

# **Don't Drink the Water: Everything You Need to Know about Emerging Contaminants**

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**NEW YORK**  
 STATE OF OPPORTUNITY

Department of  
**Environmental  
 Conservation**

## New York State's PFAS and Emerging Contaminants Response

Thomas S. Berkman, Esq.  
 Deputy Commissioner and General Counsel

October 2018

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### Nationally: Public Confidence in Water Shaken



**FLINT  
WATER CRISIS**



Lake Erie's  
summer forecast  
is looking green.



the *Charleston Gazette*  
**STATE OF EMERGENCY  
 WATER CONTAMINATED**  
 Chemical leak into Elk River affects at least 8 counties


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## Emerging Contaminants

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- The Flint, MI water crisis in 2014 highlighted serious impacts past practices and everyday products we use can have on drinking water.
- Emerging contaminants such as perfluorinated compounds (PFCs) and 1,4 – Dioxane have recently been found to be impacting groundwater and drinking water throughout the country.
- In New York, these contaminants are impacting public water supply systems and private drinking wells in several communities including: Hoosick Falls, Petersburg, Newburgh, and on Long Island.


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### New York State Focus on Emerging Contaminants

HOOSICK FALLS WATER CRISIS

NEW YORK AIR NATIONAL GUARD Stewart ANG Base Main Gate

CONTAMINATED WATER WESTHAMPTON, LONG ISLAND GLASSBORO AIR NATIONAL GUARD BASE

THE TIMES Push for PFOA action Black Friday

What's your identity?

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### New York's Response

- Recognizing this growing concern, New York took immediate action.
- In January 2016, New York became the first state to regulate PFOA as a hazardous substance followed by the regulation of PFOS in April 2016.
- DEC listed "significant threat" level sites on the Registry and identified potential sites.

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### Major Sites Being Addressed by DEC:

#### Saint-Gobain McCaffrey Street

**Consent Order commitments:**

- Full Remedial Investigation/Feasibility Study
- Interim Remedial Measures to treat contaminated municipal water supply
- Evaluation of sources for an alternative water supply
- Site Remediation

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### Saint-Gobain McCaffrey Street (Cont.)

**State Actions**

- Installation of Point-of-Entry Treatment Systems (POETs) on private drinking water systems
- Blood testing
- Public Outreach
- Nomination as Federal NPL Site



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### Stewart Air National Guard Base

**State Actions**

- Transitioned and paid for Newburgh's switch to NYC's Catskill Aqueduct for drinking water
- Funded GAC system to treat contaminated Lake Washington water (Newburgh's traditional water supply)
- Constructed draw-down system to prevent Lake Washington flooding
- Provided bottled water and municipal water hook-ups
- Installed of POETs on private drinking water systems in greater Newburgh area
- Environmental sampling
- Blood testing
- Public Outreach



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### Gabreski Air National Guard Base

**State Actions**

- Reimbursed Suffolk County for the cost of connecting private residences to public water, including the cost of four water main extensions
- Investigation to identify sources of PFOS contamination
- Review and input into United State Department of Defense's limited investigations



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**Taconic**

**Consent Order commitments:**  
 Full Remedial Investigation/Feasibility Study  
 Funding treatment for Petersburg Municipal Water System  
 Sampling private water wells and installation of POETs  
 Providing bottled water, as necessary



**State Activities:**  
 Initial testing and installation of POETs  
 Sampling of environmental media, including the Little Hoosick River




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**New York's Response - PFC Survey**

Since WQRRT inception:

- PFC Survey: surveyed **2,500** entities where contamination may be probable (e.g., airports, fire training centers, industry);
  - information is being used to identify and investigate water quality in areas where a potential for PFC contamination may exist.
- Facility Mapping/Sampling: Based on survey results, DEC and DOH identified and mapped more than **250** facilities within ½ mile of a public or private drinking water supply well. Sampled 125 sites for PFAS, so far
  - All facilities near public drinking water supplies were prioritized for immediate sampling.




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**New York's Response - Litigation**

State sues aqueous film-forming foam (AFFF) manufacturers in NY Supreme court:

- AFFF contains PFOS, PFOA, and related contaminants
- Causes of Action: Public nuisance, strict products liability - defective design, strict products liability - failure to warn, and restitution
- State files Notice of Claim against U.S. Department of Defense related to AFFF discharges at Stewart ANG Base, Gabreski Airport, Long Island MacArthur Airport, and Defense Fuel Support Point Verona




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## New York's Response - Clean Water Infrastructure Act of 2017



**Governor Cuomo Signs Legislation Investing \$2.5 Billion in Clean Water Infrastructure and Water Quality Protection**

A \$2.5 billion investment drinking water and water quality protection across New York State.

- Includes up to \$130M for mitigation/remediation of contaminated drinking water.



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## What is a Contaminant under the CWIA?

A **Contaminant** is defined as an “emerging contaminant” under the Public Health Law.

**Emerging Contaminants**, as defined in Public Health Law § 1112, are any physical, chemical, microbiological or radiological substance which are to be defined through regulations. At a minimum 1,4 Dioxane, PFOS, and PFOA are to be included as emerging contaminants.



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## ECL § 27-1203 – Mitigation and Remediation of Solid Waste Sites


The priority of this section is to mitigate and remediate solid waste sites which either cause or substantially contribute to impairment of drinking water.

**What is a Solid Waste Site? As defined under 27-1201, it is a site where:**

- The department has a reasonable basis to suspect that the illegal disposal of solid waste occurred; or
- The courts have determined that an illegal disposal of solid waste occurred; or
- The department knows or has a reasonable basis to suspect that an inactive solid was management facility which does not have a current monitoring program is impacting or contaminating one or more drinking water supplies.

DEC is currently investigating **over 2000** solid waste sites across the state.

→ A **solid waste site** is **not** a site that is currently subject to investigation or remediation.



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## ECL § 27-1203 – Mitigation and Remediation of Solid Waste Sites (cont.)

- Goals:
  - Develop a ranking system to select solid waste sites for field investigations
    - Criteria being considered includes proximity to drinking water receptors, proximity to surface waters, type of waste received and condition of cap.
  - Create a "solid waste site mitigation and remediation priority list" based on their impact on state's drinking water supply sources, and
  - Submit a comprehensive plan designed to mitigate and remediate solid waste sites impacting drinking water quality and/or public health to the Governor and Legislature starting in July 2019 and annually thereafter.
- The Department is authorized under §27-1203(6) to "implement necessary measures to mitigate and remediate the solid waste site." The department will do so in accordance with the priority list and will seek to recover costs.
- If after appropriate testing and analysis, a site is found to pose a significant threat to the public health or the environment due to the presence of hazardous waste, it is to be referred to the inactive hazardous waste disposal site remedial program (State Superfund - ECL Article 27 Title 13)



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## ECL § 27-1205 Mitigation of Contaminants in Drinking Water (Drinking Water Contamination Sites)

- Under this section, DOH must first make a threshold finding regarding public water systems before DEC begins mitigation measures at drinking water contamination sites which includes:
  1. A determination that a public water system needs to take action to reduce exposure of emerging contaminants; and
  2. A determination that the concentration of emerging contaminants constitutes and actual or potential threat to public health.
- Where contamination is present, feasible measures to mitigate must be used. These "feasible measures" have to use "available, implementable and cost effective technology."
- If a drinking water contamination site poses a significant threat to the public health or environment from a hazardous waste the site, it will be referred to the inactive hazardous waste disposal site remediation program (State Superfund – ECL Article 27 Title 13).
- When it has been determined that a public water system needs to reduce exposure to *emerging contaminants*:
  - a. DEC and DOH have authority to do the necessary mitigation, remediation, and recovery of costs; or
  - b. The Commissioner may order the owner and/or operator of the drinking water contamination site and/or any person responsible for such contamination to undertake all reasonable and necessary mitigation and remediation to meet satisfactory levels, triggering the hearing requirement.




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## Coordinated Approach to Proactively Address "Big Picture" Water Quality Issues

- ♦ Governor Cuomo's creation of Water Quality Rapid Response Team (WQRRT)
- ♦ Legislation establishing the Drinking Water Quality Council (DWQC)



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## Thank You

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**NEW YORK STATE'S  
LEADERSHIP IN RESPONDING TO  
EMERGING CONTAMINANTS**

OCTOBER 2018  
NYS BAR ASSOCIATION  
ENERGY AND ENVIRONMENTAL LAW SECTION

**ZACKARY D. KNAUB**  
FIRST ASSISTANT COUNSEL TO THE  
OFFICE OF GOVERNOR ANDREW M.  
CUOMO  
STATE CAPITOL, ALBANY, NY

GOVERNOR  
CUOMO

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**REGULATORY BACKDROP FOR EMERGING CONTAMINANTS**

- Safe Drinking Water Act of 1974 (SDWA)
  - Foundation for federal and state rules for public water systems
  - States have authority to implement SDWA as long as standards are as stringent as EPA's
  - While states have primary jurisdiction, EPA sets nationwide standards
- For contaminants known or anticipated to occur in public water systems, EPA publishes a Contaminant Candidate List (CCL).

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## REGULATORY BACKDROP - SDWA

- EPA must publish the CCL every five years and the list contains contaminants that present the greatest public health concern from exposure to drinking water.
- The CCL is used to determine if regulatory action by EPA is needed.
- Whether to regulate depends on whether: contaminant may have an adverse effect on the health of persons; is known to occur or there is substantial likelihood the contaminant will occur in public water systems with a frequency and at levels of public health concern; regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems.

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## UNREGULATED CONTAMINANT MONITORING

- As the CCL is used to evaluate contaminants known to exist in public water systems, the Unregulated Contaminant Monitoring Regulation (UCMR) is used to collect information about contaminants suspected of being present in drinking water.
- Monitoring data collected for large systems and a representative sample of small systems (>10,000 users).
- Data collected for 30 contaminants every 5 years; the last list (UCMR 4) was published December 2016; monitoring will occur from 2018-2020 for 30 contaminants.

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## EPA'S PROGRESS UNDER THE SDWA

- Despite steps to develop and publish multiple CCL and UCMR actions, EPA has been slow to make regulatory decisions under the SDWA.
- As of 2018, only two contaminants have been selected for regulatory action.
- Under the SDWA, EPA also issues health advisory levels.
- Health advisory levels are not regulatory standards; they are levels above which exposure should be reduced.

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## EPA AND PFAS

- 2009 - EPA has Provisional Health Advisory value for PFOA and PFOS at 400 ppt.
- 2014 – EPA publishes Health Effects Documents for PFOA and PFOS; Both of which were subject to peer-review
- January 2016 – EPA Region 2 Lowers health advisory to 100 ppt by press release
- May 2016 – EPA issues lifetime health advisory of 70 ppt.

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## EPA AND PFAS

- In late May 2018, the EPA hosted a National Leadership Summit in Washington, D.C. to “take action” on PFOA/S and other emerging contaminants in the environment.
- In June 2018, the ATSDR released a report showing that PFOA and PFOS may endanger human health at a far lower level than EPA has previously called safe (around 10 ppt, as opposed to 70+ ppt).
- The federal government has still not established enforceable drinking water standards for PFOA, PFOS and/or 1,4-dioxane.

