December 14, 2023

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Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460–0001

Submitted via regulations.gov

RE: EPA Proposed Rule, Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA); EPA-HQ-OPPT-2023-0496

Dear Ms Blair:

The Adhesive and Sealant Council (ASC) appreciates the opportunity to provide comments on EPA's proposed rule amending the procedures for chemical risk evaluations under Section 6 of the Toxic Substances Control Act (TSCA).[1]

The Adhesive and Sealant Council (ASC) is a trade association representing the North American adhesive and sealant value chain. The Council is comprised of 117 adhesive and sealant manufacturers, raw material and equipment suppliers, distributors and industry consultants, representing more than 75% of the U.S. industry. Offering education, legislative advocacy, professional networking and business growth solutions for its members, the ASC is the center of knowledge and catalyst for industry growth on a global basis for manufacturers, suppliers and end-users.

Overall Concerns with the Proposed Rule

ASC member companies and their customers manufacture, import, process, distribute and use chemicals subject to TSCA. Section 6 of TSCA requires that EPA systematically prioritize, evaluate, and potentially regulate existing chemicals in U.S. commerce under a risk-based approach, supported by the best available science and based on the weight of the evidence.[2] EPA first promulgated regulations prescribing the risk evaluation procedures in 2017.[3] The proposed amendments to the 2017 rule represent EPA's attempt to codify the current Administration's

[1] 88 Fed. Reg. 74292 (October 30, 2023).
[2] 15 U.S.C. 2605(a)-(b), 2625(h).
[3] 82 Fed. Reg. 33747 (July 20, 2017).

drastic change in interpretation of key statutory requirements of TSCA and its flawed view on the purpose of these requirements when the Frank R. Lautenberg Chemical Safety for the 21st Century Act amendments ("2016 TSCA Amendments") were passed by Congress. This proposed rule will have a significant impact on how EPA reviews every existing chemical substance it considers for risk evaluation going forward.

Mainly, EPA is proposing to upend the current procedures for risk evaluation by: 1) requiring inclusion of *all* conditions of use, including ambient air and water exposure pathways, in the scope of risk evaluations and prohibiting exclusion of any condition of use, no matter how small and no matter if another statute or agency can or already is addressing risks associated with the condition of use; 2) requiring that only one risk determination be made for a chemical for all of the conditions of use "collectively" (referred to as "the whole chemical approach") rather than making individual use-by-use risk determinations; 3) removing the assumption that workers wear personal protective equipment (PPE) when making determinations of risk for occupational uses of chemicals; 4) requiring consideration of "overburdened communities" in risk evaluations to address environmental justice concerns; 5) requiring consideration of aggregate exposures and cumulative risks; 6) removing key scientific definitions from the proposed rule that provide much-needed clarity as to how EPA must evaluate and select scientific data to support a risk evaluation consistent with Section 26(h) of TSCA; 6) relaxing requirements for scientific peer review ;and 7) imposing new burdens of manufacturers requesting chemical risk evaluations by requiring they provide data on *all* conditions of use of a chemical rather than specific uses that are relevant to the requestor.

Many of these issues were debated by EPA, industry, and environmental groups when the 2017 risk evaluation rule was challenged in federal court. In *Safer Chemicals Healthy Families v. EPA*,[4] the environmental groups that were petitioners in this case put forth the same arguments we see in this proposed rule about TSCA supposedly requiring risk determinations on a chemical as a whole rather than use-by-use determinations, and that TSCA prohibits EPA from excluding conditions of use from the scope of a risk evaluation. EPA, under the prior Administration, and industry intervenors opposed this interpretation of TSCA. The Ninth Circuit Court of Appeals declined to address these issues in the litigation[5]; now, these arguments are being raised again, only this time, EPA (under a new Administration) is the one using the arguments to support the proposed rule to reverse the approach adopted in the 2017 regulations for risk evaluations.

