kidney damage, kidney disease can impact a person's ability to work and live a normal life, which in turn takes a mental and emotional toll on the patient. In less severe cases, the impact on a person's quality of life may be limited, while in instances where kidney damage is severe, a person's quality of life and ability to work would be affected. While neither the precise reduction in individual risk of developing kidney toxicity from reducing TCE exposure or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to TCE.

b. Cancer effects. Chronic exposure to TCE can also lead to kidney cancer. The estimated value of the annualized benefit is $12 million to $108 million at 3% and $6 million to $57 million at 7% over 20 years. Kidney cancer rarely shows signs or symptoms in its early stages. As kidney cancer progresses, the cancer may grow beyond the kidney, spreading to lymph nodes or distant sites like the liver, lung or bladder, increasing the impacts on a person and the costs to treat it. This metastasis is highly correlated with fatal outcomes. Impacts of kidney cancer that are not monetized include the emotional, psychological and treatment impacts of the cancer on the well-being of the person.

3. Immunotoxicity. a. Non-cancer chronic effects. The TCE risk assessment identified immunotoxicity as a chronic non-cancer effect that is associated with TCE exposure. There are increased health risks for immunotoxicity to the approximately 2,670 to 6,270 workers and 42,720 to 100,320 bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

Human studies have demonstrated that TCE exposed workers can suffer from systemic autoimmune diseases (*e.g.,* scleroderma) and severe hypersensitivity skin disorders. Scleroderma is a chronic connective tissue disease with autoimmune origins. The annual incidence is estimated to be 10 to 20 cases per 1 million persons (Ref. 45), and the prevalence is four to 253 cases per 1 million persons (Ref. 46). About 300,000 Americans are estimated to have scleroderma. About one third of those people have the systemic form of scleroderma. Since scleroderma presents with symptoms similar to other autoimmune diseases, diagnosis is difficult. There may be many misdiagnosed or undiagnosed cases (Ref. 46).

Localized scleroderma is more common in children, whereas systemic scleroderma is more common in adults. Overall, female patients outnumber male patients about 4-to-1. Factors other than a person's gender, such as race and ethnic background, may influence the risk of getting scleroderma, the age of onset, and the pattern or severity of internal organ involvement. The reasons for this susceptibility are not clear. Although scleroderma is not directly inherited, some scientists believe there is a slight predisposition to it in families with a history of rheumatic diseases (Ref. 46).

The symptoms of scleroderma vary greatly from person to person with the effects ranging from very mild to life threatening. If not properly treated, a mild case can become much more serious. Relatively mild symptoms are localized scleroderma, which results in hardened waxy patches on the skin of varying sizes, shapes and color. The more life threatening symptoms are from systemic scleroderma, which can involve the skin, esophagus, gastrointestinal tract (stomach and bowels), lungs, kidneys, heart and other internal organs. It can also affect blood vessels, muscles and joints. The tissues of involved organs become hard and fibrous, causing them to function less efficiently.

Severe hypersensitivity skin disorders include exfoliative dermatitis, mucous membrane erosions, eosinophilia, and hepatitis. Exfoliative dermatitis is a scaly dermatitis involving most, if not all, of the skin. Eosinophilia, on the other hand, is a chronic disorder resulting from excessive production of a particular type of white blood cells. If diagnosed and treated early, a person can lead a relatively normal life (Ref. 45).

The monetary costs for treating these various immunotoxicity disorders will vary depending upon whether the symptoms lead to early diagnosis and this early diagnosis can then influence whether symptoms progress to mild or life-threatening outcomes. For mild symptoms, doctors' visits and outpatient treatment could be sufficient, while more severe immunotoxicity disorders, may require hospital visits. Treatments for these conditions with immune modulating drugs also have countervailing risks.

These disorders also take an emotional and mental toll on the person as well as on their families. Their quality of life may be impacted because they no longer have the ability to do certain activities that may affect or

highlight their skin disorder, such as swimming. Concerns over doctor and hospital bills, particularly if a person's ability to work is impacted, may further contribute to a person's emotional and mental stress. While neither the precise reduction in individual risk of developing this disorder from TCE exposure or the total number of cases avoided can be estimated, this should be considered.

b. Cancer effects: Non-Hodgkin's Lymphoma. EPA's 2011 IRIS assessment for TCE found that TCE is carcinogenic. Chronic exposure to TCE, by all routes of exposure, can result in non-Hodgkin's lymphoma (NHL), one of the three cancers for which the EPA IRIS TCE assessment based its cancer findings. There are increased health risks for NHL for the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

NHL is a form of cancer that originates in a person's lymphatic system. For NHL, there are approximately 19.7 new cases per 100,000 men and women per year with 6.2 deaths per 100,000 men and women per year. NHL is the seventh most common form of cancer (Ref. 47). Some studies suggest that exposure to chemicals may be linked to an increased risk of NHL. Other factors that may increase the risk of NHL are medications that suppress a person's immune system, infection with certain viruses and bacteria, or older age (Ref. 48).

Symptoms are painless, swollen lymph nodes in the neck, armpits or groin, abdominal pain or swelling, chest pain, coughing or trouble breathing, fatigue, fever, night sweats, and weight loss. Depending on the rate at which the NHL is advancing, the approach may be to monitor the condition, while more aggressive NHL could require chemotherapy, radiation, stem cell transplant, medications that enhance a person's immune system's ability to fight cancer, or medications that deliver radiation directly to cancer cells.

Treatment for NHL will result in substantial costs for hospital and doctors' visits in order to treat the cancer. The treatments for NHL can also have countervailing risks and can lead to higher susceptibility of patients to secondary malignancies (Ref. 49). The emotional and mental toll from wondering whether a treatment will be successful, going through the actual treatment, and inability to do normal activities or work will most likely be high. This emotional and mental toll will extend to the person's family and friends as they struggle with the diagnosis and success and failure of a treatment regime. If a person has children, this could affect their mental and emotional well-being and may impact their success in school. The estimated value of the monetized benefit is $32 million to $201 million at 3% and $15 million to $98 million at 7% annualized over 20 years.

4. Reproductive and endocrine effects. The TCE risk assessment identified risks of chronic non-cancer reproductive effects for workers and bystanders exposed to TCE. There are increased health risks for reproductive effects for the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

The reproductive effect for both females and males can be altered libido. The prevalence of infertility is estimated at about 10–15% of couples with a decreased libido among the factors of infertility (Ref. 50). For females, there can be reduced incidence of fecundability (6.7 million women ages 15 to 44 or 10.9% affected) (Ref. 51), increase in abnormal menstrual cycles, and amenorrhea (the absence of menstruation). Reproductive effects on males can be decreased potency, gynaecomastia, impotence, and decreased testosterone levels, or low T levels. Approximately 2.4 million men age 40 to 49 have low T levels, with a new diagnosis of about 481,000 androgen deficiency cases a year. Other estimates propose a hypogonadism prevalence of about 13 million American men (Ref. 52). Low T levels are associated with aging; an estimated 39% of men 45 or older have hypogonadism, resulting in low T levels (Ref. 53). Hormone therapy and endocrine monitoring may be required in the most severe cases.

The monetary costs of these potential reproductive effects involve doctor's visits in order to try to determine a diagnosis. In some instances, a person or couple may need to visit a fertility doctor.

The impact of a reduced sex drive can take an emotional and mental toll on single people as well as couples. For people trying to get pregnant, decreased fertility can add stress to a relationship as the cause is determined and avenues explored to try to resolve the difficulties in conceiving. A person or couples' quality of life can also be affected as they struggle with a reduced sex drive. Similar to other non-cancer effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing TCE exposure or the total number of cases avoided can be estimated, the Agency still must consider their impact.

5. Neurotoxicity. The TCE risk assessment identified neurotoxicity risks for workers and bystanders from chronic TCE exposures. There are increased health risks of neurotoxicity for the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

Studies have also demonstrated neurotoxicity from acute exposures. Neurotoxic effects observed include alterations in trigeminal nerve and vestibular function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. Developmental neurotoxicity effects include delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit (Ref. 4).

The impacts of neurotoxic effects due to TCE exposure can last a person's entire lifetime. Changes in vision may impact a person's ability to drive, which can create difficulties for daily life. Impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit can impact a child's educational progression and an adolescent's schooling and ability to make friends, which in turn can impact the type of work or ability to get work later in life.

Neurotoxicity in adults can affect the trigeminal nerve, the largest and most complex of the 12 cranial nerves, which supplies sensations to the face, mucous membranes, and other structures of the head. Onset of trigeminal neuralgia generally occurs in mid-life and known causes include multiple sclerosis, sarcoidosis and Lyme disease. There is also a co-morbidity with scleroderma and systemic lupus. Some data show that the prevalence of trigeminal neuralgia could be between 0.01% and 0.3% (Ref. 54). Alterations to this nerve function might cause sporadic and sudden burning or shock-like facial pain to a person. One way to relieve the burning or shock-like facial pain is to undergo a procedure where the nerve fibers are damaged in order to block the pain. This treatment can have lasting impact on sensation which may also be deleterious for normal pain sensation. The potential side effects of this

procedure includes facial numbness and some sensory loss.

The monetary health costs can range from doctor's visits and medication to surgeries and hospital stays. Depending upon when the neurotoxic effect occurred, the monetary costs may encompass a person's entire lifetime or just a portion.

The personal costs (emotional, mental, and impacts to a person's quality of life) cannot be discounted. Parents of a child with impaired learning, memory, or some other developmental neurotoxic effect may suffer emotional and mental stress related to worries about the child's performance in school, ability to make friends, and quality of the child's life because early disabilities can have compounding effects as they grow into adulthood. The parent may need to take off work unexpectedly and have the additional cost of doctor visits and/or medication.

For a person whose trigeminal nerve is affected, there is an emotional and mental toll as they wonder what is wrong and visit doctors in order to determine a diagnosis. Depending on the severity of the impact to the nerve, they may be unable to work. Doctor visits and any inability to work will have a monetary impact to the person. There are varying costs (emotional, monetary, and impacts to a person's quality of life) from the neurotoxic effects due to TCE exposure. However, while neither the precise reduction in individual risk of developing this disorder from reducing TCE exposure or the total number of cases avoided can be estimated, this is not a reason to disregard their impact.

6. Liver toxicity. The TCE risk assessment identified liver toxicity as an adverse effect of chronic TCE exposure. There are increased health risks for liver toxicity to the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 2).

Specific effects to the liver can include increased liver weight, increase in DNA synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation (Ref. 2). In addition, workers exposed to TCE have shown hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure (Ref. 2).

Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans (Ref. 55). Included in this number is at least 20% of those with nonalcoholic fatty liver disease (NAFLD) (Ref. 55). NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors (Ref. 55). The danger of NAFLD is that it can cause the liver to swell, which may result in cirrhosis over time and could even lead to liver cancer or failure (Ref. 55). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. In 2013, there were 1,781 reported acute cases of viral hepatitis A and the estimated actual cases were 3,500 (Ref. 56). For hepatitis B in 2013 there were 3,050 reported acute cases, while the estimated actual incidence was 19,800, and the estimated chronic cases in the United States is between 700,000 to 1.4 million (Ref. 56). For hepatitis C, in 2013 there were 2,138 reported cases; however, the estimated incidence was 29,700 and the estimated number of chronic cases is between 2.7 to 3.9 million (Ref. 56). These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals. While the incidences in this paragraph reflect adverse health outcomes beyond just exposure to TCE, the general population numbers provide a context for understanding the impact of the adverse health effects that TCE can cause.

Effects from TCE exposure to the liver can occur quickly. Liver weight increase has occurred in mice after as little as 2 days of inhalation exposure (Ref. 4). Human case reports from eight countries indicated symptoms of hepatitis, hepatomegaly and elevated liver function enzymes, and in rare cases, acute liver failure developed within as little as 2–5 weeks of initial exposure to TCE (Ref. 4).

Chronic exposure to TCE can also lead to liver cancer. There is strong epidemiological data that reported an association between TCE exposure and the onset of various cancers, including liver cancer. The estimated value of the annualized benefit is estimated to be $21 million to $133 million at 3% and $11 million to $71 million at 7% over 20 years.

Additional medical and emotional costs are associated with non-cancer liver toxicity from TCE exposure, although they cannot be quantified. These costs include doctor and hospital visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper ongoing medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease. Symptoms of jaundice include yellow or itchy skin and a yellowing of the whites of the eye, and a pale stool and dark urine. These symptoms can create a heightened emotional state as a person tries to determine what is wrong with them.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to the TCE; however, this may impact a person's ability to continue to work. In severe cases, the liver toxicity can lead to liver failure, which can result in the need for a liver transplant, if a donor is available. Liver transplantation is expensive (with an estimated cost of $575,000) and there are countervailing risks for this type of treatment (Ref. 57). The mental and emotional toll on an individual and their family as they try to determine the cause of sickness and possibly experience an inability to work, as well as the potential monetary cost of medical treatment required to regain health are significant.

D. Availability of Alternatives

TCE is commonly used in vapor degreasing systems for a variety of reasons. It is able to dissolve the greases, fats, oils, waxes, resins, gums and rosin fluxes generally used in metalworking operations and it is compatible with most metal substrates. TCE is non-flammable and it has a relatively low boiling point. It is also available at a relatively low cost. Several SERs providing input to the SBAR Panel convened in support of this rulemaking noted that TCE is particularly well-suited for use in vapor degreasing in the narrow tube, razor blade, and aerospace industries (Ref. 32).

Nevertheless, EPA identified a wide variety of technically and economically feasible alternatives for vapor degreasing with TCE. See Unit 4 of the Economic Analysis for a complete discussion of the technically and economically feasible alternatives to TCE. (Ref. 3). While some substitutes, such as methylene chloride or 1–BP, also present risks to workers, there are numerous other solvents available. These include designer solvents such as hydrofluorocarbon (HFC) and hydrofluoroether (HFE) solvent blends and hydrofluoroolefin (HFO), as well as other alternative solvents and cleaning systems, such as terpene-based cleaners, volatile methyl siloxanes, soy-based cleaners, and water-based cleaners.

Alternatives to TCE fall within several broad categories: Drop-in solvent alternatives, non-drop-in solvent alternatives (designer solvents, such as

hydrofluorocarbons, hydrofluoroolefins, and hydrofluoroethers), aqueous cleaning systems, other cleaning solvents (such as glycol ethers, siloxanes, terpenes, soy-based cleaners), and cold cleaning with TCE (Ref. 58).

EPA considered a solvent to be a drop-in alternative if it could be used in an existing vapor degreasing system with only minor modifications. One important consideration for many vapor degreasing machines is the flammability of the solvent. Heating a flammable solvent up to its boiling point increases the likelihood that, if there is a source of ignition or if the vapor concentration exceeds certain limits, the solvent will ignite or explode. Halogens (fluorine, chlorine and bromine) suppress flammability, hence their common use as fire extinguishants. For this reason, halogenated solvents are commonly used in vapor degreasing, although solvent flammability is less of a concern in closed-loop systems operated under vacuum. Depending on the type of vapor degreasing system, the drop-in solvent alternatives identified by EPA include methylene chloride, 1-bromopropane (1–BP or n-propyl bromide), and perchloroethylene. Like TCE, methylene chloride and perchloroethylene are hazardous air pollutants (HAPs) under the Clean Air Act and their use is regulated under the Halogenated Solvent NESHAP (40 CFR part 63, subpart T). Therefore, facilities that switch from TCE to methylene chloride or perchloroethylene will still be regulated by the NESHAP. In addition, although 1–BP is not currently listed as a HAP, EPA is currently considering a petition to list this chemical (Ref. 59).

There are significant hazards associated with all three of these drop-in replacements for TCE in vapor degreasing systems. However, based on EPA's analysis, the adverse effects associated with TCE exposure occur at exposure levels below the levels at which the adverse effects associated with the replacement chemicals occur (Ref. 58). With respect to methylene chloride, in August 2014, EPA issued a risk assessment of its use for paint and coating removal and EPA intends to issue a proposal to regulate this use of methylene chloride. While EPA has not specifically assessed the risks associated with using methylene chloride in vapor degreasing applications for this rulemaking, there are a number of hazard concerns associated with this chemical. The potential effects of methylene chloride exposure include death, liver toxicity, kidney toxicity, reproductive toxicity, specific cognitive impacts, and cancer (Ref. 60). Some of these effects result from a very short, acute exposure; others follow years of occupational exposure. Acute exposures may cause confusion and respiratory suppression in humans and there have been a number of deaths associated with worker exposures in homes and other job sites due to the buildup of carbon monoxide in the blood. Methylene chloride is likely to be carcinogenic in humans, so chronic exposures may increase cancer risk. Chronic exposures to methylene chloride may also lead to liver effects. However, these adverse effects are generally seen at higher exposure levels than those associated with TCE toxicity.

With respect to environmental effects, methylene chloride is volatile and releases of methylene chloride are likely to evaporate to the atmosphere, or if released to soil, migrate to groundwater (Ref. 59). It has a global warming potential (GWP) of 8.7 relative to carbon dioxide and thus can act as a greenhouse gas. Methylene chloride has been shown to biodegrade over a range of rates and conditions and is considered to be moderately persistent in the environment. Measured bioconcentration factors suggest that its bioconcentration potential is low.

EPA also has concerns for 1–BP. In May of 2016, a peer review meeting was held on EPA's draft TSCA Work Plan Chemical Risk Assessment for 1–BP. This draft assessment specifically evaluated the risks associated with the use of 1–BP in vapor degreasing (Ref. 61). According to the peer review draft, most acute exposure scenarios for vapor degreasing identified risks for adverse developmental effects that may occur as a result of a single exposure to 1–BP during a critical window of susceptibility. Likewise, chronic exposure risks for adverse neurological and developmental effects were identified in the draft risk assessment for all uses evaluated without engineering controls. In addition, the draft weight-of-evidence analysis for the cancer endpoint is sufficient to support a probable mutagenic mode of action for 1–BP carcinogenesis. However, these adverse effects are generally seen at higher exposure levels than those associated with TCE toxicity.