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## PATCHWORK REGULATORY ACTION

- New Jersey (MCLs of 14 ppt for PFOA and 13 ppt proposed for PFOS);
- Vermont (groundwater standards of 20 ppt for PFOA/S); and
- New Hampshire (enforceable groundwater standard of 70 ppt for PFOA/S)

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### NEW YORK'S LEGAL SOLUTIONS TO EMERGING CONTAMINANTS

- Clean Water Infrastructure Act of 2017 - invests \$2.5 billion in clean ground, surface, and drinking water infrastructure projects and water quality protection across New York.
- Water Quality Rapid Response Team
- Emerging Contaminant Monitoring Act
- Household Cleaning Product Disclosure Program

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### CLEAN WATER INFRASTRUCTURE ACT OF 2017

- In April 2017, Governor Andrew M. Cuomo signed the Clean Water Infrastructure Act – a \$2.5 billion investment in drinking water infrastructure, clean water infrastructure, and water quality protection across New York.
- Provides grants and loans to help local governments pay for water infrastructure capital projects, address water emergencies, and investigate and mitigate emerging contaminants.
- \$1.5 billion in grants for water infrastructure improvements
- \$75 million rebate program to give homeowners and small businesses an incentive to replace and upgrade aging septic systems
- \$110 million dedicated for source water protection initiatives, including land acquisition

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### WATER QUALITY RAPID RESPONSE TEAM

- Team Created in 2016 in direct response to discovery of PFAS in public water supplies.
- Team led by Departments of Environmental Conservation and Health to quickly investigate water quality contamination across the state.
- Targeted sampling of sites where PFOA and PFOS is suspected.
- Results:
  - Identified 38 systems for testing; PFOA/PFOS not detected in majority of samples and positive detections were below EPA's 70 ppt health advisory level
  - One well not used for drinking water tested above EPA health advisory level

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### WATER QUALITY ACT RESPONSE



- CWIA funding available to test groundwater and to help communities address aging infrastructure.
- System upgrades include modern filtration systems and connecting private wells to public water systems.
- Sampling of inactive landfills across the state.

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### NY DRINKING WATER QUALITY COUNCIL

- Established pursuant to Public Health Law § 1113
- Provides recommendations to the NY Department of Health on emerging contaminants in drinking water
  - Notification levels
  - Maximum Contaminant Levels
- Established to address some of the most technically challenging aspects of drinking water regulation.

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### NY DRINKING WATER QUALITY COUNCIL

- Council consists of representative of state and local government, academia, and the public.
- Membership includes:
  - Health Commissioner Zucker
  - Environmental Conservation Commissioner Seggos
  - Six other members appointed by Governor representing water purveyors, experts in health risk assessment, water quality standards development, engineering and microbiology.
  - Four members appointed by the legislature.

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## OTHER NEW YORK ACTIONS - FIREFIGHTING FOAM

- Governor's Office prioritized funding from the Environmental Protection Fund to launch collection program for firefighting foam.
- Departments of Environmental Conservation and of Homeland Security and Emergency Services have worked to collect outdated, unlabeled or mixed firefighting foam.
- As of Summer 2018, more than 25,000 gallons of contaminated foam have been collected and properly disposed.
- Litigation filed to recover costs from manufacturers of firefighting foams incurred by the State to address PFOA/PFOS impacts.




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## OTHER NEW YORK ACTION - CONT'D

- Blood Testing:
  - Department of Health oversaw blood sampling in Hoosick Falls and Newburgh
  - Outreach campaign in 2016 and 2017 to provide testing and educate citizenry on results. Approx. 2,900 people tested in Hoosick and more than 3,000 in Newburgh
- Fish Testing for PFCs: agencies working to collect and analyze fish near Hoosick Falls and Newburgh for emerging contaminants
- Household Cleansing Product Information Disclosure Program
  - Under the program, manufacturers of cleaning products sold in the State of New York are required to disclose the ingredients of their products on their websites and identify any ingredients that appear on authoritative lists of chemicals of concern. Includes emerging contaminant disclosure.
  - Authorized under Environmental Conservation Law Article 35 and New York Code of Rules and Regulations Part 659. Legislation advance in 2018 legislative session to expand that to personal care products.
- Planning for Alternative Water Supplies, Full Plume Containment, and other remedies.

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## OTHER NEW YORK ACTIONS - TAKING THE LEAD

- Full scale demonstration of treatment technology such as ultraviolet light.
- Collaboration with University of Stony Brook on treatment technology.
- \$5 million grant as part of CWIA.




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## OTHER NEW YORK ACTION - PRESSING EPA

- Since smaller public systems are not required to test under UCMR requirements, fewer than 200 of the 9,000 public water supplies will be required to test under EPA rules.
- Governor's Rapid Response Team ensures testing of all public water systems on Long Island in response to 1,4 dioxane.
- Governor, State Agencies and legislature call on EPA to develop MCLs.



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Special Thanks to Jennifer Maglienti, Assistant Counsel for Energy and the Environment for assistance in the preparation of this presentation.

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# PFAS Have Emerged - Where Do We Go From Here?

Mark Maddaloni DrPH, DABT  
Cardno/ChemRisk

NY Bar Association  
October 20<sup>th</sup>, 2018



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# Introduction

- ▶ PFOA Exposure Guideline Development - EPA/ATSDR/NJDEP
- ▶ Regulatory Update
- ▶ The Role of Biomonitoring Programs
- ▶ Potential Clinical Intervention



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# Exposure Guideline Development

- ▶ Toxicity Assessment 
- ▶ Exposure Assessment 
- ▶ Policy 



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### Comparison of EPA and State PFAS values (ppt)

adopted from C.M. Smith PhD, Mass DEP

	PFOS	PFOA	PFNA	PFHxS	PFHpA	PFBS
<b>USEPA</b> Health Advisories	70 Sum of both					
<b>CT</b> Drinking Water Action Levels	70 Sum of all five					
<b>VT</b> Drinking water and groundwater standards	20 Sum of both					
<b>VI</b> Drinking Water Health Advisory	20 Sum of all five					
<b>MA</b> Office of Research and Standards Guideline for Drinking Water	70 Sum of all five					
<b>MN</b> Drinking Water Guidelines	27 (under review)	35		PFOS value recommended		2,000
<b>NJ</b> Recommended MCLs	13	14	13 (proposed)			

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### EPA/NJDEP/ATSDR PFOA Assessments

	RfD (ug/kg- day)	Toxic Endpoint	Dose/ Response Method	Dose Metric	Uncertainty Factor (UF)	Exposure Parameter	RSC	Drinking Water Value
EPA	0.02	Repro/dev delayed bone formation in mice	LOAEL	PK model HED	300	Lactating woman (.054 L/kg- day)	20%	70 ppt
NJDEP	0.002	Increased liver weight in mice	BMDL <sub>10</sub>	PK model HED	*300 data base uncertainty 10	70 kg adult 2 L/day (.029 L/kg- day)	20%	14 ppt
ATSDR	0.003	Neurodevelop and skeletal effects in mice	LOAEL	PK model HED	300	N/A	N/A	N/A

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### EPA Hosted PFAS Meeting (May, 22-23, 2018) 4 Step Action Plan

- ▶ EPA will initiate steps to evaluate the need for a maximum contaminant level (MCL) for PFOA and PFOS.
- ▶ EPA is initiating steps to designate PFOA and PFOS as "hazardous substances" through one of the available statutory mechanisms
- ▶ EPA is currently developing groundwater cleanup recommendations for PFOA and PFOS at contaminated sites and will complete this task by fall of this year.
- ▶ EPA is taking actions with our federal and state partners to develop toxicity values for GenX and PFBS.




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EPA will initiate steps to evaluate the need for a maximum contaminant level (MCL) for PFOA and PFOS.

- ▶ MCL development is a slow-moving train. Follows a detailed SDWA process
- ▶ Not a lot of movement since the May Summit
- ▶ Acting Adm. Andrew Wheeler to release PFAS Management Plan in Fall, 2018



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EPA is initiating steps for designating PFOA and PFOS as "hazardous substances" through one of the available statutory mechanisms

- ▶ OLEM chaired intra-agency workgroup began statutory analysis in June
- ▶ Regular conference calls that include EPA Regional reps.
- ▶ Breadth of listing is at issue (e.g., include GenX, PFBS, PFNA, etc.)
- ▶ Exploring multiple regulatory mechanisms:
  - ▶ CWA sections 311 and 307(a)
  - ▶ CAA section 112
  - ▶ RCRA section 3001
  - ▶ TSCA section 7
  - ▶ CERCLA section 102

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EPA is currently developing groundwater cleanup recommendations for PFOA and PFOS at contaminated sites

- ▶ Scheduled to be completed by the Fall, 2018
- ▶ Draft guidance currently under internal EPA review
- ▶ Existing OW Health Advisory is 70 ppt

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EPA is taking actions with our federal and state partners to develop toxicity values for GenX and PFBS.

- ▶ OW the lead for GenX; ORD the lead for PFBS
- ▶ Focused on oral Reference Doses (RfDs)
- ▶ No inhalation toxicity assessment (i.e., RfC)
- ▶ Cancer assessment
  - ▶ No evidence for PFBS
  - ▶ Insufficient evidence for GenX
- ▶ Both drafts had positive peer reviews

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### The Role of Biomonitoring Programs

Newburgh, NY – a Tale of Two Cities  
Population approx. 30,000  
Post-Industrial River Town 50 Miles North of NYC



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### Newburgh's Reservoir Contaminated with PFOS



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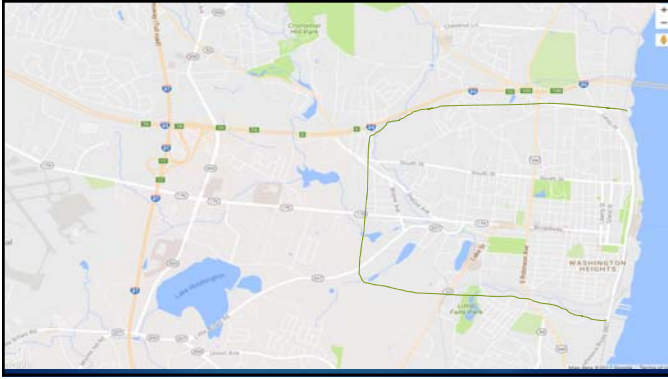
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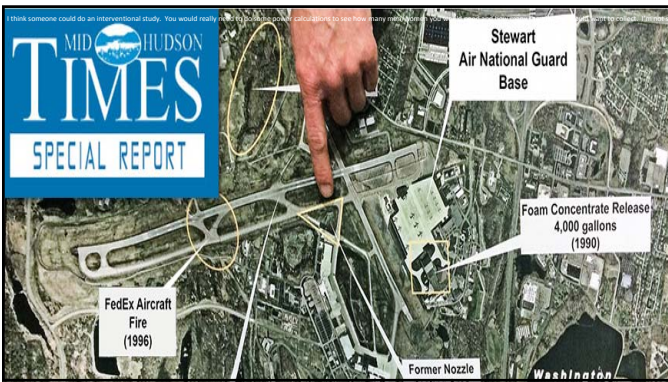
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### Newburgh UCMR Results

Prior to May 19<sup>th</sup> 2016, the EPA Short-Term Health Advisory for PFOS was 200 ppt

- PFOS contamination was first detected and reported to the U.S. EPA in 2014 as part of the EPA Unregulated Contaminant Monitoring Rule requiring large water supplies to test for select unregulated contaminants.
- From December 2013 to October 2014, the City collected four samples that had detections of PFOS ranging from 140 to 170 ppt and reported these results to EPA and to the public in Annual Water Quality Reports.

