November 7, 2025

Nancy Beck,
Principal Deputy Assistant Administrator
Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Ave., NW
Washington, DC 20460=0001

Re: Procedures for Chemical Risk Evaluation Under TSCA
Submitted at: www.regulations.gov
Docket No. EPA-HQ-OPPT-2025-0260

Dear Principal Deputy Assistant Administrator Beck:

The American Coatings Association (ACA) is a voluntary, nonprofit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The Association's membership represents 90% of the U.S. paint and coatings industry, including downstream users (or processors) of chemicals and chemical manufacturers. Our membership includes companies that manufacture paint, coatings, sealants and adhesives and their raw materials, whose manufacturing processes or products may be affected by the outcome of EPA's risk evaluations. ACA is eager to assist EPA in developing an effective system for chemical risk evaluations with successful implementation of the *Lautenberg Act's* mandates.

ACA appreciates the opportunity to submit comments regarding revisions to procedures for chemical risk evaluation under TSCA. ACA strongly believes that EPA must develop a robust and data-driven chemicals management program under TSCA, promoting an understanding of chemical safety and risk at the national level. Many of EPA's proposed changes promote that goal. ACA strongly supports EPA's proposal to remove the whole chemical approach as a requirement for TSCA risk evaluations while allowing EPA to reach risk determinations on individual conditions of use. We believe these changes promote greater consideration of actual exposure potential related to a condition of use. Similarly, EPA must consider standard risk mitigation practices during risk evaluation to evaluate actual exposure and potential

unreasonable risk. This would include standard PPE and existing exposure levels. Any deviations from existing requirements should be driven by scientific analysis, with input from the broader scientific and industrial hygiene community, rather than being driven by policy choices.

EPA's proposal raises several procedural issues affecting the outcome of risk evaluations. EPA must maintain flexibility to conduct aggregate exposure assessments when justified, without a requirement to do so generally. ACA supports developing processes for changing a final risk evaluation with notice and comment for substantive changes. ACA also supports limiting data submission requirements for manufacturer-requested risk evaluations to the manufacturer's conditions of use.

ACA supports adopting relevant definitions to promote consistency, transparency and accuracy in how EPA gathers and interprets data. ACA supports adopting definitions of *weight of the evidence*, *reasonably foreseen* and *de minimis*. We provide suggested definitions below.

Please consider the following details:

I. ACA supports removing codification of the "whole chemical approach."

ACA supports EPA's proposal to remove language codifying the "whole chemical approach." This approach is not suitable for highly sophisticated industrial and commercial operations since it has led to unnecessary workplace controls without consideration of actual workplace practices. The "whole chemical approach" encourages regulating to the least protected use, while unnecessarily imposing those requirements on sophisticated chemical users.

ACA supports EPA's proposal to identify conditions of use that do not contribute to the unreasonable risk finding on an individual or cumulative basis during the final risk evaluation. It is imperative to our members that EPA and the rules governing risk evaluations do not lose sight of individual conditions of use that are subject to evaluation. By making "a single risk determination of the chemical substance," EPA communicates to the public that the entire substance presents an unreasonable risk, despite efforts to mitigate this perception. ACA remains concerned that this blanket approach to risk determinations identifies all manufacturers and processors of a chemical as "bad actors." This creates confusion among the regulated community, downstream chemical users and the public as to those conditions of use that influenced EPA's risk determination.

A risk evaluation process where EPA considers circumstances associated with each condition of use requires EPA to reach a conclusion for each condition with respect to whether it contributes to an unreasonable risk finding or not. For example, EPA states

that an unreasonable risk determination may be made on a singular condition of use.[1] If there are 30 conditions of use for that chemical in total, in this example EPA would find that the chemical is not an unreasonable risk in 29, or most, of its uses.