Even before this proposed rule, these issues resurfaced in June 2021 when EPA announced that it was going to start implementing the "whole chemical" approach, "no assumption of PPE" policy, and approach for expanding the scope of risk evaluations to be all inclusive.[6] Even without a rulemaking, EPA has been forging ahead and implementing these policy changes by re-doing and re-working risk evaluations and risk determinations for the "first ten" chemicals that have undergone risk evaluation. Between 2021 and 2023, EPA has issued revised risk determinations

[4] *Safer Chemicals, Healthy Families v. US EPA*, 943 F.3d 397 (9th Cir. 2019).
[5] The Ninth Circuit declined to rule on the Petitioners' challenge regarding use-by-use determinations because the issue was not justiciable. And, the Court found the challenge regarding exclusion of conditions of use to "fail on the merits" because the provisions that Petitioners took issue with did not assert discretion to exclude conditions of use from a risk evaluation.
[6] See EPA press release "EPA Announces Path Forward for TSCA Chemical Risk Evaluations" (June 30, 2021), available at: https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

for all of the "first ten" chemicals except for asbestos, and issued a revised supplemental risk evaluation for 1,4-dioxane[7] to include more conditions of use that were previously excluded from the original risk evaluation. EPA also proposed a screening level methodology to evaluate potential exposures for fenceline communities from air and water pathways not previously included in risk evaluations.[8]

The proposed rule is EPA's attempt to incorporate the June 2021 policy choices into an enforceable regulation. Our members are concerned with how EPA is currently evaluating existing chemicals under TSCA Section 6 and how it plans to continue doing so in the future. Because EPA has already taken actions to implement its policy interpretations for chemical risk evaluations, we are *already* seeing the consequences of these policies on EPA's progress (or lack thereof) on the "first ten" chemicals. As explained further below, we are concerned that the proposed amendments to the risk evaluation rule are inconsistent with the statutory text and legislative intent of TSCA, violate TSCA's science standards, and are overall problematic and unreasonable interpretations of TSCA. They will result in unwieldy, expansive, unscientific risk evaluations that lead to overregulation of chemicals. And, EPA will not have the resources to complete such cumbersome evaluations in a timeframe consistent with TSCA's statutory deadlines. EPA should not adopt the changes in the proposed rule if it wants to make progress on reviewing existing chemicals in an efficient manner that also ensures public confidence in EPA decisions on the safety of chemicals in commerce.

I. EPA Must Not Finalize the "Whole Chemical Approach" Because It Violates TSCA Section 6, Renders Other Parts of the Statute Moot, Is Not the Best Available Science, and Would Mislead the Public About the Risks of Chemicals.

a. The "whole chemical" approach violates TSCA Section 6.

TSCA Section 6 requires that EPA "conduct risk evaluations…to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, **under the conditions of use**."[9] The term "conditions of use" means "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[10] EPA must define the specific conditions of use it plans to evaluate for a given chemical when it determines the scope of a risk evaluation. The scope includes "the hazards, exposures, **conditions of use**, and the potentially exposed or susceptible subpopulations the

[7] See supplemental risk evaluation for 1,4-dioxane, released July 2023: https://www.epa.gov/system/files/documents/2023-07/1.%20Draft%20Supplement%20to%20the%20Risk%20Evaluation%20for%2014-Dioxane%20-%20public%20release%20-%20hero%20-%20July%202023.pdf.

[8] See EPA "TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities": https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-screening-level-approach-assessing-ambient-air-and#:~:text=The%20proposed%20screening%20level%20methodology,with%20such%20releases%20and%20exposures.

[9] 15 U.S.C. 2605(b)(4)(A).

[10] 15 U.S.C. 2602(4).