1–BP is a volatile liquid with high vapor pressure, moderate water solubility, and high mobility in soil (Ref. 61). It is expected to exhibit low adsorption to soil and thus can migrate rapidly through soil to groundwater. 1–BP is slowly degraded by sunlight and reactants when released to the atmosphere. Based on the estimated half-life of nine to twelve days, long range transport via the atmosphere is possible. Biotic and abiotic degradation studies have not shown this substance to be persistent (overall environmental half-life less than two months). While no measured bioconcentration studies for 1–BP are available, an estimated bioaccumulation factor of 12 suggests that bioconcentration and bioaccumulation in aquatic organisms are low.

EPA is also concerned about the adverse health effects associated with perchloroethylene (tetrachloroethylene) exposure. Based on the available human epidemiologic data and experimental and mechanistic studies, EPA has concluded that it poses a potential human health hazard for noncancer toxicity to the central nervous system, kidney, liver, immune and hematologic system, and on development and reproduction. (Ref. 62) Neurotoxicity has been identified as a sensitive endpoint following either oral or inhalation exposure. In addition, EPA has determined that perchloroethylene (tetrachloroethylene) is likely to be carcinogenic to humans by all routes of exposure (Ref. 62). As with methylene chloride and 1–BP, the adverse health effects associated with perchloroethylene (tetrachloroethylene) are generally seen at higher exposure levels than those associated with TCE toxicity. Perchloroethylene presents low to moderate risk to aquatic organisms (Ref. 62). It is moderately persistent, with a low bioaccumulation potential.

In contrast, aqueous cleaning systems present less risk to workers. Water-based cleaners have been used for many years in applications where users originally used TCE or other chlorinated solvents in vapor degreasing. In these systems, water-based cleaners are used to clean grease or oil from parts, the parts are rinsed, sometimes with deionized water if a spot free part is required for the next process, and dried. The cleaner concentrate, typically made up of boric acid or gluconic acid and other constituents, is generally diluted to between about 5% and 20% in a heated wash bath, depending on the cleaning task and the agitation in the equipment. The rinse is generally heated as well. Often driers composed of air knives that drive the water from the part are used.

Depending on the circumstances, several different types of equipment capable of using water-based cleaners can replace vapor degreasing machines that use TCE. Ultrasonic cleaning systems have transducers for generating the ultrasonic action in a bath. There are some immersion systems where the parts are placed on a platform and moved up and down in the cleaning

agent. In certain circumstances parts can be sprayed at pressures of about 60 psi and greater in spray cabinets. Conveyorized spray systems, where the parts go through high pressure spray at between about 80 and 120 psi, are also used in some cases. These systems often have wash, rinse and dry sections.

Water-based cleaners have a few characteristics to consider when evaluating replacements for TCE vapor degreasing (Ref. 63). Since TCE is used primarily to clean metal parts, the water cleaners often contain rust or corrosion inhibitors, which typically are present at very low concentrations, to protect the metals (Ref. 61). In addition, in order to be used in spray equipment, water-based cleaners must be formulated with a non-foaming surfactant. However, there are numerous water-based cleaners available on the market that have been formulated for these purposes (Ref. 64). In addition, the SBAR Panel convened in support of this rulemaking heard from several SERs about the increased water use associated with aqueous cleaning systems (more than 10,000 gallons a day). While this water can be reused in the degreasing system, any effluent is considered industrial wastewater for which a permit may be required under the Clean Water Act (Ref. 32).

SERs providing input to the SBAR Panel noted that, in general the use of TCE in vapor degreasing is declining very rapidly in certain sectors, but is still the method of choice for some, especially for small, intricate parts and substrates (*e.g.,* small tubes). Several SERs contended that none of the currently available chemical alternatives are good substitutes for TCE because of the health hazards associated with the substitutes, potential upcoming regulations and use restrictions on substitutes, compliance with the NESHAP limitations, and cost. In addition, some degreasing applications require highly efficient cleaning, such as electronics and glass to metal seals, which must be absolutely free of soil. A SER stated that no substitutes for critical glass to metal seals have been identified. Several SERs stated that substitutes with lower boiling points are not viable alternatives because they volatilize during processes involving elevated temperatures and because they cannot be shipped in standard drums. Most SERs indicated that replacing their open-top vapor degreasing systems with more sophisticated systems or alternative systems using aqueous cleaners would be very expensive, estimates ranged from $350,000 to $650,000. In contrast, one SER noted that water-based, or aqueous cleaning systems can be developed to replace most TCE-based vapor degreasing systems (Ref. 32). This same SER also stated that potential drawbacks to aqueous cleaning systems are the increased water use and the need for additional facility space. According to this SER, aqueous systems are typically much larger than vapor degreasing systems and aqueous operations often require multiple stages to reach the same cleaning efficiency as vapor degreasers.

Based on this input from the SERs, EPA is specifically requesting additional comments, information, and data to assist EPA in evaluating the availability of alternatives to TCE in vapor degreasing applications, including information on the costs to achieve TCE exposure reductions or to transition to alternative chemicals or processes. In addition, EPA will consider granting a time-limited exemption, under the authority of TSCA section 6(g), for a specific condition of use for which EPA can obtain documentation: That the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; that compliance with the proposed ban would significantly disrupt the national economy, national security, or critical infrastructure; or that TCE vapor degreasing in a specific application, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. To this end, EPA requests comment on a process for receiving and evaluating petitions and requesting EPA promulgate critical use exemption rules. Under this process, entities who believe that their specific condition of use is a critical or essential use under TSCA section 6(g) would submit a petition for an exemption rulemaking with supporting documentation that they believe demonstrates that the use meets the statutory criteria. EPA would review the petition for completeness and, if the documentation warrants further action, respond to the petition by publishing a proposal in the **Federal Register** inviting comment on a proposed exemption. EPA would consider the comments received, along with any additional information reasonably available, and then take final action on the proposed exemption. EPA requests comment on the specific kinds of documentation that should be required from entities seeking an exemption rulemaking in order to facilitate EPA's and later, the public's review. EPA also requests comment on the appropriate timeframes for EPA action, given that the documentation for any given use could be technical and extensive, and that EPA may also need to develop additional information, such as economic estimates, in order to promulgate an exemption rule under TSCA section 6(g). Finally, members of the potentially regulated community who believe that their operation is a critical or essential use should provide as much detail as possible to EPA about their operation during this comment period, including information on any evaluations of alternatives, the costs to transition to another chemical or process, and any other relevant information. This would assist EPA in reviewing the specific condition of use, as well as in establishing provisions for future exemption petitions.

EPA urges vapor degreasing facilities to think strategically about their choices should TCE be banned for their use or if they are in the market to replace or upgrade vapor degreasing equipment for other reasons. To the extent that a process currently using TCE in a vapor degreasing system can be converted to a significantly less toxic alternative, such as an aqueous cleaning system, it will avoid significant risks to workers and also reduce the likelihood that further actions on toxic solvents by EPA or other regulatory authorities will spur another process change.

E. Impacts of the Proposed and Alternative Regulatory Options

This unit describes the estimated costs of the proposed and alternative regulatory actions that EPA considered.

1. Proposed approach to prohibit manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing and require downstream notification. The costs of the proposed approach are estimated to include equipment modification costs, product costs, electricity, disposal, and other costs associated with using alternative solvents or systems. Although the proposal imposes costs resulting from downstream notification and recordkeeping requirements, these actions required under this proposed rule are identical in requirement and coverage to those included as part of the earlier proposed rule on TCE use in aerosol degreasing and spot cleaning at dry cleaning facilities (Ref. 1) that is a companion to this proposed rule. These notification and recordkeeping costs were accounted for as part of that proposal and are not included in the costs for this rule. Overall, EPA estimates that 50% of users will switch to drop-in alternatives, 25% will

convert to aqueous cleaning systems, and 25% will convert to other alternatives. The total costs for switching from TCE-based vapor degreasing to a substitute are estimated to be approximately $30 million to $45 million per year (annualized at 3% over 20 years) and $32 million to $46 million (annualized at 7% over 20 years).

2. Option that bans manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing except in airless vacuum-to-vacuum closed-loop systems where proper PPE is used and a requirement for downstream notification. Given equipment costs and the burden of establishing a respiratory protection program which involves training, respirator fit testing and the establishment of a medical monitoring program, EPA anticipates that companies not currently using airless vacuum-to-vacuum systems would choose to switch to substitutes instead of purchasing an airless system and adopting a program for PPE because substitutes are readily available and are more technically and economic feasible. EPA also assumes that this would be the case even if this alternative were expressed as a performance-based air exposure limit for TCE. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 10,000 are $30,000 at 3% and $32,000 at 7% per vapor degreasing machine over 20 years. In addition, there would be higher EPA administration and enforcement costs with respiratory protection program than there would be with an enforcement program under the proposed approach. Further, even if cost were not an impediment, there are many limitations to the successful implementation of respirators with an APF of 10,000 in a workplace.

3. Options that exclude downstream notification. For those options that exclude downstream notification, the options are less cost effective and more burdensome to enforce. This is even though EPA assumes monetized enforcement costs to be the same under all options for the purpose of this proposed rulemaking because EPA was unable to monetize the extent to which enforcement costs would vary by regulatory option. The proposed approach to prohibit manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing and require downstream notification is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to the greatest extent the potential for TCE products to be intentionally or unintentionally misdirected into the prohibited uses. Enforcement under the other options would be more difficult since the key requirements are directly placed on the larger number of product users. Under these other options, enforcement activities must target firms that might perform the activity where a TCE use is restricted or prohibited. Therefore, EPA considers downstream notification to be a critical component of this proposal and EPA also finds that incorporating downstream notification reduces the burden on society by easing implementation, compliance, and enforcement.

VII. Monetized Benefits and Costs of the Proposed Rule, the Alternatives EPA Considered, and Comparison of Benefits and Costs

The health endpoints associated with TCE exposure are serious. The following is a discussion of the impacts of the most significant cancer and non-cancer effects associated with TCE exposure, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

A. Benefits of the Proposed Rule and the Alternatives That EPA Considered

The risk reduction from preventing TCE exposure cannot be comprehensively quantified or monetized even though the adverse effects are well-documented, the TCE risk assessment estimating these risks has been peer-reviewed, and the benefits of reducing the risk of these health endpoints can be described. It is relatively straightforward to monetize the benefits of reducing the risk of the costs of the effects of cancer (kidney cancer, liver cancer, non-Hodgkin's lymphoma) due to TCE exposure. The estimated value of the annualized benefit is estimated to be $65 million to $447 million at 3% and $32 million to $227 million at 7% over 20 years. It is currently not possible to monetize the benefits of reducing the risks of the costs of non-cancer effects (all developmental toxicity, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity) of TCE exposure. There are two reasons for this. First, dose response information and concentration response functions in humans are not available. This information would allow EPA to estimate the number of population-level non-cancer cases that would be avoided by reducing exposures to levels corresponding with MOE benchmarks. Second, even it were possible to calculate the number of cases avoided, EPA may not be able to monetize the benefits of these avoided cases due to limitations in data needed to apply established economic methodologies. However, being unable to quantitatively assess individual risk and population-level non-cancer cases avoided from TCE exposure does not negate the impact of these effects. Similarly, the inability to monetize an adverse effect does not reflect the severity of the effect, the lifetime nature of the impact, or the magnitude of the benefit in preventing the adverse impact from TCE exposure, such as a cardiac malformation, on a person. In considering the benefits of preventing TCE exposure, EPA considered the type of effect, the severity of the effect, the duration of the effect, and costs and other monetary impacts of the health endpoint.

The alternative options that EPA considered are unlikely to result in the same health benefits as the proposed rule for the reasons discussed in Unit VI. However, EPA was unable to quantify the differences in benefits that would result from the alternatives.

B. Costs of the Proposed Rule and the Alternatives That EPA Considered

The details of the costs of the proposed approach for use of TCE in vapor degreasing are discussed in Unit VI.C. Under the proposed option, costs to users of TCE in vapor degreasing applications range from $30 million to $45 million (annualized at 3% over 20 years) and $32 million to $46 million (annualized at 7% over 20 years). Costs of downstream notification and recordkeeping for manufacturers, processors, and distributors on an annualized basis over 20 years are $3,200 and $4,400 using 3% and 7% discount rates respectively. However, the costs of the downstream notification and recordkeeping requirements were already accounted for in the prior proposal on TCE use in aerosol degreasing and as a spotting agent in dry-cleaning facilities, and thus are not included in the total costs for this proposal.

The primary alternative that EPA considered is a requirement that TCE be used for vapor degreasing only in certain closed systems and that workers operating the systems and in the immediate area wear PPE with an APF of 10,000. The estimated annualized costs of this option are $32 million to $46 million annualized over 20 years at 3% and $34 million to $47 million annualized over 20 years at 7%.

C. Comparison of Benefits and Costs

The monetized benefits for preventing the risks resulting from TCE exposure from this use significantly outweigh the estimated costs. Simply comparing the costs and monetized benefits of prohibiting the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing, prohibiting commercial use of TCE in vapor degreasing, and requiring downstream notification demonstrates that the monetized benefits of this proposed action outweigh the costs. However, EPA believes that the balance of costs and benefits cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects as well as cancer. As discussed previously, the multitude of potential adverse effects associated with TCE exposure can profoundly impact an individual's quality of life. Some of the adverse effects associated with TCE exposure can be immediately experienced and can affect a person from childhood throughout a lifetime (*e.g.,* cardiac malformations, developmental neurotoxicity, and developmental immunotoxicity). Others (*e.g.,* adult immunotoxicity, kidney and liver failure or cancers) can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature.

While the risk of non-cancer health effects associated with TCE exposure cannot be quantitatively estimated, the qualitative discussion in this Unit highlights how some of these non-cancer effects occurring much earlier in life from TCE exposure may be as severe as cancer's mortality and morbidity and thus just as life-altering. These effects include not only medical costs but also personal costs such as emotional and mental stress that are impossible to accurately measure.

While the impacts of non-cancer effects cannot be monetized, EPA considered the impacts of these effects in deciding how best to address the unreasonable risks presented by TCE use in vapor degreasing. Considering only monetized benefits would significantly underestimate the impacts of TCE-induced non-cancer adverse outcomes on a person's quality of life to perform basic skills of daily living, including the ability to earn a living, the ability to participate in sports and other activities, and the impacts on a person's family and relationships.

Thus, considering costs, benefits that can be monetized (risk of cancer), and benefits that cannot be quantified and subsequently monetized (risk of developmental toxicity, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity), including benefits related to the severity of the effects and the impacts on a person throughout her/his lifetime in terms of medical costs, effects on earning power and personal costs, and the emotional and psychological costs, the benefits of preventing exposures to TCE emissions from vapor degreasing systems outweigh the costs. Further, if EPA were to consider only the benefits that can be monetized in comparison to the cost, the monetized benefits from preventing kidney and liver cancer and non-Hodgkin's lymphoma from the use of TCE in vapor degreasing (the annualized monetized benefits on a 20 year basis range from approximately $65 million to $447 million at 3% and $32 million to $227 million at 7%) far outweigh the costs of the proposal to ban the use of TCE in vapor degreasing (the annualized costs on a 20 year basis range from approximately $30 million to $45 million at 3% and $32 million to $46 million at 7%). Considering the costs and benefits of the proposed and alternative options, while both address the unreasonable risks from TCE exposure, the proposed approach is more cost effective because it achieves the same or greater benefits at lower costs. For more information, see Section 7 in the Economic Analysis.

VIII. Overview of Uncertainties

A discussion of the uncertainties associated with this proposed rule can be found in the TCE risk assessment (Ref. 2) and in the supplemental analysis (Ref. 30) for use of TCE in vapor degreasing. A summary of these uncertainties follows.

EPA used a number of assumptions in the TCE risk assessment and supporting analysis to develop estimates for occupational exposure scenarios and to develop the hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include the possibility that releases of and exposures to TCE vary from one vapor degreasing machine to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. In estimating the risk from vapor degreasing, there are uncertainties in the number of workers exposed to TCE and in the inputs and algorithms of the models used to estimate exposures.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the benefits are most pronounced in estimating the benefits from preventing the non-cancer adverse effects because these benefits generally cannot be monetized due to the lack of concentration-response functions in humans leading to the ability to estimate the number of population-level non-cancer cases and limitations in established economic methodologies. Additional uncertainties in benefit calculations include the potential risks for adverse health effects that the alternatives may pose and the estimates of the alternatives that users might choose to adopt. While there are some products that have comparable risks, there are a number of alternatives that are likely to be of lower risk, although EPA is unable to estimate the incremental change in the risk. To account for this uncertainty, EPA includes a lower and a higher estimate for the benefits from eliminating exposure to TCE. The lower benefits estimate assumes no benefits for TCE users that keep the same vapor degreasing machines and switch to methylene chloride, perchloroethylene, 1–BP, or designer solvent alternatives, assumes that TCE users switching to any other alternative suffer no adverse health effects associated with the alternatives (*i.e.,* accrue the full benefits from eliminating TCE exposure), and applies a lowering factor to cancer risk estimates. The higher benefits estimate includes the benefit from entirely eliminating TCE exposure for all alternative compliance strategies, assumes that no risks are introduced by alternatives, and does not apply a lowering factor to cancer risk estimates. This inability to adequately account for adverse health effects of alternatives in the benefits analysis is expected to contribute most to the uncertainty in the estimates.

In addition, under certain assumptions EPA's economic analysis estimates that some TCE users will see a cost savings when switching to aqueous systems and certain other solvents. Standard economic theory suggests that financially rational companies would choose technologies that maximize profits so that regulatory outcomes would not typically result in a cost savings for the regulated facilities. There could be several reasons that cost savings might occur in the real world. Potential reasons include lack of complete information or barriers to obtaining information on the cost savings associated with alternatives as well as investment barriers or higher interest rates faced by firms. Additionally, there may be costs

associated with these alternatives that are not adequately accounted for in the analysis. To evaluate the effect of this uncertainty, EPA has included a sensitivity analysis that sets the cost savings to zero for these compliance alternatives (Ref. 3 at section 8.2). EPA also recognizes that these firms might experience positive costs of compliance rather than zero costs, so that the actual total costs could be higher than those in the sensitivity analysis. However, EPA has no current basis to estimate these potentially higher costs, since the available data appear to show that there are lower cost substitutes available. EPA requests comment and/or data on any hidden costs that may be missing from the analysis, or any other information that may help explain why some firms appear to be missing current opportunity for cost-savings substitutes.