ACA appreciates EPA's stated intent under the 2024 rule to "provide a rationale and explanation as to which conditions of use or exposure pathways are significant contributors to risk."[2] The 2024 rule however was silent on communications relating to those conditions of use that are *not* significant contributors or that do not contribute to the unreasonable risk determination in any way. EPA's statement of an intent to provide rationale acknowledges agency communications on conditions of use as a critical procedure in risk communication under TSCA. TSCA has become a highly watched area of regulatory law as EPA has undergone risk evaluations on chemicals subject to litigation and legislation. It is important for the public to have clear information regarding the status of their uses following a risk evaluation.

EPA's current practice in the risk evaluation documents generally includes listings which convey the conditions of use that contribute to the unreasonable risk finding and those that do not. *The Coalition strongly urges EPA to continue this practice, while codifying its authority to determine risk for individual conditions of use.*
Moreover, we think it is consistent with agency intent, current practice, and balanced risk communication to add the following language to the end of proposed section 702.37(a)(5):

> EPA will determine whether a chemical substance does or does not present an unreasonable risk after considering the risks posed under all of the conditions of use, *as determined by the Administrator*, and, where EPA makes a determination of unreasonable risk, EPA will identify the conditions of use that contribute to such determination~~.~~*, those that are not significant contributors to the risk, and those which do not contribute to the unreasonable risk determination.*

We urge EPA to capture this important additional procedural element in the rule itself due to the importance of risk communication, and to avoid miscommunication concerns. Since under a revised rule, EPA could make a risk determination on each condition of use, ACA emphasizes the importance of communicating risk outcomes for each condition of use. This addition to the rule would enhance current practice by more clearly discerning conditions of use and their contribution to risk.

[1] 88 Fed. Reg. 74302.
[2] 88 Fed. Reg. at 74302-74303.

In addition, EPA has not identified how or when a condition of use will qualify as a significant contributor to the risk determination. We urge EPA to provide further explanation of this point in the final rule. For example, as explained in a prior section of these comments, EPA must take reasonably available and verifiable information on workplace protection into account during the risk evaluation phase, and such information should be used to draw conclusions with respect to the relative contribution of a condition of use. Finally, in the interest of risk communication that is balanced, transparent and fair, we support EPA's proposal to ensure that the procedures for risk evaluation include conveying information to the public on conditions of use that do *not* contribute to an unreasonable risk determination.

II. ACA supports modifications that would allow for greater flexibility in scoping conditions of use.

ACA supports EPA's proposal to remove language added in the 2024 rule that limits the Administrator's discretion to identify and exclude conditions of use when appropriate. ACA supports robust and accurate risk evaluations. We support EPA's use of its scoping discretion on a case-by-case basis, as supported by the best available science and weight of the scientific evidence. ACA can envision situations where a use is adequately covered by another regulatory program, or the use is at a *de minimis* level such that it should not be included in the risk evaluation.

ACA also emphasizes the importance of making case-by-case determinations regarding scope of risk evaluations. With TSCA functioning as the overarching chemical safety statute designed to inform other programs within EPA and other agencies, ACA recognizes that in some instances EPA may include already regulated uses or uses involving *de minimis* amounts within scope, where data indicates a need for further evaluation. EPA's proposed changes to regulatory language would provide EPA with this discretion.

With respect to the scope of the risk evaluation, other agency statutes, and worker protection, we think EPA's approach has been too simplistic. It is not enough to simply decide whether or not to "assume" that risk evaluations must be comprehensive every time, that the agency should or should not "assume" to include or exclude circumstances regulated by other agency statutes, or "assume" that PPE is or is not used, or foreclose the agency's ability to make risk determinations through orders at some earlier stage in the overall process. In all cases, EPA should adopt a balanced and objective approach that takes reasonably available, scientifically sound and verifiable information into account.