Administrator expects to consider…."[11] EPA must "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures **under the conditions of use** of the chemical substance."[12]

These statutory provisions make clear that EPA, in performing risk evaluations and risk determinations, must do so based on EPA's evaluation of the conditions of use of the chemical. EPA's process for prioritization, risk evaluation, and risk management incorporate the concept of "conditions of use." For example, TSCA Section 6(a), which governs risk management, refers to the determination made by EPA under TSCA Section 6(4)(b), which is the determination of unreasonable risk "under the conditions of use."[13] EPA cannot simply read out of TSCA the requirement to evaluate and make risk determinations under "the conditions of use." EPA's approach of making a single determination for a chemical ignores that TSCA Section 6 is structured in a manner which directs EPA to identify individual conditions of use, evaluate them, and make a risk determination for that condition of use. For EPA to arbitrarily consider the conditions of use "collectively" and make one determination for the whole chemical disregards the overall use-by-use approach taken TSCA Section 6.

b. The "whole chemical" approach would render other parts of the statute superfluous, which is not what Congress intended.

Congress intended that EPA not only find that some uses of chemicals present an unreasonable risk, but also some uses *do not* present an unreasonable risk. However, contrary to Congressional intent, if EPA adopts the "whole chemical" approach, it likely will never make a "no unreasonable risk" determination for the chemical. All conditions of use of every chemical will go to risk management, where EPA will be forced use its Section 6(a) authorities to regulate *all* conditions of use, even conditions of use where EPA found *no* unreasonable risks.[14]This is nonsensical and not an efficient use of limited agency resources.

EPA states that even one condition of use could "drive" an unreasonable risk determination for the whole chemical: "EPA may determine that a chemical substance presents an unreasonable risk based on risk associated with even a single condition of use."[15] Because EPA, under this approach, will probably never issue a "no unreasonable risk determination," other parts of TSCA that contemplate such findings will be rendered superfluous, which is not what Congress intended.

[11] 15 U.S.C. 2605(b)(4)(D).
[12] 15 U.S.C. § 2605(b)(4)(F) (emphasis added).
[13] 15 U.S.C. 2605(a).
[14] We have already seen this happen with EPA's proposed risk management rules for the "first ten" chemicals where some conditions of use were found in the original risk determinations to "not present" an unreasonable risk AND in the revised risk determinations were found "not to drive" the unreasonable risk determination. Yet, because all conditions of use proceeded to risk management, those uses that did not present a risk were still proposed to be regulated. For example, for TCE, EPA had found consumer use of TCE in pepper spray to not present an unreasonable risk. Yet, EPA is proposing to ban this condition of use. 88 Fed. Reg. 74712, 74763 (October 31, 2023).
[15] 88 Fed. Reg. at 74303.

For example, TSCA Section 6(i) provides that a "no unreasonable risk" determination by EPA following a risk evaluation is considered a final agency action (and, thus, subject to judicial review[16]) that does not trigger risk management.[17] And, Section 6(b)(4)(A) requires that EPA risk evaluations determine "*whether* a chemical substance presents an unreasonable risk…under the conditions of use,"[18] meaning EPA will decide for each condition of use identified in the scope whether it does or does not present an unreasonable risk. [19]

And, TSCA's Section 18 preemption provisions also refer to federal preemption of state actions for which "no unreasonable risk" determinations have been made under TSCA Section 6(i).[20] Without EPA's ability to decide certain conditions of use do not present an unreasonable risk, businesses will not be able to take advantage of part of TSCA's rigorous preemption provisions. Preemption was one of the most important issues discussed during TSCA reform, and Congress agreed it was critical to curb the emerging patchwork of state regulations by having regulatory decisions from EPA preempt certain state actions.[21] In doing so, TSCA provides that when EPA makes a "no unreasonable risk" determination for a condition of use of a chemical, then that final agency action preempts state action for the same condition of use addressed by EPA. However, under the whole chemical approach, since EPA will not be making "no unreasonable risk" determinations, this provision under TSCA Section 18 would simply not happen.

These provisions would be rendered superfluous if EPA implements the whole chemical approach, which is inconsistent with the intent of TSCA. Congress intended for there to be both no unreasonable risk determinations and unreasonable risk determinations for chemicals undergoing risk evaluation.

c. The "whole chemical" approach is vague, unscientific, and will result in overregulation of chemicals.

