Public Comment to Obtain Input on Risk-Based Prioritization Procedural Rule under TSCA section 6(b)(1)

Docket EPA-HQ-OPPT-2016-0399

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We, the undersigned academic and clinical scientists from universities across the U.S., appreciate the opportunity to provide comments to the U.S. Environmental Protection Agency (EPA) on its implementation of the Amended Toxic Substances Control Act (TSCA) process for prioritization.

The new amendments to TSCA represent an important opportunity for EPA to update their scientific approaches to evaluating the potential risks posed by industrial chemicals in commerce. Furthermore, EPA's decisions on prioritization will have broad implications for future assessments of environmental chemicals more generally. We welcome EPA's engagement with the public in this process and would like to take this opportunity to voice strong support for a prioritization process that is transparent, nonbiased, and appropriately incorporates modern scientific principles. In particular, we recommend EPA:

1. Clarify that "sufficient" data is necessary to categorize a chemical as low priority and that strong, affirmative data is needed to conclude that a chemical does <u>not</u> pose an unreasonable risk;
2. Designate any chemical whose use in commerce results, or may result, in exposures to pregnant women and developing children to be of high priority unless there is sufficient data to show that it does not pose a risk to these and other vulnerable populations;
3. Utilize existing knowledge presented in risk or hazard evaluations completed by EPA itself (for example, by the Integrated Risk Information System program) and other government agencies (i.e., National Toxicology Program) or authoritative bodies (i.e., the International Agency for Research on Cancer and California's Prop 65 lists) to expedite science-based prioritization.

Regarding number 1 above, under the statute, EPA "shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish (without consideration of costs or other non-risk factors), that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance." Accordingly, EPA should require strong, affirmative data to conclude that a chemical does NOT pose an "unreasonable" risk, as the health and associated economic consequences of being wrong --- i.e., thinking a chemical does not pose a risk when in fact it does pose a risk, are very high. Specifically, <u>chemicals that do not yet have enough evidence to make a conclusion about their toxicity should not be designated as not posing an unreasonable risk, nor should chemicals with "unknown" toxicity be considered a low health risk and thus a low priority.</u>

This is consistent with modern science based decision-making in clinical sciences, where decisions reflect the extent to which we can be confident that desirable effects of an intervention outweigh its undesirable effects. This approach is also informed by more than a half century of lessons in the regulation of toxic chemicals, including (1) exposure to toxic chemicals increase over time, for example, from workers to consumer to future generations; (2) the nature of harm expands over time, from one adverse endpoint to many; and (3) "safe" limits get lower over time, not higher.

Similarly, EPA should also develop clear language that defines how "sufficient" evidence of low priority will be determined, before making any such determinations. As discussed above, this should not simply be a default category in which chemicals are assigned based on the lack of data to demonstrate that

there is "unreasonable" risk. We recommend that this evaluation utilize only the highest quality data, identified as such from a review of the available evidence that is undertaken using systematic review methodology, whether for exposure or health effects. The evaluation of evidence should also incorporate knowledge or defaults to ensure that risks to vulnerable populations such as children and pregnant women are considered and consequently demonstrate that risks to these groups meet the criteria defined beforehand as "sufficient" evidence for low priority.

EPA should draw from existing knowledge presented in risk or hazard evaluations completed by EPA itself (for example, by the Integrated Risk Information System program) and other government agencies (i.e., National Toxicology Program) or authoritative bodies (i.e., the International Agency for Research on Cancer, the California Environmental Protection Agency Proposition 65). These assessments provide evidence summaries and integration of existing data and can provide ready to use determinations regarding the state of the scientific evidence. Using hazard and risk assessments already produced by authoritative bodies is both scientifically appropriate for the prioritization and will greatly improve the efficiency of the prioritization process.

In summary, EPA needs to expeditiously evaluate data for prioritization, and should incorporate 21st century science in its methods and approaches while balancing the demands to make timely decisions based on evaluating the strengths and limitations of available data. Delays in decision making come at a cost, as exposures to potentially toxic chemicals mount faster than science. Our comments above can be implemented into EPA's prioritization process so that it can adequately characterize and address the most concerning risks from toxic chemical exposures in our children, families, and for future generations.

Best,

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