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## Newburgh PFOS Time line

**City of Newburgh**  
Press Release

83 Broadway, Newburgh, N.Y. 12550  
(845) 569-7301 – Fax: (845) 569-7370

*For immediate release*  
May 2, 2016

**STATE OF EMERGENCY DECLARED IN THE CITY OF NEWBURGH**

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## WITH NEW EPA ADVISORY, DOZENS OF COMMUNITIES SUDDENLY HAVE DANGEROUS DRINKING WATER

David Sinden  
Nov. 20, 2016, 11:30 a.m.

**THE EPA ANNOUNCED** new drinking water health advisory levels today for the industrial chemicals PFPA and PFOS. The new levels – 47 parts per billion (ppb) for both chemicals – are significantly lower than standards the agency issued in 2005, which were 4 ppb for PFPA and 2 ppb for PFOS. In areas where both PFPA and PFOS are present, the advisory suggests a maximum treatment level of 47 ppb. While the old levels were calculated based on the assumption that people were drinking the contaminants only for weeks or months, the new standards assume lifetime exposure and reflect more recent research.

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## Response to Newburgh to PFOS Contamination in Washington Lake

- ▶ Lead agency NYSDEC/NYSDOH
- ▶ Municipal water supply switched to Brown's Pond then to NYC Catskill aqueduct
- ▶ Washington Lake water level rise > pump and treat with mobile GAC
- ▶ Permanent GAC filtration system being installed - October, 2017 deadline
- ▶ NYSDOH "Catch and Release" Advisory for Washington Lake (7/24/17)
- ▶ NYSDOH PFOS blood sampling program
  - ▶ Approx 3,000 have applied for testing
  - ▶ Approx 1,500 blood samples obtained
  - ▶ Preliminary results (N = 495)

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## E-mail MM to City Manager, Michael Claravino (2/16/17)

- ▶ Thought the call went well yesterday. If I were to make an educated pharmacokinetic guesstimate of a central tendency (e.g., arithmetic mean) value for serum PFOS level in the first batch of residents tested, it would be 20 ug/liter +/- 5 ug/liter.

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**Department of Health**  
 INFORMATION SHEET March 2017  
 Newburgh Area PFC Biomonitoring Group-Level Results

**TABLE 2**  
**PFOS and PFOA blood test results by gender and age group**  
 For residents currently served by City of Newburgh public water  
 Participants tested November 1 – January 29, 2017

	Number of participants	PFOS level in µg/L		PFOA level in µg/L	
		Geometric mean	50 <sup>th</sup> percentile	Geometric mean	50 <sup>th</sup> percentile
<b>Total</b>	495	19.3	20.2	3.3	3.3
<b>By gender</b>					
Females	271	18.0	18.5	3.2	3.1
Males	222	20.9	22.2	3.5	3.5
<b>By age group</b>					
0-17	71	8.7	8.7	2.1	2.0
18-39	92	12.4	12.9	2.3	2.4
40-59	139	19.5	19.8	3.3	3.2
60 and older	193	31.7	34.8	4.6	4.9

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## Interpretation of Serum PFAS Results

- ▶ Compare to background
  - ▶ General U.S population 12 and older (NHANES 2013-2014)
    - ▶ PFOA 50<sup>th</sup> percentile = 2.1 ug/l (Hoosick Falls 30X higher)
    - ▶ PFOS 50<sup>th</sup> percentile = 5.2 ug/l (Newburgh 4X higher)
- ▶ Limited clinical usefulness
  - ▶ C-8 (PFOA) medical monitoring program
    - ▶ Pregnancy-induced hypertension, kidney/testicular cancer, thyroid disease, ulcerative colitis, and **hypercholesterolemia**
- ▶ Potential utility > identify individuals for "clinical intervention"
  - ▶ PFAS glacial biological T<sub>1/2</sub> (PFOA = 2-4 yrs; PFOS = 4-6 yrs)
  - ▶ Expedite elimination (Hoosick Falls public meeting)

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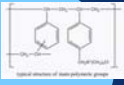
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## Cholestyramine (CSM) to Reduce Biological Half Life of PFAS

- ▶ Anion Exchange Resin FDA Approved For Treatment Of Hyperlipidemia
- ▶ Sequesters Bile Acids Secreted Into GI Lumen - Not Absorbed
- ▶ 3M Report (1999)
  - ▶ CSM Treatment - 9.5 Fold Increase In Fecal Elimination In Rats
  - ▶ "Supports The Concept Of Using CSM In Humans To Promote Excretion Of PFOS"
- ▶ Gastrointestinal Elimination Of Perfluorinated Compounds Using Cholestyramine
  - ▶ Limited (n=8) clinical study
  - ▶ Measured fecal PFAS elimination pre and post CSM treatment
- ▶ CB study - small subset (N = 36 ) of larger biomonitoring cohort (N = 54,000) incidentally maintained on CSM regimen had a dramatic reduction in serum PFOS concentration
  - ▶ Alan Ducatman, MD Re: CB, Impacted community. "Cholestyramine is doing something for sure to PFOS"
- ▶ 2019 EPA/ORD funded proof-of concept study
  - ▶ PFAS pre-treated zebrafish will be dosed with CSM
  - ▶ Measure reduction in body burden compared to control group



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## The End

## Questions?



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## Perfluoroalkyl substances (PFAs) including PFOA and PFOS

Risk Assessment 101

Judith Schreiber, Ph.D.  
Schreiber Scientific, LLC

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### Major Points

- PFAs are a class of chemicals containing fluorine that are persistent in the environment and in animals and people, remaining for many years
- Adverse effects from exposure are significant at low levels as evidenced by animal and human studies. 'Acceptable levels' therefore are low.
- Proposed MCLs and advisories differ due to selection of critical studies, differences related to uncertainty factors, default assumptions and modifying factors

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### What are Perfluorinated Chemicals?

- A large class of chemicals called perfluorochemicals containing fluorine which include Perfluorooctanoic acid (PFOA) and Perfluorosulfonic acid (PFOS), and many variations commonly referred to as Perfluoroalkyl substances (PFAs). The majority of studies have evaluated PFOA and PFOS
- They do not occur naturally and are found in the environment as a result of manufacture, widespread industrial and consumer uses, and disposal.
- PFAs are extremely persistent, are resistant to environmental degradation, and remain in soil, water, dust, food and other sources.

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### Why are health authorities concerned?

- Widespread usage has resulted in the ubiquitous presence of PFAs in rivers, soil, air, house dust, food, and in drinking water from both surface and groundwater sources, generally at low levels.
- With half-lives of many years, PFAs also persist in people and are found in the blood serum of almost all US residents and populations worldwide.
- Drinking water becomes the predominant source of exposure in communities with drinking water supplies that are contaminated with PFAs.

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### Toxicity

- Human and animal studies have identified similar adverse effects and cancer risks
- In experimental animals, PFAs have been found to cause immune, neurobehavioral, liver, endocrine and metabolic toxicity, generally at levels well above human exposures to the general population
- However, in exposed populations ingesting contaminated drinking water, concentrations may approach levels that increase risks of adverse effects

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### Developmental and Early Childhood Concerns

- Prenatal exposure of mice to PFOA and other PFAs found effects including delayed mammary gland development, fewer terminal end buds, and increased liver weights in the offspring
- Evidence of effects on children include delayed mammary gland development, later age at menarche (menstruation), effects on renal function, and asthma
- Adverse effects on sperm quality in men, and endometriosis in US women have been reported, which may be related to prior exposures

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### Developmental and Early Childhood Concerns

- The US Environmental Protection Agency's assessment found that "exposure to PFOA and PFOS over certain levels may result in adverse effects, including developmental effects to fetuses during pregnancy or to breastfed infants"
- These effects include low birthweight, accelerated puberty, skeletal variations, liver effects, immune effects, thyroid effects, cholesterol changes, and cancer (testicular and kidney)
- The Agency for Toxic Substance and Disease Registry (part of the Centers for Disease Control) produced an 800 page Public Comment Draft which came to similar conclusions

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### Cancer Risks

- Toxicological studies in rodents have found increases in tumors related to exposure to PFAs
- Evidence of carcinogenic effects of these chemicals in humans are based primarily on occupational studies which found increases in kidney cancer and testicular cancer
- The USEPA Science Advisory Board, the International Agency for Research on Cancer, and the report of the C8 scientific advisory panel have identified these chemicals as likely carcinogens

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### Cancer Risks

- For non-occupational exposure, a study in a New Jersey community with significantly elevated PFAs in drinking water, elevated incidence of kidney and testicular cancers were identified
- New York State Department of Health community study in the Hoosick Falls area did not find increased cancer risk in a limited study. A new more comprehensive study is being conducted.

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### Risk Assessment

- How do health authorities develop Maximum Contaminant Levels (MCLs)?
- Why are there differing proposed MCLs and Advisories?
- Similar to legal issues, the science is not 'black or white', but shades of grey subject to interpretation
- Professional judgement in study evaluation and uncertainties

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### Evaluation of research studies

- Hundreds of studies have been performed to evaluate harmful effects – some show effects while others do not
- The weight of evidence shows that similar effects are seen in animals and humans
- It is clear that PFAs cause adverse effects, but there are differences in how animals and humans absorb, distribute and eliminate these chemicals

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### Identification of studies demonstrating effects at low levels

- Neurodevelopmental and skeletal effects in mice
- Delayed eye opening and and decreased pup weight in rats
- Developmental effects on bone growth and male puberty
- Mammary gland effects and increased liver weights
- Immunological effects in animals and people

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### Uncertainty Factors used in Risk Assessment

- Risk assessment for public health protection must account for not only what is known about a chemical's adverse effects, but also what is not known about differences between animals and humans, children compared to adults, differences in absorption, metabolism and excretion, and other unknowns
- How do we account for these differences and unknowns?

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### Uncertainty Factor for Human Variation

- Human variation
- An Uncertainty Factor of 10 (UF H) is applied to account for variation in susceptibility across the human population, and to account for the possibility that the available data may not protect individuals who are most sensitive to the effect
- We do not want people exposed to the levels that are affiliated with harm

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### Uncertainty Factor for Animal and Human Differences

- Uncertainty Factor for Animal and Human Differences (UF A)
- In the case of PFAs, there are substantial differences between humans and animals in how these chemicals are absorbed, distributed and metabolized. The Uncertainty Factor for animal and human differences is generally 3 or 10, determined using professional judgement
- The ramifications of these differences on the developmental effects, toxic effects and cancer risks are not well-understood

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### Uncertainty Factors for 'Lowest-Observed-Effect-Level' Studies

- Animal studies sometimes find effects even at the lowest dose tested
- In these situations, an Uncertainty Factor is applied to protect against effects that may have been seen at lower dose levels
- Uncertainty Factor (UF LOEL of 10 or 3) is typically applied

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### Uncertainty Factor for Less than Chronic Studies

- The suitability of using sub-chronic studies for risk assessment is evaluated
- When test dosing may be only several weeks or months (sub-chronic) rather than lifetime, other chronic effects may have been found if the study duration were longer.
- Uncertainty Factor (UF SC of 10)

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### Uncertainty Factor for Database

- Uncertainty Factor (UF data) to account for incomplete database upon which to evaluate adverse health effects
- When data are not available for a complete understanding, an Uncertainty Factor of 10 is applied
- Especially when the database does not adequately address organ systems or lifestage at doses that are lower than those that increase risk of other effects.

