BEFORE THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

STATEMENT FOR THE RECORD OF THE
AMERICAN CHEMISTRY COUNCIL

October 3, 2018

The American Chemistry Council (ACC) appreciates the opportunity to provide this statement to the Senate Environment and Public Works Committee regarding EPA's proposed rule, "Strengthening Transparency in Regulatory Science." ACC and its members have a strong interest in EPA's adoption and implementation of the proposal that will strengthen the science EPA uses to make decisions.

ACC believes that EPA's proposal correctly codifies an important good governance principle: that government agencies should be as transparent as possible, within the bounds of the law, about scientific information they rely on and the justifications for the significant regulatory decisions they make.

EPA's proposal builds on the principles underlying the Administrative Procedure Act (APA), Executive Orders 12866, 13777, and 13783, and guidance developed by the Office of Management and Budget (OMB). In our view, the proposal is consistent with these foundational elements.

In particular, ACC supports the proposed expansion of the Office of Science and Technology Policy's (OSTP) 2013 memorandum entitled "Increasing Access to the Results of Federally Funded Scientific Research." The proposal directs federal agencies and offices to develop and submit plans to OSTP, which ensure that, to the extent practicable, peer-reviewed publications and digital scientific data resulting from federally-funded scientific research are accessible to the public, the scientific community, and industry.

The 2013 OSTP directive requires each agency to develop a public access plan that maximizes access to federally-funded "digitally formatted scientific data"[1] while also protecting confidentiality, personal privacy, confidential business information (CBI), intellectual property rights, and U.S. competitiveness.[2] In 2016, EPA issued its Plan to

[1] As defined in OMB circular 110 as "the digital recorded factual material commonly accepted in the scientific community as necessary to validate research findings, including data sets used to support scholarly publications. . ." It is a definition consistent with that of "research data" in the regulatory text of EPA's proposal.

[2] More than 20 federal agencies have developed and implemented Data Access Plans, including EPA, the National Institutes of Health (NIH), the Center for Disease Control (CDC), and the Food and Drug Administration (FDA).

Increase Access to Results of EPA-funded Scientific Research in response to the OSTP directive.[3] Importantly, EPA's proposal on Strengthening Transparency extends these commitments beyond the government-funded requirement of the OSTP directive to "dose response data and models underlying pivotal regulatory science regardless of the source of funding or identity of the party conducting the regulatory science."[4]

EPA's focus on dose-response data and models appropriately reflects the evolution of toxicology from a largely observational science to a discipline that applies advanced scientific techniques and knowledge. Research programs within academia, government, and private sector labs have greatly improved our ability to investigate and understand the underlying biological mechanisms, modes of action, and dose responses of toxicants. We can now evaluate biological events leading to toxicity and consider how (in a dose-response manner) these biological events relate to potential risks to human health. This was not possible 10-to-20 years ago.

Importantly, these improvements should translate to:

- The application of transparent weight-of-the-evidence approaches to the assessment of human relevance
- The development of points of departure
- The derivation of protective human health equivalent dosages that minimize the use of uncertainty factors and variability.

EPA's proposed rule will promote the application of this knowledge to improve the scientific basis of government regulatory policies and industry product stewardship.

For environmental concerns, exposure-response is the more appropriate relationship to evaluate because most of the environmental test guidelines require quantifying concentrations in media external to the organism for use as the exposure metric. Toxicity information, and — when available — knowledge of mechanisms, are integrated with exposure-response models for risk-based environmental safety decision making.

ACC encourages EPA to implement best available scientific procedures under this rulemaking. The Agency should move away from the outdated linear concept of how biology operates toward biologically-based mechanisms, i.e., mode of action (MOA) and adverse outcome pathways (AOP) for both cancer and non-cancer effects, that clearly establish the threshold nature of toxicological endpoints for derivation of points of departure for establishing regulatory values and making regulatory decisions.[5, 6]

---

[3] Plan to Increase Access to Results of EPA-Funded Scientific Research (USEPA, November 29, 2016) https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[4] ACC suggests improvements to EPA's terminology in the preamble that are described later in these comments in sections VI and VII.

[5] Critics of this proposed policy appear to overlook the fact that the call to evaluate different dose response models is entirely consistent with the Agency's Cancer Guidelines, which have been in place since 2005. See Guidelines for Carcinogen Risk Assessment https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038594/

As we noted earlier, EPA's proposed rule is consistent with and builds on policies implemented by previous administrations. In our comments to EPA on the proposal, we noted in particular that implementation would be aided by a policy statement or guidance that commits the Agency to afford greater weight to studies using validated test methods and procedures, models, and approaches, when and where those data are based on publicly accessible data, and transparent computer algorithms. Guidance to assist implementation of the rule should include specific examples and/or case studies, perhaps drawing from recent EPA rulemakings, to demonstrate what constitutes regulatory science that is material to EPA's significant regulatory decisions. Other scientifically relevant and reliable studies and data should not be eliminated from consideration, but rather, accorded less weight when integrating evidence from multiple studies within and across different lines of evidence.

We believe the proposal is consistent with the relevant provisions of Section 26 of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, approved by an overwhelming Congressional majority in 2016.[7] EPA's proposed rule is an important step toward ensuring that the science the Agency relies on in decision-making is transparent and accessible.

---

[7] TSCA Section 26(h)-(k) (15 U.S.C. §2625(h)-(k)) provides:

(h) Scientific Standards.—In carrying out sections 2603, 2604 and 2605, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed in a manner consistent with the best available science, and shall consider as applicable—

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the use of the Administrator in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

(i) Weight of Scientific Evidence.—The Administrator shall make decisions under sections 2603, 2604, and 2605 based on the weight of the scientific evidence.

(j) Availability of Information.—Subject to section 2613, the Administrator shall make available to the public—

(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this title;

(2) any information required to be provided to the Administrator under section 2603;

(3) a nontechnical summary of each risk evaluation conducted under section 2605(b); and

(4) a list of studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies;

(5) each designation of a chemical substance under section 2605(b), along with an identification of the information, analysis, and basis used to make the designations.

(k) Reasonably Available Information.—In carrying out sections 2603, 2604, and 2605, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.