

## Comments by NYSBA Environmental and Energy Law Section on EPA’s Proposed Rule re “Strengthening Transparency in Regulatory Science”

**EPA Docket ID No. EPA-HQ-OA-2018-0259**

Environmental #7

May 31, 2018

The New York State Bar Association Section of Environmental and Energy Law (“SEEL”) submits these comments on the rule proposed by the United States Environmental Protection Agency (“EPA”) entitled “Strengthening Transparency in Regulatory Science” (“Proposed Rule”), published in the Federal Register on April 30, 2018.<sup>1</sup>

SEEL urges EPA not to finalize the Proposed Rule. The Proposed Rule is inconsistent with EPA’s statutory mandate under various environmental laws to use the best available scientific data to protect public health and welfare and the environment. Further, the Proposed Rule is subject to, and does not comply with, Executive Order 12898 concerning environmental justice and diversity of health studies.

In summary, the Proposed Rule requires that underlying data supporting scientific studies concerning the environmental or health impacts of pollutants be made publicly available for independent validation in order for EPA to use such data in making regulatory decisions. The Proposed Rule further provides that EPA will conduct independent peer review on all data it uses to justify its regulatory decisions. While SEEL supports EPA’s goal of basing its rulemaking on the strongest scientific evidence possible and fostering transparency, we are concerned that the Proposed Rule unduly limits the scientific data EPA can consider and conflicts with EPA’s statutory obligations.

EPA’s core mission, reflected in numerous environmental statutes, is to protect public health and the environment.<sup>2</sup> These same statutes require that EPA, in fulfilling

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<sup>1</sup> See 83 Fed. Reg. 18,768 (Apr. 30, 2018).

<sup>2</sup> See, e.g., Clean Water Act § 102, 33 U.S.C. § 1252 (directing Administrator to develop comprehensive programs to protect surface and ground waters); Safe Drinking Water Act § 1412, 42 U.S.C. § 300g-1 (directing Administrator to develop national primary drinking water regulations to protect public health); Solid Waste Disposal Act § 1003, 42 U.S.C. § 6902 (purpose of act is to promote protection of public health and the environment by improving management of solid and hazardous wastes); Clean Air Act § 101(b), 42 U.S.C. § 7401(b) (purpose of act is to protect and improve air quality to promote public health and welfare); see also <https://www.epa.gov/aboutepa/our-mission-and-what-we-do> (“The mission of EPA is to protect human health and the environment”).

this mission, support and rely on the best available science. While the specific terms of each statute vary, their direction is similar: EPA is charged with conducting and supporting research into the impacts of pollutants on human health and the environment,<sup>3</sup> using available scientifically accepted data to determine when pollutants pose a danger to human health or the environment,<sup>4</sup> and establishing standards with a sufficient margin of safety to protect public health.<sup>5</sup>

Indeed, this requirement that EPA use the latest or best available science is repeated in numerous environmental statutes. The Clean Air Act, for example, directs the Administrator to reflect “the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare ...” when updating air quality criteria.<sup>6</sup> The Clean Water Act similarly directs the Administrator to update water quality

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<sup>3</sup> See, e.g., Clean Air Act § 103, 42 U.S.C. § 7403 (Administrator is charged conducting and supporting investigations and research concerning air pollutants, long- and short-term health effects of air pollutants, and long- and short term causes, effects and trends of damage to ecosystems from air pollutants); Comprehensive Environmental Response, Compensation and Liability Act § 311, 42 U.S.C. § 9660 (Administrator and Secretary of Health and Human Services charged with supporting and conducting studies, including concerning risks to human health from hazardous substances).

<sup>4</sup> See, e.g., Clean Water Act § 304(a)(1), 33 U.S.C. § 1314(a)(1) (directing Administrator to develop and periodically update criteria for water quality that accurately reflects “the latest scientific knowledge”); Clean Air Act § 107(a)(2), 42 U.S.C. § 7408(a)(2) (in issuing and updating air quality criteria, Administrator is required to reflect “*the latest scientific knowledge* useful in indicating the kind and extent of all identifiable effects on public health or welfare ...”) (emphasis added); Safe Drinking Water Act § 1412 (b)(3)(A), 42 U.S.C. § 300g-1(b)(3)(A) (in establish maximum contaminant level goals and national drinking water standards, Administrator is required to use “best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and ... data collected by accepted methods or best available methods ...”); Toxic Substances Control Act, 15 U.S.C. § 2625(h), (i) (for decisions based on science, requiring EPA to operate in a manner consistent with the best available science and make decisions based on the weight of the scientific evidence).

<sup>5</sup> See, e.g., Clean Air Act § 109, 42 U.S.C. § 7409 (directing Administrator to adopt and every five years thereafter to review, national primary air quality standards adequate to protect public health, with an adequate margin of safety); Safe Drinking Water Act § 1412 (b)(4)(A), 42 U.S.C. § 300g-1(b)(4)(A) (directing Administrator to set maximum contaminant level goals for drinking water “at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety”).