There are also uncertainties in the estimates of the number of affected vapor degreasing machines, and for numbers of processors and distributors of TCE-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records. The estimate for number of facilities using TCE-containing vapor degreasing machines is based upon available industry information and an industry expert (Ref. 3). To estimate the number of processors, EPA relied on public 2012 CDR data. The number of sites is reported in the CDR data as a range. The midpoint of the reported ranges was used to estimate the total number of sites using the chemical. Furthermore, the CDR data only includes processors immediately downstream of those reporting to CDR. Finally, EPA estimated the number of wholesaler firms distributing products containing TCE by taking a ratio of the number of Chemical and Allied Products Merchant Wholesaler firms to Basic Chemical Manufacturing firms and applying it to the estimated number of manufacturers and processors of TCE (Ref. 3).

EPA will consider additional information received during the public comment period. This includes public comments, scientific publications, and other input submitted to EPA during the comment period.

IX. Analysis Under TSCA Section 9 and TSCA Section 26(h) Considerations

A. TSCA Section 9(a) Analysis

Section 9(a) of TSCA provides that, if the Administrator determines in her discretion that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. If the other agency responds by declaring that the activities described do not present an unreasonable risk or if that agency initiates action under its own law to protect against the risk within the timeframes specified by TSCA section 9(a), EPA is precluded from acting against the risk under sections 6(a) or 7 of TSCA.

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this proposed rule, EPA has consulted with OSHA.

OSHA assures safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA adopted an eight-hour time weighted average PEL of 100 ppm along with a ceiling limit in 1971 shortly after the agency was formed. It was based on the ACGIH recommended occupational exposure limit that was in place at that time. OSHA recognizes that the TCE PEL and many other PELs issued shortly after adoption of the OSHA Act in 1970 are outdated and inadequate for ensuring protection of worker health. OSHA recently published a Request for Information on approaches to updating PELs and other strategies to managing chemicals in the workplace (Ref. 12). OSHA's current regulatory agenda does not include revision to the TCE PEL or other regulations addressing the risks EPA has identified when TCE is used in vapor degreasing or the uses identified in a prior proposal (Ref. 1), aerosol degreasing or for spot cleaning in dry cleaning facilities (Ref. 12).

This proposed rule and the related proposal (Ref. 1), which EPA intends to finalize together, address risks in both workplace (both private- and public-sector) and consumer settings from exposure to TCE in vapor degreasers, aerosol spray degreasers, and as a spot cleaner at dry cleaning facilities. With the exception of TSCA, there is no Federal law that provides authority to prevent or sufficiently reduce these cross-cutting exposures. No other Federal regulatory authority, when considering the exposures to the populations and within the situations in its purview, can evaluate and address the totality of the risk that EPA is addressing in this proposal and the prior proposal on TCE uses (Ref. 1). For example, OSHA may set exposure limits for workers but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals. Further, OSHA does not have direct authority over state and local employees, and it has no authority at all over the working conditions of state and local employees in states that have no OSHA-approved State Plan under 29 U.S.C. 667. Other Federal regulatory authorities, such as CPSC, have the authority to only regulate pieces of the risks posed by TCE, such as when used in consumer products.

Moreover, recent amendments to TSCA, Public Law 114–182, alter both the manner of identifying unreasonable risk under TSCA and EPA's authority to address unreasonable risk under TSCA, such that risk management under TSCA is increasingly distinct from analogous provisions of the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act, or the OSH Act. These changes to TSCA reduce the likelihood that an action under the CPSA, FHSA, or the OSH Act would reduce the risk of TCE from these uses to a sufficient extent under TSCA. Whereas (in a TSCA section 6 rule) an unreasonable risk determination sets the objective of the rule in a manner that excludes cost considerations, 15 U.S.C 2605(b)(4)(A), subject to time-limited conditional exemptions for critical chemical uses and the like, 15 U.S.C. 2605(g), a consumer product safety rule under the CPSA must include a finding that ''the benefits expected from the rule bear a reasonable relationship to its costs.'' 15 U.S.C. 2058(f)(3)(E). Additionally, recent amendments to TSCA reflect Congressional intent to ''delete[] the paralyzing 'least burdensome' requirement,'' 162 Cong. Rec. S3517 (June 7, 2016). However, a consumer product safety rule under the CPSA must impose ''the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated.''15 U.S.C. 2058(f)(3)(F). Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action under the FHSA relative to action under TSCA. 15 U.S.C. 1262. Gaps also exist between OSHA's authority to set workplace standards under the OSH Act and EPA's amended obligations to sufficiently address chemical risks under TSCA. To set PELs for chemical exposure, OSHA must first establish that the new standards are economically feasible and technologically feasible. 79 FR 61387 (2014). But under TSCA, EPA's substantive burden under TSCA § 6(a) is

to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being determined without consideration of cost or other nonrisk factors.

TSCA is the only regulatory authority able to prevent or reduce risks from these uses of TCE to a sufficient extent across the range of uses and exposures of concern. In addition, these risks can be addressed in a more coordinated, efficient and effective manner under TSCA than under two or more different laws implemented by different agencies. Furthermore, there are key differences between the newly amended finding requirements of TSCA and those of the OSH Act, CPSA, and the FHSA. For these reasons, in her discretion, the Administrator does not determine that unreasonable risks from the use of TCE in vapor degreasers, aerosol spray degreasers, and as a spot cleaner at dry cleaning facilities may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

B. TSCA Section 9(b) Analysis

If EPA determines that actions under other Federal laws administered in whole or in part by EPA could eliminate or sufficiently reduce an unreasonable risk, section 9(b) of TSCA instructs EPA to use these other authorities unless the Administrator determines in the Administrator's discretion that it is in the public interest to protect against such risk under TSCA. In making such a public interest finding, TSCA section 9(b)(2) states: ''the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk . . . and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk.''

Although several EPA statutes have been used to limit TCE exposure, as discussed in Unit III.A., regulations under these EPA statutes have limitations because they largely regulate releases to the environment, rather than direct human exposure. SDWA only applies to drinking water. CAA does not apply directly to worker exposures or consumer settings where TCE is used. Under RCRA, TCE that is discarded may be considered a hazardous waste and subject to requirements designed to reduce exposure from the disposal of TCE to air, land and water. RCRA does not address exposures during use of products containing TCE. Only TSCA provides EPA the authority to regulate the manufacture (including import), processing, and distribution in commerce, and use of chemical substances.

For these reasons, the Administrator does not determine that unreasonable risks from the use of TCE in vapor degreasers, aerosol spray degreasers, and as a spot cleaner at dry cleaning facilities could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

C. Section 26(h) Considerations

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. For example, EPA based its proposed determination of unreasonable risk presented by the use of TCE in vapor degreasing systems on the completed risk assessment, which followed a peer review and public comment process, as well as using the best available science and methods (Ref. 2). A supplemental analysis was performed to better characterize the exposed populations and estimate the effects of various control options. This supplemental analysis was performed consistent with the methods and models used in the risk assessment. These analyses were developed for the purpose of determining whether the particular risks are unreasonable. They were also developed to support risk reduction by regulation under section 6 of TSCA, to the extent risks were determined to be unreasonable. It is reasonable and consistent to consider these analysis in this rulemaking for such relevant purposes.

The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, can be found on EPA's Assessments for TSCA Work Plan Chemicals Web page at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals.*

X. Major Provisions and Enforcement of the Proposed Rule

This proposal relies on general provisions in the proposed Part 751, Subpart A, which can be found at 81 FR 91592 (December 16, 2016).

A. Prohibitions on TCE Manufacturing (Including Import), Processing, Distribution in Commerce, and Commercial Use

This proposal would prohibit the manufacture (including import), processing, distribution in commerce, and commercial use of TCE in vapor degreasing.

B. Downstream Notification

EPA has authority under TSCA section 6 to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. Many TCE manufacturers and processors are likely to manufacture or process TCE or TCE containing products for other uses that would not be regulated under this proposal. Other companies may be strictly engaged in distribution in commerce of TCE, without any manufacturing or processing activities, to customers for uses that are not regulated. As discussed in the prior proposal on TCE use in aerosol degreasers and as a spot remover agent in dry cleaning facilities, EPA is proposing a requirement for downstream notification by manufacturers (including importers), processors, and distributors of TCE for any use to ensure compliance with the proposed prohibitions on the manufacture, processing, distribution in commerce, and commercial use of TCE. Downstream notification is necessary for effective enforcement of the rule because it provides a record, in writing, of notification on use restrictions throughout the supply chain, likely via modifications to the Safety Data Sheet. Downstream notification also increases awareness of restrictions on use, which is likely to decrease unintentional uses of TCE. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The specific requirement, that persons who manufacture (including import), process, or distribute in commerce TCE for any use would have to provide written notification of the restrictions to persons to whom TCE is shipped, was included in an earlier proposal on TCE use (Ref. 1). The specific recordkeeping requirements were also contained in the prior proposal (Ref. 1). Those provisions would require manufacturers (including importers), processors, and distributors of TCE for any use to retain documentation of the identity and

contact information for persons to whom TCE was shipped as well as the amount of TCE shipped, and a copy of the notification that was provided. This documentation would have to be retained for 3 years from the date of shipment.

As presented in the prior proposal (Ref. 1), the estimated costs of downstream notification and recordkeeping on an annualized basis over 20 years are $3,200 and $4,400 using 3% and 7% discount rates respectively.

C. Enforcement

TSCA section 15 makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA section 6. Therefore, any failure to comply with this proposed rule when it becomes effective would be a violation of TSCA section 15. In addition, TSCA section 15 makes it unlawful for any person to: (1) Fail or refuse to establish and maintain records as required by this rule; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by TSCA section 11.

Violators may be subject to both civil and criminal liability. Under the penalty provision of TSCA section 16, any person who violates TSCA section 15 could be subject to a civil penalty for each violation. Each day of operation in violation of this proposed rule when it becomes effective could constitute a separate violation. Knowing or willful violations of this proposed rule when it becomes effective could lead to the imposition of criminal penalties and imprisonment. In addition, other remedies are available to EPA under TSCA sections 7 and 17.

Individuals, as well as corporations, could be subject to enforcement actions. TSCA sections 15 and 16 apply to ''any person'' who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false information or cause it to be reported.

D. Implementation Dates and Incentives

As proposed in the prior action on TCE use (Ref. 1), the downstream notification requirements and the recordkeeping requirements applicable to manufacturers (including importers) and processors of TCE for any use and persons who distribute TCE in commerce for any use (other than retailers) would take effect 45 days after the final rule is issued. EPA is proposing to make the ban on manufacturing (including importing), processing, or distributing in commerce TCE for vapor degreasing uses, the downstream notification requirements, and the recordkeeping requirements effective 18 months after publication of the final rule. The ban on the use of TCE in vapor degreasing systems would take effect six months after that, or two years after publication of the final rule. EPA heard from the SERs who provided input to the SBAR Panel that converting from a vapor degreasing system that uses TCE to one that does not is often a time-intensive process (Ref. 32). SERs had different ideas on how long it would take for the conversion process. One SER observed that many users do not know exactly how clean their products must be, or how clean their existing system gets them. According to this SER, testing is needed to determine the required cleaning efficiency, and it can take six months for the testing. Changing to a new system could take an additional twelve to eighteen months. Another SER agreed with the estimate of two years for a changeover, while still another SER thought it could take anywhere from six months to four years. In light of this input, EPA believes that it is reasonable to establish the compliance date for the prohibition on TCE in vapor degreasing at two years from the date the final rule is promulgated. EPA believes that, in most cases, the transition can be made within this time, but EPA requests comment on whether there are special situations which may require more time.

EPA would like to encourage as many companies as possible to adopt less hazardous technologies, such as aqueous cleaning systems, instead of switching to an alternative that also presents health risks for workers, albeit of a lower magnitude than TCE. EPA's analysis indicates that the best answer for many vapor degreasing operations may be a switch to water-based cleaners, even though there are higher upfront costs. An effective system that works for a given application and that is acceptable to customers must be researched and designed, new equipment and cleaning solutions must be purchased, new permits may be required, operating and safety procedures must be updated, and affected employees must learn to operate the new equipment. However, once the system is up and running properly, operation of the system on an annual basis is likely to be less expensive and much less hazardous to employees than a vapor degreasing system using TCE.

EPA requests comment on its analysis of the alternatives and the impacts of switching to less hazardous cleaners. EPA is particularly interested in comments and information on water and energy use associated with water-based cleaners and other less-toxic solvents, as well as on the costs of conversion from a system that uses TCE and the length of time such a conversion would take.

EPA is also requesting comment on potential incentives for vapor degreasing facilities to switch to less toxic alternatives. TSCA does not provide the authority for EPA to offer incentives such as tax credits, so there are a limited number of regulatory incentives available to EPA. One potential incentive would be a delayed implementation date for a ban on TCE use in vapor degreasing. This incentive would allow vapor degreasing facilities that intend to convert to aqueous cleaning systems a longer period of time to make the conversion. One way to administer this incentive would be to require vapor degreasing facilities to specifically request an extension for a certain length of time. Of course, in order to limit misuse of this extension opportunity, EPA would have to also require documentation of the facility's clear intention to convert to an aqueous cleaning system. This might include a description of the steps the company has already taken to implement a change to aqueous substitutes, or a description of the specific plan for implementing the change within the extension period requested, with some sort of documentation, such as a contract to purchase equipment. EPA also notes that TSCA section 6(d) generally provides that compliance dates for the start of a ban or phase-out promulgated under section 6(a) must be as soon as practicable, but not later than five years after the rule is promulgated, except for those critical or essential uses exempted under TSCA section 6(g). EPA requests comments on all aspects of this potential incentive, including comments on the length of time that should be allowed for an extension, what documentation should be required, and which technologies or solvents should be eligible for an extension and how to define them. EPA also requests comments on other potential incentives or regulatory flexibilities that EPA could incorporate to encourage the adoption of safer degreasing technologies. Finally, in keeping with the SBAR Panel recommendation regarding flexibility for small businesses, EPA requests comment on whether there are flexibilities other than delayed implementation dates that would be particularly advantageous for small

businesses while still ensuring that they address the unreasonable risks to which their workers may be exposed.

XI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

1. EPA. Trichloroethylene; Regulation of Certain Uses under TSCA § 6(a). Proposed Rule. **Federal Register**. (81 FR 91592, December 16, 2016) (FRL–9949–86).
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21. European Chemicals Association. Opinion on an Application for Authorisation for Trichloroethylene: Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist (11 September 2015).
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XII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an economic analysis of the potential costs and benefits associated with this action, which is available in the docket and summarized in Unit VII. (Ref. 3).

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted to OMB for review and comment under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by the Agency has been assigned EPA ICR No. 2541.02. You can find a copy of the ICR in the docket for this proposed rule (Ref. 65), and it is briefly summarized here.

The information collection activities required under the proposed rule include a downstream notification requirement and a recordkeeping requirement. The downstream notification would require companies that ship TCE to notify companies downstream in the supply chain of the prohibitions of TCE in the proposed rule. The proposed rule does not require the regulated entities to submit information to EPA. The proposed rule also does not require confidential or sensitive information to be submitted to EPA or downstream companies. The recordkeeping requirement mandates companies that ship TCE to retain certain information at the company headquarters for three years from the date of shipment. These information

collection activities are necessary in order to enhance the prohibitions under the proposed rule by ensuring awareness of the prohibitions throughout the TCE supply chain, and to provide EPA with information upon inspection of companies downstream who purchased TCE. EPA believes that these information collection activities would not significantly impact the regulated entities.

Respondents/Affected Entities: TCE manufacturers, processors, and distributors.

Respondent's Obligation to Respond: Mandatory.

Estimated Number of Respondents: 697.

Frequency of Response: On occasion.

Total Estimated Burden: 348.5 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total Estimated Cost: $16,848 (per year).

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov.* Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 21, 2017. EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq.,* EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact. The complete IRFA is available for review in the docket and is summarized here (Ref. 66).

1. Need for the rule. Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. Based on EPA's risk assessment of TCE (Ref. 2), EPA's proposed determination is that the use of TCE in vapor degreasing presents an unreasonable risk of injury to health and that the provisions of this proposal are necessary to address the unreasonable risk.

2. *Objectives and legal basis.* The legal basis for this proposal is TSCA section 6(a), which provides authority for the Administrator to apply requirements to the extent necessary so that a chemical substance or mixture no longer presents an unreasonable risk of injury to health or the environment. Additionally, for a chemical substance, such as TCE, which is listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6.

3. *Small entities covered by this proposal.* EPA estimates that the proposal would affect approximately 2,500 to 6,000 small entities. The majority of these entities are commercial users of TCE in vapor degreasing machines in a variety of occupational settings such as metal plating, electronics assembly, metal or composite part fabrication, and repair shops.

4. *Compliance requirements and the professional skills needed.* To address the unreasonable risks that EPA has identified, this proposal would prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; prohibit commercial use of TCE in vapor degreasing; and require manufacturers, processors, and distributors, except for retailers, to provide downstream notification of this prohibition throughout the supply chain (*e.g.,* via a Safety Data Sheet (SDS)), and to keep records. Complying with the prohibitions, the downstream notification, and the recordkeeping requirements involve no special skills. However, design and implementation of an alternative to vapor degreasing with TCE may involve special skills, such as engineering experience.

5. *Other Federal regulations.* Other Federal regulations that affect the use of TCE in vapor degreasing are discussed in Unit III.A. of this preamble. Because the NESHAP regulates only emissions from vapor degreasing facilities, not worker exposures, and because the 1971 OSHA PEL is not sufficiently protective, EPA's proposal is not duplicative of other Federal rules nor does it conflict with other Federal rules.

6. *Regulatory alternatives considered.* EPA considered a wide variety of control measures and the Economic Analysis (Ref. 3) examined several alternative analytical options. However, EPA determined that most of the alternatives did not effectively address the unreasonable risk presented by TCE in vapor degreasing. The primary alternative considered by EPA was to allow the use of TCE in closed-loop vapor degreasing systems and require respiratory protection equipment for workers operating the equipment in the form of a full face piece self-contained breathing apparatus (SCBA) in pressure demand mode or other positive pressure mode with an APF of 10,000 with an alternative to the specified APF respirator of an air exposure limit. Depending on air concentrations and proximity to the vapor degreasing equipment, other employees in the area would also need to wear respiratory protection equipment. While this option would address the unreasonable risks presented by TCE in vapor degreasing, EPA's Economic Analysis indicates that this option is more expensive and, thus less cost effective than switching to a different solvent or cleaning system.

