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# EPA Will Discontinue Use of Exposure Modeling Thresholds When Assessing Health and Environmental Risks of New Chemicals

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Government Regulation

The U.S. Environmental Protection Agency (EPA) announced on August 22, 2022, that as part of its commitment to re-evaluate policies and practices under the Toxic Substances Control Act (TSCA) New Chemicals Program to ensure they adhere to statutory requirements and the Biden Administration's executive orders and directives, it has updated its policy to discontinue the use of exposure modeling thresholds when assessing the health and environmental risks of new chemicals under TSCA. EPA intends to implement this policy change as soon as feasible.

According to EPA, the policy to use exposure modeling thresholds was put in place in the mid-1990s to focus limited resources on exposures with the greatest potential to affect human health and the environment. EPA states that "[t]hrough the experience of reviewing over a thousand pre-manufacture notices (PMNs) each year, the Program observed that when a chemical is released in relatively small amounts to air or from landfills, that the risks posed by such releases would be small and would not likely be unreasonable -- and thus chose to impose exposure release thresholds below which programmatic resources would not be expended to quantify associated risks."

EPA notes that since then, due in part to the automation of modeling, it has become less burdensome to complete these calculations. Furthermore, according to EPA, removing the thresholds supports President Biden's Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," which calls on federal agencies to advance equity, including by reviewing and revising as needed government policies and programs impacting underserved communities.

EPA states that more completely understanding the potential risks posed by releases of chemicals to overburdened and vulnerable communities is a priority. According to EPA, removing the modeling thresholds in its review of new chemicals will help both EPA and overburdened and vulnerable communities better understand these potential risks. Completing the modeling for all potential exposures that may result from air releases (fugitive and stack from industrial/commercial sites) and releases to groundwater from landfills, rather than only those above an established threshold, "will allow for a more fulsome understanding of the potential risks to these communities."

The New Chemicals Program will implement this change by making minimal changes to the coding in

the New Chemical Review application to remove the thresholds and will update standard operating procedures and training materials for exposure and human health risk assessors. EPA states that it will implement this policy change “as soon as feasible.” According to EPA, despite the resource challenges it is currently facing in the TSCA program, it anticipates that the change “will have minimal impact on the amount of time it takes to complete new chemical reviews and that the benefits gained from a more comprehensive accounting of all potential air and water releases will help ensure any needed protections are in place before a new chemical can come to market.”

## Commentary

Bergeson & Campbell, P.C. (B&C®) was surprised by this announcement. There had been signals that EPA was taking this approach on a case-by-case basis, but to our knowledge, EPA did not solicit broader engagement with stakeholders to vet the issue. What is not clear is why EPA is taking this a step beyond what is stated in the announcement. For example, EPA did not state the scientific basis for doing away with the modeling thresholds, which were established under EPA’s low release and exposure (LoREX) criteria. When EPA published the LoREX criteria in a Final Rule in 1995, it stated “the LoREX incineration air release eligibility criterion of $^{3}$, like the ambient surface water criterion [of *experience gained in conducting risk assessments on over 25,000 new chemical substances since 1979*” (emphasis added).

Notwithstanding the lack of transparency in EPA’s announcement, B&C disagrees that unilaterally scuttling this policy is scientifically justified or that it will add “minimally” to EPA’s workload. EPA already struggles with completing its human health assessments; it is not clear why EPA thinks it will “add minimally” to its effort, because having to assess otherwise negligible exposures means that EPA will have to calculate vanishingly small exposures by all possible routes and calculate risks for each. Such an expansion of EPA’s efforts might be justified if there was likely to be unreasonable risks resulting from such minimal exposures. The point of the “negligible” threshold is that there is a defensible threshold of exposure below which health risk is not expected.

The concept of a threshold to identify safe levels of exposure for data poor substances is often referred to as a “threshold of toxicological concern” (TTC). The Office of Pollution Prevention and Toxics’ (OPPT) sister office, the Office of Pesticide Programs, and the U.S. Food and Drug Administration both employ, and have for years, TTC or TTC-like approaches in their assessments on, for example, fragrances used as inert ingredients in antimicrobial pesticide formulations and substances used in food-contact articles. Moreover, EPA’s own scientists evaluated the utility of the TTC approach, along with chemical-specific high throughput exposure estimates (HTE), and concluded that “coupling TTC with HTE offers promise as a pragmatic first step in ranking substances as part of a risk-based prioritization approach.” EPA’s own scientists further advanced contributions in this area by deriving new inhalation TTC values for environmentally relevant chemicals.

Unlike the above examples that were communicated through notice and comment rulemaking in the *Federal Register* or underwent peer review before publication in scientific journals, OPPT did not provide an opportunity for members of the public to comment on this significant change, nor did EPA provide the peer-reviewed scientific basis for this change. We note, in contrast, that EPA’s peer-reviewed publication record on the use of TTC approaches supports the use of modeling thresholds. We further note that the 1995 Final Rule stated that EPA could require lower release thresholds when it concluded they were necessary; therefore, it is unclear why OPPT has chosen to do away with this approach entirely rather than revising its modeling thresholds, if data support doing so.

B&C does not question whether EPA has the authority to implement this policy change; rather, we question EPA's stated commitment to following the science and the law, and its commitment to work collaboratively with stakeholders. For example, EPA's scientific integrity policy states: "At the EPA, promoting a culture of scientific integrity is closely linked to transparency. The Agency remains committed to transparency in its interactions ***with all members of the public***" (emphasis added). EPA's failure, however, to provide the scientific justification for doing away with modeling thresholds not only falls short of meeting its scientific integrity policy, but also this decision undermines the public's trust that EPA is committed to making transparent decisions that meet the scientific standards under TSCA Section 26.



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