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### Why do MCLs differ among health authorities?

- Risk assessments conducted by health authorities and others have evaluated the available data, but have calculated 'acceptable' levels that differ from one another
- All are in the parts per trillion (ppt) range, acknowledging the serious effects at low levels of exposure
- Differences occur due to inconsistent application of uncertainty factors, selection of the studies used, and determination of which adverse effect is used in the risk assessment

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### PFASs in context with other chemicals of concern

- The range of proposed MCLs and advisories for PFAs is from 1 ppt to 70 ppt
- Let's put this in context of other environmental contaminants of concern.
- The MCL for polychlorinated biphenyls (PCBs) is 0.5 parts per billion (ppb) in drinking water, equal to 500 ppt.
- The MCL for benzene is 5 ppb, equal to 5,000 ppt
- These MCLs are far higher than even the highest MCL proposed for PFAs of 70 ppt, indicating the high degree of concern regarding exposure to these chemicals

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### The Bottom Line

- To protect public health and the environment, PFASs should be minimized to prevent continued exposure
- Health authorities agree that these chemicals are highly toxic, cause developmental effects, increase cancer risks, and will remain in body tissue for many years even after exposure stops
- EPA, ATSDR (CDC), as well as states with advisories have developed drinking water levels in the parts per trillion range demonstrating the seriousness of exposure to these chemicals

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# Per- and Polyfluoroalkyl Substances (PFAS)

## Frequently Asked Questions

### What are PFAS?

PFAS are a large group of man-made chemicals that have been used since the 1950s. Use of some of these chemicals has decreased in the United States over the last 10 years. People can still be exposed to PFAS because they are still present in the environment. PFAS do not break down easily in the environment. They also build up in the bodies of exposed humans and animals. Over the last decade, interest in PFAS has grown.

### How can I be exposed to PFAS?

ATSDR and our state health partners are studying exposure to PFAS at a number of sites. PFAS are found near areas where they are manufactured or used. Listed below are places where they can be found.

- Public water systems and drinking water wells, soil, and outdoor air near industrial areas with frequent PFAS use
- Indoor air in spaces that contain carpets, textiles, and other consumer products treated with PFAS to resist stains
- Surface water (lakes, ponds, etc.) and run-off from areas where aqueous (water-based) film-forming fire fighting foam (AFFF) was often used (like military or civilian airfields)
- Locally caught fish from contaminated bodies of water
- Food items sold in the marketplace

### Consumer products can be source of exposures to PFAS. These products include

- Some grease-resistant paper, fast food wrappers, microwave popcorn bags, pizza boxes, and candy wrappers
- Nonstick cookware such as Teflon<sup>®1</sup> coated pots and pans
- Stain resistant coatings such as Scotchguard<sup>®1</sup> used on carpets, upholstery, and other fabrics
- Water resistant clothing such as Gore-Tex<sup>®1</sup>
- Cleaning products
- Personal care products (shampoo, dental floss) and cosmetics (nail polish, eye makeup)
- Paints, varnishes, and sealants

Recent efforts to stop using some PFAS in consumer products appear to have lowered exposure in the U.S. population. CDC surveys have shown that blood levels of PFAS have dropped over time. People who work with PFAS are more likely to be exposed than the general population. Workers may be exposed to PFAS by inhaling them, getting them on their skin, and swallowing them, but inhaling them is the most likely route for exposure.

### How can I reduce my exposure to PFAS?

PFAS are found in people and animals all over the world. They are found in some food products and in the environment (air, water, soil, etc.). Completely stopping exposure to PFAS is unlikely. But, if you live near sources of PFAS contamination you can take steps to reduce your risk of exposure to PFAS:

- Some states have warnings about eating fish from bodies of water with high PFAS levels. Check with your state public health and environmental quality departments to learn the types and local sources of fish that are safe to eat.
- If your water contains PFAS, you can reduce exposure by using an alternative or treated water source for drinking, food preparation, cooking, brushing teeth, and any activity that might result in ingestion of water.
- It is safe to shower and bathe in PFAS-contaminated water. Neither routine showering or bathing are a significant source of exposure. Studies have shown very limited absorption of PFAS through the skin.

## How can PFAS affect people's health?

Scientists are not sure about the health effects of human exposure to PFAS. Some studies in humans have shown that certain PFAS may affect the developing fetus and child, including possible changes in growth, learning, and behavior. In addition, they may decrease fertility and interfere with the body's natural hormones, increase cholesterol, affect the immune system, and even increase cancer risk.

- PFAS build up and stay in the human body and the amount goes down very slowly over time. So scientists and doctors are concerned about their effects on human health.
- Some studies show that animals given PFAS have changes in the liver, thyroid, pancreas, and hormone levels. Scientists are not sure what animal data means about human health. PFAS act differently in humans than they do in animals and may be harmful in different ways.

## How can I learn more?

Contact 1-800-CDC-INFO for updated information on this topic.

Contact the Consumer Product Safety Commission at (800) 638-2772 if you have questions about the products you use in your home.

Visit the following websites for more information:

### ATSDR Websites

<http://www.atsdr.cdc.gov/pfc/index.html>

### Environmental Protection Agency

<http://www2.epa.gov/chemical-research/perfluorinated-chemical-pfc-research>

## List of Common PFAS and Their Abbreviations

Compound	Abbreviation
Perfluorobutane sulfonate	PFBS
Perfluorohexane sulfonate	PFHxS
Perfluorooctane sulfonate	PFOS
Perfluoroheptanoic acid	PFHpA
Perfluorooctanoic acid	PFOA
Perfluorononanoic acid	PFNA
Perfluorodecanoic acid	PFDA
Perfluoroundecanoic acid	PFUnA
Perfluorododecanoic acid	PFDoA
Perfluorooctane sulfonamide	PFOSA
2-(N-Methyl-perfluorooctane sulfonamido) acetate	Me-PFOSA-AcOH
2-(N-Ethyl-perfluorooctane sulfonamido) acetate	Et-PFOSA-AcOH

### Notes

<sup>1</sup>Use of trade names is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry, the Public Health Service, or the U.S. Department of Health and Human Services

## 1 Introduction

Per- and polyfluoroalkyl substances (PFAS) became contaminants of emerging concern in the early 2000s. In recent years federal, state, and international authorities have established a number of health-based regulatory values and evaluation criteria. The terms ‘regulatory’ or ‘regulation’ are used in this fact sheet to refer to requirements that have gone through a formal process to be promulgated and legally enforceable as identified under local, state, federal, or international programs. The terms ‘guidance’ and ‘advisories’ apply to all other values.

## 2 Regulation of PFAS

The scientific community is rapidly recognizing and evolving its understanding of PFAS in the environment, causing an increased pace of development of guidance values and regulations. A recent analysis of data acquired under the USEPA’s Unregulated Contaminant Monitoring Rule (UCMR) program found that approximately six million residents of the United States had drinking water with concentrations of perfluorooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS), or both, above the USEPA’s Lifetime Health Advisory (LHA) of 70 nanograms per liter (ng/L, equivalent to parts per trillion [ppt]) (Hu et al. 2016). Many of the public water systems with detections of PFOA or PFOS above the USEPA LHA have taken action to reduce these levels. However, most public water systems that supply fewer than 10,000 customers and private wells were not included in the third round of monitoring, or UCMR3 program, and remain untested.

Human health protection is the primary focus of the PFAS regulations, guidance, and advisories developed to date. The values for PFOS and PFOA can vary across programs, with differences due to the selection and interpretation of different key toxicity studies, choice of uncertainty factors, and approaches used for animal-to-human extrapolation. The choice of exposure assumptions, including the life stage and the percentage of exposure assumed to come from non-drinking water sources, may also differ (see Table 5-1).

In addition to values that specify health-based concentration limits, agencies have used various strategies to limit the use and release of PFAS. For example, the USEPA worked with 3M to achieve the company’s voluntary phase-out and elimination of PFOS (USEPA 2000), and with the eight primary U.S. PFOA manufacturers to eliminate or reduce PFOA and many PFOA precursors by 2015 (USEPA 2017a). Buck et al. (2011) define precursors as PFAS polymers or other functional derivatives that contain a perfluoroalkyl group and “degrade in the environment to form PFOS, PFOA, and similar substances.” Additionally, the Organisation for Economic Cooperation and Development OECD (2015a) has described various international policies, voluntary initiatives, biomonitoring, and environmental monitoring programs to control PFAS. More information is in the *History and Use Fact Sheet*.

## 3 Regulatory Programs

Authority for regulating PFAS is derived from a number of federal and state statutes, regulations, and policy initiatives. This section provides a brief overview of the major federal statutes and regulatory programs that govern PFAS, along with examples of representative state regulatory programs.

### 3.1 Federal PFAS Regulations

#### 3.1.1 Toxic Substances Control Act (TSCA)

The TSCA authorizes the USEPA to require reporting, record-keeping, and testing of chemicals and chemical mixtures that may pose a risk to human health or the environment. Section 5 of TSCA allows the USEPA to issue Significant New Use Rules (SNURs) to limit the use of a chemical when it is newly identified, or a significant new use of an existing chemical is identified, before it is allowed into the marketplace (USEPA 2017a). The USEPA has applied a SNUR to PFOS in four separate actions and to 277 chemically-related PFAS (USEPA 2017i). Collectively, these SNURs placed significant restrictions on the use and import of PFAS, allowing only limited uses in select industries and for certain applications. In

ITRC has developed a series of six fact sheets to summarize the latest science and emerging technologies regarding PFAS. The purpose of this fact sheet is to:

- describe the primary state and U.S. federal programs that are being used to regulate PFAS
- summarize current regulatory and guidance values for PFAS in groundwater, drinking water, surface water/effluent, and soil (Tables 4-1 and 4-2)
- provide information (summarized in Tables 5-1 and 5-2) regarding the basis for differences between various drinking water criteria for perfluorooctanoate (PFOA) and perfluorooctane sulfonate (PFOS)

## Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS) *continued*

In addition, one of the rules required companies to report all new uses in the manufacture, import, or processing of certain PFOA-related chemicals for use in carpets or for aftermarket treatment. A recently proposed SNUR (USEPA 2015c) would designate the manufacture, import, and processing of certain PFOA and PFOA-related chemicals (long-chain perfluoroalkyl carboxylates [PFCAs]) as a significant new use. The significant new use would apply to any use that is not ongoing after December 31, 2015, and for all other long-chain PFCAs for which there is currently no ongoing use (USEPA 2015a).