As required by section 609(b) of the RFA, EPA also convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an IRFA. A copy of the full SBAR Panel Report is available in the rulemaking docket. The Panel recommended that EPA seek additional information on critical uses; availability, effectiveness, and costs of alternatives; implementation timelines; and exposure information to provide flexibility to lessen impacts to small entities, as appropriate. Throughout this preamble, EPA has requested information with respect to these and other topics. The Panel made the following specific recommendations:

a. *Critical uses.* The Panel recommended that EPA provide exemption, in accordance with TSCA section 6(g), for those critical uses for which EPA can obtain adequate documentation that:

- No technically and economically feasible safer alternative is available;
- Compliance with the ban would significantly disrupt the national economy, national security, or critical infrastructure; or
- The specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

To that end, the Panel recommended that EPA include in its proposal specific targeted requests for comment directed towards identifying critical uses (such as the aeronautics industry and national security) and obtaining information to justify exemptions. The Panel also recommended that EPA request public comment on allowing the use of TCE in closed-top vapor degreasing systems with the use of appropriate PPE.

b. *Alternatives.* The Panel recommended that EPA ensure that its analysis of the available alternatives to TCE in vapor degreasing complies with the requirements of section 6(c)(2)(C) and includes consideration, to the extent legally permissible and practicable, of whether technically and economically feasible alternatives that benefit health or the environment, compared to the use being prohibited or restricted, will be reasonably available as a substitute when the proposed requirements would take effect. Specifically, the Panel recommended that EPA:

- Evaluate the feasibility of using alternatives, including the cost, relative safety, and other barriers (such as space constraints, cleaning efficiency, increased energy use, cycle time, boiling points, and water use restrictions); and
- Take into consideration the current and future planned regulation of compounds the Agency has listed as alternatives.

c. *Implementation timelines.* The Panel recommended that EPA provide regulatory flexibility, as applicable, based on additional information, such as delayed compliance or a phase-out option, for small businesses that may be affected by the rule and in its proposal specifically request additional information regarding timelines for transitioning to alternative chemicals or technologies.

d. *Cost information.* The Panel also recommended that EPA specifically evaluate the cost to small business degreasing services without a viable alternative to TCE (*i.e.,* the cost of going out of business). The Panel recommended that EPA request additional information on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

e. *Exposure information.* The Panel recommended that EPA include in its proposal specific requests for additional pertinent exposure data that may be available.

f. *Risk assessment.* The Panel recommended that EPA recognize the concerns that the SERs had on the risk assessment by referring readers to the risk assessment and the Agency's Summary of External Peer Review and Public Comments and Disposition document, which addresses those concerns, in the preamble of the proposed rulemaking.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The requirements of this action would primarily affect persons who commercially use TCE in vapor degreasing equipment. The total estimated annualized cost of the proposed rule is approximately $30 million to $45 million at 3% and $32 million to $46 million at 7% (Ref. 3).

E. Executive Order 13132: Federalism

EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt state law. EPA provides the following preliminary federalism summary impact statement. The Agency consulted with state and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. EPA invited the following national organizations representing state and local elected officials to a meeting on May 13, 2015, in Washington DC: National Governors Association; National Conference of State Legislatures, Council of State Governments, National League of Cities, U.S. Conference of Mayors, National Association of Counties, International City/County Management Association, National Association of Towns and Townships, County Executives of America, and Environmental Council of States. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 67). Although EPA provided these organizations an opportunity to provide follow-up comments in writing, no written follow-up was received by the Agency.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rulemaking would not have substantial direct effects on tribal government because TCE is not manufactured, processed, or distributed in commerce by tribes. TCE is not regulated by tribes, and this rulemaking would not impose substantial direct compliance costs on tribal governments. Thus, EO 13175 does not apply to this action. EPA nevertheless consulted with tribal officials during the development of this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes.

EPA met with tribal officials in a national informational webinar held on May 12, 2015 concerning the prospective regulation of TCE under TSCA section 6, and in another teleconference with tribal officials on May 27, 2015 (Ref. 68). EPA also met with the National Tribal Toxics Council (NTTC) in Washington, DC and via teleconference on April 22, 2015 (Ref. 68). In those meetings, EPA provided background information on the proposed rule and a summary of issues being explored by the Agency. These officials expressed concern for TCE contamination on tribal lands and supported additional regulation of TCE.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is an economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children, specifically on the developing fetus. Accordingly, we have evaluated the environmental health or safety effects of TCE used in vapor degreasing on children. The results of this evaluation are discussed in Units I.F., II.C., IV., and VI.C. of this preamble and in the economic analysis (Ref. 3).

Supporting information on the exposures and health effects of TCE exposure on children is also available in the Toxicological Review of Trichloroethylene (Ref. 4) and the TCE risk assessment (Ref. 2).

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution in Commerce, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution in commerce, or use. This rulemaking is intended to protect against risks from TCE, and does not affect the use of oil, coal, or electricity.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the U.S. Units IV. and VI. of this preamble address public health impacts from TCE. EPA has determined that there would not be a disproportionately high and adverse health or environmental effects on minority, low income, or indigenous populations from this proposed rule.

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export certification, Hazardous substances, Import certification, Recordkeeping.

Dated: January 11, 2017.

Gina McCarthy,

Administrator.

Therefore, 40 CFR part 751, as proposed to be added at 81 FR 91592 (December 16, 2016), is proposed to be further amended to read as follows:

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

■ 1. The authority citation for part 751 continues to read as follows:

Authority: 15 U.S.C. 2605.

■ 2. In § 751.303, add the definition ''Vapor'' in alphabetical order to read as follows:

§ 751.303 Definitions.

* * * * *

Vapor degreasing means a cleaning process involving heating a solvent to produce a hot vapor which is then used to remove contaminants such as grease, oils, dust, and dirt from fabricated parts and other materials.

■ 3. Add § 751.309 to read as follows:

§ 751.309 Vapor degreasing.

(a) After [*date 18 months after the date of publication of the final rule*], all persons are prohibited from manufacturing (including import), processing, and distributing in commerce TCE and mixtures containing TCE for use in vapor degreasing.

(b) After [*date 2 years after the date of publication of the final rule*], all persons are prohibited from commercial use of TCE and mixtures containing TCE in vapor degreasing.

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contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by EPA on these applications. For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation Web site for additional information on this process *(http://www2.epa.gov/pesticide-registration/public-participation-process-registration-actions*). EPA received the following applications to register new uses for pesticide products containing currently registered active ingredients:

1. *EPA Registration Number:* 279–3055. *Docket ID Number:* EPA–HQ–OPP–2016–0352. *Applicant:* FMC Corporation, Agricultural Products Group, 1735 Market St., Philadelphia, PA 19103. *Active Ingredient:* Bifenthrin. *Product Type:* Insecticide. *Proposed Use:* Avocado; Low Growing Berry Subgroup 13–07G; Peach Subgroup 12–12B; Pepper/Eggplant Subgroup 8–10B; Pome Fruit Group 11–10 (except Mayhaw); Pomegranate; Small Fruit Vine Climbing Subgroup 13–07F (except Fuzzy Kiwifruit); and Tomato Subgroup 8–10A. *Contact:* RD.

2. *EPA Registration Number:* 279–3108. *Docket ID Number:* EPA–HQ–OPP–2016–0352. *Applicant:* FMC Corporation, Agricultural Products Group, 1735 Market St., Philadelphia, PA 19103. *Active Ingredient:* Bifenthrin. *Product Type:* Insecticide. *Proposed Use:* Caneberries (Subgroup 13–07A); Cranberry; Fruit, Citrus Group 10–10; Low Growing Berries (Subgroup 13–07G) except Cranberry; Nut, Tree Group 14–12; Peach Subgroup 12–12B; Pepper/Eggplant (Subgroup 8–10B); Pome Fruit Group 11–10 (except Mayhaw); Pomegranate; Small Fruit Vine Climbing except Fuzzy Kiwifruit (Subgroup 13–07F); and Tomato (Subgroup 8–10A). *Contact:* RD.

3. *EPA Registration Number:* 279–3313. *Docket ID Number:* EPA–HQ–OPP–2016–0352. *Applicant:* FMC Corporation, Agricultural Products Group, 1735 Market St., Philadelphia, PA 19103. *Active Ingredient:* Bifenthrin. *Product Type:* Insecticide. *Proposed Use:* Brassica, Leafy Greens Subgroup 4–16B; Caneberries (Subgroup 13–07A); Fruit, Citrus Group 10–10; Nut, Tree Group 14–12; Peach Subgroup 12–12B; Pepper/Eggplant (Subgroup 8–10B); Pome Fruit Group 11–10 (except Mayhaw); Pomegranate; Small Fruit Vine Climbing except Fuzzy Kiwifruit (Subgroup 13–07F); and Tomato (Subgroup 8–10A). *Contact:* RD.

4. *EPA Registration Numbers:* 279–3315 and 279–3329. *Docket ID Number:* EPA–HQ–OPP–2016–0352. *Applicant:* FMC Corporation, Agricultural Products Group, 1735 Market St., Philadelphia, PA 19103. *Active Ingredient:* Bifenthrin, zeta-Cypermethrin. *Product Type:* Insecticide. *Proposed Use:* Avocado. *Contact:* RD.

5. *EPA Registration Number:* 11678–66. *Docket ID Number:* EPA–HQ–OPP–2016–0352. *Applicant:* ADAMA Makhteshim, 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604. *Active Ingredient:* Bifenthrin. *Product Type:* Insecticide. *Proposed Use:* Cranberry. *Contact:* RD.

6. *EPA File Symbol:* 46597–U. *Docket ID Number:* EPA–HQ–OPP–2016–0605. *Applicant:* Chemstar Corp., 120 Interstate West Parkway, Suite 100, Lithia Springs, GA 30122. *Active Ingredient:* Hypochlorous Acid. *Product Type:* Antimicrobial. *Proposed Use:* End-use product for antimicrobial fruit and vegetable wash. *Contact:* AD.

7. *EPA Registration Numbers:* 66222–99, 66222–236, and 66222–261. *Docket ID Number:* EPA–HQ–OPP–2016–0352. *Applicant:* Makhteshim Agan of North America, Inc. (d/b/a ADAMA), 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604. *Active Ingredient:* Bifenthrin. *Product Type:* Insecticide. *Proposed Use:* Cranberry. *Contact:* RD.

8. *EPA Registration Number:* 73049–45. *Docket ID Number:* EPA–HQ–OPP–2016–0659. *Applicant:* Valent BioSciences Corporation, 870 Technology Way, Libertyville, IL 60048. *Active Ingredient:* Aminoethoxyvinylglycine Hydrochloride (AVG). *Product Type:* Plant Growth Regulator (PGR). *Proposed Use:* Blueberries at flowering. *Contact:* BPPD.

9. *EPA Registration Number:* 73049–58. *Docket ID Number:* EPA–HQ–OPP–2016–0659. *Applicant:* Valent BioSciences Corporation, 870 Technology Way, Libertyville, IL 60048. *Active Ingredient:* Aminoethoxyvinylglycine Hydrochloride (AVG). *Product Type:* Plant Growth Regulator (PGR). *Proposed Use:* Muskmelon seed production and olive trees at flowering. *Contact:* BPPD.

10. *EPA Registration Numbers:* 80289–1, 80289–7, 80289–8, 80289–18, 80289–20, and 80289–21. *Docket ID Number:* EPA–HQ–OPP–2016–0573. *Applicant:* Isagro S.p.A. d/b/a Isagro USA, Inc., 430 Davis Dr., Suite 240, Morrisville, NC 27560. *Active Ingredient:* Tetraconazole. *Product Type:* Fungicide. *Proposed Use:* Dried Shelled Pea and Bean (except Soybean) (Crop Subgroup 6C), Barley, Rapeseed (Crop Subgroup 20A), and Wheat. *Contact:* RD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 2, 2016.

Rob McNally,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2016–30178 Filed 12–14–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2016–0597; FRL–9954–68]

Chemical Data Reporting; Requirements for Inorganic Byproduct Chemical Substances; Notice of Intent To Negotiate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Intent to Establish Negotiated Rulemaking Committee and Negotiate a Proposed Rule.

SUMMARY: EPA is giving notice that it intends to establish a Negotiated Rulemaking Committee under the Federal Advisory Committee Act

(FACA) and the Negotiated Rulemaking Act (NRA). The objective of the Negotiated Rulemaking Committee will be to negotiate a proposed rule that would limit chemical data reporting requirements under section 8(a) of the Toxic Substances Control Act (TSCA), as amended by the Frank. R. Lautenberg Chemical Safety for the 21st Century Act, for manufacturers of any inorganic byproduct chemical substances, when such byproduct chemical substances are subsequently recycled, reused, or reprocessed. The purpose of the Negotiated Rulemaking Committee will be to conduct discussions in a good faith attempt to reach consensus on proposed regulatory language. This negotiation process is required by section 8(a)(6) of TSCA. The Negotiated Rulemaking Committee will consist of representatives of parties with a definable stake in the outcome of the proposed requirements.

DATES: Comments must be received on or before January 17, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0597, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Susan Sharkey, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8789; email address: *Sharkey.susan@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including manufacture as a byproduct chemical substance) or import chemical substances listed on the TSCA Inventory. The following list of North American Industrial Classification System (NAICS) codes are not intended to be exhaustive, but rather provides a guide to help readers determine whether this action may apply to them:

- Chemical manufacturers and importers (NAICS codes 325 and 324110; *e.g.,* chemical manufacturing and processing and petroleum refineries).
- Chemical users and processors who may manufacture a byproduct chemical substance (NAICS codes 22, 322, 331, and 3344; *e.g.,* utilities, paper manufacturing, primary metal manufacturing, and semiconductor and other electronic component manufacturing).

If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. What action is the Agency taking?

As required by the Negotiated Rulemaking Act of 1996 (NRA), EPA is giving notice that the Agency intends to establish a Negotiated Rulemaking Committee. The objective of this Negotiated Rulemaking Committee will be to develop a proposed rule providing for limiting chemical data reporting requirements, under TSCA section 8(a), for manufacturers of any inorganic byproduct chemical substances, when such byproduct chemical substances are subsequently recycled, reused, or reprocessed. This negotiation process, which includes the establishment of a federal advisory committee, is required by section 8(a)(6) of the Toxic Substances Control Act (TSCA), as amended by the Frank. R. Lautenberg Chemical Safety for the 21st Century Act (''Lautenberg Act'').

B. What is the Agency's authority for this action?

This notice announcing EPA's intent to establish a Negotiated Rulemaking Committee to negotiate a proposed regulation was developed under the authority of sections 563 and 564 of the Negotiated Rulemaking Act (NRA) (5 U.S.C. 561, Pub. L. 104–320). This Negotiated Rulemaking Committee will be a statutory committee under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2, section 9(a)(1)). Any proposed regulation resulting from the negotiation process would be developed under the authority of TSCA section 8 (15 U.S.C. 2607), as amended by the Lautenberg Act (Pub. L. 114–182).

III. Negotiated Rulemaking

A. Why is the Agency pursuing a negotiated rulemaking?

In the Lautenberg Act, Congress mandated that EPA undertake a negotiation process, pursuant to the NRA, aimed at developing a rule to limit TSCA section 8(a) chemical data reporting requirements for manufacturers of any inorganic byproduct chemical substances, when such byproduct chemical substances are subsequently recycled, reused, or reprocessed.

EPA sees potential benefits from undertaking this negotiated rulemaking process. A regulatory negotiation process will allow EPA to engage directly with informed, interested, and affected parties, all of whom are working together to resolve their differences. Because a negotiating committee includes representatives from the major stakeholder groups affected by or interested in the rule, the number of public comments on any proposed rule may be reduced and those comments that are received may be more moderate. EPA anticipates that few substantive changes would be

needed to any proposed rule resulting from the negotiated rulemaking process. Finally, EPA recognizes an observation of the Administrative Conference of the United States: ''Experience indicates that if the parties in interest were to work together to negotiate the text of a proposed rule, they might be able in some circumstances to identify the major issues, gauge their importance to the respective parties, identify the information and data necessary to resolve the issues, and develop a rule that is acceptable to the respective interests, all within the contours of the substantive statute.'' ACUS Recommendation 82–4.

B. What is the concept of negotiated rulemaking?

Negotiated rulemaking is a process in which a proposed rule is developed by a committee composed of representatives of all those interests that will be significantly affected by the rule. Decisions are made by consensus, which the NRA defines as the unanimous concurrence among interests represented on a Negotiated Rulemaking Committee, unless the Negotiated Rulemaking Committee itself unanimously agrees to use a different definition. To start the process, the Agency identifies all interests potentially affected by the rulemaking under consideration. To help in this identification process, the Agency publishes a notice in the **Federal Register**, such as this one, which identifies a preliminary list of interests and requests public comment on that list. Following receipt of the comments, the Agency establishes a committee representing these various interests to negotiate a consensus on the terms of a proposed rule. Representation on the Negotiated Rulemaking Committee may be direct, that is, each member represents a specific interest, or may be indirect, through coalitions of parties formed for this purpose. The Agency is a member of the Negotiated Rulemaking Committee representing the Federal government's own set of interests. The Negotiated Rulemaking Committee is facilitated by a trained mediator, who facilitates the negotiation process. The role of this mediator, or facilitator, is to apply proven consensus building techniques to the advisory committee setting.

If a regulatory negotiation advisory committee reaches consensus on the provisions of a proposed rule, the Agency, consistent with its legal obligations, would use such consensus as the basis of a proposed rule, to be published in the **Federal Register**. This provides the required public notice and allows for a public comment period. All participants and interested parties would retain their rights to comment and to seek judicial review. EPA anticipates, however, that any preproposal consensus agreed upon by this Negotiated Rulemaking Committee would effectively address all major issues prior to publication of a proposed rulemaking.

C. What is the Agency commitment?

In initiating this regulatory negotiation process, EPA is making a commitment to provide adequate resources to ensure timely and successful completion of the process. This commitment includes making the process a priority activity for all representatives, components, officials, and personnel of the Agency who need to be involved in the rulemaking, from the time of initiation until such time as a final rule is issued or the process is expressly terminated. EPA will provide administrative support for the process and will take steps to ensure that the Negotiated Rulemaking Committee has the dedicated resources it requires to complete its work in a timely fashion. These include the provision or procurement of such support services as: Properly equipped space adequate for public meetings and caucuses; logistical support; distribution of background information; the service of a facilitator; and such additional research and other technical assistance as may be necessary. If there is consensus within the Negotiated Rulemaking Committee, EPA will use the consensus to the maximum extent possible, consistent with the legal obligations of the Agency, as the basis for a rule proposed by the Agency for public notice and comment. The Agency is committed to working in good faith to seek consensus on a proposal that is consistent with the legal mandate of TSCA.

