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EPA Proposes A Cumulative Risk Approach for Chemical Risk Assessment under TSCA

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In late February 2023, EPA released for public comment its *Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act* ("Draft Principles"), which proposes a set of principles for evaluating cumulative risks for chemicals undergoing risk evaluation under the Toxic Substances Control Act ("TSCA"). In conjunction with the Draft Principles, EPA also released its "*Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substances Control Act*," ("Draft Proposed Phthalates Cumulative Risk Approach"), an approach for applying these Draft Principles to the evaluation of cumulative risks posed by certain phthalates undergoing TSCA risk evaluations. EPA referred to these documents as the "first steps" towards the Agency conducting cumulative risk assessments under TSCA.

Stakeholders that manufacture, import, process, distribute, use, or dispose of chemicals (or products containing the chemicals) that EPA evaluates under Section 6 of TSCA could be impacted by EPA's guidance, which may influence future risk management restrictions or bans on these chemicals. The guidance reflects a departure from past practice because EPA has previously approached TSCA Section 6 risk evaluations by evaluating the unreasonable risks posed by a single chemical under its conditions of use. However, under a cumulative risk assessment approach, EPA could simultaneously assess categories of chemicals or multiple chemicals with similar effects. EPA states that the cumulative risk assessment approach may be helpful in mitigating identified unreasonable risks and for providing information to communities that may be overburdened by pollution.

EPA Authority Under TSCA to Conduct Cumulative Risk Assessments

EPA acknowledges in the Draft Principles that TSCA does not explicitly require EPA to conduct a

cumulative risk analysis; nevertheless, Section 26(h) of TSCA requires that, in carrying out risk evaluations, EPA must use scientific information, technical procedures, measures, methods, protocols, models, or methodologies employed in a manner consistent with the best available science and based on the weight of the scientific evidence. EPA recognizes that, for some chemicals being evaluated, the “best available science” may indicate that a cumulative risk assessment is appropriate to ensure that risks to human health and the environment are adequately characterized. EPA also states that the TSCA risk evaluation rule, 40 C.F.R. Part 702 Subpart B, does not prescribe a particular method for risk characterization thus allowing EPA the flexibility to select the most appropriate method based on the best available science and the weight of the scientific evidence.

Finally, Section 26(c) of TSCA allows EPA, in performing any action authorized or required to be taken under TSCA regarding a chemical substance or mixture, to take that action with respect to a category of chemical substances or mixtures. Chemical categories are defined under TSCA as substances that are similar in molecular structure; in physical, chemical, or biological properties; in use; in mode of entrance into the human body or environment; or which are in “some other way suitable for classification.” EPA states that this broad definition provides it with the flexibility to group chemical substances for inclusion in a cumulative risk assessment.

Defining Cumulative Risk

In the Draft Principles, EPA defines cumulative risk as the “analysis, characterization, and possible quantification of the combined risks to human health or the environment from multiple agents or stressors.” EPA recognizes that “stressors” refers to both chemical and non-chemical stressors (which may include lifestyle conditions and socioeconomic, radiological, biological, and other physical stressors). EPA’s focus for quantitative cumulative risk estimation under TSCA is on chemical exposure but may include discussion of non-chemical stressors in a qualitative manner and on a case-by-case basis.

EPA’s Draft Principles for Cumulative Risk Assessment include consideration of the following:

- Exposures to the general population as well as exposures to potentially exposed susceptible subpopulations, including workers, consumers, bystanders, fenceline communities, and tribal populations.

- Relevant pathways of exposure including, but not limited to, ingestion of contaminated groundwater, inhalation of volatile compounds emitted in an indoor environment, or dermal exposure to products during use.