While we urge EPA to continue to strive for comprehensive risk evaluations, ACA agrees that EPA has – and should maintain – discretion under TSCA to exclude certain

conditions of use from the risk evaluation. The TSCA legislative record could not be clearer as to Congress' intent:

> The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the Agency is given the discretion to determine the conditions of use considered in the scope that the Agency will address in its evaluation of the priority chemical.[3]

In contrast, the 2024 rule seeks to foreclose the discretion provided by Congress (e.g., §702.37(a)(4) states "EPA will not exclude conditions of use from the scope of the risk evaluation. . ."). However, the past two years have shown that such an approach can be difficult to achieve within the times set by Congress. Moreover, in the future, EPA may want to have the ability to do a targeted risk evaluation, should a particular use be identified that does not rise to an imminent harm standard under Section 7, but is nonetheless in the interest of public health and environmental protection to address expeditiously. We think that simply retaining a more discretionary approach on both counts – the agency's ability to decide what qualifies as a condition of use, and what ones to include in the scope of the risk evaluation – is the preferred public policy and legal position. EPA should avoid a rigid statutory interpretation.

III. ACA supports consideration of workplace risk mitigation strategies during the risk evaluation including existing OELs.

ACA supports consideration of actual exposure by considering standard workplace risk mitigation practices during a risk evaluation. ACA supports adopting proposed clarifications related to occupational exposure, such that EPA will take into account reasonably available information on the implementation and use of occupational exposure control measures such as engineering controls, administrative controls and PPE.

In the 2024 risk evaluation rule, EPA opted to minimize consideration of workplace exposure controls during risk evaluation as a policy choice, reasoning as follows:

1. Including PPE in the risk evaluation conflates risk evaluation with risk mitigation.
2. Workers may be exposed because they are not covered by OSHA requirements, PPE is not sufficient to address the risk or PPE does not fit or function properly.
3. OSHA PELs are largely outdated.
4. TSCA mandates are broader than OSHA mandates. Under TSCA EPA must consider risk based on TSCA standards for best available science, while

[3] 162 Cong. Rec. at S3519, June 7, 2016; 88 Fed. Reg. at 74298.

considering risk to potential exposed and susceptible subpopulations without consideration of costs or other non-risk factors.

a. EPA must consider existing risk mitigation practices as part of the risk evaluation to assess actual exposure.

Consideration of existing PPE and exposure controls is critical to an understanding of *actual* exposure, and in effect, does not conflate risk evaluation with risk mitigation. TSCA requires consideration of the totality of "circumstances" associated with *actual* conditions of use, including the use of PPE documented in industry comments. More specifically, EPA is tasked with evaluating the "conditions of use" defined as:

> the *circumstances*, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of (emphasis added).[4]

EPA's current approach, adopted in the 2024 risk evaluation rule, is not consistent with the important phrasing in the statutory definition above for the agency to consider the "circumstances" associated with "conditions of use."

ACA supports robust and accurate assessment of risk, based on data provided by industry and the best available science. Consideration of PPE and risk management practices must be incorporated into the risk assessment when the agency is provided with information that meets TSCA's robust screening practices. EPA must also consider existing legal requirements addressing workplace safety. To date, EPA has commonly ignored or failed to fully incorporate practices of a majority of employers, who comply with requirements of OSHA (Occupational Safety and Health Administration) and other standardization bodies whose requirements remain enforceable by OSHA.

EPA instead assumes that these requirements are not enforceable or TSCA requires regulating for a minority of companies not subject to OSHA requirements or that are out of compliance. ACA supports making data-driven decisions as to the efficacy and widespread use of common workplace safety practices. EPA should have the discretion to consider data indicating that a specific use or type of business is not covered by OSHA or that the sector does not use standard risk mitigation practices. Such information would be part of the totality of circumstances associated with a condition of use. However, EPA should not assume that such unprotected workers exist where data does not identify such workers, especially considering that data typically indicates robust and sophisticated workplace safety practices are widespread.

[4] 15 U.S.C. § 2602(4); 40 C.F.R. § 702.33.

b. EPA must carefully consider existing exposure values and scientifically justify any recommended deviations resulting in an ECEL.