### 3.1.2 Safe Drinking Water Act (SDWA)

The SDWA is the federal law that protects public drinking water supplies throughout the nation (USEPA 1974). Under the SDWA, the USEPA has authority to set enforceable Maximum Contaminant Levels (MCLs) for specific chemicals and require testing of public water supplies. The SDWA applies to all public water systems in the United States but does not apply to private domestic drinking water wells nor to water not being used for drinking.

USEPA has not established MCLs for any PFAS. However, in May 2016, USEPA established an LHA for PFOA and PFOS in drinking water of 70 ng/L. This LHA is applicable to PFOA and PFOS individually, or in combination, if both chemicals are present at concentrations above the reporting limit (USEPA 2016b, c). The LHA supersedes USEPA's 2009 short-term (week to months) provisional Health Advisories of 200 ng/L for PFOS and 400 ng/L for PFOA (USEPA 2009c), which were intended for use as interim guidelines while USEPA developed the LHA. The LHA for PFOA and PFOS is advisory in nature; it is not a legally enforceable federal standard and is subject to change as new information becomes available (USEPA 2016b, c).

Much of the current data available regarding PFAS in public drinking water was generated by USEPA under UCMR3 (USEPA 2017f). USEPA uses the UCMR to collect data for chemicals that are suspected to be present in drinking water but do not have health-based standards set under the SDWA. The third round of this monitoring effort, or UCMR3, included six PFAS:

- perfluorooctanesulfonic acid (PFOS)
- perfluorooctanoic acid (PFOA)
- perfluorononanoic acid (PFNA)
- perfluorohexanesulfonic acid (PFHxS)
- perfluoroheptanoic acid (PFHpA)
- perfluorobutanesulfonic acid (PFBS)

Samples were collected during a consecutive 12-month monitoring period between 2013 and 2015 from large public water systems (PWS) serving more than 10,000 people, and a limited number of smaller systems determined by USEPA to be nationally representative. Some of the six PFAS mentioned above were detected in 194 out of 4,920 PWS tested (~4%), which serve about 16.5 million people in 36 states and territories (Hu et al. 2016). However, Hu et al. (2016) note that the UCMR3 data may under-report the actual presence of low-level PFAS due to the relatively high reporting limits for EPA method 537.

**Table 3-1. UCMR3 occurrence data**

Exceed LHA (70 ppt)	Number of PWS	Percent of PWS
PFOS	46	0.9 %
PFOA	13	0.3 %
Σ PFOA + PFOS <sup>1</sup>	63	1.3 %
Note 1: PWS that exceeded the combined PFOA and PFOS health advisory (USEPA 2016d; 2017o)		

Many of the public water systems where PFOA or PFOS were detected in UCMR3 above the USEPA LHA have taken action to reduce these levels. Occurrence data produced by the UCMR program are used by the USEPA, as well as some states, to help determine which substances to consider for regulation. All of the data from the UCMR program are published in the National Contaminant Occurrence Database (NCOD) and available for download from USEPA's website (USEPA 2017f).

## Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS) *continued*

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When the USEPA determines there may be an imminent and substantial endangerment from a contaminant that is present in or likely to enter a public water supply, under Section 1431 of the SDWA USEPA may issue Emergency Administrative Orders (EAOs) to take any action necessary to protect human health if state and local authorities have not acted (42 U.S.C. §300i). USEPA has issued at least three such EAOs to protect public and private water supply wells contaminated with PFAS (USEPA 2009d; 2014b; 2015a).

### **3.1.3 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)**

PFAS, including PFOA and PFOS, are not listed as CERCLA hazardous substances but may be addressed as CERCLA pollutants or contaminants (40 CFR 300.5). CERCLA investigations are beginning to include PFAS when supported by the conceptual site models (for example, USEPA 2017c). PFAS have been reported for 14 CERCLA sites during 5-year reviews (USEPA 2014a).

CERCLA does not contain any chemical-specific cleanup standards. However, the CERCLA statute requires, among other things, that Superfund response actions ensure protectiveness of human health and the environment, and comply with federal laws and regulations that constitute “applicable or relevant and appropriate requirements” (ARARs); the statute also provides possible ARAR waivers in limited circumstances. The lead agency (as defined in 40 CFR 300.5) identifies potential ARARs and to-be-considered values (TBCs), based in part on the timely identification of potential ARARs by states. Risk-based goals may be calculated and used to determine cleanup levels when chemical-specific ARARs are not available or are determined not to be sufficiently protective (USEPA 1997).

#### **3.1.3.1 CERCLA Protection of Human Health**

The tables in Section 4 include current state regulatory and guidance values for PFAS. These values are not automatically recognized as ARARs. In the Superfund program, USEPA Regions evaluate potential ARARs, including state standards, on a site-specific basis to determine whether a specific standard or requirement is an ARAR for response decision and implementation purposes. Determining if a state requirement is promulgated, substantive, and enforceable are some of the factors in evaluating whether a specific standard may constitute an ARAR (40 CFR 300.5; 40 CFR 300.400(g); USEPA 1988; USEPA, 1991).

Risk-based cleanup goals are calculated when chemical-specific ARARs are not available or are determined not to be protective (USEPA 1997). The USEPA’s Regional Screening Level (RSLs) Generic Tables (USEPA 2017m) and the RSL online calculator (USEPA 2017l) provide screening levels and preliminary remedial goals. These goals are based on toxicity value calculations that have been selected in accordance with the USEPA’s published hierarchy (USEPA 2003a). Currently, PFBS is the only PFAS listed in the RSL generic tables. For PFBS, the generic tables provide a non-cancer reference dose, screening levels for soil and tap water, and soil screening levels for the protection of groundwater. The RSL calculator supports site-specific calculations for PFBS, PFOA, and PFOS in tap water and soil. Non-cancer reference doses are provided for PFOA and PFOS. A cancer ingestion slope factor is also provided for PFOA, but screening levels are based on the non-cancer endpoint. Although less frequently used, the USEPA also provides tables and a calculator for Removal Management Levels (RMLs). In general, RMLs are not final cleanup levels, but can provide a reference when considering the need for a removal action (for example, drinking water treatment or replacement) (USEPA 2016a).

Because RSLs and RMLs are periodically updated, they should be reviewed for revisions and additions before using them. RSLs and RMLs are not ARARs, but they may be evaluated as TBCs. The USEPA has emphasized that RSLs are not cleanup standards (USEPA 2016g) and suggests that final remedial goals be derived using the RSL calculator so that site-specific information can be incorporated.

#### **3.1.3.2 CERCLA Protection of the Environment**

CERCLA requires that remedies also be protective of the environment. Risk-based cleanup goals that are protective of the environment are site-specific and depend on the identification of the protected ecological receptors.

### **3.1.4 Other Federal Programs**

PFAS are not currently regulated under the Resource Conservation and Recovery Act (RCRA), the Clean Water Act (CWA), nor the Clean Air Act (CAA).

## Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS) *continued*

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### 3.2 State PFAS Regulations

Several states have been actively involved with addressing PFAS contamination across multiple regulatory programs. Examples of key state programs for water, soil, remediation, hazardous substances, and consumer products are described below, and information about regulatory, advisory and guidance values are discussed in Section 4 and presented in Tables 4-1 and 4-2. At the present time, no state requires monitoring of public water supplies for PFAS. The Texas Risk Reduction Program (TRRP) has derived risk-based inhalation exposure limits (RBELs) for select PFAS. These RBELs are applicable to PFAS that may volatilize from soil to air at remediation sites managed under the TRRP rule (Texas Commission on Environmental Quality [TCEQ], 2017).

#### 3.2.1 Product Labeling and Consumer Products Laws

PFOS, PFOA, and their salts are under consideration for 'Listing' as potential Developmental Toxicants under California's Proposition 65 (Office of Environmental Health Hazard Assessment [CA OEHHA] 2016). If finalized, the listing will include labeling requirements for manufacturers, distributors, and retailers, and will prohibit companies from discharging these PFAS to sources of drinking water. Washington has required the reporting of PFOS in children's products since 2011 (Washington State 2008). Proposed rules would require reporting of PFOA in children's products starting in January 2019. Washington also tests products for chemicals to ensure manufacturers are reporting accurate information.

#### 3.2.2 Chemical Action Plans

Washington prepares chemical action plans (CAPs) under an administrative rule that addresses persistent, bioaccumulative, and toxic (PBT) chemicals (Washington State 2006). These CAPs are used to identify, characterize, and evaluate uses and releases of specific PBTs or metals. Washington is currently preparing a PFAS CAP that is expected to be completed in 2018.

#### 3.2.3 Designation as Hazardous Waste or Hazardous Substance

Regulations that target select PFAS as hazardous wastes or hazardous substances have been promulgated in Vermont and New York, and are under development in several other states. Vermont regulates PFOA and PFOS as hazardous wastes when present in a liquid at a concentration > 20 ppt, but allows exemptions for: (1) consumer products that were treated with PFOA and are not specialty products; (2) remediation wastes managed under an approved CAP or disposal plan; and (3) sludge from wastewater treatment facilities, residuals from drinking water supplies, or leachate from landfills when managed under an approved plan (VTDEC 2016).

In 2017, the New York State Department of Environmental Conservation (NYDEC) finalized regulations that identify PFOA, ammonium perfluorooctanoate, PFOS (the acid) and its salt, perfluorooctane sulfonate, as hazardous substances that may be found in Class B firefighting foams (NYDEC 2017). The regulations specify storage and registration requirements for Class B foams that contain at least 1% by volume of one or more of these four PFAS, and prohibit the release of one pound or more of each into the environment during use. If a release exceeds the one-pound threshold, it is considered a hazardous waste spill and must be reported; cleanup may be required under the State's Superfund or Brownfields programs (NYDEC 2017).

#### 3.2.4 Drinking Water, Groundwater, Surface Water, Soil, and Remediation Programs

Several states have developed standards and guidance values for PFAS in drinking water and groundwater (see Section 4 tables). Many states have either adopted the USEPA LHAs for PFOA and PFOS or selected the same health-based values, choosing to use the concentrations as advisory, non-regulated levels to guide the interpretation of PFOA and PFOS detections. Other states, such as Vermont, Minnesota, and New Jersey, have developed health-based values based on their own analysis of the scientific data. Michigan is currently the only state that regulates certain PFAS in surface water, although Minnesota has established enforceable discharge limits for specific waterbodies. New Jersey has adopted an Interim Ground Water Quality Standard for PFNA, and its drinking water advisory body has recommended proposed MCLs for PFOA and PFNA. While several states have adopted enforceable groundwater standards for PFOA and PFOS, no state other than New Jersey currently has MCLs (or proposed MCLs) for PFAS.

In California, when evaluating the discharge or cleanup of chemicals, the Regional Water Quality Control Boards (RWQCBs) are required to initially set the effluent limitation or cleanup standard at the background concentration of each chemical. This is done regardless of whether there is a drinking water standard or other health-based value available. For anthropogenic chemicals such as PFAS, the initial value is the analytical detection limit in water. Technical, economic, and health-based criteria are also considered (for example, CA RWQCB 2016).



## Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS) *continued*

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Various states address the remediation of PFAS in groundwater and soil; guidance and advisory values may be used by state remediation programs to determine site-specific cleanup requirements (see Section 4 tables). Texas has developed toxicity criteria for 16 PFAS under the TRRP (TCEQ, 2017). These criteria are used to calculate risk-based soil and groundwater values and can also be used for other media such as sediment and fish tissue.