D. What is the negotiating consensus?

A key principle of negotiated rulemaking is that agreement is by consensus of all the interests. Thus, no one interest or group of interests is able to control the process. Again, the NRA defines consensus as the unanimous concurrence among interests represented on a Negotiated Rulemaking Committee, unless the Negotiated Rulemaking Committee itself unanimously agrees to use a different definition. In addition, experience has demonstrated that using a trained mediator to facilitate this process will assist all potential parties, including EPA, to identify their interests in the rule and so to be able to reevaluate previously stated positions on issues involved in this rulemaking effort.

IV. Chemical Data Reporting for Inorganic Byproduct Chemical Substances

A. Chemical Data Reporting (CDR) Framework

Under TSCA, EPA regulates the manufacture, processing, distribution, use, and disposal of chemical substances in the United States. The TSCA Inventory of Chemical Substances (TSCA Inventory) lists the chemical substances which are manufactured or processed in the United States (also called ''existing chemical substances''). Chemical substances not on the TSCA Inventory are known as ''new chemical substances'' and are required to be reviewed through EPA's new chemical program (under TSCA section 5) prior to the commencement of manufacture or processing. There are over 85,000 chemical substances listed on the TSCA Inventory.

In 1986, EPA created the Inventory Update Reporting (IUR) regulation under TSCA section 8 to collect, every four years, limited information on the manufacture (which includes import) of organic chemical substances listed on the TSCA Inventory, thereby providing more up-to-date production volume information on the chemical substances in U.S. commerce. In 2005, EPA amended the IUR to require the reporting of information on inorganic chemical substances and to collect additional manufacturing, processing, and use information. EPA has since made additional changes to the reporting requirements, and in 2011 changed the name of the reporting rule to Chemical Data Reporting. CDR regulations are currently codified at 40 CFR part 711. EPA believes CDR is the only current reporting obligation under TSCA section 8(a) that is likely to affect the manufacturers of inorganic byproduct chemical substances. Information collected under CDR is used to support Agency programs, providing exposure-related data for chemical substances subject to TSCA in U.S. commerce. This information is also made publicly available, to the extent possible while continuing to protect submitted information claimed as confidential business information.

Manufacturers of inorganic chemical substances first reported under the IUR in 2006. They also reported under the CDR in 2012 and 2016. Specific reporting requirements for these manufacturers were phased in, to allow for the industry to better understand the reporting requirements and for EPA to

gain a better understanding of the industry. In recent years, the regulatory requirement to report byproduct chemical substances (and the availability of exemptions from that requirement) has been a frequent topic of discussion.

B. Inorganic Byproduct Chemical Substances Under CDR

A byproduct chemical substance is a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture. Such byproduct chemical substances may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage. Because byproduct chemical substances are manufactured for a commercial purpose, such manufacturing is reportable under CDR unless covered by a specific reporting exemption. CDR contains a specific reporting exemption for the manufacture of byproduct chemical substances, limited to cases where those byproduct chemical substances are not *used* for any commercial purposes (or are only used for certain limited commercial purposes) after they are manufactured. 40 CFR 711.10(c). Inorganic byproduct chemical substances are often recycled. The recycling of a byproduct chemical substance may qualify as a commercial purpose beyond the limited commercial purposes encompassed by 40 CFR 711.10(c). If so, then the CDR exemption for the manufacturer of a byproduct chemical substance is unavailable.

Beginning in 2006, EPA became aware of a variety of questions raised by the manufacturers of inorganic byproduct chemical substances about their obligations to report their manufacture of those byproduct chemical substances. EPA has since provided detailed guidance to address a variety of questions that have been raised. See 75 FR 49675–6 (2010); 76 FR 50832–3, 50849–50851 (2011). In 2011, EPA also stated that it would examine CDR information related to byproduct chemical substances to identify whether there are segments of byproduct chemical substance manufacturing for which EPA can determine that there is no need for the CDR information to continue to be collected, either for 2016 or for future reporting cycles. 76 FR 50832–3 (2011). EPA did not amend the CDR requirements for the 2016 reporting cycle. Documents providing information to assist inorganic byproduct chemical substance manufacturers with reporting under CDR requirements include: Instructions for the 2016 TSCA CDR (Ref. 1); CDR Byproduct and Recycling Scenarios (Ref. 2); TSCA CDR Fact Sheet for the Printed Circuit Board Industry (Ref. 3); and TSCA CDR Fact Sheet for Reporting Manufactured Chemical Substances from Metal Mining and Related Activities (Ref. 4).

On June 22, 2016, TSCA was amended by the Lautenberg Act. TSCA now includes a requirement that EPA enter into a negotiated rulemaking, pursuant to the NRA, to develop and publish a proposed rule to limit the reporting requirements under TSCA section 8(a), for manufacturers of any inorganic byproduct chemical substances, when such byproduct chemical substances, whether by the byproduct chemical substance manufacturer or by any other person, are subsequently recycled, reused, or reprocessed. The objective of the negotiated rulemaking process is to develop and publish a proposed rule by June 22, 2019. In the event a proposed rule is developed through the negotiated rulemaking process, a final rule ''resulting from such negotiated rulemaking'' must be issued by December 22, 2019. 15 U.S.C. 2607(a)(6).

EPA construes its obligation to propose and finalize a rule under TSCA section 8(a)(6) as being contingent on the Negotiated Rulemaking Committee reaching a consensus. EPA's interpretation is based on several factors. First, TSCA section 8(a)(6)(A) does not give any direction on how CDR reporting requirements for the specified byproduct chemical substance manufacturers should be limited, other than directing that the particular limitations should be negotiated. Second, EPA's obligation to finalize a rule under TSCA section 8(a)(6)(B) presupposes that such rule would be one ''resulting from such negotiated rulemaking.'' While EPA would have authority to issue an amendment to the CDR even if negotiation failed to achieve a consensus, such a rule would not be a rule *resulting from* the negotiated rulemaking. Accordingly, TSCA section 8(a)(6)(B) presupposes that the negotiated rulemaking process reached a consensus in directing EPA to issue a final rule. If the obligation to issue a final rule is so contingent, then it stands to reason that the prior obligation to issue a proposal is similarly contingent. Third, the time allotted for issuing a final rule (*i.e.,* six months) is relatively short, consistent with a presupposition that the proposal in question would be the product of a successful negotiation. As noted in Unit III., the process of responding to comment on a proposal would likely be simplified if that proposal is itself the result of a previously negotiated consensus. For the reasons described above, if consensus cannot be reached, and there is no agreement upon which to base a proposal, then there is no further statutory obligation to issue a proposal or a final rule.

V. Proposed Negotiating Procedures

A. Interests Involved

Section 562 of the NRA defines the term ''interest'' as one of ''multiple parties which have a similar point of view or which are likely to be affected in a similar manner.'' We anticipate that the following key interests are likely to be significantly affected by the rule to be addressed by the Negotiated Rulemaking Committee while negotiating how to limit CDR requirements for manufacturers of any inorganic byproduct chemical substances, when such byproduct chemical substances are subsequently recycled, reused, or reprocessed:

- Inorganic chemical manufacturers and processors, including metal mining and related activities;
- Recyclers, including scrap recyclers;
- Industry advocacy groups;
- Environmental advocacy groups;
- Federal, State, or Tribal governments; and
- Employee advocacy groups, such as labor unions.

B. Negotiated Rulemaking Committee Formation

The Negotiated Rulemaking Committee will be formed and operated in full compliance with the requirements of FACA in a manner consistent with the requirements of the NRA.

C. Negotiated Rulemaking Committee Membership

The Agency intends to conduct the negotiated rulemaking proceedings with particular attention to ensuring full and adequate representation of those interests that may be significantly affected by a rule providing for limiting CDR requirements for inorganic byproduct chemical substances. We have listed those interests likely to be significantly affected by a rule in Unit V.A., and the following list identifies the parties that the Agency has initially identified as representing interests likely to be significantly affected by a rule:

- Aluminum Association
- American Chemistry Council
- American Coal Ash Association

- Environmental Defense Fund
- Institute of Scrap Recycling Industries
- IPC—Association Connecting Electronics Industries
- North American Metals Council
- National Mining Association
- U.S. Environmental Protection Agency
- Utility Solid Waste Activities Group

The listed parties have been preliminarily identified by EPA as being either a potential member of the Negotiated Rulemaking Committee, or a potential member of a coalition that would in turn nominate a candidate to represent one of the significantly affected interests listed in Unit V.A. This list is not presented as a complete or exclusive list from which Negotiated Rulemaking Committee members will be selected, nor does inclusion on the list mean that a party on the list has agreed to participate as a member of the Negotiated Rulemaking Committee or as a member of a coalition. This list merely indicates those parties that represent interests that EPA has tentatively identified as being significantly affected by a rule providing for limiting CDR requirements for inorganic byproduct chemical substances.

EPA anticipates that the Negotiated Rulemaking Committee will be comprised of approximately 10–25 members representing significantly affected interests. The EPA Administrator will select members carefully to ensure that there is a balanced representation of such interests on the Negotiated Rulemaking Committee. EPA anticipates that the Negotiated Rulemaking Committee will contain representatives from industry, environmental groups, and state, local, and tribal governments.

One purpose of this document is to determine whether the negotiated rulemaking will significantly affect interests that are not listed in Unit V.A., as well as whether the list of parties the Agency has listed identifies accurately and comprehensively a group of stakeholders representing the significantly affected interests listed in Unit V.A. EPA requests comment and suggestions on the list of significantly affected interests, as well as the list of proposed representatives of those interests. EPA recognizes that any regulatory actions it takes under this program may at times affect various segments of society in different ways, and that this may in some cases produce unique interests in a rule based on demographic factors. Particular attention will be given by the Agency to ensure that any unique interests that have been identified in this regard, and that may be significantly affected by any rule resulting from the negotiation, are represented.

This document affords potential participants the opportunity to request representation in the negotiations. Request such representation by submitting a comment as described under **ADDRESSES** in this notice.

Section 565(b) of the NRA requires the Agency to limit membership on a Negotiated Rulemaking Committee to 25 members, unless the Agency determines that more members are necessary in order for the Negotiated Rulemaking Committee to function or to achieve balanced membership. The Agency believes that the negotiating group should not exceed 25 members, which would make it difficult to conduct effective negotiations. EPA is aware that there are many more than 25 potential participants to consider for the Negotiated Rulemaking Committee. The Agency does not believe, nor does the NRA contemplate, that each significantly affected interest must participate directly in the negotiations; however, each significantly affected interest can be adequately represented. To have a successful negotiation, it is important for significantly affected interests to identify and form coalitions that adequately represent those interests. These coalitions, to provide adequate representation, must agree to support, both financially and technically, a member to the Negotiated Rulemaking Committee whom they will choose to represent their interest. The Agency believes it is very important to recognize that interested parties who are not selected to membership on the Negotiated Rulemaking Committee can still make valuable contributions to this negotiated rulemaking effort in any of several ways:

- The party could request to be placed on the Negotiated Rulemaking Committee mailing list, submitting written comments, as appropriate;
- The party could attend the Negotiated Rulemaking Committee meetings, which are open to the public, caucus with his or her interest's member on the Negotiated Rulemaking Committee, or even address the Negotiated Rulemaking Committee (usually allowed at the end of an issue's discussion or the end of the session, as time permits); or
- The party could assist a workgroup that might be established by the Negotiated Rulemaking Committee.

An advisory committee may convene informal workgroups to assist the Negotiated Rulemaking Committee in ''staffing'' various discrete and technical matters (*e.g.,* researching or preparing summaries of the technical literature or comments on particular matters such as economic issues) so as to facilitate Negotiated Rulemaking Committee deliberations. They also might assist in estimating costs and drafting regulatory text on issues associated with the analysis of the affordability and benefits addressed, and formulating drafts of the various provisions and their justification previously developed by the Negotiated Rulemaking Committee. Given their staffing function, workgroups usually consist of participants who have expertise or particular interest in the technical matter(s) being studied. Because it recognizes the importance of this staffing work for the Negotiated Rulemaking Committee, EPA will provide appropriate administrative and technical expertise for such workgroups.

EPA requests comment regarding particular appointments to membership on the Negotiated Rulemaking Committee. Members can be individuals or organizations. If the effort is to be successful, participants should be able to fully and adequately represent the viewpoints of their respective interests. Those who wish to be appointed as members of the Negotiated Rulemaking Committee should submit a request to EPA by submitting a comment as described under **ADDRESSES** in this notice. The list of potential Negotiated Rulemaking Committee members provided earlier in this document includes those who have been initially identified by EPA as being either a potential member of the Negotiated Rulemaking Committee, or a potential member of a coalition that would in turn nominate a candidate to represent one of the significantly affected interests on the Negotiated Rulemaking Committee.

EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

D. Good Faith Negotiation

Negotiated Rulemaking Committee members should be willing to negotiate in good faith and have the authority, from her or his constituency, to do so. The first step is to ensure that each member has good communications with her or his constituencies. An intra-interest network of communication should be established to bring information from the support organization to the member at the table, and to take information from the table back to the support organization. Second, each organization or coalition should, therefore, designate as its

representative an official with credibility and authority to insure that needed information is provided and decisions are made in a timely fashion.

Negotiated rulemaking efforts can require a very significant contribution of time by the appointed members. The convening meeting of the Negotiated Rulemaking Committee is expected to be held in March 2017, and the work of the Negotiated Rulemaking Committee is expected to conclude approximately in September 2017.

Other qualities that can be very helpful are negotiating experience and skills, as well as sufficient technical knowledge to participate in substantive negotiations. Certain concepts are central to negotiating in good faith. One is the willingness to bring key issues to the bargaining table in an attempt to reach a consensus, instead of keeping issues in reserve. The second is a willingness to keep the issues at the table and not take them to other forums. Finally, good faith includes a willingness to move away from the type of positions usually taken in a more traditional rulemaking process, and instead explore openly with other parties all ideas that may emerge from the discussions of the Negotiated Rulemaking Committee.

E. Facilitator

The facilitator will not be involved with the substantive development of any proposed rule. Rather, the facilitator's role generally includes facilitating the meetings of the Negotiated Rulemaking Committee in an impartial manner and impartially assisting the members of the Negotiated Rulemaking Committee in conducting discussions and negotiations.

F. EPA Representative

The EPA representative will be a full and active participant in the consensus building negotiations. The Agency's representative will meet regularly with various senior Agency officials, briefing them on the negotiations and receiving their suggestions and advice, in order to effectively represent the Agency's views regarding the issues before the Negotiated Rulemaking Committee. EPA's representative also will ensure that the entire spectrum of federal governmental interests affected by the rulemaking, including the Office of Management and Budget (OMB) and other Departments and agencies, are kept informed of the negotiations and encouraged to make their concerns known in a timely fashion.

VI. Comments Requested

EPA requests comment on the extent to which the issues, interests, Negotiated Rulemaking Committee representatives, and procedures described in this document are adequate and appropriate.

VII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA (2016). Instructions for Reporting 2016 TSCA CDR, *https://www.epa.gov/sites/production/files/2016-05/documents/instructions_for_reporting_2016_tsca_cdr_13may2016.pdf.* Retrieved October 21, 2016.
2. EPA (2012). CDR Byproduct and Recycling Scenarios, *https://www.epa.gov/sites/production/files/documents/2012_cdr_byproducts_scenaros_0.pdf.* Retrieved October 21, 2016.
3. EPA (2016). TSCA CDR Fact Sheet: Byproducts Reporting for the Printed Circuit Board Industry, *https://www.epa.gov/sites/production/files/2016-02/documents/final_cdr_fact_sheet_printed_circuit_board_2_22_16.pdf.* Retrieved October 21, 2016.
4. EPA (2016). TSCA CDR Fact Sheet: Reporting Manufactured Chemical Substances from Metal Mining and Related Activities, *https://www.epa.gov/sites/production/files/2016-05/documents/cdr_fact_sheet_metal_mining_5may2016.pdf.* Retrieved October 21, 2016.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 7, 2016.

Jim Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2016–30177 Filed 12–14–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[9956–91–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of Oregon's request to revise/modify its EPA Administered Permit Programs: The National Pollutant Discharge Elimination System EPA-authorized program to allow electronic reporting.

DATES: EPA's approval is effective December 15, 2016.

FOR FURTHER INFORMATION CONTACT: Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On November 3, 2016, the Oregon Department of Environmental Quality (OR DEQ) submitted an application titled ''National Pollutant Discharge Elimination System'' for revision/modification to its EPA-approved program under title 40 CFR to allow new electronic reporting. EPA reviewed OR DEQ's request to revise/modify its EPA-authorized programs and, based on this review, EPA determined that the application met the standards for

fungus pathogenic to adult insects) to help control *Aedes* species of mosquitoes, vectors of the zika virus. Deployment is in a container ''trap'' designed to attract the egg-laying adult mosquito, and was initially targeted for Puerto Rico, where the zika virus was being locally transmitted. While in the trap depositing eggs, the adult mosquito is coated with the pesticide mixture, and then visits other egg-laying sites, distributing pyriproxyfen in the process. The pyriproxyfen kills the larva by preventing development into an adult, while the *Beauvaria bassiana* slowly kills the adult mosquito over 8–10 days. Use is allowed in other areas of the U.S. if zika-transmitting mosquitoes are detected. May 6, 2016 to May 6, 2017.

Department of Defense

Armed Forces Pest Management Board

Specific exemption. EPA authorized use of permethrin for treatment of unoccupied military aircraft to comply with disinsection requirements of Italy and other counties, to prevent dissemination of potential insect disease vectors such as the *Aedes* mosquito, vector of the zika virus. July 13, 2016 to July 13, 2017.