Establishment of alternative exposure values must be carefully considered and scientifically justified. EPA underestimates the importance of OSHA PELs, ACGIH TLVs and other established OELs. EPA dismisses the OSHA PELs as outdated and/or limited by feasibility and economic considerations. ACA recommends that EPA conduct a case-by-case analysis of PELs and other OELs and why a variance is necessary. For example, the OSHA PEL for methylene chloride is a conservative exposure limit, lower than the ACGIH TLV, STEL and other established OELs. ACGIH also routinely reviews its TLVs to update according to the latest state of the science.

In the preamble to the methylene chloride risk mitigation rule and in other rulemakings, EPA considers its role and authority in protecting workers, other potentially susceptible subpopulations and the public generally. EPA identifies what it sees as a regulatory gap in OSHA's authority that TSCA is designed to address, in its view. As a starting point, EPA notes that OSHA rarely cites violations of the Occupational Safety and Health Act's General Duty Clause for chemical-specific exposure since the clause provides a high threshold for violations:

> To prove a violation of the General Duty Clause, OSHA must prove employer or industry recognition of the hazard, that the hazard was causing or likely to cause death or serious physical harm, and a feasible method to eliminate or materially reduce the hazard was available. In rare situations, OSHA has cited employers for violation of the General Duty Clause where exposures were below a chemical-specific permissible exposure limit (PEL). In such situations, OSHA must demonstrate that the employer had actual knowledge that the PEL was inadequate to protect its employees from death or serious physical harm. Because of the heavy evidentiary burden on OSHA to establish violations of the General Duty Clause, it is not frequently used to cite employers for employee exposure to chemical hazards.[5]

EPA explains that not only are OSHA PEL's outdated, but OSHA's requirement to set standards that are technologically and economically feasible prevent it from imposing requirements that ensure no significant risk to workers from chemical exposures. These statements underestimate the effect of existing exposure limits. It is not a "heavy burden" to demonstrate actual knowledge of an exposure value commonly used in industry during

[5] Preamble to EPA's Proposed Risk Mitigation Rule at Section II(C)(1)(a) – General Duty Clause of the OSH Act, 88 Fed. Reg. 28284, 28288 (May 3, 2023).

an OSHA safety audit. As noted above, industrial hygienists use a variety of references, other than OSHA PELs to develop workplace protection programs that abate risk. These references are commonly updated and available to industry, forming a common set of exposure values and protective measures. Any failure to provide protective measures in compliance with these industry practices rises to the level of an enforceable violation of the OSH Act under the General Duty Clause. Moreover, EPA risk evaluations must be based on science, not assumptions related to enforcement.

As the body of reference materials generated by industrial hygienists form a convenient reference, it is not overly burdensome for EPA and OSHA to refer to those materials when noting practices that are not adequately protective. EPA may consider further data related to OSHA enforcement practices under the General Duty Clause, but enforcement activity is not informative to establishing a protective exposure limit. EPA should focus on evaluating whether the existing limit is adequately protective and revising it if necessary to abate a clearly defined risk, rather than creating a "risk-based" standard assuming a lack of enforcement.

Deficiencies in the current derivation of ECELs are illustrated by EPA's methylene chloride risk mitigation rule.[6] EPA notes that the OSHA PEL for methylene chloride is not adequately protective since it was limited by feasibility considerations when it was set in 1997. In its 1997 methylene chloride exposure rule, OSHA proceeds to explain that it will continue to monitor methylene chloride related exposure to determine if the ppm PEL is adequately protective. EPA is presumably building on OSHA's 1997 standard.

EPA uses the same data set from OSHA's assessment, and yet derives a radically lower workplace limit, based largely on policy decisions. If such a departure from the established exposure limit is needed for workplace protection, ACA suggests further analysis of why the 25 ppm OSHA standard is not protective, considering that the workplace action level is half of the PEL. That is, workers are not exposed at 25 ppm. If a worker is exposed at 12.5 ppm or higher, an employer takes measures to reduce exposure to bring it below 12.5 ppm. ACA also suggests further analysis of workplace medical monitoring records to identify problems with current practices.