- Non-TSCA uses. Notably, EPA states that it can also consider non-TSCA uses in cumulative risk assessments. While EPA cannot directly regulate non-TSCA uses (e.g., food, drugs, pesticides), EPA states that “incidental effects” caused by or resulting from TSCA Section 6(a) regulation of non-TSCA uses are not prohibited. Potential risks of non-TSCA uses may also help inform EPA’s risk determinations for exposures from uses that are covered under TSCA. For example, EPA may take into account exposure to multiple chemical substances resulting from non-TSCA uses and/or naturally occurring sources, should it decide to conduct a cumulative risk assessment.

- Grouping categories of chemicals that may be similar based on toxicology and or co-exposure patterns.

- Use of default assumptions of dose additions when chemicals are toxicologically similar, unless the evidence supports another approach.

EPA's Draft Principles are generally consistent with EPA's existing guidance documents on cumulative risk, approaches of the European Commission and World Health Organization (WHO), and approaches used by EPA's CERCLA/Superfund program. EPA intends to take a "fit for purpose" approach and use a hierarchical or tiered approach to assessments, which means that it intends to refine its analyses only when highly conservative assumptions do not demonstrate an adequate margin of exposure. Refined analyses will be dependent on available data. EPA states that it may use its TSCA Section 4 test order authority to obtain toxicology data to inform similarity and to gather information on product formulation, emissions testing, and manufacturing processes to inform co-exposures.

EPA's release of these documents is consistent with EPA Administrator Regan's Agency-wide directive to take steps to better serve marginalized communities using cumulative impact assessment. While the Draft Principles do not address cumulative impacts, which refer to the total burden—positive, neutral, or negative—from chemical and non-chemical stressors and their interactions that affect the health, well-being, and quality of life of an individual, community, or population at a given point in time or over a period of time, EPA sees the Draft Principles as an important step in the process of developing the capability to examine risk to people from exposure to multiple chemicals with similar effects.

Draft Proposed Methodology for Cumulative Risk Assessment of Certain Phthalates

In 2007, EPA asked the National Research Council (NRC) to evaluate whether a cumulative risk assessment approach would be appropriate for phthalates. In 2008, NRC concluded that sufficient data were available to conduct a cumulative risk assessment. In the Proposed Phthalates Cumulative Risk Approach, EPA describes an approach to conduct a cumulative risk assessment on di-ethylhexyl phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), di-isobutyl phthalate (DIBP), and dicyclohexyl phthalate (DCHP), as well as di-isononyl phthalate (DINP) and di-isodecyl phthalate (DIDP), which are two phthalates subject to manufacturer-requested risk evaluations under TSCA. EPA is intending to use the principle of dose addition with a focus on the most sensitive effect that is observed as part of phthalate syndrome (effects on the male reproductive system). Because of the effects observed, EPA will focus on susceptible populations that include pregnant women, women of reproductive age, male infants, male toddlers, and male children.

EPA has proposed that all of the listed phthalates except for DIDP are toxicologically similar and induce effects on the developing male reproductive system. EPA proposes to group these phthalates and EPA's draft conceptual model proposes to include both non-attributable and non-TSCA exposures as part of the phthalate cumulative risk assessment because certain non-TSCA (*e.g.,* dietary) and non-attributable (*e.g.,* household dust) exposure pathways are anticipated to be major contributors to phthalate exposure leading to cumulative risk.

Consistent with EPA's TSCA approach for risk evaluation, EPA intends to complete individual phthalate risk evaluations, focusing on TSCA-specific conditions of use. Results of EPA's phthalate cumulative risk assessment are anticipated to inform its individual phthalate risk determinations, pending completion of the cumulative risk assessment in parallel with the individual phthalate risk evaluations.

Opportunity for Stakeholder Input

Public comments on the Draft Principles document and the Draft Proposed Phthalates Cumulative Risk Approach are due by April 28, 2023, so that the comments can be considered when the two draft documents are peer reviewed by the Science Advisory Committee on Chemicals (SACC) May 8-11, 2023. The SACC will review the draft documents and provide scientific advice and recommendations to EPA. EPA has published registration information for the SACC meeting in the *Federal Register*.

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