### 4 Available Regulations, Advisories, and Guidance

Regulatory, advisory, and guidance values have been established for PFOS, PFOA, and several other PFAS in environmental media as well as various terrestrial biota, fish, and finished products. Tables 4-1 and 4-2, provided as a separate Excel file, are intended to identify currently available U.S. and international standards and guidelines for groundwater, drinking water, surface water, and effluent or wastewater (Table 4-1), and soil (Table 4-2). The available standards list is changing rapidly. These tables are published separately so they can be updated periodically by ITRC. The fact sheet user should visit the ITRC web site ([www.itrcweb.org](http://www.itrcweb.org)) to access current versions of the tables.

Table 4-1 presents the available PFAS water values established by the USEPA, each pertinent state, or country (Australia, Canada and Western European countries). The specific agency or department is listed with the year it was published, the media type (groundwater, drinking water, surface water, or effluent), and whether it was published as guidance or as a promulgated rule.

Table 4-2 presents the available PFAS soil values established by the USEPA, each pertinent state, or country (Australia, Canada and Western European countries). Soil screening levels for both groundwater protection and human health are presented. The specific agency or department is listed with the year the value was published.

### 5 Basis of Standards and Guidance

Drinking contaminated water is a potential source of human exposure (see reviews in Lindstrom et al. 2011; NJ DWQI 2017a). As noted above, UCMR3 sampling detected PFOA or PFOS concentrations above the EPA Lifetime HA of 70 ng/L in the source water for municipal systems that supply approximately 6 million U.S. residents (Hu et al 2016). Although there are other potential sources that may lead to PFAS exposures (for example, consumer products), protection of the potable water supply is the primary driver behind most of the available state and federal regulations and guidance, due to the potential for exposure and the known or presumed toxicity of these compounds.

While numerous animal and human studies have evaluated both non-cancer and cancer health effects related to exposure to a limited number of PFAS, including PFOA and PFOS, little to no health-effects data are available for many PFAS. As a result, many of the available standards and guidance are for PFOA and PFOS. In animal studies, PFOA exposure has been associated with adverse effects on the developmental, reproductive, and immune systems and the liver (see summary of original research in USEPA 2016f). There is also evidence of both PFOA and PFOS affecting immune systems, including reduced disease resistance (National Toxicology Program [NTP] 2016) and tumors in rats (USEPA 2016e, f). These and other effects have also been found in human epidemiological studies (ATSDR 2016; C8SP 2017; USEPA 2016e, f; NTP 2016). The International Agency for Research on Cancer (IARC) concluded that PFOA is “possibly carcinogenic to humans (Group 2B)” (IARC 2016), and USEPA concluded that there is suggestive evidence of carcinogenic potential for both PFOA and PFOS in humans (USEPA 2016e, f).

Tables 5-1 and 5-2, provided as a separate Excel file, summarize the differences in the PFOA (Table 5-1) and PFOS (Table 5-2) values for drinking water in the United States, demonstrating that they are attributable to differences in the selection and interpretation of key toxicity data, choice of uncertainty factors, and the approach used for animal-to-human extrapolation. Differences in values are also due to the choice of exposure assumptions, including the life stage used, and the percentage of exposure assumed to come from non-drinking water sources. Only those agencies that have used science or policy decisions that are different from those of the USEPA LHAs are shown. The available information is increasing rapidly and these tables will be updated periodically by ITRC. The fact sheet user should visit the ITRC web site ([www.itrcweb.org](http://www.itrcweb.org)) to access the current version of the tables.

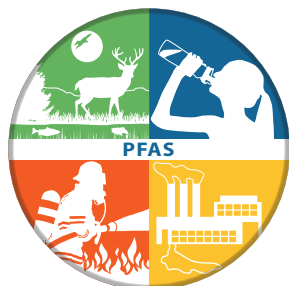
Some states have not yet developed values or adopted the USEPA LHA. It may be appropriate to consult with the lead regulatory authority (local or federal) to determine the appropriate values to use for site evaluation.

# Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS) *continued*

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## 6 References and Acronyms

The references cited in this fact sheet, and the other ITRC PFAS fact sheets, are included in one combined list that is available on the ITRC web site. The combined acronyms list is also available on the ITRC web site.



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ECOS

### Introduction

The purpose of this fact sheet is to provide interim guidance to aid physicians and other clinicians with patient consultations on perfluoroalkyl and polyfluoroalkyl substances (PFAS). It highlights what PFAS are, which chemicals fall into this category of substances, identifies health effects associated with exposure to various PFAS, and suggests answers to specific patient questions about potential PFAS exposure.

### Background

#### What are PFAS?

PFAS, sometimes known as PFCs, are synthetic chemicals that do not occur naturally in the environment. There are many different types of PFAS such as perfluorocarboxylic acids (e.g., PFOA, sometimes called C8, and PFNA) and perfluorosulfonates (e.g., PFOS and PFHxS). PFAS may be used to keep food from sticking to cookware, to make sofas and carpets resistant to stains, to make clothes and mattresses more waterproof, and to make some food packaging resistant to grease absorption, as well as use in some firefighting materials. Because PFAS help reduce friction, they are also used in a variety of other industries, including aerospace, automotive, building and construction, and electronics.

#### Why are PFAS a possible health concern?

According to the U.S. Environmental Protection Agency (EPA), PFAS are considered emerging contaminants. An “emerging contaminant” is a chemical or material that is characterized by a perceived, potential, or real threat to human health or the environment or by a lack of published health standards.

PFAS are extremely persistent in the environment and resistant to typical environmental degradation processes. The pathway for dispersion of these chemicals appears to be long-range atmospheric and oceanic currents transport. Several PFAS and their potential precursors are ubiquitous in a variety of environments. Some long-chain PFAS bioaccumulate in animals and can enter the human food chain.

PFOS and PFOA are two of the most studied PFAS. Exposure to PFOA and PFOS is widespread and global. PFOS and PFOA also persist in the human body and are eliminated slowly. Both PFOS and PFOA can be found in blood, and at much lower levels in urine, breast milk and in umbilical cord blood.

PFOS and PFOA may pose potential adverse effects for human health given their potential toxicity, mobility, and bioaccumulation potential. The likelihood of adverse effects depends on several factors such as amount and concentration of PFAS ingested as well as the time span of exposure.

### Routes of Exposure and Health Effects

#### What are the main sources of exposure to PFAS?

For the general population, ingestion of PFAS is considered the major human exposure pathway. The major types of human exposure sources for PFAS include:

- Drinking contaminated water.
- Ingesting food contaminated with PFAS, such as certain types of fish and shellfish.
- Until recently, eating food packaged in materials containing PFAS (e.g., popcorn bags, fast food containers, and pizza boxes). Using PFAS compounds has been largely phased out of food packaging materials.
- Hand-to-mouth transfer from surfaces treated with PFAS-containing stain protectants, such as carpets, which is thought to be most significant for infants and toddlers.

- Workers in industries or activities that manufacture, manipulate or use products containing PFAS may be exposed to higher levels than the general population.

### **What are other low level exposure sources?**

Individuals can also be exposed by breathing air that contains dust contaminated with PFAS (from soil, carpets, upholstery, clothing, etc.), or from certain fabric sprays containing this substance.

Dermal exposure is a minor exposure pathway. Dermal absorption is slow and does not result in significant absorption.

### **What are the potential PFAS exposure risks to fetuses and children?**

Recent research evaluating possible health effects to fetuses from PFAS exposures have shown that developing fetuses can be exposed to PFAS when umbilical cord blood from their mothers crosses the placenta during pregnancy. It is important to note that different PFAS have varying levels of permeability to the placental barrier.

Newborns can be exposed to PFAS through breast milk. The level of neonatal exposure depends on the duration of breastfeeding. Older children may be exposed to PFAS through food and water, similar to adults. In addition, young children have a higher risk of exposure to PFAS from carpet cleaners and similar products, largely due to time spent lying and crawling on floors in their early years.

### **How long do PFAS remain in the body?**

PFAS with long carbon chains have estimated half-lives ranging from 2-9 years such as:

- PFOA 2 to 4 years
- PFOS 5 to 6 years
- PFHxS 8 to 9 years

### **What are exposure limits for PFAS in drinking water?**

The Environmental Protection Agency (EPA) has published a Lifetime Health Advisory (LTHA) recommending that the concentration of PFOA and PFOS in drinking water, either individually or combined, should not be greater than 70 parts per trillion (0.07 parts per billion). The LTHA concentrations do not represent definitive cut-offs between safe or unsafe conditions, but rather provide a margin of protection for individuals throughout their life from possible adverse health effects. EPA health advisories are non-regulatory recommendations and are not enforceable.

### **What are PFAS levels in the U.S. population?**

Most people in the United States and in other industrialized countries have measurable amounts of PFAS in their blood.

The National Health and Nutrition Examination Survey (NHANES) is a program conducted by the Centers for Disease Control and Prevention (CDC) to assess the health and nutritional status of adults and children in the United States. NHANES (2011–2012) measured the concentration of PFAS in the blood of a representative sample of the U.S. population (12 years of age and older). The average blood levels found were as follows:

- PFOA: 2.1 parts per billion, with 95% of the general population at or below 5.7 parts per billion
- PFOS: 6.3 parts per billion, with 95% of the general population at or below 21.7 parts per billion
- PFHxS: 1.3 parts per billion, with 95% of the general population at or below 5.4 parts per billion

In the last decade, major manufacturers of PFOA and PFOS related products joined EPA in a global stewardship program to phase out production of these agents by 2015. Based on data collected from previous NHANES

cycle years, levels of PFOA and PFOS are generally decreasing in the blood of the general population as a result of this important initiative.

## Health Studies

### How can PFAS potentially affect human health?

Studies in humans and animals are inconsistent and inconclusive but suggest that certain PFAS may affect a variety of possible endpoints. Confirmatory research is needed.

Below are summaries of studies in animals and humans.

#### Animal Studies:

Adverse health effects have been demonstrated in animal studies, but these occurred at exposure levels higher than those found in most people. The main health effects observed were: enlargement and changes in the function of the liver, changes in hormone levels (e.g., reduced testosterone synthesis, potential to affect T<sub>4</sub> and TSH levels) and adverse developmental outcomes. Developmental and reproductive effects, including reduced birth weight, decreased gestational length, structural defects, delays in postnatal growth and development, increased neonatal mortality, and pregnancy loss have all been associated with prenatal rodent exposure to PFOS and PFOA.

#### Human Studies:

##### C8 Health Project

The C8 Health Project was a large epidemiological study conducted because drinking water in six water districts across two states near Parkersburg, West Virginia were contaminated by release of PFOA (also called C8) from the 1950s until 2002 (when the contamination was discovered). These releases migrated and contaminated the air, parts of the Ohio River, and ground water. The study included 69,030 persons ≥18 years of age. The C8 Science Panel analyzed study data and found probable links (as defined by litigation) between elevated PFOA blood levels and high cholesterol (hypercholesteremia), ulcerative colitis, thyroid function, testicular cancer, kidney cancer, preeclampsia, as well as elevated blood pressure during pregnancy. Residents in the area of these releases showed 500 percent higher PFOA-concentrations in blood compared to a representative U.S. population (i.e., NHANES).

