December 14, 2023

Submitted via regulations.gov

Susanna W. Blair
Immediate Office
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: **Proposed Rule, Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74292 (Oct. 30, 2023), Docket No. EPA-HQ-OPPT-2023-0496**

Dear Dr. Blair:

The American Chemistry Council (ACC) is pleased to submit the attached comments on the Proposed Rule, Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74292 (Oct. 30, 2023), Docket No. EPA-HQ-OPPT-2023-0496.[1]

If adopted, these changes would significantly broaden and complicate TSCA risk evaluations. They would hinder EPA's ability to meet statutory deadlines for risk evaluations. And they would drive arbitrary, unnecessarily restrictive risk management decisions. The Agency's re-interpretation of the 2016 TSCA amendments upon which EPA has relied to rationalize these major changes to the procedures for TSCA risk evaluations is inconsistent with Congressional intent and with a reasonable interpretation of the law taken as a whole.

EPA's proposed revisions are unworkable, could create due process problems with respect to lack of notice to potentially regulated entities, and are simply not reasonable to implement. They should be withdrawn. EPA should retain the existing framework rule as it was originally promulgated.

[1] ACC represents the leading companies engaged in the multibillion-dollar business of chemistry. ACC members apply the science of chemistry to make innovative products, technologies and services that make people's lives better, healthier, and safer. ACC is committed to improved environmental, health, safety, and security performance through Responsible Care®; common sense advocacy addressing major public policy issues; and health and environmental research and product testing. ACC members and chemistry companies are among the largest investors in research and development, and are advancing products, processes, and technologies to address climate change, enhance air and water quality, and progress toward a more sustainable, circular economy.

We incorporate our previous comments on the revised risk determinations by reference.[2]

Please let me know if you have any questions regarding these comments. I can be reached at 202-249-6440 or Suzanne_Hartigan@americanchemistry.com.

Sincerely,

Suzanne Hartigan, Ph.D.
Senior Director, Regulatory and Scientific Affairs

[2] Comments of the American Chemistry Council on the Draft Revised Toxic Substances Control Act (TSCA) Risk Determination for 1,4-Dioxane; Docket ID EPA-HQ-OPPT-2016-0723-0115;
Comments of the American Chemistry Council on the Draft Revision to the Toxic Substances Control Act (TSCA) Risk Determination for 1-Bromopropane (1-BP); Docket ID EPA-HQ-OPPT-2016-0741-0108;
Comments of the American Chemistry Council on the Draft Revision to the Toxic Substances Control Act (TSCA) Risk Determination for Carbon Tetrachloride; Docket ID EPA-HQ-OPPT-2016-0733-0115;
Comments of the American Chemistry Council on Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination, Docket ID EPA-HQ-OPPT-2019-0237-0119;
Comments of the American Chemistry Council on Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination for Colour Index Pigment Violet 29 (PV29) (Docket ID EPA-HQ-OPPT-2016-0725-0081);
Comments of the American Chemistry Council on the Draft Revisions to Toxic Substances Control Act (TSCA) Risk Determinations for: Perchloroethylene (PCE) (Docket ID EPA-HQ-OPPT-2016-0732-0120), n-Methylpyrrolidone (NMP) (Docket ID EPA-HQ-OPPT-2016-0743-0126), Methylene Chloride (MC) (Docket ID EPA-HQ-OPPT-2016-0742-0127), Trichloroethylene (TCE) (Docket ID EPA-HQ-OPPT-2016-0737-0133)

Comments of the American Chemistry Council
on
Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA)
88 Fed. Reg. 74292
EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP
December 14, 2023

I. Introduction

The Toxic Substances Control Act (TSCA) was amended in 2016. The amended statute required EPA to start up and manage, in perpetuity, a process for identifying and prioritizing chemicals for risk evaluation, conducting those risk evaluations, making determinations of risk at the end of the risk evaluation, and – where determining that unreasonable risk exists – conducting a risk management process and regulating to the extent necessary so that the chemical no longer presents unreasonable risk.