IV. ACA supports removing codification of requirements related to aggregate exposure assessments.

ACA supports EPA's proposal to delete regulatory language requiring EPA to explain why it chooses not to conduct an aggregate exposure assessment. ACA supports EPA's

[5] OSHA *Occupational Exposure to Methylene Chloride*, Final Rule, 62 Fed. Reg. 1494, 1562 (Jan. 10, 1997).

discretion to conduct an aggregate exposure assessment when supported by the best available science under the weight of scientific evidence.

V. ACA supports removing the term "overburdened communities" from consideration as a PESS.

ACA supports EPA's proposal to remove the term "overburdened communities" from the regulatory definition of "potentially exposed and susceptible subpopulations" (also known as PESS). As EPA has noted, it is a vague term that lends itself to scoping the risk evaluation in an overly broad manner. It is also redundant of groups included within the existing definition of PESS.

VI. ACA supports defining "weight of the scientific evidence."

ACA supports defining "weight of scientific evidence" in this rule, based on the definition implemented in the 2017 rule, with some modifications. ACA prefers modifying the definition in the 2017 rule instead of adopting the definition in E.O. 14303 since the 2017 definition provides for more detailed consideration of quality screening implied in the E.O. 14303 definition. ACA believes EPA made the right decision in 2017 to finalize the risk evaluation procedural rule with a codified definition at 40 C.F.R. § 702.33 for this term. That decision was deliberative, after receiving and assessing extensive public comment, and it recognizes that this definition also instills important procedural guard rails. We oppose replacing the definition of "weight of scientific evidence" by relying on general agency guidance documents[7] as was done with the 2024 revisions.

With the 2024 revision, EPA's rationale for eliminating this definition lacked transparency, in that the agency did not demonstrate that the "weight of scientific evidence" definition is limited or impacted the legitimacy of the risk evaluation process. In proposing the 2024 deletion, EPA stated that the existing definition (from 2017) is "problematic and inconsistent with typical risk assessment practice."[8] EPA pointed to the National Academies of Science, Engineering, and Medicine ("NASEM") report, *The Use of Systemic Review in EPA's Toxic Substances Control Act Risk Evaluations*, which stated concerns with the manner in which the term "weight of scientific evidence" was defined in terms of a separate and critical concept, "systemic review."[9] However, EPA rejected the recommendation to simply refine the definition to distinguish its role.[10] Instead, EPA eliminated the definition altogether and relied on four guidance documents that described the "weight of scientific evidence" assessment. In this regard, the 2024 rule, currently in effect, is contrary to and fails to implement NASEM's

[7] 88 Fed. Reg. at 74311.
[8] 88 Fed. Reg. at 74310.
[9] 88 Fed. Reg. at 74311.
[10] NAESM notes that changing a definition can be difficult and suggests that a minimum EPA adopt a specific term to describe the weight of the scientific evidence throughout the evaluation integration step. Seeing as EPA is undergoing a rulemaking, the recommendation to change the definition is relevant as it is a possibility through this proposed rule.

recommendations. NASEM's report highlights how undefined terms and processes can result in compromising the integrity of the risk evaluation process:

> The committee found that transparency of the entire risk evaluation process is compromised across all of its elements. Neither clear questions nor protocols have been developed for the systematic reviews. Consequently, the review process is not documented from its start, and clarity is lacking when the review is finished and published. Overall, the committee found that the lack of information and details about the specific processes used for the identification of evidence reduced confidence in the findings. The OPPT processes and practices are not consistent with the standard of practice for systematic review.[11]

As underscored by the NASEM report, the need to provide transparency to the public regarding the risk evaluation process persists, regardless of perceived weaknesses in the definition included in the 2017 rule.