National Aeronautics and Space Administration

Specific exemption. EPA authorized use of ortho-phthalaldehyde, immobilized to a porous resin, to treat the International Space Station (ISS) internal active thermal control system (IATCS) coolant for control of aerobic and microaerophilic water bacteria and unidentified gram negative rods. August 31, 2016 to August 31, 2017.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 30, 2016,

Michael Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2016–30175 Filed 12–14–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9956–49–Region 6]

Notice of Proposed Administrative Settlement Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: The Environmental Protection Agency is giving notice of two proposed administrative settlements concerning the Scrub-A-Dubb Barrel Company Superfund Site, located in the City of Lubbock, Lubbock County, Texas.

DATES: Comments must be submitted on or before January 17, 2017.

ADDRESSES: The proposed settlements and additional background information relating to the settlements are available for public inspection at 1445 Ross Avenue, Dallas, Texas 75202–2733. Copies of the proposed settlements may be obtained from Robert Werner, Enforcement Officer, 1445 Ross Avenue, Dallas, Texas 75202–2733 or by calling (214) 665–6724. Comments should reference the Scrub-A-Dubb Barrel Company Superfund Site, located in the City of Lubbock, Lubbock County, Texas and EPA CERCLA Docket Number 06–09–16 for the Enterprise Products BBCT LLC settlement and EPA CERCLA Docket Number 06–10–16 for the Foster Testing, Inc. settlement and should be addressed to Robert Werner, Enforcement Officer, at the address listed above.

FOR FURTHER INFORMATION CONTACT: Amy Salinas, Attorney, 1445 Ross Avenue, Dallas, Texas 75202–2733 or call (214) 665–8063.

SUPPLEMENTARY INFORMATION: In accordance with Section 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (CERCLA), 42 U.S.C. 9622(h)(1), notice is hereby given of two proposed administrative settlements concerning the Scrub-A-Dubb Barrel Company Superfund Site, located in the City of Lubbock, Lubbock County, Texas.

The settlements require two settling parties, Enterprise Products BBCT, LLC, and Foster Testing, Inc., to pay a total of $147,800.00 as payment of response costs to the Hazardous Substances Superfund. The settlements include a covenant not to sue pursuant to Section 107 of CERCLA, 42, U.S.C. 9607.

For thirty (30) days beginning the date of publication of this notice, the Agency will receive written comments relating to this notice and will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at 1445 Ross Avenue, Dallas, Texas 75202–2733.

Dated: November 24, 2016.

Ron Curry,

Regional Administrator (6RA).

[FR Doc. 2016–29886 Filed 12–14–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2016–0675; FRL–9956–03]

TSCA Reporting and Recordkeeping Requirements; Standards for Small Manufacturers and Processors

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amended the Toxic Substance Control Act (TSCA). TSCA, as amended, requires EPA to review the size standards for small manufacturers and processors, which are currently used in connection with reporting regulations under TSCA Section 8(a). In particular, EPA must make a determination whether a revision of those standards is warranted. EPA's preliminary determination is that revisions to currently codified size standards for TSCA Section 8(a) are indeed warranted. As part of the ongoing review process, the EPA is requesting public comment on whether a revision of the current size standard definitions is warranted at this time.

DATES: Comments must be received on or before January 17, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0675, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Lynne Blake-Hedges, Chemistry, Economics, and Sustainable Strategies Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8807; email address: *blake-hedges.lynne@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture or process chemical substances or mixtures. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Basic Chemical Manufacturers (NAICS code 3251);
- Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filament Manufacturers (NAICS code 3252);
- Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturers (NAICS code 3255);
- Paint, Coating, and Adhesive Manufacturers (NAICS code 3255);
- Other Chemical Product and Preparation Manufacturers (NAICS code 3259); and
- Petroleum Refineries (NAICS code 32411).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. What action is the agency taking?

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends the Toxic Substance Control Act (TSCA), the nation's primary chemicals management law. A summary of the new law, is available at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act.* This particular action involves the revised TSCA section 8(a)(3)(C), which requires EPA, after consultation with the Administrator of the Small Business Administration, to review the adequacy of the standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of TSCA sections 8(a)(1) and 8(a)(3). TSCA furthermore requires that (after consulting with the Small Business Administration and providing public notice and an opportunity for comment) EPA make a determination as to whether revision of the standards is warranted.

In the 1980s, the EPA issued standards that are used in identifying which businesses qualify as small manufacturers and processors for purposes of the reporting and recordkeeping rules issued under TSCA section 8(a). (Under TSCA, manufacture includes import, so references to chemical manufacture include chemical import.) These size standards describe who is generally exempt from reporting requirements under TSCA section 8(a). This exemption arises because TSCA section 8(a)(1) generally exempts small manufacturers and processors from reporting requirements, except in limited cases set forth in TSCA section 8(a)(3).

In 1982, the EPA finalized standards for determining which manufacturers of a reportable chemical substance qualified as small manufacturers for purposes of a particular set of TSCA section 8(a) rules. These are the Preliminary Assessment Information Reporting (PAIR) rules, codified in 40 CFR part 712, subpart B. The small manufacturer standard for PAIR rules is found at 40 CFR 712.25(c).

In 1988 EPA established general small manufacturer standards for use in other rules issued under TSCA section 8(a) (40 CFR 704.3). For example, these are the standards that now apply to the Chemical Data Reporting (CDR) rule (40 CFR part 711). The general standards are somewhat different from the earlier standards that are codified for use in the PAIR rules. The general small manufacturer standard is as follows:

Small manufacturer or importer means a manufacturer or importer that meets either of the following standards:

(1) *First standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

(3) *Inflation index.* EPA shall make use of the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA shall provide **Federal Register** notification when changing the total annual sales values.

Certain rules issued under TSCA section 8(a) directly codify slight variations of the general small manufacturer standards at 40 CFR 704.3. (See, *e.g.,* 40 CFR 704.45). Other rules issued under TSCA section 8(a) establish (for use in a particular rule) analogous standards for small processors (See, *e.g.,* 40 CFR 704.33).

As an initial step in evaluating whether a change in these current size standards are warranted, EPA reviewed the change in the Producer Price Index (PPI) for Chemicals and Allied Products between 1988 (the year the size

standards were last revised) and 2015 (the most recent year of PPI data available) (Ref. 1). EPA found that the PPI has changed by 129 percent, far exceeding the 20 percent inflation index specified as a level above which EPA may adjust annual sales levels in the current standard if deemed necessary. Furthermore, among the more than 500 revenue-based size standards set by the Small Business Administration (SBA), the lowest is $5.5 million, and more than 75% of those standards are in excess of $7.5 million. Some revenue-based standards are as high as $38.5 million. Thus, EPA's existing $4 million annual sales standard is an outlier at the low end of this range. Because of the magnitude of the increase in the PPI since the last revision of the size standards and the current annual sales standard is comparatively low given current revenue-based size standards developed by SBA, EPA has preliminarily determined that a revision to currently codified size standards is warranted.

EPA is requesting public comment on the adequacy of the current standards and whether revision of the standards is warranted. In the event that EPA determines that a revision to the standards is warranted, any such revision would occur by subsequent rulemaking, which would involve a further opportunity for public notice and comment. Accordingly, the scope of this first action (*i.e.,* the determination) will not necessarily include responding to stakeholder comments as to what specific amendments ought to be made to the standards.

EPA is also in the process of consulting with the SBA on the adequacy of the current standards and whether revision of the standards is warranted. (Ref. 2.) EPA has requested that SBA provide its input within 15 business days of receiving EPA's consultation request. When SBA's consultation response becomes available, EPA plans to add that response to the docket for this preliminary determination.

III. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. Bureau of Labor Statistics. ''Producer Price Index, Series WPU06, Chemicals and Allied Products, 1933–2015''. Retrieved November 14, 2016 from *http://data.bls.gov/cgi-bin/srgatet.*
2. Jones, Jim. Letter to Maria Contreras-Sweet. ''Consultation under Section 8(a)(3)(C) the Toxic Substances Control Act''. December 7, 2016.

Authority: 15 U.S.C. 2607(a)(3)(C).

Dated: December 7, 2016.

Jim Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2016–30176 Filed 12–14–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0022; FRL–9955–76]

Pesticide Product Registrations; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before January 17, 2017.

ADDRESSES: Submit your comments, identified by the Docket Identification (ID) Number and the File Symbol or EPA Registration Number of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Steve Knizner, Antimicrobials Division (AD) (7510P), main telephone number: (703) 305–7090, email address: *ADFRNotices@epa.gov;* Robert McNally, Biopesticides and Pollution Prevention Division (BPPD) (7511P), main telephone number: (703) 305–7090, email address: *BPPDFRNotices@epa.gov;* or Michael Goodis, Registration Division (RD) (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the application summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not

Initial Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

Prepared for the Committees on Energy and Commerce, and Appropriations of the U.S. House of Representatives, and the Committees on Environment and Public Works, and Appropriations of the U.S. Senate

Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, D.C. 20460

January 2017

Contents

1 Introduction

1.1 Overview of New Law

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Public Law [P.L.114-182]), signed by President Obama on June 22, 2016, substantially amended the Toxic Substances Control Act (TSCA) to enhance public health, chemical safety and interstate commerce by providing the Environmental Protection Agency (EPA) with significant new authorities and obligations such as:

- **Clear and enforceable deadlines.** The EPA is now required to systematically prioritize and evaluate existing chemicals on a specific schedule. Within a few years, the EPA's chemicals program will have to ensure that risk evaluations are being conducted on at least 20 chemicals at a time, beginning another chemical risk evaluation as soon as one is completed.

- **Requirement to evaluate chemicals purely on the basis of the health and environmental risks they pose.** Now, the EPA will have to evaluate a chemical's safety purely based on the health and environmental risks it poses—including to susceptible and highly exposed populations, like children and the elderly, and to workers who use chemicals daily as part of their jobs—without consideration of costs or other non-risk factors and then take steps to eliminate any unreasonable risks the EPA finds.

- **Requirement to address risks:** EPA must take timely action to address identified risks, an activity known as "risk management" which may include, but is not limited to, labeling, restrictions, bans, and/or phase-outs, where warranted, so that the chemical in question will no longer present an unreasonable risk. However, when taking steps to reduce risk, the Administrator must consider if technically and economically feasible alternatives are available and if restriction on a condition of use would disrupt the national economy, national security, or critical infrastructure.

- **Requirement that the EPA make an affirmative determination on every new chemical.** Previously, new chemicals were allowed to enter the marketplace unless the EPA made a specific determination that regulatory controls were needed. Now, an affirmative safety determination must be made before a new chemical can enter the marketplace and before a significant new use is allowed for an existing chemical.

- **Increased transparency of chemical data while protecting legitimate confidential business information (CBI)**. The EPA must review most chemical identity CBI claims within 90 days and 25 percent of a subset of other types of CBI claims within 90 days.

- **A source of sustainable funding for the EPA to carry out its new responsibilities.** The EPA will now be able to collect 25 percent of its costs for administering certain sections of TSCA as amended, or up to $25 million a year for the first three years, whichever is less, in user fees from chemical manufacturers and processers, supplemented by congressional budgeting, to pay for implementation of the amended law.

1.2 Purpose of this Report

Under section 26(m)(1) of TSCA as amended, the EPA is required to submit this initial report to Congress not later than 6 months after the date of enactment. The agency is directed to include several elements in the report, including descriptions of the EPA's capacity to conduct and publish risk evaluations under TSCA sections 6(b)(4)(C)(i) and (ii) and 6(b)(2) and the resources necessary to conduct such risk evaluations, the likely demand for risk evaluations and the anticipated schedule for accommodating that demand under TSCA section 6(b)(4)(C)(ii), and EPA's capacity to promulgate rules to address risks identified in these risk evaluations under TSCA section 6(a) as required, based on risk evaluations conducted and published under TSCA section 6(b). The EPA is also directed to discuss efforts to increase capacity to conduct and publish the EPA-initiated risk evaluations under TSCA section 6(b).

1.3 Overview of Relevant Statutory Requirements

1.3.1 EPA-Initiated Risk Evaluations

Under TSCA section 6(b)(2)(A), the EPA is required to ensure that risk evaluations are being conducted on 10 chemical substances within 180 days of enactment. The law further requires that these first 10 chemicals be drawn from the 90 chemicals on the EPA's TSCA Work Plan. On November 29, 2016, the EPA named the first 10 chemicals that will undergo risk evaluation under the new law: https://www.epa.gov/newsreleases/epa-names-first-chemicals-review-under-new-tsca-legislation. From publication date, December 19, 2016, EPA has a three-year timeframe, by law, to complete risk evaluations for these chemicals.

For the EPA-initiated risk evaluations beyond these first 10 chemicals, the EPA must establish a risk-based prioritization process to determine which chemicals will be evaluated, identifying them as either "high" or "low" priority substances as set forth in TSCA section 6(b)(1)(A). A high priority designation is required when the EPA determines, without consideration of cost or other non-risk factors, that the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and a potential route of exposure, including to susceptible subpopulations [TSCA section 6(b)(1)(B)]. High priority designation triggers a requirement that the EPA conduct a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations [TSCA section 6(b)(4)(A)]. The amended law requires that these risk evaluations include all known or reasonably foreseen uses of the chemical, while requiring that they be completed within 3 years (with a possibility of 6-month extension) [TSCA section 6(b)(4)(G)].

Under TSCA as amended, the EPA is required to begin a risk evaluation for a new chemical each time a risk evaluation (other than an industry-requested evaluation) is completed such that the EPA maintains the pace of at least 20 EPA-initiated risk evaluations underway from the end of calendar year (CY) 2019 forward [TSCA section 6(b)(2)]. The EPA plans to initiate additional risk evaluations in 2018 and 2019, ramping up to having twenty EPA-initiated risk evaluations underway by the end of CY 2019.

1.3.2 Manufacturer-requested Evaluations

TSCA section 6(b)(4)(C)(ii) provides a mechanism for manufacturers to submit a request that the EPA evaluate specific chemicals as prescribed by a risk evaluation process rule mandated by the new law. The new law also gave manufacturers an opportunity to request, by September 19, 2016, that the EPA conduct risk evaluations for certain persistent, bioaccumulative, and toxic (PBT) chemicals in the EPA's 2014 Work Plan, as an alternative to expedited risk management action as described in "Section 6 Risk Management Rules" below. Requests for risk evaluations were made for two such chemicals that can be used in fragrance mixtures. As a result, the EPA will be evaluating these two PBT chemicals.

For these manufacturer-requested risk evaluations, if the EPA receives a sufficient number of compliant requests, the law requires that they account for between 25-50 percent of the number of the EPA-initiated risk evaluations. Under full implementation (meaning, that the full number of risk evaluations actions are underway), the EPA will be undertaking 5-10 manufacturer-requested evaluations assuming that not more than 20 EPA-initiated evaluations are underway and that sufficient requests are made that comply with the criteria EPA is required to promulgate as mandated by the new law. In resourcing the costs for these manufacturer-requested risk evaluations, the law requires that manufacturers requesting evaluations pay costs as follows:

- For chemicals on the TSCA Work Plan, manufacturers pay 50 percent of costs of the risk evaluations.

- For all other chemicals, manufacturers pay 100 percent of the costs of risk evaluation.

1.3.3 Section 6 Risk Management Rules

When unreasonable risks are identified, the EPA generally must finalize risk management actions within two years, or four years if an extension is needed. [TSCA section 6(c)(1)] Costs, benefits of the substance, and other factors will be considered when determining appropriate action to address risks. Risk management rules must require full compliance as quickly as practicable. For requirements other than ban and phase-out requirements, rules must require full compliance by no later than five years after promulgation; bans or phase-outs must begin no later than five years after promulgation and be completed as soon as practicable. [TSCA section 6(d)].

Under TSCA section 6(h), there is a specific process to address certain PBT chemicals on the 2014 TSCA Work Plan. For these chemicals, unless a manufacturer requests that they undergo a risk evaluation, a risk evaluation is not required if EPA determines that exposure is likely, and action to reduce exposure to the extent practicable must be proposed no later than three years after enactment and finalized 18 months later. The EPA determined that seven chemicals met the PBT criteria set forth in the new law and subsequently received a request that two be evaluated under TSCA section 6(b). The remaining five PBT chemicals are being addressed as noted above.

2 Capacity to Implement Specific Provisions of the Law Regarding Risk Evaluations and Regulatory Actions

The EPA is continuing to expeditiously implement the provisions of the new law, which became effective upon enactment. An overview of the immediate actions and other early steps that the EPA is undertaking in our First-Year TSCA Implementation Plan are found here: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-5.

For purposes of this report, as directed under section 26(m)(1) of TSCA as amended, estimated resources necessary to conduct the anticipated minimum number of risk evaluations is provided as well as information on capacity specifically related to risk evaluations and associated promulgation of rules.

2.1 Estimated Resources Necessary for Risk Evaluations

The estimates for resources necessary for risk evaluations take into account the requirement to identify 10 chemicals for risk evaluation by 180 days after enactment and to complete these risk evaluations within a three-year timeframe from publication of the list of chemicals. In addition, EPA must have at least 20 EPA-initiated risk evaluations underway from the end of CY2019 forward. To accomplish an ongoing pace of at least 20 EPA-initiated risk evaluations underway by the end of CY2019, EPA anticipates ramping up from 10 risk evaluations in FY2017 to 15 in FY2018, reaching 20 by the end of FY2019.

In addition to the EPA-initiated risk evaluations, TSCA section 6(b)(4)(C)(ii) provides a mechanism for manufacturers to submit a request that the EPA evaluate specific chemicals. The new law also gave manufacturers an opportunity to request, by September 19, 2016, that the EPA conduct risk evaluations for certain persistent, bioaccumulative, and toxic (PBT) chemicals. Requests for risk evaluations were made for two such chemicals. In addition to the PBT chemicals, in a given year EPA currently estimates two manufacturer-requested evaluations underway for work plan chemicals and five to eight underway for non-work plan chemicals. This preliminary estimate is based on the possibility manufacturers may request a greater number of non-work plan chemicals be evaluated sooner than may otherwise occur under the prioritization process.

The estimates presented in the following table are for the EPA's annual costs, which are calculated by dividing the average lifecycle costs of the actions (estimated $3.7 million per evaluation) by the number of years the statute provides for the agency to complete those actions (without the extension options provided in the statute), and then multiplying the result by the numbers of actions required/anticipated to be underway each year. See footnote explaining how risk evaluations for PBTs affect the numbers in the tables.

