Coalition for Chemical Innovations (CCI)

EPA Should Rely on Actual, Not Modeled, Data in Making TSCA Section 5 Decisions

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Introduction

This white paper explains why the U.S. Environmental Protection Agency's (EPA) practice of using the outputs of its models rather than relying upon the information provided by premanufacture notice (PMN) submitters under Toxic Substances Control Act (TSCA) Section 5 fails to meet the statutory requirements of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act).

The Lautenberg Act Encourages the Use of Actual Data Whenever Possible

Over the years, TSCA stakeholders, including non-governmental organizations and EPA itself, have expressed concern over the fact that more data are not available to evaluate the potential risk of chemicals, especially new chemical substances.[1] One of the primary drivers of the Lautenberg Act was to authorize EPA to require chemical stakeholders to generate more appropriate toxicity and exposure data to inform EPA's risk decisions.

EPA emphasizes its critical need for data in its Points to Consider[2] document and in numerous public statements, guidance, training, and private communications. EPA's Office of Pollution Prevention and Toxics (OPPT) repeatedly encourages submitters to include as much detail as possible in their PMN submissions about operations and conditions of use, including estimates of releases and exposures, and test data related to effects on health or the environment. In fact, 40 C.F.R. Section 720.50(a) requires that companies include full reports or standard literature citations for data (on toxicity and exposure) on the substances that are known or in the possession of the submitter.

The Lautenberg Act also requires that EPA meet certain scientific standards "consistent with the best available science,"[3] using the "weight of the scientific evidence,"[4] and considering "reasonably available information."[5] As discussed below, EPA's current practices and policies fail to meet these standards.

EPA's Current Practice Is to Ignore Actual Data If They Are Less Conservative Than Modeled Data

During its review of new and existing chemicals, EPA routinely and, in our view, inappropriately dismisses submitted actual data in preference to its modeled data or data on analogs.

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The problem is most acute when EPA is evaluating workplace exposures and releases. Regardless of the data provided on workplace exposures and facility releases, EPA evaluates the conditions of use using its engineering model, ChemSTEER. Less routinely, but as inappropriately, EPA defers to its toxicity models (notably ECOSAR and the Organization for Economic Cooperation and Development (OECD) QSAR Toolbox) in preference to measured toxicity data.

The effect of EPA's practice is to diminish, if not extinguish entirely, the value of measured data in EPA risk evaluations. A submitter might, for example, conduct an extensive industrial hygiene (IH) monitoring exercise to document how well dust exposures are controlled in its and its customers' facilities. Even with access to these monitoring data, however, EPA would inexplicably rely on its own evaluation of exposures using EPA's "worst case" exposure scenario, in this case a level that is comparable to concentrations found in a dust storm.

If EPA's practice is always to assume that another entity handling the same substance might not take the protective measures provided by the PMN submitter, the IH monitoring data are entirely gratuitous and add no value to EPA's decision-making process.

Similarly, EPA imposes a *de facto* requirement that particle size data (PSD) be submitted with PMNs for solids. If PSD are not provided with the submission, EPA routinely asks the submitter for these data during a completeness check prior to EPA starting the review period and delays the PMN review until such data are provided. Even when PSD are provided, however, EPA dismisses the data and relies on its own assumptions that the substance might be produced in a particle size range that would be considered hazardous. In cases where the PSD show the particle size is in the non-hazardous size range, overriding actual data distorts EPA's review and yields a result that is misrepresentative of the substance's risk potential. When amending TSCA, Congress did not intend the gratuitous development of data that EPA can ignore.

Even more frustrating for submitters than having EPA dismiss or devalue submitted data, deferring instead to its models, is that EPA does not provide meaningful comment on its decisions to submitters. EPA may dismiss the data with uniquely unhelpful phrases like "not conservative" or "not representative," but EPA provides no criteria for what would be acceptable and sufficient to use in preference to its models. EPA states in reply that it will "evaluate" any data that the submitter provides. Evaluation with a reflexive decision to reject is unhelpful and unlawful.

Further, EPA assessors routinely question the conclusions of studies performed under internationally recognized standards by internationally recognized experts simply because the assessors disagree with the study's results or conclusions. For EPA routinely to use modeled data in preference to measured toxicology test data generated to meet OECD study methods that are recognized by EPA and other internationally recognized chemical control authorities makes no sense. That the EPA

assessor's evaluation is more "protective" is not a justification for ignoring quality scientific evidence. The assessor's imposition of his or her preference in place of the more rigorous scientific standard is scientific malpractice.

If all the data submitted are systematically ignored, the data cannot inform the outcome of EPA's review. Submitters are left with the inevitable conclusion that there is no reason to develop and submit these voluntary data to inform EPA's review, particularly given the associated costs, delays, possible release of confidential data in the study reports, and potentially unnecessary use of animals. Most significantly, without these data, EPA's conclusion will continue to be erroneous and baseless.

EPA Should Follow Congressional Direction and Use Actual Data Whenever Possible

When EPA devalues, dismisses, and/or ignores entirely measured data, EPA is not being conservative; EPA is being outcome-determinative and biased against chemical innovation. In implementing a practice that preferentially chooses the most conservative assumptions despite data indicating more realistic exposures and conditions of use, EPA fails to meet the scientific standards in TSCA Section 26. EPA is also failing to meet one of the primary purposes of TSCA, to encourage, incentivize, or, if necessary, require the development and submission of data on a substance so that EPA can evaluate whether a substance does, may, or does not present an unreasonable risk to health and the environment using sound science. EPA's current approach is undermining the purpose of TSCA reform by devaluing data.

For more information, please e-mail info@chemicalinnovations.org.

[1] Wilson, M. P., and Schwarzman, M. R. 2009. Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry, and Environmental Health, *Environ. Health Perspect.*, 117(8), 1202-1209, available at https://ehp.niehs.nih.gov/doi/10.1289/ehp.0800404.

[2] EPA, Points to Consider When Preparing TSCA New Chemical Notifications (June 2018), available at https://www.epa.gov/sites/default/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf.

[3] TSCA § 26(h), 15 U.S.C. § 2625(h).

[4] TSCA § 26(i), 15 U.S.C. § 2625(i).

[5] TSCA § 26(k), 15 U.S.C. § 2625(k).