<sup>6</sup> § 108(a), 42 U.S.C. § 7408(a); see also § 112(e)(2)(A), 42 U.S.C. § 7412(e)(2)(A) (in establishing priorities for adopting standards for hazardous air pollutants, Administrator shall consider “the known or anticipated adverse effects of such pollutants on public health and the environment”); § 112(f)(1)(C), 42 U.S.C. § 7412(f)(1)(C) (requiring Administrator to report to Congress on human health risk from hazardous pollutants, including “any available epidemiological or other health studies”).

criteria based on “the latest scientific knowledge.”<sup>7</sup> The Toxic Substances Control Act directs the Administrator, when making decisions based on science, to act “in a manner consistent with the best available science” and consider a number of factors, including the reasonableness of the methods used to develop the information, the completeness of the data, the extent of uncertainty, and independent verification or peer review.<sup>8</sup> Notably, public availability or independent verification are not disqualifying requirements.

This repeated statutory requirement that EPA use the “latest,” “best available,” and “peer-reviewed” science conflicts with EPA’s proposal to use only publicly available scientific data. None of the environmental statutes restrict reliable scientific evidence to studies where all underlying data has been made publicly available. Indeed, there are many reasons why data cannot, or cannot easily, be made public, including privacy and individual confidentiality concerns, particularly when related to personal health information.

All high quality scientific research, regardless of the public availability of its raw data, should equally be used by EPA in establishing regulatory standards. Were EPA to reject otherwise reliable epidemiological or similar health evidence because underlying data could not be made available without violating privacy or confidentiality, EPA would not be using “the latest scientific knowledge” or “the best available peer reviewed science” in violation of its statutory obligations. Further, EPA would be ignoring data that would ensure its ability to meet its obligations to establish standards protective of public health, with “an adequate margin of safety.”

The Proposed Rule’s provisions allowing data to be made public in controlled processes (section 30.5) and EPA to grant exemptions to the rule’s requirements (section 30.9) do not resolve the rule’s inconsistencies with environmental statutes. Where all underlying data cannot be made publicly available, the Proposed Rule requires the Administrator to make a case-by-case determination whether to exempt the data from disclosure requirements. This exemption will not ensure that EPA considers the latest or best available data, lacks consistent standards, and in any event will likely be difficult and time consuming to administer.

The Proposed Rule’s requirement that EPA conduct independent peer review of scientific evidence on which it relies is also of concern. The Proposed Rule applies this peer review requirement uniformly, and does not exempt studies that have already been independently peer reviewed, as many health and scientific studies are. Although SEEL understands the importance of peer reviews of scientific studies, EPA has not explained

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<sup>7</sup> § 304(a)(1), 33 U.S.C. § 1314(a)(1); *see also* § 104(l)(1), 33 U.S.C. § 1254(l)(1) (Administrator shall develop and periodically update “latest scientific knowledge available in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water”); § 502(13), 33 U.S.C. § 1362(13) (defining “toxic pollutant” as pollutants which “on the basis of information available to the Administrator” cause significant harmful health effects).

<sup>8</sup> 15 U.S.C. § 2625(h).

why EPA must conduct additional peer review of data that has already been reviewed. This is of particular concern as many environmental statutes require EPA to periodically review, and where appropriate revise, regulatory standards. For example, the Clean Air Act requires that EPA review air quality criteria and national ambient air quality standards every five years.<sup>9</sup> EPA has repeatedly failed to meet this schedule.<sup>10</sup> If EPA were now to add independent peer review to its periodic review of standards, it would be even less able to meet this mandated time-frame.

SEEL is also concerned that the Proposed Rule does not comply with Executive Order 12898. Executive Order 12898 requires EPA to identify and address “disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations.” Executive Order 12898 § 1-101.<sup>11</sup> The Executive Order specifically addresses federal human health and environmental research, requiring federal agencies to ensure epidemiological and clinical research activities represent “segments at high risk from environmental hazards, such as minority populations, low-income populations and workers who may be exposed to substantial environmental hazards.” *Id.* § 3-301. EPA’s determination that the Proposed Rule is not subject to Executive Order 12898 because “it does not establish an environmental health or safety standard”<sup>12</sup> too narrowly construes the scope of the Executive Order and the potentially broad impact of its Proposed Rule. Executive Order 12898 by its terms applies to agency policies and agency conduct of programs as well as to agency adoption of regulatory standards. And as the Proposed Rule concerns the scientific evidence EPA will consider in its regulatory decision-making, including epidemiological and clinic research on the health impacts of pollutants, it has the potential to directly implicate the concerns addressed by the Executive Order.

SEEL appreciates the opportunity to comment on this important issue.

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<sup>9</sup> Clean Air Act, § 109(d)(1), 42 U.S.C. § 7409(d)(1).

<sup>10</sup> *See Am. Lung Ass’n v. Reilly*, No. 91-CV-4114 (E.D.N.Y. 1992); *Am. Lung Ass’n v. Whitman*, No. 03-CV-778 (D.D.C. 2003); *see also Am. Lung Ass’n v. EPA*, 134 F.3d 388 (D.C. Cir. 1998) (challenging EPA refusal to update sulfur dioxide standard).

<sup>11</sup> Available at <https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf>.

<sup>12</sup> 83 Fed. Reg. at 18,773 (Apr. 30, 2018).