**Table 1: Overview of C8 and Other Human Studies**

<b>Cholesterol</b>	<p>Some epidemiological studies demonstrated statistically significant associations between serum PFOA and PFOS levels and total cholesterol in:</p> <ul style="list-style-type: none"> <li>- workers exposed to PFAS, and</li> <li>- residents of communities with high levels of PFOA in the drinking water compared to NHANES data that is representative of the U.S. population.</li> </ul> <p>Other studies have found no association between PFAS exposures and the total cholesterol levels.</p>
<b>Uric acid</b>	<p>Several studies have evaluated the possible association between serum PFOA and serum PFOS levels and uric acid. Significant associations were found between serum PFOA and uric acid levels at all evaluated exposure levels.</p>
<b>Liver effects</b>	<p>A number of human studies have used liver enzymes as biomarkers of possible liver effects. In occupational studies, no associations between liver enzymes and serum PFOA or PFOS levels were consistently found. A study of highly</p>

	exposed residents demonstrated significant associations but the increase in liver enzymes was small and not considered to be biologically significant.
<b>Cancer</b>	<p>The International Agency for Research on Cancer (IARC) has classified PFOA as possibly carcinogenic and EPA has concluded that both PFOA and PFOS are possibly carcinogenic to humans.</p> <p>Some studies have found increases in prostate, kidney, and testicular cancers in workers exposed to PFAS and people living near a PFOA facility. Findings from other studies report otherwise and most did not control for other potential factors including heavy smoking. Additional research is needed to clarify if there is an association.</p>

Note: Additional studies have identified possible associations between ulcerative colitis, thyroid disease and pregnancy induced hypertension and higher exposure to PFAS.

### What health screenings were used in the C8 study?

The C8 Medical Panel suggested health screening to evaluate the C8 study population that included blood tests for cholesterol, uric acid, thyroid hormones and liver function as well as other age or situationally appropriate screenings like blood pressure and urine protein measures. For individual patients exposed to PFAS who are not among the C8 study screening population, there are no official guidelines supporting health screening. However the tests listed above are well established in clinical medicine and may be a consideration to discuss with your patient based on the patient history, concerns and symptoms.

### What are potential health effects from prenatal PFAS exposure to fetuses?

Multiple studies have reported an association between elevated maternal blood and cord blood concentrations of PFAS (primarily PFOS and PFOA) and decreased birth weight. Specifically, one meta-analysis suggests that each 1 ng/mL increase in prenatal PFOA levels is associated with up to 18.9 g reductions in birth weight (Johnson, 2014). Studies have also observed decreased birth weight with prenatal exposures to PFOS. The association between maternal PFAS level and decreased birth weight is not statistically significant across all studies. Further, the observed reduction in birth weight does not consistently equate with increased risk of a low birth weight (LBW) infant. Only one study revealed a statistically significant association between LBW risk and PFOS (Stein 2009); no studies have found a statistically significant association between LBW risk and PFOA.

**Additional studies are needed to conclusively link the relationships between fetal PFAS exposure and health effects.**

## Patient Questions and Key Message Answers

As a clinician, you know careful listening and patient engagement is critical for ensuring quality patient care, especially when health concerns are raised. Perhaps the most difficult challenge in speaking with patients about their health concerns is addressing uncertainty. If your patient has concerns about an exposure to PFAS, you may face the challenge of helping your patient cope with the uncertainty of potential health effects from a PFAS exposure.

Based on feedback from clinicians and from individuals who have spoken to their health care provider about their PFAS exposure concerns, a set of patient questions have been identified. To assist you in speaking with your patients about their concerns, key messages and supporting facts needed to answer the anticipated patient questions are provided in the table below for your information and potential use.

**Table 2: Patient Questions and Key Message**

Questions Patients May Ask	Key Patient Messages	Key Message Supporting Facts
<p><b>There are high levels of PFAS in my water. What should I do?</b></p>	<p>If the water you use is above the EPA health advisory level for PFOA and PFOS, you can reduce exposure by using an alternative water source for drinking, food preparation, cooking, brushing teeth or any activity that might result in ingestion of water.</p>	<p>Potential health effects are associated with exposure to PFAS.</p> <p>EPA has established a lifetime health advisory for PFOA and PFOS in drinking water. This advisory states that the concentration of PFOA and PFOS in drinking water, either individually or combined, should not be greater than 70 parts per trillion.</p> <p>There needs to be additional research to establish levels of health risk, but patients may want to reduce exposures below the EPA health advisory level to be on the safe side.</p> <p>A home water filtration system can reduce the contaminant levels in drinking water. Researchers are still clarifying how to best use home filtration for PFAS contamination. Installing a home filtration system or using a pitcher-type filter may reduce PFAS levels. However, these filters may not reduce PFAS enough to meet the EPA Lifetime Health Advisory (LTHA) level. Three factors determine how much PFAS are removed by filtration. These factors are the PFAS contaminant levels, the type of filter, and how well the filter is maintained. Manufacturers of the filtration system may be able to make recommendations to optimize removal of PFAS. This may include more sophisticated media cartridges or increasing the frequency of exchanging filter media.</p> <p>For bottled water questions (how it is treated and if it is safe) contact the CFSAN Information Center at</p>

Questions Patients May Ask	Key Patient Messages	Key Message Supporting Facts
<p><b>Could my health problems be caused by PFAS exposure?</b></p> <p><b>(Based on the health problems the patient has, there are two possible responses to this question.)</b></p> <p><b>(a)</b> If the patient’s health problem is in the list below, it may potentially be associated with PFAS exposure, based on limited evidence from human studies. The potential health effects include:</p> <ul style="list-style-type: none"> <li>- Thyroid function (potential to affect T<sub>4</sub> and TSH levels)</li> <li>- High cholesterol</li> <li>- Ulcerative colitis</li> <li>- Testicular cancer</li> <li>- Kidney cancer</li> <li>- Pregnancy-induced hypertension</li> <li>- Elevated liver enzymes</li> <li>- High uric acid</li> </ul> <p><b>(b)</b> If the patient’s health problem is not in the bulleted list above, then there is no current evidence that it is related to PFAS exposure. (However, research is ongoing and not all health outcomes have been adequately studied.)</p>	<p><b>(a)</b> Although the evidence is not conclusive, your health problem could potentially be associated with exposure to PFAS. However, health effects can be caused by many different factors, and there is no way to know if PFAS exposure has caused your health problem or made it worse.</p> <p><b>(b)</b> Based on what we know at this time, there is no reason to think your health problem is associated with exposure to PFAS.</p>	<p>1-888-SAFEFOOD (1-888-723-3366).</p> <p>For supporting facts on the listed health effects in this question <b>(a)</b>, see “<b>How can PFAS potentially affect human health.</b>” The information on potential illnesses and health effects will be briefly reviewed for each of these illnesses or health effects. This information can be found in this fact sheet on page 3 and 4.</p> <p>If your patient presents with health concerns that might be associated with PFAS exposure, it is appropriate to discuss the patient’s concerns and perform a thorough health and exposure history and also a physical exam relative to any symptoms reported.</p>
<p><b>Are there future health problems that might occur because of PFAS exposure?</b></p>	<p>We know PFAS can cause health issues but there is no conclusive evidence that predicts PFAS exposure will result in future health problems. We can watch for symptoms related to PFAS associated health problems and investigate any that you notice, especially those that reoccur.</p>	<p>Studies in humans and animals are inconsistent and inconclusive but suggest that certain PFAS can cause possible health effects.</p> <p>Additional research is needed to better understand health risks associated with PFAS exposure.</p>



Questions Patients May Ask	Key Patient Messages	Key Message Supporting Facts
<p><b>Should I get a blood test for PFAS?</b></p>	<p>If you are concerned and choose to have your blood tested, test results will tell you how much of each PFAS is in your blood but it is unclear what the results mean in terms of possible health effects. The blood test will not provide information to pinpoint a health problem nor will it provide information for treatment. The blood test results will not predict or rule-out the development of future health problems related to a PFAS exposure.</p>	<p>There currently is no established PFAS blood level at which a health effect is known nor is there a level that predicts health problems. Most people in the US will have measureable amounts of PFAS in their blood. There are no health-based screening levels for specific PFAS that clinicians can compare to concentrations measured in blood samples. As a result, interpretation of measured PFAS concentrations in individuals is limited in its use. The patient may be aware of blood and urine test for PFAS being taken at other locations. These tests are used by public health officials to investigate community-wide exposure in order to understand the kinds and amounts of PFAS exposures in a community and how those exposures compare to those in other populations. Serum PFAS measurements are most helpful when they are part of a carefully designed research study.</p>
<p><b>What do my PFAS blood tests results mean?</b></p>	<p>The blood test for PFAS can only tell us the levels of specific PFAS in your body at the time you were tested.</p> <p>The blood tests results cannot be interpreted and used in patient care.</p> <p>The blood test results cannot predict or rule-out the development of future problems related to a suspected exposure.</p>	<p>There is currently no established PFAS blood level at which a health effect is known nor is there a level that is clearly associated with past or future health problems.</p> <p>The individual patient's blood concentration of PFAS can only be compared to the average background blood concentration levels for different PFAS that are nationally identified through the representative sampling of the NHANES studies conducted by CDC.</p> <p>A patient's PFAS concentrations can only show the patient if his or her blood levels are within range of the national norms or if the</p>

Questions Patients May Ask	Key Patient Messages	Key Message Supporting Facts
		individual's levels are high or low compared to the national background averages.
<p><b>An adult patient asks:</b></p> <p><b>“Should I be tested for any of the potential health effects associated with PFAS exposure (like cholesterol and uric acid levels, or liver and thyroid function, etc.)?”</b></p>	<p>Let's look at your health history and past lab results and discuss what steps we may want to consider moving forward.</p> <p>One way we can address cholesterol is through your annual physical.</p> <p>For others PFAS associated conditions, we need to watch for symptoms and investigate any that you notice, especially those that reoccur.</p> <p>If any unusual symptoms occur, we will investigate those and treat as needed.</p> <p>Laboratory tests will not tell us if PFAS are the cause of any of your health symptoms or abnormal lab results, but conducting these routine health screenings and watching for any related symptoms do offer us a way to better understand your current health status.</p>	<p>Health effects associated with PFAS are not specific and can be caused by many other factors.</p> <p>There are no guidelines to support laboratory testing to monitor PFAS health concerns.</p> <p>However, if your patient is concerned about PFAS exposure, discussing routine cholesterol screening can reassure the patient that his or her PFAS exposure concerns are being addressed. Some of the other possible health effects can be screened for based on symptoms.</p>
<p><b>A parent asks:</b></p> <p><b>“Should I have my child tested for any of the potential health effects associated with PFAS exposure (like cholesterol and uric acid levels, or liver, thyroid function, etc.)?”</b></p>	<p>The American Academy of Pediatrics has endorsed cholesterol testing for children starting at 9 years of age.</p> <p>Following this guidance cholesterol level testing can be done for older children.</p> <p>If cholesterol level measures are outside the normal range, we can discuss options for bringing cholesterol levels within the normal range for your child.</p> <p>For very young children, keeping well child visits is the best plan of action to monitor your child's</p>	<p>According to NHLBI guidelines endorsed by the American Academy of Pediatrics, all children should be screened for cholesterol levels between ages 9 and 11 years, and again between ages 17 and 21 years, even those who are not at an increased risk of high cholesterol and heart disease.</p> <p>Health effects associated with PFAS are not specific and can be caused by many other factors.</p> <p>There are no guidelines to support use of laboratory testing to monitor PFAS health concerns.</p>