In the proposed rule, EPA does not provide a reasoned explanation for how it will actually make a single risk determination for a "whole chemical." EPA states that it may make an unreasonable risk determination for a substance based on "even a single condition of use."[22] And, EPA says it "intends to identify the conditions of use that *significantly contribute*" to the risk determination.[23] EPA provides no discussion of what a "significant contributor" to a risk determination means. Nor does it explain how one condition of use can render an entire chemical to pose an unreasonable risk when all other conditions of use do not present a risk. EPA's description of the whole chemical approach in the proposed rule is unclear, and is divergent from EPA's 2021 policy announcement. In that announcement, EPA described the whole chemical approach as

[16] 15 U.S.C. 2618(a).
[17] 15 U.S.C. 2605(i).
[18] 15 U.S.C. 2605(b)(4)(A).
[19] See also the Congressional record discussing "no unreasonable risk" determinations, 162 Cong. Rec. S3520 (June 7, 2016) (emphasis added).
[20] 15 U.S.C. 2617(a)(1)(B), (c).
[21] Congress cites that "address[ing] when federal actions under TSCA preempt requirements of state and local governments related to restricting and banning chemical substances," a major provision of TSCA reform legislation. House Report 114-176 at 17.
[22] 88 Fed. Reg. at 74303.
[23] 88 Fed. Reg. at 74321.

making a determination of unreasonable risk for the whole chemical "when it is clear the *majority* of the conditions of use warrant one determination."[24] EPA has also explained the whole chemical approach as making a single determination when "a *substantial amount* of the conditions of use drive the unreasonable risk."[25]

EPA has provided inconsistent explanations of how it will decide, once it makes individual findings for each condition of use of a chemical, whether the chemical "as a whole" presents an unreasonable risk. This lack of a reasoned explanation will make the risk evaluation process unpredictable and inconsistent in its application.

Further, EPA's vague explanation for how it will make risk determinations highlights how unscientific and arbitrary the process actually is. EPA will actively disregard some of its own findings for conditions of use over others in making an overall risk determination for the chemical. In some cases, EPA admits it may actually disregard its findings for all conditions of use save for one, and that condition of use will drive the entire unreasonable risk determination. This approach does not reflect the best available science or the weight of the scientific evidence, as required by TSCA Section 26(h). Nor does EPA's undefined approach provide the public with adequate notice as to how the agency is going to make critical decisions about the risks of chemicals.

d. The "whole chemical" approach would mislead the public about the risks of chemicals.

Under the whole chemical approach, EPA essentially brands a chemical as unsafe. EPA does not consider the potential market impacts that this approach could have on chemicals that, under many conditions of use, are safe (based on EPA's own risk evaluations). Consumers are unlikely to read the entirety of a TSCA risk determination to understand what the risk determination means for the chemical. Even if they do review a risk determination, it is still not clear that consumers will understand what EPA has concluded about a given chemical's risk to human health or the environment when it has one "unreasonable risk" determination but other variable statements as to "drivers" of the risk. While EPA believes this type of concern can be addressed through effective risk communication,[26] this is simply not enough to guarantee that there will not be adverse economic or social impacts from making a generalized and misleading conclusion that a "whole chemical" is unsafe. Misled consumers may voluntarily deselect the chemical. Retailers may impose unnecessary restrictions on their suppliers so that products cannot contain the chemical. Or, states may decide to regulate the chemical. The use-by-use risk determination approach is a much more rational, understandable, science and risk-based approach for risk determinations because it clearly associates EPA's risk determination with the specific condition of use that was evaluated.

[24] Emphasis added. See EPA press release, "EPA Announces Path Forward for TSCA Chemical Risk Evaluations," June 30, 2021: https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.
[25] Final Unreasonable Risk Determination for HBCD (June 2022), Document ID EPA-HQ-OPPT-2019-0237-0125, Section 5.1.1, pp. 2-3 (emphasis added).
[26] 88 Fed. Reg. at 74303.