EPA should not relegate important scientific terms like this one to guidance. As EPA recognized in 2017, defining this term provides for "confidence, increase[s] transparency, predictability, and provide[s] the public with assurance[s] that EPA will adhere to the requirement of the statute."[12] Under the 2017 rule, the term "weight of the scientific evidence" was defined at 40 C.F.R. § 702.33 as follows:

> Weight of the scientific evidence means a systematic review method, applied in a manner suited to the nature of evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

Again, we strongly urge EPA to reinstate an improved version of this definition. A failure to define this term would demonstrate disregard for the process that swayed EPA to invest in defining this term just six years ago. Surely, this is not EPA's intent. At that time, EPA agreed that inclusion of the term would provide "transparency to the public regarding the process for how the Agency reviews scientific information used in risk evaluations without stifling scientific advances."[13]

ACA proposes the following modification of weight of scientific evidence to align with the NASEM report and maintain the integrity of the 2017 final rule:

> Weight of scientific evidence means ~~a systematic review method, applied in a manner suited to the nature of evidence or decision, that uses a pre-established protocol~~ *an* evaluation to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

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[11] National Academies of Sciences Engineering and Medicine. The Use of Systematic Review in EPA's Control Act Risk Evaluations, pp. 6-7. The National Academies Press. Washington, DC 2021. https://doi.org/10.17226/25952.

[12] 82 Fed. Reg. at 33731

[13] 82 Fed. Reg. at 33733.

ACA believes that removing the phrase "a systematic review method, applied in a manner suited to the nature of evidence or decision, that uses a pre-established protocol" is sufficient to distinguish the weight-of-evidence analysis from the systematic review process. This proposed update to the definition removes reference to "systemic review" and incorporates the language from the term used in the TSCA legislative history.[14] There, the Congressional Record notes that the original definition would not "prevent the Agency from considering academic studies or any other category of study."[15] This proposal incorporates some of that language and maintains that discretion for EPA.

VII. ACA supports defining "reasonably foreseen."

ACA supports adopting a definition of "reasonably foreseen" to promote consistency and transparency in how EPA identifies reasonably foreseen conditions of use. ACA recommends alignment with Section 5 practices while focusing the definition on feasible commercial uses rather than speculative or hypothetical uses, even when identified in a patent, or misuse. Misuse should not be considered "reasonably foreseen." Misuse instead is a matter for enforcement. EPA should not regulate commercial uses based on an assumption of misuse. Similarly a patented use is not always a feasible, commercial use such that it is "reasonably foreseen."

ACA suggest the following definition of reasonably foreseen:

> *reasonably foreseen* means a condition of use of a chemical substance that is not currently intended or known, but which a reasonable person would expect to occur in the future based on facts, patterns of use, market trends, or analogous chemical behavior. This does not include speculative, hypothetical, or misuse of a chemical.

VIII. ACA supports defining *de minimis* uses.

ACA supports defining de minimis uses. Although ACA recommends considering de minimis uses on case-by-case basis, without establishing a standard de minimis thresholds, EPA should defer to the OSHA Hazard Communication thresholds of 1% for most hazards and 0.1% for certain health hazards. These thresholds reflect reasoned consideration of concentrations that are indicative of hazard in a mixture that are internationally known and recognized. EPA should carefully consider any deviation from these standards.

ACA also emphasizes that *de minimis* thresholds should not be used to trigger standardized regulatory approaches or outcomes. Rather, EPA must consider *de minimis* amounts on a case-by-case basis to determine when a condition of use involving a *de minimis* amount should be included in the risk evaluation or where modified risk mitigation strategies are appropriate due to a de minimis amount. ACA also encourages EPA to consider *de minimis* amounts in a determination of no unreasonable risk for a condition of use.

ACA proposed the following definition of *de minimis*:

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[14] U.S. Senate Congressional Record, 162 Cong. Rec. S3518 (daily ed. June 7, 2016). https://www.congress.gov/114/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf/ca

[15] *Id*.

De Minimis means a level of presence, exposure, or use of a chemical substance under a condition of use that, based on reasonably available information and the weight of scientific evidence, is unlikely to result in meaningful risk to human health or the environment. This may include:

- *Concentrations below established toxicological thresholds;*
- *Concentrations below background environmental levels;*
- *Uses with negligible exposure potential (e.g., closed systems);*
- *Incidental or trace quantities not contributing to cumulative risk.*

IX. ACA supports developing a process for revising a final risk evaluation.

ACA strongly agrees that EPA must develop procedures to revise a final risk evaluation and those procedures must be codified in regulations to promote consistency and transparency. EPA and industry will inevitably face changes to scientific understanding and availability of commercialized uses after a final risk evaluation is completed, warranting reconsideration. ACA recommends requiring publication of draft changes open to public comment, where EPA proposes changing risk evaluation determinations for any condition of use. EPA should maintain discretion to make editorial and other non-substantive changes after final publication, without public comment.