Questions Patients May Ask	Key Patient Messages	Key Message Supporting Facts
	<p>health and watch for symptoms of illness.</p> <p>We can discuss any symptoms you notice, especially those that reoccur.</p> <p>If any unusual symptoms occur, we will investigate those and treat as needed.</p> <p>Laboratory tests will not tell us if PFAS are the cause of any of your child’s health symptoms and are not recommended. Conducting routine well child visits and watching for any related symptoms do offer us a way to better understand your child’s current health status.</p>	<p>However, if your patient presents with health concerns that have been associated with PFAS exposures, discussing recommended cholesterol screening, can reassure the patient’s parents that their concerns are being addressed. Some of the other possible health effects can be screened for based on symptoms.</p>
<p><b>How will exposure to PFAS affect my pregnancy?</b></p>	<p>Exposure to PFAS before pregnancy has been associated with pregnancy-induced hypertension and pre-eclampsia.</p> <p>We will monitor your blood pressure closely, as we do for all pregnant women; however, there is no need for additional blood pressure measurements as a result of your exposure.</p>	<p>Health effects associated with PFAS are not specific and can be caused by many other factors.</p> <p>Pregnancy induced hypertension occurs in many pregnancies and the specific etiology is often unknown.</p>
<p><b>Is it safe for me to breastfeed my baby?</b></p>	<p>Breastfeeding is associated with numerous health benefits for infants and mothers.</p> <p>At this time, it is recommended that you as a nursing mother continue to breastfeed your baby.</p> <p>The science on the health effects of PFAS for mothers and babies is evolving.</p> <p>However, given the scientific understanding at this time, the benefits of breastfeeding your baby outweighs those of not breastfeeding.</p>	<p>Extensive research has documented the broad and compelling advantages of breastfeeding for infants, mothers, families, and society.</p> <p>Some of the many benefits include immunologic advantages, lower obesity rates, and greater cognitive development for the infant as well as a variety of health advantages for the lactating mother.</p> <p>Even though a number of environmental pollutants readily pass to the infant through human milk, the advantages of</p>

Questions Patients May Ask	Key Patient Messages	Key Message Supporting Facts
		breastfeeding continue to greatly outweigh the potential risks in nearly every circumstance.
<p><b>How will exposure to PFAS affect my child’s immunizations?</b></p> <p><b>Will I need to get my child vaccinated again?</b></p>	<p>Although few studies have reported that PFOS and PFOA might slightly lower the immune response to some immunizations, these studies have not suggested a need to re-evaluate the normal immunization schedule.</p> <p>There is no recommendation for repeating any vaccinations.</p>	<p>A study with 656 children has reported that elevated levels of PFOA and PFOS in serum are associated with reduced humoral immune response to some routine childhood immunizations (rubella, tetanus and diphtheria) among children aged five to seven years.</p> <p>Studies have not suggested a need to re-evaluate the normal immunization schedule nor the use of an immunize booster for impacted children.</p>
<p><b>I have been very anxious about health risks from PFAS exposure. How can I deal with this uncertainty?</b></p>	<p>It is normal to be anxious about uncertain risks.</p> <p>I am here to listen to your questions and will do my best to provide honest answers.</p> <p>First let’s identify ways to reduce ongoing exposures to PFAS so that overtime we can lower your health risks.</p> <p>Let’s set up appointment for (X date) and we can discuss any new questions you have and check to see if there are any changes in how you feel.</p> <p>In the meantime, I have more information that may answer questions that you may have later about PFAS.</p>	<p>Listen sympathetically and explore the concerns of the patient</p> <p>Check for serious stress issues such as ongoing depression and treat accordingly.</p> <p>Review resources/references at the end of this fact sheet.</p>

## Resources

Below is a list of resources that can be helpful to clinicians. These include the Pediatric Environmental Health Specialty Units (PEHSU). The PEHSU are a national network of experts available to provide consultation and education to clinicians and communities wishing to learn more about PFAS and other hazardous substances. These units are staffed by clinicians with environmental health expertise in pediatrics, reproductive health, occupational and environmental medicine, medical toxicology, and other related areas of medicine.

Resource	Link
ATSDR: PFAS Overview Toxic Substance Portal ToxFAQs	<a href="http://www.atsdr.cdc.gov/pfc/index.html">http://www.atsdr.cdc.gov/pfc/index.html</a> <a href="http://www.atsdr.cdc.gov/substances/index.asp">http://www.atsdr.cdc.gov/substances/index.asp</a> <a href="http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=1116&amp;tid=237">http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=1116&amp;tid=237</a>
CDC: PFCs	<a href="http://www.cdc.gov/biomonitoring/PFCs_FactSheet.html">http://www.cdc.gov/biomonitoring/PFCs_FactSheet.html</a>
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EPA: PFAS	<a href="https://www.epa.gov/chemical-research/research-perfluorooctanoic-acid-pfoa-and-other-perfluorinated-chemicals-pfcs">https://www.epa.gov/chemical-research/research-perfluorooctanoic-acid-pfoa-and-other-perfluorinated-chemicals-pfcs</a>
IARC	<a href="http://www.iarc.fr/">http://www.iarc.fr/</a>
NIEHS: PFAS	<a href="https://www.niehs.nih.gov/health/materials/perflourinated_chemicals_508.pdf">https://www.niehs.nih.gov/health/materials/perflourinated_chemicals_508.pdf</a>
NHLBI Lipid Screening in Children & Adolescents	<a href="https://www.nhlbi.nih.gov/health-pro/guidelines/current/cardiovascular-health-pediatric-guidelines/full-report-chapter-9">https://www.nhlbi.nih.gov/health-pro/guidelines/current/cardiovascular-health-pediatric-guidelines/full-report-chapter-9</a>
PEHSU	<a href="http://www.pehsu.net/">http://www.pehsu.net/</a>
Uncertainty and Stress in the Clinical Setting	<p>Helping Patients and Clinicians Manage Uncertainty During Clinical Care - <a href="https://publichealth.wustl.edu/helping-patients-and-clinicians-manage-uncertainty-during-clinical-care/">https://publichealth.wustl.edu/helping-patients-and-clinicians-manage-uncertainty-during-clinical-care/</a></p> <p>Navigating the Unknown: Shared Decision-Making in the Face of Uncertainty J Gen Intern Med. 2015 May; 30(5): 675–678. <a href="http://tinyurl.com/zrd587f">http://tinyurl.com/zrd587f</a></p> <p>Patient Health Questionnaire to determine if patient is suffering from depression. <a href="http://tinyurl.com/gv6h3wk">http://tinyurl.com/gv6h3wk</a></p> <p>Uncertainty Toolbox: Principles in the Approach to Uncertainty in the Clinical Encounter-J Gen Intern Med. 2015 May; 30(5): 675–678. <a href="http://tinyurl.com/gtlf2mk">http://tinyurl.com/gtlf2mk</a></p>



## POLLUTION

# EPA gears up for controlling poly- and perfluorochemical pollution

Agency plans legal limit on four PFASs in drinking water, creating liability for PFOS and PFOA contamination

by **Cheryl Hogue**

MAY 22, 2018 | APPEARED IN VOLUME 96, ISSUE 22

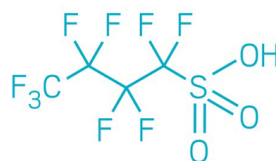
**T**he U.S. EPA is moving on several fronts to control four poly- and perfluorinated alkyl compounds (PFASs) that contaminate or threaten to taint drinking water in at least 20 states across the nation. Some of these efforts will take years to complete.

Agency Administrator Scott Pruitt announced a four-pronged plan to address PFASs on May 22 at a meeting with representatives of states and tribes, other federal agencies, and industry groups, along with congressional aides and a sprinkling of environmental and community activists. No academic scientists, who have done much work on identifying PFAS contamination and the toxicity of these substances, were present at the meeting.

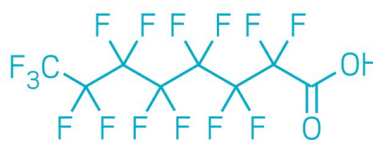
In a first step, EPA will evaluate the need to set a legally enforceable drinking water limit for two substances formerly widely used but no longer manufactured in the U.S., perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), Pruitt said. These two substances, which are each linked to health problems, contaminate drinking water **across the U.S.**

EPA in 2016 established a nonbinding **advisory level of 70 ppt** for the compounds, individually or combined. PFOA and PFOS pollution stems from decades of industrial activity, including chemical manufacturing and the disposal of waste tainted with the substances. It is also found near military sites **where fire-fighting foams** containing these chemicals have been and continue to be used.

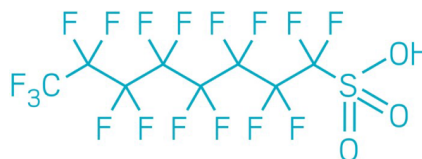
In a second action, Pruitt said EPA will propose designating PFOA and PFOS pollution as hazardous waste. This would establish liability for companies responsible for PFOA and PFOS pollution to clean it up, a boon for state regulators struggling to get remediation efforts underway. In a related third step, EPA is developing recommendations for cleaning up these two compounds



**Perfluorobutane sulfonic acid**



**Perfluorooctanoic acid**



**Perfluorooctanesulfonic acid**

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at contaminated sites, guidance that Pruitt said will be completed this autumn. Both actions will help address concerns of state regulators who, through the Environmental Council of the States, **say** the current situation leaves EPA and states lacking clear authority to order investigations or cleanup of PFAS pollution.

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In a fourth move, EPA is working with states and other federal agencies to establish human health toxicity values for two fluorochemicals that in the last decade or so replaced PFOA and PFOS, respectively: hexafluoropropylene oxide dimer acid (HFPO-DA), which is formed through hydrolysis of Chemours's GenX fluoroether surfactant; and perfluorobutanesulfonic acid, which is a **3M**

### product.

At the meeting, Carel Vandermeijden, director of engineering for a **North Carolina water utility** that is contending with **a river water supply tainted with HFPO-DA** and other fluorochemicals, said ratepayers so far are stuck with the bill for removing PFAS from drinking water.

The largest trade association for the U.S. chemical industry, the American Chemistry Council, endorsed the use of best available science to determine an appropriate maximum contaminant level in drinking water for PFOS, PFOA, and other so-called legacy PFASs that are no longer made or used domestically. At the meeting, Jessica Bowman, ACC senior director of global fluorochemistry, also expressed support for a possible EPA move that Pruitt did not mention—a regulation to prohibit imports of productions containing legacy PFASs.

Chemical & Engineering News

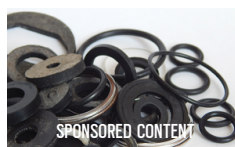
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