II. EPA Must Not Finalize its Proposal to Prohibit Exclusions of Conditions of Use in the Scope of a Risk Evaluation because this Violates TSCA Section 6 and Section 9, and Is Inconsistent with TSCA's Tight Deadlines for Completion of Risk Evaluations and Risk Management Rules.

a. Prohibiting EPA from being able to choose which conditions of use it considers in risk evaluations violates TSCA Section 6.

In determining the scope of a risk evaluation, EPA must include in the scoping document "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider…."[27] This "expects to consider" language indicates that EPA will select the conditions of use it expects to evaluate in a risk evaluation, and which conditions of use it will not evaluate. Further, the "conditions of use" of a chemical are "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."[28] The use of the term "as determined by" EPA again indicates that EPA has discretion to choose the conditions of use within the scope of a risk evaluation. If Congress had intended that EPA evaluate *all* conditions of use of a chemical in a risk evaluation without any discretion to exclude any, it would have indicated so in the statute.

b. This policy violates TSCA Section 9, which requires coordination and in some cases deference to other federal authorities.

TSCA is intended to be a "gap filling" statute, where it regulates exposures of concern that are not already adequately addressed by other EPA or other federal authorities. The entirety of TSCA Section 9 reinforces this "gap filing" purpose of TSCA. Section 9(a) provides that if EPA determines that a substance presents an unreasonable risk such that risk may be prevented or reduced to a sufficient extent under another federal law, EPA must submit a report to the agency and request action on the chemical.[29] And, Section 9(b) requires that EPA coordinate actions taken under TSCA with other EPA laws, and if EPA determines that the risk can be eliminated or reduced to a sufficient extent by actions taken under other EPA laws, EPA must use those other laws to protect against such risks.[30] And, Section 9(d) provides that in administering TSCA, EPA must consult and coordinate with other federal agencies to avoid duplicative requirements.[31]

Congress clearly included these safeguards to avoid TSCA being used in a way that layers requirements on top of existing ones, causing over-regulation and confusion as to how to comply with multiple laws covering the same exposures. Congress intended for EPA to defer to other agencies or other EPA statutes to regulate in areas in which other agencies or programs are more appropriate and better suited to address those exposures., Consistent with this approach, Congress intended EPA to have the discretion to exclude conditions of use of a chemical that it believes can be sufficiently addressed by other laws. And this approach is reasonable, as other EPA authorities and in some cases other federal agencies have the requisite experience and

[27] 15 U.S.C. 2605(b)(4)(D).
[28] 15 U.S.C. 2602(4) (emphasis added).
[29] 15 U.S.C. 2608(a).
[30] 15 U.S.C. 2608(b).
[31] 15 U.S.C. 2608(d).

expertise to address such exposures under their purview. EPA must be able to comply with its obligations under Section 9 of TSCA, and it would be unable to do so if EPA revises its regulations to prohibit exclusion of conditions of use from the scope of a TSCA risk evaluation. This is certainly not what was intended—for EPA to violate one section of TSCA in order to comply with another.

c. This policy will result in significantly expanded risk evaluations, contrary to EPA's statutory deadlines for risk evaluations and risk management rules.

Congress established a rigorous schedule in which EPA is to conduct and complete risk evaluations for chemicals. The intent was that EPA make progress on reviewing and regulating existing chemicals, as compared to the glacial pace in which EPA was doing so prior to the 2016 TSCA Amendments. EPA must complete the scope of a risk evaluation within six months,[32] and the risk evaluation within three years (with the option to extent the deadline by up to six months).[33] Risk management rules must be promulgated two years after that (with the option to extend by two years).[34]

EPA has already missed these deadlines for the "first ten" chemicals, and for the 20 chemicals undergoing risk evaluation. Part of the reason for this is because EPA has continued to go back and expand the risk evaluations—for example, like adding a supplemental evaluation to add new exposure pathways for 1,4-dioxane—and redoing risk determinations. If EPA is not permitted to exclude any conditions of use from the scope of a risk evaluation, risk evaluations will be extremely comprehensive and unwieldy. They will include exposures that can be addressed by other laws and exposures of very low concern, like conditions of use where the use of the chemical is only *de minimis*. EPA should not be forced to expend its limited resources conducting risk evaluations that will not produce useful information about the risks of a chemical. EPA should be allowed to focus risk evaluations on the conditions of use for which it has the most concerns in order to ensure it will achieve the statutory deadlines mandated by TSCA while also providing the public health protections sought by Congress.