ACA suggests the following public comment processes based on the type of change:

- Allow revisions to correct minor errors that will not change the risk determinations without re-prioritization or reopening the risk evaluation. If the correction of an error would result in a change to the risk determination for any condition of use, EPA should be required to publish a new draft and seek public comment
- Allow revisions when information used in the initial risk evaluation is retracted or otherwise found deficient with publication of a revised draft risk evaluation open to public comment.
- Allow revisions when new information that would make a change to the unreasonable risk determination for any COU is identified that was not identified or considered during the initial risk evaluation. EPA must publish a revised draft risk evaluation open to public comment.
- Require re-prioritization if EPA or a petitioner identifies new conditions of use such that a SNUN or a SNUR could potentially conflict with requirements in an existing chemicals risk mitigation rule and current data identified through the SNUN process could further update and improve the Section 6 risk evaluation.

X. ACA supports modifications to data submission requirements for manufacturer requested risk evaluations.

ACA supports the proposed modifications to data submission for manufacturer-requested risk evaluations that limit data submission to the manufacturer's conditions of use. EPA's proposed changes to the rule, however, are not clearly consistent with this principle. For example, the proposed text in 702.45(c)(5)(vii) requires information on "Consumer products containing the chemical." This could be read to apply to manufacturers that do not directly manufacture consumer products, especially when read in conjunction with 702.45(c)(4) indicating that a manufacturer must provide "all information…that supports the identification of the requested circumstances." Paragraph (c)(6) furthers this requirement by requiring an explanation if the manufacturer is unable to provide this information. Where a manufacturer is not requesting review of uses relevant to consumer products, it should not be required to submit this information.

XI. Conclusion.

ACA appreciates the opportunity to provide comment. ACA provides the following suggestions:

- Delete current regulatory language requiring EPA to conduct risk evaluations using the whole chemical approach.
- Adopt regulatory language establishing EPA's discretion to issue findings of no unreasonable risk or unreasonable risk based on individual conditions of use in the final risk evaluation or earlier where justified.
- Adopt regulatory language requiring clear communication of conditions of use that do not contribute to unreasonable risk, those that significantly contribute to unreasonable risk and those that contribute to unreasonable risk. That is, EPA should communicate differentiation of the degree of contribution, including those that do not contribute to unreasonable risk.
- Adopt regulatory language related to EPA's discretion to include or exclude conditions of use, including consideration of de minimis amounts and the discretion to include or exclude those amounts based on the best available science and the weight of the scientific evidence.
- Adopt proposed language allowing consideration of workplace risk mitigation practices (PPE, existing exposure values, etc.) during risk evaluation.
- Provide guidance related to consideration of existing OELs, including those promulgated by standardization bodies and professional organizations, while requiring EPA to scientifically justify any deviation that EPA may derive in an ECEL.
- Do not codify a requirement to conduct an aggregate exposure assessment or requiring written justification for declining to do so.

- Remove the term "overburdened communities" from consideration as a PESS.
- Adopt a definition of *weight of the evidence*, considering ACA's suggested definition based on recommendations of the *National Academies of Science, Engineering, and Medicine* ("NASEM").
- Adopt a definition of reasonably foreseen, considering ACA's suggested definition.
- Adopt a definition of *de minimis*, considering ACA's suggested definition.
- Provide a process to revise final risk evaluations, with notice and comment on revised draft risk evaluations for substantive changes.
- Modify data submission requirements for manufacturer-requested risk evaluations, limiting data submission to conditions of use relevant to the manufacturer's uses.

Respectfully submitted,

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