These are our best current estimates and in some areas costs may vary from averages. Separate estimates are provided for the EPA-initiated evaluations required under the statute and for manufacturer-requested risk evaluations (broken out between evaluations of chemicals on the

TSCA Work Plan[1] and for evaluation of chemicals not on the TSCA Work Plan[2]). Under full implementation (meaning, that the full number of risk evaluations actions are underway), the EPA will be undertaking 5-10 manufacturer-requested evaluations assuming that not more than 20 EPA-initiated evaluations are underway and that sufficient requests are made that comply with the required criteria. Our best current estimates for risk evaluations include both direct and indirect factors.

Note also that actions prompted by TSCA Section 21 Petitions are not addressed in this report as the number, nature and complexity of these petitions are unknown. However, it should be noted, the agency does expect to receive petitions under the new law which may result in additional risk evaluations.

Table 1: TSCA Risk Evaluations, Numbers Underway and Resources Estimates

	Total Dollars (Pay + Non-Pay) in Millions					
	FY 2017	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Full[3]**
Risk Evaluations						
EPA-Initiated						
Number Underway	10	15	20	20	20	20
Direct Annual Cost	$10.0	$15.1	$20.1	$20.1	$20.1	$20.1
Total Annual Cost	$12.3	$18.5	$24.7	$24.7	$24.7	$24.7
Manufacturer-Requested: 50 percent Fee[4]						
Number Underway	0	4	4	4	2	2
Direct Annual Cost	$0.0	$3.0	$3.0	$3.0	$1.0	$1.0
Total Annual Cost	$0.0	$3.7	$3.7	$3.7	$1.2	$1.2
Manufacturer-Requested: 100 percent Fee						
Number Underway	0	5	8	8	8	8
Direct Annual Cost	$0.0	$5.1	$8.1	$8.1	$8.1	$8.1
Total Annual Cost	$0.0	$6.2	$9.9	$9.9	$9.9	$9.9
Total						
Number Underway	10	24	32	32	30	30
Direct Annual Cost	$10.0	$23.2	$31.2	$31.2	$29.2	$29.2
Total Annual Cost	$12.3	$28.4	$38.3	$38.3	$35.8	$35.8

[1] For manufacturer-requested risk evaluations of TSCA Work Plan chemicals, user fees are set by the statute at 50 percent of the costs and EPA anticipates that the incidence of such evaluations identifying unreasonable risks will be the same as for the EPA-initiated evaluations (90 percent) because TSCA Work Plan chemicals had been identified as risk assessment priorities.

[2] For manufacturer-requested risk evaluations of chemicals not on the TSCA Work Plan, user fees are set by the statute at 100 percent of the costs. The EPA anticipates that the incidence of such evaluations identifying unreasonable risks will be less than that for the EPA-initiated evaluations, as manufacturers may request evaluations for chemicals they believe will not present significant risks. Pending future experience, the EPA developed an initial assumption that 50 percent of these evaluations will result in findings of unreasonable risks.

[3] The Full column reflects a generic future year when the EPA's implementation of all provisions of the statute have reached specified minimum levels.

[4] Two PBTs to be assessed under TSCA section 6(h) are included in the Manufacturer-Requested: 50 percent Fee category commencing in FY 2018. These are expected to be completed in FY 2020, after which the estimated number of evaluations underway in this category is comprised of two other evaluations per year.

2.2 Statutory Requirements for Appropriations and Fees

Under TSCA section 26(b), the EPA is authorized to set fees which will ensure a sustainable source of funding to annually defray 25 percent of the costs to the Administrator of carrying out sections 4, 5 and 6, and of collecting, processing, reviewing and providing access to and protecting from disclosure, as appropriate, chemical information under section 14. For the first three years, fees are subject to a $25 million cap. Thereafter, the fees can be adjusted on a recurring three-year basis for inflation, and to ensure the fees continue to be set at a level that is designed to defray 25 percent of the EPA's annual costs. [TSCA section 26(b)(4)(F)].

A rule to implement the fee collection provisions of the new law is currently under development. The EPA actively engaged with industry in 2016 to gather input on the potential fee structure. A one-day public meeting was held in August, an industry-specific consultation meeting was held in September, and a docket was opened to collect written comments from the public.

The authority to assess fees is conditioned on annual appropriations for EPA's Chemical Risk Review and Reduction (CRRR) Program, excluding fees, being held at least equal to the amount provided for FY 2014 [TSCA section 26(b)(5)].

2.3 Capacity to Implement Specific Provisions of the Law

The EPA developed experience in conducting chemical risk assessments under TSCA over the past several years under the TSCA Work Plan Chemicals approach. This resulted in issuance of the first five chemical risk assessments under TSCA in more than 20 years, three of which identified risks warranting exercise of TSCA section 6 regulatory authorities. Through that experience, the EPA developed a better understanding of capacity needs, including skill sets, level of effort, and infrastructure.

The new law calls for a more comprehensive review of each chemical and its uses, accelerates the EPA's pace in undertaking assessments, mandates completion timeframes and requires immediate commencement of work to develop section 6 rules where risks are identified. The substantially increased requirements and tight deadlines under the new law require increased staffing levels and contractor resources dedicated to conducting and publishing risk evaluations and promulgating rules based on the risk evaluations. The agency has developed much of the needed experience to address these requirements and has begun bringing on the additional staff and contractor support needed. The agency is considering and expanding options to reduce the long lead times to bring on the highly skilled staff and specialized contractors needed for these scientifically demanding, technically complex tasks. The agency is also conducting in-house training of new and existing staff to better equip them to meet the expanded requirements and accelerated time frames for the risk evaluations and management actions.

In addition, implementation of TSCA as amended will necessitate a faster pace for information technology (IT) infrastructure and process improvements. EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) is making progress on these systems and processes improvements and is also establishing a central project management tool for achieving milestones as well as facilitating alignment of skill sets with project needs. Further, as risk management actions are taken, additional regional work and agency implementation activities, such as education, outreach

and partnerships with external stakeholders, will be needed to ensure the efficacy and efficiency of the TSCA program.

3 Summary

TSCA as amended, provides the EPA with significant new authorities and obligations such as: clear and enforceable deadlines; requirement to evaluate chemicals purely on the basis of the health and environmental risks they pose, to address risks, and make an affirmative determination on every new chemical; increased transparency of chemical data while protecting legitimate confidential information; and a source of sustainable funding for the EPA to carry out its new responsibilities. The EPA is continuing to expeditiously implement the provisions of the new law, which became effective upon enactment.

Under TSCA section 26(b), the EPA is authorized to set fees which will ensure a sustainable source of funding to annually defray 25 percent of the costs of carrying out TSCA sections 4, 5 and 6, and of collecting, processing, reviewing and providing access to and protecting from disclosure as appropriate chemical information under TSCA section 14. For the first three years, fees are subject to a $25 million cap and can be adjusted on a recurring three-year basis for inflation or if fees no longer are adequate to defray 25 percent of the EPA's annual costs described above [TSCA section 26(b)(4)(F)].

The EPA looks forward to a continued partnership with Congress to successfully implement the provisions of this law which created a framework and roadmap for taking regulatory action to enhance public health, chemical safety and interstate commerce. The Executive Branch will keep Congress updated as resource estimates are refined and the understanding of the workload becomes clearer.

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WHAT DOES A REFORMED TSCA MEAN FOR PRIVATE RIGHTS OF ACTION UNDER STATE LAW?

Thomas R. Smith
January 27, 2017

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TSCA Preemption: 15 U.S.C. § 2617(a)

- No statutes or administrative actions regarding information development of a chemical substance after EPA has issued a rule, etc. related to testing;
- No statutes, administrative actions, or criminal penalties prohibiting manufacture, distribution, processing after EPA has made a finding that a chemical substance either does or does not pose an unreasonable risk;
- No statutes or administrative actions necessitating notification of use of a chemical substance when EPA already has done so.

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Potential EPA Actions

- Prohibit/restrict manufacturing or distribution in commerce or manner or method of commercial use;
- Limit the amount of the substance that may be processed;
- Prohibit/restrict manufacturing for a particular use/in a concentration in excess of an EPA-spec'd level;
- Limit amount that may be distributed for a particular use/above a specified concentration.
- Require minimum warnings and instructions with respect to the substances.
- 15 U.S.C. § 2605(a)

If EPA finds a chemical poses an "unreasonably risk," then it establishes a rule (1) prohibiting and/or restricting use of the chemical; (2) stating effects of the chemical on human health and the environment, magnitude of exposure, benefits of the chemical, and economic consequences of the rule; and (3) potential alternatives available as a substitute. (15 U.S.C. § 2605(c))

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Preemption: Savings

- No preemption of state or federal common law or statutory rights and remedies
- "Clarification of no preemption"
- EPA action cannot be dispositive in a civil action
- Court retains authority with respect to admission of evidence

- Why did Congress include this provision?
- SCOTUS, reading preemption and savings clauses together, along with reviewing Congressional history, has arrived at different results based on the language therein

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Savings: Why Did Congress Include this Provision

- Public Cigarette Smoking Act of 1969
  - *Cipollone v. Liggett Group*
  - Act preempted common law tort claims relying on failure to warn b/c would have greater requirements than statutorily mandated warning label
- Federal Insecticide, Fungicide, and Rodenticide Act
  - *Bates v. Dow Agrisciences, LLC*
  - Common law failure to warn claims preempted by labeling requirements, depending on state requirement equivalency
- Medical Device Act
  - *Riegel v. Medtronic, Inc.*
  - Common law claims challenging device safety receiving premarket approval preempted by federal law
- Federal Food, Drug, and Cosmetic Act
  - *Mut. Pharm. Co. v. Bartlett*
  - State law design defect cause of action based on inadequate warning preempted by FDA approval of drug

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Savings: Why Did Congress Include this Provision?

- Federal Boat Safety Act of 1971
  - *Sprietsma v. Mercury Marine*
  - Narrow preemption, broad savings → no preemption of state common law actions
- Federal Motor Vehicle Safety Standard
  - *Geier v. American Honda Co.*
  - Narrow preemption, broad savings → implied preemption

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Savings: The Act

- Legislative history demonstrates keen awareness of this background
- Congressional Record contains explicit reference to preemption/savings:
  - Clarifying Congress' intent that no express, implied, or actual conflict exists between the Act/any federal regulatory action and state federal, or maritime tort
    - (*Geier v. American Honda Motor Co.*)
  - Ensuring EPA imposes only *minimum* requirements for warnings so that a "reasonable" person can always do more
    - (*Wyeth v. Levine*)

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Savings: What does it mean for litigators and litigants in toxic tort cases?

- Even though Congress went to great lengths to clarify what it meant by "preemption" and "savings" in the Act, it would be a mistake to conclude that EPA actions under the Act will be irrelevant to the litigation of state law toxic tort claims.
- The Act explicitly grants courts final authority on the admission into evidence or any other use of the Act and/or manifestations of its implementation

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How will EPA actions under the Act impact a trial?

- Potential Rulings
  - Finding on unreasonable risk is:
    - Admissible or inadmissible altogether
    - Admissible for certain issues, limiting instructions
  - Failure to warn claims and minimum labeling
- Plaintiff and defense attorneys each will be motivated to use EPA findings under the Act to their client's benefits, but, as the Act states, such use cannot be dispositive in any action

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Relevance

- Will an EPA finding on unreasonable risk have any tendency to make a fact of consequence in determining the action more or less probable than without the evidence?
  - For what is it being offered?
- Example: *Parker v. Mobil Oil Corp.*: "[S]tandards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation."

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Prejudicial v. Probative

- Would the probative value of an EPA finding on unreasonable risk be substantially outweighed by potential for prejudice, confusion, misleading the jury, undue delay, waste of time, or cumulative evidence?
- Congress's Intent: EPA determination shall not be interpreted as "in either the plaintiff's or defendant's favor dispositive in any action"

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How Will the Evidence be Offered?

- Federal Court: FRE 803(8) – Public record exception to the rule against hearsay
  - Conclusions and opinions are admissible if satisfying trustworthiness requirement
- New York: Limited express public records exception, common law
- *Daubert* Line of Attack

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Expert Testimony

- Expert testimony likely will be a vehicle to admit EPA findings and studies, even if hearsay, because experts may reasonably rely on inadmissible evidence if normally relied upon in their field to come to conclusions
- Challenge the expert's qualifications or the use of EPA evaluations and findings in connection with a particular case

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Motion in Limine

- A preliminary determination, made near or at the beginning of trial, for a ruling on evidence – should it be admitted, excluded, limited, etc.
- Could determine the likelihood of success at trial
- Could lead to settlement of a case

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Cautionary Instruction

- A court may admit EPA findings, but with a cautionary instruction, usually based on prejudicial-probative arguments
- Most likely where a court is faced with the Congressional Record's admonition of permitting EPA findings to be dispositive in court, but the evidence is highly relevant and probative
- Can a cautionary instruction mitigate the risks?

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Minimum Labeling Requirements

- Congress had *Wyeth v Levine* in mind
- Sets the stage for trial judges admitting compliance with EPA requirements, but with an instruction that compliance is not conclusive regarding duty to warn
- Has *Wyeth* been limited in a way that could impact this outcome?
  - What did EPA *actually* review?

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WHAT DOES A REFORMED TSCA MEAN FOR PRIVATE RIGHTS OF ACTION UNDER STATE LAW?

As the Act is implemented, these issues will evolve.

For further information on TSCA, and other toxic tort-related matters, visit https://www.bsk.com/practices/toxic-tort-environmental-litigation-pubtype1

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WHAT DOES A REFORMED TSCA MEAN FOR PRIVATE RIGHTS OF ACTION UNDER STATE LAW?

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Background

Under the *Frank R. Lautenberg Chemical Safety Reform for the 21st Century Act* (the "Act"), EPA has been given broad authority and a responsibility to assess the risks of chemical substances and make findings as to whether a substance presents an "unreasonable risk of injury to health or the environment." If, after evaluating a substance, EPA concludes that it presents an "unreasonable risk," EPA may take several different actions:

- It may prohibit or restrict the manufacturing, processing, or distribution in commerce of the substance;
- It may limit the amount of the substance that may be manufactured, processed, or distributed;
- It may prohibit or restrict the manufacturing, processing, or distribution of the substance *for a particular use,* or for a particular use in *a concentration in excess of a level* specified by EPA.
- It may limit the amount that may be manufactured, processed, or distributed *for a particular use* or for a *particular use above a specified concentration*.
- It may require *minimum warnings and instructions* with respect to the substances.
- It may prohibit or regulate any *manner or method* of commercial use of the substance.
- It may prohibit or regulate the manner or method of *disposal* of the substance.
- It may require manufacturers or processors to *give notice* of EPA's determination with respect to a substance to distributing, persons in

possession of or exposed to a substance, and to the public, and require them to replace or repurchase the substance.

Of course, EPA may also make a finding that the substance does not pose an unreasonable risk of harm, and allow it to be used without restriction.

Congress' Concern with Preemption

The Act contains a number of carefully crafted provisions defining when, and to what extent, these actions taken by EPA will preempt state statutes or regulations pertaining to a substance evaluated by EPA. In addition, Congress concerned itself with the effect that EPA actions under TSCA might have on state law causes of action for personal injury or property damage, *i.e.,* state "toxic tort" actions.

Congress was motivated to address preemption in this context because, under other federal statutes regulating substances or devices, federal law has been held to displace some or all state law causes of action pled by plaintiffs. For example, in *Cipollone v. Liggett Group*, the Supreme Court held that § 5(b) of the Public Health Cigarette Smoking Act of 1969 preempted common law tort claims to the extent they rely on a failure-to-warn theory that would have imposed greater requirements than the statutorily mandated warning label. *See* 505 U.S. 504, 524-25 (1991). Similarly, courts have held common law claims based on failure-to-warn and fraud could be preempted by the labeling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), depending on whether the state-law labeling requirements were equivalent to FIFRA requirements. *See Bates v. Dow Agrisciences, LLC*, 544 U.S. 431, 453 (2005).

Likewise, any common law claims that challenge the safety or effectiveness of a medical device that has received premarket approval from the FDA under the Medical Device Amendments of 1965 (MDA) also have been found to be preempted by federal

law. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2007). Significantly, the extent of regulatory review and the restrictions that may be imposed by the FDA on medical devices granted premarket approval under the MDA are comparable to the authority and procedures granted to EPA under the Lautenberg Act. *See id*., at 317-19.

Finally, in *Mut. Pharm. Co. v. Bartlett*, the Supreme Court held that a state law design defect cause of action based on an inadequate warning was preempted by provisions of the Federal Food, Drug and Cosmetic Act (FDCA) requiring FDA approval of generic drugs. *See* 133 S. Ct. 2466, 2480 (2013). *But see Wyeth v. Levine*, 555 U.S. 555 (2008) (holding that a state common law cause of action based on an inadequate warning was not preempted by the FDCA because the relevant regulation did not prohibit the manufacturer from including an enhanced warning, and the statute did not include an express preemption provision for prescription drugs).

The Act's "Savings" Provision

In light of this background, Congress considered the possible preemptive effect of EPA actions under the amended TSCA. While the Act specifies many instances in which EPA actions under TSCA will preempt state statutes and regulations related to chemical substances evaluated by EPA, Congress opted to preserve state common law causes of action arising out of uses of those substances. It did so in a detailed, four-paragraph "Savings" provision that reads as follows:

> (g) SAVINGS
>
> (1) No preemption of common law or statutory causes of action for civil relief or criminal conduct
>
> (A) In general
>
> Nothing in this chapter, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any standard, rule, requirement, standard of

> performance, risk evaluation, or scientific assessment implemented pursuant to this chapter, shall be construed to preempt, displace, or supplant any State or Federal common law rights or any State or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.
>
> (B) Clarification of no preemption
>
> Notwithstanding any other provision of this chapter, nothing in this chapter, nor any amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.
>
> (2) No effect on private remedies
>
> (A) In general
>
> Nothing in this chapter, nor any amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rules, regulations, requirements, risk evaluations, scientific assessments, or orders issued pursuant to this chapter shall be interpreted as, in either the plaintiffs or defendant's favor, dispositive in any civil action.
>
> (B) Authority of courts
>
> This chapter does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this chapter or rules, regulations, requirements, standards of performance, risk evaluations, scientific assessments, or orders issued pursuant to this chapter.