III. EPA Must Not Finalize its Proposal to No Longer Assume PPE Use for Occupational Uses of Chemicals.

EPA's proposal to no longer consider exposure reductions based on the use of PPE by workers is arbitrary and capricious. EPA's proposal essentially indicates that it does not matter what evidence they have when considering worker exposures when developing a risk evaluation. Instead, EPA will assume in all cases that PPE is not used (or not used in a compliant manner) in the workplace. This assumption about widespread noncompliance with OSHA standards or other worker safety standards is not based on the best available science. For this approach to be science-based, EPA would have to cite to data for each chemical's conditions of use to prove that, based on data for that specific condition of use, PPE is not used properly. In all of the revised risk determinations for the "first ten" chemicals thus far, EPA has not done this. And, EPA does not appear to intend to do this at all, as it wants to

[32] 15 U.S.C. § 2605(b)(4)(D).
[33] 15 U.S.C. § 2605(b)(4)(G).
[34] 15 U.S.C. § 2605(c)(1).

codify this approach in a procedural rule applicable to all risk evaluations no matter what the evidence for a given chemical and condition of use suggests about PPE usage.

This is an overly-precautionary approach that will result in overly-conservative determinations of risk to workers. While EPA says it will address PPE in the risk management stage, this is not a solution to the problem. If EPA does not consider data about PPE usage in making a risk determination, that will guarantee that almost every industrial or commercial condition of use of a chemical will be found to present an unreasonable risk or found to "drive" an unreasonable risk determination. Then, all of these conditions of use will be forced to go to risk management, where EPA will impose new or duplicative worker protection program controls and an existing chemical exposure limit (ECEL) that, based on EPA's current risk management proposals, will be orders of magnitude below the current occupational exposure limit. This approach is arbitrary and not based on the best available science as required under TSCA. EPA cannot ignore existing OSHA standards and other industrial hygiene practices that have been in place for decades to address worker exposures to chemicals.

IV. EPA Must Not Require, Rather Than Leave to EPA Discretion, Consideration of Aggregate Exposures and Cumulative Risk.

EPA proposes to further expand the scope of TSCA risk evaluations by requiring that EPA must consider aggregate exposures. And, it is taking comment on whether EPA should require cumulative risk assessments. Neither of these are required under TSCA. We do not support requiring such additional evaluations in TSCA risk evaluations because they will only serve to expand the scope of evaluations and delay completion of evaluations long past their statutory deadlines. And, TSCA only requires that the unreasonable risks of a substance under its conditions of use be evaluated under a TSCA risk evaluation.[35] TSCA does not permit evaluation of *other* chemicals and non-chemical stressors to making a risk evaluation and determination for the chemical.

V. It is Inappropriate for EPA to Insert Environmental Justice Communities in the Definition of "Potentially Exposed Subpopulations" in this Proposed Rule.

EPA proposes to add "overburdened communities" to the definition of "potentially exposed or susceptible subpopulations" (PESS). That means that in a risk evaluation, EPA will be required to consider exposures to overburdened communities. TSCA defines PESS to mean "a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."[36] Notably, "overburdened communities" is not included on this list.

Congress intended for PESS considerations in risk evaluations to include persons who are disproportionally susceptible to chemical exposures, such as the groups identified in the statute.

[35] 15 U.S.C. 2605(b)(4)(A).
[36] 15 U.S.C. § 2602(12).