The amended statute required EPA to immediately establish three procedural rules to implement the statute and the new requirements for risk evaluation and risk management. The first was a process rule to segregate the list of chemicals in commerce, or the "TSCA Inventory," so it is clear which chemicals on the list are no longer being manufactured and used ("in commerce"). The second was a process rule to inform the selection of chemicals for prioritization for risk evaluation. The third was a process rule to inform the risk evaluations themselves:

> ESTABLISHMENT OF PROCESS.—Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).[1]

EPA finalized the Risk Evaluation process rule – also called a risk evaluation framework rule – promptly, and the rule became effective on September 18, 2017. EPA now proposes revisions to the Toxic Substances Control Act's (TSCA) Procedures for Chemical Substance Risk Evaluation[2] ("risk evaluation framework rule" or "framework rule") that would mandate significant, comprehensive changes to TSCA's current risk evaluation procedures. The proposed changes represent a wholesale re-interpretation of TSCA Section 6's risk evaluation provisions and a complete reconsideration of the 2017 final risk evaluation framework rule. EPA's stated purpose for making these changes – to achieve "more protective rules for workers and communities" under TSCA[3] – represents legal and policy overreach, well beyond what Congress contemplated in the bipartisan TSCA amendments in 2016.[4] Taken as a whole, these proposed changes would undermine the 2016 amendments' purposefully focused, systematic, and science-based approach to the evaluation and regulation of existing TSCA chemicals.

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[1] 15 U.S.C. § 2605(b)(4)(B).
[2] 40 C.F.R. Part 702, Subpart B; 82 Fed. Reg. 33726 (July 20, 2017).
[3] U.S. Environmental Protection Agency, News Release (Oct. 19, 2023). Available at https://www.epa.gov/newsreleases/epa-proposes-rule-strengthen-tsca-risk-evaluation-process-protect-workers-and.
[4] Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182 (2016), amending 15 U.S.C. §§ 2601 et seq.

EPA characterizes its proposed changes to the 2017 framework rule as "targeted amendments" based upon the Agency's reconsideration of the current rule in light of: the statutory text and structure and Congressional intent; the November 19, 2019 opinion of the U.S. Court of Appeals for the Ninth Circuit; the Biden Administration's Executive Order 13990; and lessons learned from EPA's implementation of the risk evaluation program to date.[5] However, the Agency's proposed changes go well beyond "targeted" adjustments to the existing framework. EPA has proposed comprehensive changes to the current rule that greatly exceed describing the process by which EPA will apply the statutorily mandated criteria for risk evaluations. When all the revisions are applied, they would result in more restrictive regulations of chemicals than are necessary or warranted under the statute. For example, EPA has proposed:

- a mandate to forego scoping of TSCA risk evaluations and instead include "all" conditions of use of a chemical in every TSCA risk evaluation;
- a mandate to make only a "single risk determination" of an evaluated chemical substance, without regard to differences presented by the chemical under varying conditions of use;
- a "no personal protective equipment (PPE)" assumption about workplace exposures – instead of relying on reasonably available information about actual practices and realistic conditions of use in workplaces, including OSHA-regulated chemical manufacturing workplaces;
- revisions addressing categories of chemical substances, aggregate exposure, cumulative risk assessment and over-burdened communities to more regularly address "combined exposures" to TSCA chemicals in TSCA risk evaluations; and
- deletion of the regulatory definitions of the two statutory terms, "best available science" and "weight of the scientific evidence," which form the basis of EPA's application of TSCA's Section 26 scientific standard on decisions such as Section 6 risk determinations.

Taken together, the synergistic effects of multiple scope expansions, without consideration of *de minimis* levels, non-TSCA uses, aggregate exposures, and potential cumulative risk assessment render EPA's proposed changes to the risk evaluation framework rule completely unworkable. Risk evaluations covering "all conditions of use" and addressing combined exposures to TSCA chemical substances would be extraordinarily complex. As a result, statutory deadlines for risk evaluations would be regularly missed. Moreover, making single risk determinations for a "whole chemical" provides the regulatory community with inadequate information to prepare for risk management. Further, combined exposures to multiple substances would make it impossible to address EPA's potential risk management requirements. The Agency's re-interpretation of the 2016 TSCA amendments upon which EPA has relied to support these major changes to the procedures for TSCA risk evaluations is inconsistent with Congressional intent and with a reasonable interpretation of the law taken as a whole.

II. General Comments

[5] 88 Fed. Reg. 74292, 74293 (Oct. 30, 2023).

A. EPA's Proposed Revisions to the Risk Evaluation Framework Rule Would Lead to Broader, More Complex and Unwieldy Risk Evaluations, with Consequential Impacts

l. All Conditions of Use (COUs)

Many TSCA chemicals are "building block" chemicals with myriad industrial, commercial, and consumer uses. There are tens of thousands of existing TSCA chemicals and many of these have hundreds, thousands, tens, or hundreds of thousands of "conditions of use."[6] Based on its re-interpretation of the statute, EPA declares it lacks discretionary authority to determine which conditions of use of a priority chemical should be included in a chemical's risk evaluation. Based on this interpretation, EPA proposes to mandate that every TSCA risk evaluation's "scope" include "all" conditions of use and "all" exposure pathways. EPA makes clear in the preamble that "all" conditions of use and exposure pathways means "all." EPA would include:

- conditions of use with minimal exposure potential;
- exposure pathways already regulated under other environmental statutes under EPA's jurisdiction (e.g., Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act);
- conditions of use subject to other federal laws, such as the Occupational Safety and Health Act; and
- even those conditions of use which the Agency believes do **not** present unreasonable risk.[7]

This proposed mandate to forego scoping and instead include every condition of use in each risk evaluation, regardless of circumstances and needs, and without regard to the statutory deadlines to complete risk evaluations within a maximum of 3 ½ years, is imprudent and contrary to EPA's own risk assessment guidance. It would establish an unyielding mandate for every risk evaluation to be as complex as possible and would be unworkable in the context of the rest of the statute.

The proposed changes to the framework rule would reverse EPA's previous decision to exclude exposure pathways addressed by other environmental statutes from the risk evaluations conducted under Section 6. While the Agency had previously decided that TSCA Section 6(b)(4)(D) provided EPA discretion to exclude exposure pathways addressed by other EPA offices, the proposed framework rule seeks to codify the Agency's June 30, 2021 announcement that it would no longer follow this approach. According to the preamble, this decision is based on EPA's reconsideration of "the text of the relevant statutory provisions, overarching statutory structure and context, and legislative history."[8]

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[6] "Conditions of use" is defined in TSCA Section 3(4) 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." 15 U.S.C. § 2602(4).
[7] 88 Fed. Reg. at 74296-98.
[8] Id. at 74299.

As part of its rationale, EPA cites two excerpts from the Senate's discussion of the House/Senate Conference Report which it suggests are supportive of an "all in" approach.[9] However, EPA does not include the following statements from the same discussion of direct relevance to the consideration of all pathways and conditions of use -

> Mr. INHOFE. Senator VITTER and I rise today to discuss a few provisions in the bill with the desire of clarifying what the Congressional intent was behind specific provisions of the legislation. Senator VITTER, I would like to start with a question to you on the purpose of the term ''conditions of use'' and how that term is supposed to be applied by EPA in risk evaluations?
>
> Mr. VITTER. Thank you Senator INHOFE. There are many important provisions of this law and I think clarifying what Congress intended is very important to ensure the legislative intent is understood and followed. To specifically address your first question, the term ''conditions of use'' is specifically 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.' The conditions of use of a chemical substance drive the potential for exposure to a chemical. Exposure potential, when integrated with the hazard potential of a chemical, determines a chemical's potential for risk. So EPA's understanding of a chemical's conditions of use—and importantly it is the circumstances 'the Administrator' determines—will be critical to EPA's final determination of whether a chemical is safe or presents an unreasonable risk that must be controlled. Finally, to address your question of how this is supposed to be applied by EPA in risk evaluations, it is important to note that many TSCA chemicals have multiple uses—industrial, commercial and consumer uses. EPA has identified subcategories of chemical uses for regular chemical reporting requirements, so the Agency is well aware that some categories of uses pose greater potential for exposure than others and that the risks from many categories of uses are deemed negligible or already well controlled. 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 that the Agency will address in its evaluation of the priority chemical. This assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law's strict deadlines. Without this discretion to focus chemical risk assessments on certain conditions of use, the Agency's job would be more difficult.[10]

As explained by Senator Vitter, and counter to the Agency's conclusion, the intent of the House/Senate compromise language was to give the Agency "the discretion to determine the

[9] Id. 74297. Rather than provide the full discussion from the record of the Senate's discussion, EPA includes only selective excerpts which the Agency argues "imply" its revised interpretation of the law.
[10] 162 Cong. Rec. S3511, S3519 (daily ed. June 7, 2016). Available at https://www.congress.gov/114/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf.

conditions of use that the Agency will address in its evaluation of the priority chemical." The discussion also echoes the other benefits to a discretionary approach which the Agency had previously identified, but now discounts: the ability to (1) focus on the conditions of use that raise the greatest potential for exposure and (2) more effectively comply with the law's strict deadlines.

EPA also discounts the Agency's previous conclusion that the language of Section 9(b)(1) grants the Agency the discretion to exclude pathways regulated under those other authorities from TSCA risk evaluations. In explaining the decision to reverse its previous position, EPA points to legislative history from TSCA's original 1976 enactment.[11] Citing the 1976 language, EPA argues that Section 9(b) is "properly interpreted in the context of risk management action rather than any preceding evaluation of risk." However, prior to the 2016 amendments, risk evaluation was included as part of a risk management action and not treated as a separate activity. The legislators enacting the original 1976 statute did not separate risk evaluation from risk management, nor could they have contemplated that a future Congress would decide to create such separation. Consequently, the 1976 Conference Committee's report does not support the Agency's current interpretation of legislative intent.