15 U.S.C. § 2617(g).

These detailed provisions not only clearly anticipate suits brought related to chemical substances subject to TSCA, but also provide interpreting courts specific guidance in the event a preemption issue is raised – *i.e.*, it informs courts that private rights of action at common law generally should be permitted in spite of an action's implication of a TSCA-associated action.

Congress has included similar "savings" provisions in other statutes, with mixed results. For example, in *Sprietsma v. Mercury Marine*, the Supreme Court was called upon to determine, *inter alia*, whether "a state common-law tort action seeking damages from the manufacturer of an onboard motor is pre-empted by the enactment of the Federal Boat Safety Act of 1971" ("FBSA"). *See* 537 U.S. 51, 54 (2002). The statute contained both a preemption provision and a savings provision. The preemption provision at issue prohibited States from establishing, effecting, or enforcing "law[s] or regulation[s]" dealing with recreational vessels and equipment safety that were "not identical to a regulation" made under the FBSA. *Id.* at 58-59. The savings provision stated, "[c]ompliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under state law." *Id.* at 59. According to the Court, the express preemption of only "laws or regulations" indicated preemption only of positive enactments, not common law; and the savings clause's general reference to "liability at common law," combined with its assumption that there are a significant number of such cases to save, "buttressed" the conclusion that common law claims were not preempted by the FBSA. *Id*. at 63.

In another case, *Geier v. Am. Honda Motor Co.*, the Supreme Court similarly found that the language of a preemption provision, combined with a broad savings clause, did not expressly preempt state common law torts. 529 U.S. 861, 868 (2000). The Court did, however, find that the plaintiff's claim, alleging a failure to install airbags in a vehicle, was *impliedly* preempted by a Federal Motor Vehicle Safety Standard promulgated under the applicable regulation. *Id.* at 881. According to the Court, since the purpose of the Standard was to have a *variety* of passive restraints, not just air

bags, permitting a state tort claim on the grounds that the manufacturer of a vehicle did not install an air bag would conflict with the Standard's purpose, and it was therefore preempted. *Id.*

The legislative history of the Act demonstrates that Congress was keenly aware of this body of law, and contains evidence that it intended to preserve common law causes of action in all circumstances. The Congressional Record of the Senate debate on this bill on June 7, 2016 includes a memorandum introduced by Senator Boxer, entitled "Detailed Analysis and Additional Views of Democratic Members on the Motion to Concur in the House Amendment to the Bill H.R. 2576 Entitled 'An Act to Modernize the Toxic Substances Control Act, and for Other Purposes,' June 7, 2016." This lengthy memorandum, setting forth the view of Democratic Senators, includes a specific reference to the savings clause in the Act and the *Geier* decision, discussed briefly above:

> This section further clarifies Congress' intent that no express, implied, or actual conflict exists between any federal regulatory action and any state, federal or maritime tort action, responding to the perceived conflict contemplated in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) and its progeny.

Cong. Rec., June 7, 2016, S3518.

Likewise, this memorandum addresses the effect of an EPA requirement for labeling of a chemical substance, with specific reference to the *Wyeth* case, also cited above:

> [The Act] ensures that the requirements EPA can impose to address an unreasonable risk to health or the environment include requiring "clear and adequate minimum" warnings. The addition of the work "minimum" was intended to avoid the sort of litigation that was undertaken in *Wyeth v. Levine*, 555 U.S. 555 (2009), when a plaintiff won a Supreme Court

> decision after alleging that the harm she suffered from a drug that had been labeled in accordance with FDA requirements had nevertheless been inadequately labeled under Vermont law. This ensures that manufacturers or processors of chemical substances and mixtures can always take additional measures, if in the interest of protecting health and the environment, it would be reasonable to do so.

Cong. Rec., June 7, 2016, S3517.

The implication of the last sentence of this passage, stating that manufacturers and processors can always do more than EPA requires, is that they may be held liable by a jury in a common law tort action if they fail to do so.

The broad no-preemption language of 15 U.S.C. § 2617(g)(1)(A) is buttressed by § 2617(g)(1)(B), entitled "Clarification of no preemption," which adds that nothing in the Act:

> shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

The combination of this seemingly all-encompassing language and the comments entered into the Congressional Record lead to the inescapable conclusion that Congress intended that nothing in the Act, nor anything that EPA does in implementing the Act, should preclude a plaintiff from having his or her day in court on any state law tort theory.

But it would be a mistake to conclude that EPA actions under the Act will be irrelevant to the litigation of state law toxic tort claims. In fact, Congress expressly opened the door for ligation over how EPA's TSCA decisions should impact tort actions.

Specifically, subparagraph (2)(B) of the "Savings" provision, subtitled "Authority of courts," expressly preserves the authority of trial courts to make decisions:

> with respect to the *admission into evidence or any other use* of this chapter or rules, regulations, requirements, standards of performance, risk evaluations, scientific assessments, or orders issued pursuant to this chapter. (emphasis added).

In order words, trial courts retain broad discretion to determine whether, and if so, how, EPA actions under the Act can be used in the litigation of a toxic tort action.

This broad authority comes with one significant qualification, however: subparagraph (2)(A) says that nothing in the Act, nor any EPA action taken thereunder, "shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action." In other words, while trial courts have discretion to determine how EPA actions under the Act can be used in civil litigation, those EPA actions cannot be outcome-determinative. The most obvious application of this limitation would be that EPA determinations cannot by themselves be the basis for summary judgment or a directed verdict.

The Use of EPA Findings in Toxic Tort Litigation

So, in the real world of toxic tort litigation, how might trial lawyers and judges work within this statutory framework? Plaintiff lawyers will want to use EPA findings of unreasonable risk or determinations setting safe concentrations of chemicals offensively to make their cases, while defense lawyers will seek to exclude or limit the use of such adverse findings. Conversely, defense attorneys will want to admit into evidence findings that their client's product does *not* pose an unreasonable risk or cause a condition that the plaintiff claims was caused by the product.

Potential rulings by a trial court could include the following:

- An EPA finding of an unreasonable risk is inadmissible.
- EPA's ultimate conclusion that a chemical poses an unreasonable risk is inadmissible, but some or all of the risk evaluation upon which it is based, including the analysis of the underlying studies and data, is admissible.
- An EPA finding on the issue of unreasonable risk is admissible, without qualification.
- An EPA finding on the issue of unreasonable risk is admissible, but with a cautionary instruction that it is not dispositive.
- An EPA finding is admissible as to one or more issues, but not as to others (e.g. admissible on the standard of care, but not on the issue of causation).
- An EPA finding with respect to a particular use is either admissible or inadmissible to prove the degree of risk posed by a different use.
- An EPA determination of a minimum labeling requirement is either admissible or inadmissible with regard to a failure to warn claim.

These rulings will, of course, be contingent upon the rules of evidence applicable to any case. Therefore, the very first question a judge must ask with regard to TSCA-related EPA findings is whether the findings are relevant to the case, *i.e.*, whether an EPA finding on unreasonable risk "has any tendency to make a fact more or less probable than it would be without the evidence," and that "the fact is of consequence in determining the action." *See* FED. R. EVID. 401; *see also People v. Davis*, 43 N.Y.2d 17, 27 (1977) (citations omitted). The relevance of an EPA finding may depend on the purpose for which it is offered. For example, the New York Court of Appeals has held that "standards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation." *Parker v Mobil Oil Corp.,* 7 N.Y.3d 434, 450 (2006). This principle could be used to argue that an EPA finding that a chemical substance poses an unreasonable risk when used at a certain concentration is

irrelevant, and therefore inadmissible, if offered to prove that exposure above that concentration caused harm to a plaintiff.

A litigator attempting to persuade a Court not to admit an EPA finding on unreasonable risk may argue that the probative value of the finding "is substantially outweighed by potential for prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." *See* FED. R. EVID. 403; *see also Davis*, 43 N.Y.2d at 27 (citations omitted). For example, a plaintiff attorney may wish to use an EPA finding of unreasonable risk offensively, but a defense lawyer could argue that the probative value of that unreasonable risk finding is low because it was based on a set of circumstances different than the one at hand, while the risk for prejudice to the defendant and misleading the jury is very high, and therefore, inadmissible. A similar argument might be grounded in the language of the Act's savings clause, that a determination by EPA shall not be interpreted as "in either the plaintiff's or defendant's favor, dispositive in any civil action." The argument would be that a jury would be swayed by the EPA finding to a degree that it would effectively become dispositive, and therefore should not be admitted, because it would have the very impact that Congress said is prohibited.

A litigator attempting to keep an EPA finding on unreasonable risk out of evidence may argue that the finding, or the contents of any EPA report containing the finding, is inadmissible hearsay, *i.e.*, an out of court statement offered for the truth of the matter asserted. *See* FED. R. EVID. 801; *see also Nucci v. Proper*, 95 N.Y.2d 597, 602 (2001) (citations omitted).

If in federal court, most likely the proponent of the evidence would offer the finding, or the report on which the finding is based, as a public record, and therefore, within an exception to the rule against hearsay. *See* FED. R. EVID. 803(8); *see generally* David R. Kott, et. al., "The Admissibility of Opinions Contained in Public Records," BLOOMBERG BNA NEWS (May 29, 2013)*, available at* https://www.bna.com/the-admissibility-of-opinions-contained-in-public-records/.

Rule 803(8) states that a public record is not excluded by the rule against hearsay if it is a "record or statement of a public office" that:

> sets out: (i) the office's activities; (ii) a matter observed while under a legal duty to report, but not including, in a criminal case, a matter observed by law-enforcement personnel; or (iii) in a civil case or against the government in a criminal case, factual findings from a legally authorized investigation; and (B) the opponent does not show that the possible source of the information or other circumstances indicate a lack of trustworthiness.

See FED. R. EVID. 803(8). The Supreme Court has held that both factually based conclusions *and* opinions are admissible under this exception to the rule against hearsay, as long as the report satisfies the trustworthiness requirement. *See Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 170 (1988). It is the burden of the opponent of the evidence to demonstrate that the report indicates a lack of trustworthiness, which "necessarily depends on the circumstances." *See* FED. R. EVID. 803, Notes of the Advisory Committee on 2014 amendments. While it may be expected that the public record exception will ordinarily support the admissibility of EPA determinations under the Act, this is not necessarily the result in all cases, and in appropriate circumstances, a court might be persuaded that the finding lacks trustworthiness. For example, in *Junk v. Terminix Int'l Co., Ltd. P'ship*., the Court upheld the inadmissibility of an EPA report

where the report itself contained a "prominent disclaimer," and thus, did not satisfy the trustworthiness prong of FED. R. EVID. 803(8). *See* 628 F.3d 439, 449 (8th Cir. 2010).

New York procedure does not have an express public records exception comparable to FED. R. EVID. 803(8). *But see* CPLR 4520 (certificate as affidavit of public office) and CPLR 4540 (authentication of official record of court or government office in the United States). It does recognize, however, a common law exception to the hearsay rule for public documents. Frumer & Biskind, *Bender's New York Evidence*, § 118.01[2]. This common law exception, like FED. R. EVID. 803(8), is subject to the trial court's determination of trustworthiness, and so comparable arguments could be made regarding admissibility of EPA findings.

An alternative line of attack against admissibility would be to argue that, if the records contain evaluative conclusions, they must satisfy the more stringent *Daubert* standard in assessing the reliability of expert testimony. *See* Kott, "The Admissibility of Opinions Contained in Public Records." For example, according to Kott, in a Southern District of Illinois case, the Court "found an internal affairs and Illinois state police investigations report inadmissible because the report referenced results of a polygraph test." *See id.* (citing *Beberena v. Pasquino*, No. 03-557, 2006 BL 116502, *1-2 (S.D. Ill. Nov. 9, 2006)). Thus, a litigator could argue that where a report contains evaluative conclusions, but its methodology cannot be shown to be reliable, it should not be admitted into evidence.

Frequently, the method used to test the admissibility of the EPA-derived evidence will be a motion *in limine*, i.e., a preliminary determination, made near or at the beginning of trial, for a ruling that evidence is inadmissible or would be prejudicial if

admitted and should be excluded or limited. *See Maliqi v. 17 East 89th Street Tenants, Inc.*, 25 Misc. 3d 182, 880 N.Y.S. 2d 917, 921 (Sup. Ct. Bronx Cnty. 2009); *Drago v. Tishman Const. Corp. of New York,* 4 Misc. 3d 354*,* 777 N.Y.S. 2d 889, 893 (Sup. Ct. New York Cnty. 2004); *Chamblee v. Harris & Harris, Inc.*, 154 F. Supp. 2d 670, 677 (S.D.N.Y. 2001). A pretrial ruling on evidence obtained from a motion *in limine* will often determine the likelihood of success at trial and it may be instrumental in leading to settlement of a case.

Expert testimony is likely to be the vehicle for introducing EPA findings and/or the studies on which the EPA findings are based. *See United States v. W.R. Grace*, 504 F.3d 745, 758-66 (9th Cir. 2007) (discussing FED. R. EVID. 703, which permits experts to reasonably rely on inadmissible evidence in forming an opinion or delivering testimony if of a type normally relied upon by experts in the particular field); *Hiclicky v. Dreyfuss*, 6 N.Y.3d 636, 648 (2006) (citations omitted) (discussing the "professional reliability exception to the hearsay rule" in New York, which "enables an expert witness to provide opinion evidence based on otherwise inadmissible hearsay, provided it is demonstrated to be the type of material commonly relied on in the profession."). Trial lawyers therefore should carefully evaluate expert witness disclosures and expert reports for references to EPA TSCA evaluations and reports and consider whether there is a basis to challenge the use of the EPA evaluations and findings in the context of the particular case.

A court faced with a challenge to the admissibility of some or all of an EPA finding might resolve the issue by admitting the evidence, but with a cautionary instruction. Whether a cautionary instruction is warranted will depend, in part, on the

prejudicial-probative arguments the parties make with regard to weighing the values of an EPA determination on unreasonable risk. This technique is likely to be employed by courts faced with the argument alluded to above, in which a lawyer contends that an EPA finding is likely to be dispositive, and therefore, contrary to the Act's proscription of an EPA finding being interpreted as dispositive. That is, the court may rule the EPA finding admissible, but instruct the jury that EPA's determination is not conclusive on the issue before them, but rather one piece of evidence the jury may consider in making its own independent finding. This is essentially the approach taken by the trial judge in the *Wyeth* case, who "instructed the jury that it could consider evidence of Wyeth's compliance with FDA requirements but that such compliance did not establish that the warnings were inadequate." *Wyeth,* 555 U.S. at 562. As noted above, Congress had the *Wyeth* case in mind when it drafted the provision in the Act granting EPA authority to establish "minimum" labeling requirements, thereby setting the stage for trial judges to admit evidence of compliance with EPA-mandated labeling requirements, but with an instruction that compliance with those requirements is not conclusive regarding the duty to warn.

In a recent article discussing the *Wyeth* ruling and its impact on preemption jurisprudence, Diane E. Lifton and Danielle Rosen argue that recent case developments have narrowed the scope of its holding. *See* Diane E. Lifton & Danielle Rosen, "*Seufert v. Merck* and *Cerveny v. Aventis*: The Intersection of Science and Federal Preemption in Pharmaceutical Product Liability Litigation," BLOOMBERG LAW INSIGHTS, Vol. 31, No. 36 (2016). Specifically, in *Wyeth*, one of the reasons the Court found in favor of the plaintiff was that there was not "'clear evidence' that the FDA would have rejected the warning

sought by the plaintiff." *See id*., at 872. Two recent cases, however, answer what the Court may have done with evidence that the FDA:

> (1) considered the specific risk plaintiff claims the manufacturer should have warned of in its drug product labeling; (2) examined whether the science establishes the existence of a causal association between the drug and that risk and found it lacking; and (3) continued to approve the product (or related products) without changes to the label with respect to that risk.

See id. (citing *Seufert v. Merck Sharpe & Dohme Corp.*, No. 13cv2169, 2016 BL 227777 (S.D. Cal. May 11, 2016), *appeal docketed*, No. 16-55853 (9th Cir. June 15, 2016); *Cerveny v. Aventis, Inc.*, No. 2:14-cv-00545, 2016 BL 80932 (D. Utah Mar. 16, 2016), *appeal docketed*, No. 16-4050 (10th Cir. Apr. 13, 2016)). Specifically, the cases "suggest that a regulatory record reflecting the FDA's review of the science regarding the risk at issue, without a label change, ultimately can result in a finding that the FDA would have rejected plaintiffs' proposed warning[.]" *See id.*, at 874.

Using the "suggestions" from these cases, a defense attorney faced with challenges from an opponent on the effect of an EPA determination of a minimum labeling requirement, based on the legislative history that manufacturers, processors, and distributors can "take additional measures, if in the interest of protecting health and the environment, it would be reasonable to do so," should look at the history leading up to EPA's determination and note whether the issues raised by plaintiff were rejected as important or risky by EPA. This review could provide support for an argument that the minimum labeling standard, in fact, is powerful evidence of the standard of care, increasing the probative value of the minimum warning requirement and decreasing the potential for undue prejudice, confusing the issues, and misleading the jury, and perhaps provide a convincing argument against a proposed cautionary instruction.

A litigator who opposes admissibility of EPA's finding on the issue of unreasonable risk will want to argue that even a cautionary instruction cannot mitigate the risks of prejudice, confusion, etc., whereas a proponent will argue the opposite. *Compare Dodson v. CBS Broad, Inc.*, 423 F. Supp. 2d 331, 334-35 (S.D.N.Y. 2006) (excluding an EEOC determination where it had a "low probative value" "compared to the risk that the jury will be unduly influenced despite any limiting instruction."), *with Chamblee v. Harris & Harris, Inc.*, 154 F. Supp. 2d 670, 678 (S.D.N.Y. 2001) (admitting the finding of the New York State Division of Human Rights, but not the report, where the jury would "view the evidence of the EEOC 'probable cause' finding in the context of a limiting instruction that a finding of 'probable cause is not a final determination of liability[.]'"). Trial judges will have considerable discretion in balancing these competing arguments.

Conclusion

These examples illustrate the fact that notwithstanding the Act's clear statements precluding preemption of common law claims, EPA evaluations and determinations under the Act may have a significant role to play in toxic tort litigation, with the ultimate impact of those actions being worked out on a case-by-case basis. The Act's savings clause may have answered the general question of preemption, but it created a fertile ground for litigation over the ways in which EPA's review of chemical substances will influence the outcome of individual claims.