An "overburdened community" does not fit with these other types of groups because their susceptibility (like women, children or the elderly) is not tied to the individual, but a location. And, EPA does not define what an overburdened community is, or what criteria to use to identify such a community. This approach will result in overly expansive risk evaluations that, again, EPA will not be able to complete within its statutory timeframes. Potentially thousands of communities could fit the bill for an "overburdened community" because they may have close proximity to businesses that use the chemical, or EPA may otherwise find they are more susceptible to chemical exposures generally. This approach is not what Congress intended and it would not make the risk evaluation process workable.

VI. EPA Should Not Remove Key Scientific Definitions from the Existing Risk Evaluation Rule.

EPA proposes to remove the definition of "best available science" and "weight of scientific evidence" in the risk evaluation regulations. While these terms are used in TSCA Section 26, they are not defined. TSCA only provides a list of criteria for EPA to consider in using the best available science.[37] Therefore, EPA's current definitions of best available science and weight of the evidence are critical for the regulated community to understand how EPA is going to approach consideration of scientific data in a risk evaluation. EPA should not remove these regulatory definitions because this would result in a lack of transparency and clarity about the scientific standards EPA will use in risk evaluations.

VII. EPA Should Not Only Require Peer Review of Certain "Portions" of a Risk Evaluation.

EPA proposes to conduct peer review on only "portions"[38] of a risk evaluation and not an entire risk evaluation. And, it and states that, when it uses peer-reviewed products from another EPA office or another authoritative body, peer review under TSCA may not be required.[39] It is inconsistent with TSCA's mandate to use the best available science to forego peer review of risk evaluations (or even portions of a risk evaluation. Even if documents have been peer reviewed by other EPA offices, that does not necessarily mean the review will be appropriate under TSCA. EPA should not forego robust peer review when TSCA risk evaluations are complex and have the potential to lead to significant restrictions of a chemical's conditions of use.

VIII. EPA Must Not Finalize Its Proposed Revisions to the Manufacturer-Initiated Risk Evaluation Process Because the Proposed Changes Will Make this Option Prohibitive for Manufacturers.

TSCA's permits manufacturers to request EPA to conduct risk evaluations (manufacturer-requested risk evaluations or MRREs). [40] This process was intended by Congress to be a benefit for industry so that EPA could fast track decisions on the risks of chemicals, and EPA's decision would preempt potential state action on that same chemical for the same conditions of use. Under the current process, manufacturers can request risk evaluations be conducted on chemicals under

[37] 15 U.S.C. 2625(h).
[38] 88 Fed. Reg at 74323.
[39] 88 Fed. Reg. at 74308.
[40] 15 U.S.C. § 2605(b)(4)(C)(ii).

certain conditions of use of interest to the manufacturer, as the results of the risk evaluation would actually be relevant to their business.

Now, EPA proposes that manufacturers who request risk evaluations for a chemical must request and provide supporting data for *all* conditions of use. This complete burden shift onto the manufacturer is inappropriate, as this was not intended when Congress included this option in TSCA Section 6. And, manufacturers would have to expend significant resources to identify all known, intended and reasonably foreseen conditions of use for a chemical and provide data on these conditions of use (to the extent the information is known to or reasonably ascertainable by them). The significant burdens and expense[41] EPA proposes to foist on to manufactures will render the MRRE process unusable. No manufacturer would be incentivized to use this option if they have to meet all of the additional requirements and cover all conditions of use. Congress would not have included the MRRE process if it did not intend for it to be used. EPA should not finalize the revisions to the MRRE process.

IX. Conclusion

Thank you for the opportunity to provide these comments. Please contact me at bill.allmond@ascouncil.org if you have any questions.

Sincerely,

William E. Allmond, IV
President

[41] Note manufacturers already have to pay a hefty fee for EPA to conduct an MRRE. In the proposed TSCA Fee rule, EPA proposed that this manufacturer fee be at least $3M. 87 Fed. Reg. 68647 (November 16, 2022).