While EPA discusses Section 9(b)(1)'s requirement to "coordinate actions" with those taken under other laws administered by the Agency, it ignores the subsequent language that the subsection "shall not be construed to relieve the Administrator of any requirement imposed on it by such other Federal laws." These requirements extend not only to actions that may be taken under other laws but also to the criteria for determining whether such action is necessary.

The intention to evaluate all exposure pathways, as evidenced in the recent draft supplemental risk evaluation for 1,4-dioxane, directly overlaps with the activities regulated by the Agency under the Clean Water Act, Clean Air Act, Safe Drinking Water Act, and other statutes. One cannot reasonably conclude that it was Congress' intent to supplant these other statutes, or to render them obsolete, in the amendments to TSCA. Moreover, the application of TSCA's "unreasonable risk" criteria to evaluating exposures which are subject to different criteria under these other statutes creates significant potential for conflicting goals and priorities.[12] Evaluating exposures under the criteria outlined in TSCA, without also incorporating the criteria outlined in these other EPA statutes, is counterproductive, and potentially violates the mandate to adhere to the requirements of the other statutes.

EPA should have a process whereby it considers the applicability of *de minimis* thresholds on a case-by-case basis and should not lock itself into a framework rule that requires consideration of non-TSCA uses. EPA has yet to finalize even a single risk management rule following some of the initial risk evaluations, but it is increasingly clear that a consistent approach to *de minimis*, and appropriate recognition and establishment of *de minimis* levels or concentration limits, will

[11] 88 Fed. Reg. at 74299. ACC was unable to locate the excerpt included in the Preamble as the Conference Committee report from which it is apparently drawn is no longer available online. The reference provided in the Preamble does not include the quoted language.

[12] For example, Section 1412(b)(1)(A) of the Safe Drinking Water Act requires that EPA determine that regulation of a contaminant presents "a meaningful opportunity for health risk reduction for persons served by public water systems." *See* 42 U.S.C. § 300g-1(b)(1)(A).

be essential to operationalize levels below which unreasonable risk is not presented and to avoid over regulation. Likewise, EPA should ensure that it retains flexibility to include or exclude in the scope of a particular risk evaluation non-TSCA uses. For example, in a future evaluation, an agency may have just completed its own, state of the art risk evaluation on chemical uses under its jurisdiction, making it unnecessary, redundant, and a waste of resources for EPA to duplicate the effort.

2. Single Risk Determination

EPA's second proposed mandate is that it must always make a single risk determination of the chemical substance as a whole at the end of each "comprehensive" risk evaluation, rather than risk determinations based upon the chemical under its specific conditions of use. This proposal creates additional, unnecessary complexity and uncertainty about how EPA would regulate a chemical substance determined to present unreasonable risk. Single risk determinations of a chemical substance also – generally inaccurately – imply that "all" conditions of use of the chemical must either present an "unreasonable risk" or present "no unreasonable risk." It is impossible to reconcile this type of risk determination with the best available science standard of TSCA.

EPA's "single risk determination" proposal is also inconsistent with the statute. For instance, TSCA Section 6(b)(4)(A) requires EPA to make a determination of risk under the specific "conditions of use" for that chemical. As stated above, these conditions of use are to be first identified by the Agency at the scoping stage of the risk evaluation process. Had Congress intended for EPA to make a singular risk determination for each existing chemical being evaluated under Section 6, it would not have imposed a limitation that the risk determinations be related to the conditions of use identified in the scope.

EPA's "whole chemical" policy approach has evolved several times since EPA first introduced the policy in June 2021. It is now being proposed as a regulatory mandate for EPA to issue a "single" risk determination of a chemical substance, not "use by use" risk determinations. Unlike its earlier manifestations, EPA supports this proposed rule change with its additional mandate to include "all" conditions of use in the scope of every risk evaluation. The chemical substance will be determined either as "presents unreasonable risk" or "does not present unreasonable risk." As discussed elsewhere in these comments, EPA's mandate to require "all" conditions of use in the scope of every risk evaluation is not required by the statute.

Except for vague discussions in the preamble and the rule about "fit for purpose" consideration of conditions of use, the proposed rule does not make clear how EPA will decide how it will make that whole chemical substance risk determination when the risk evaluation's analyses clearly show that some conditions of use of the chemical present unreasonable risk and some conditions of use do not. EPA also has not made clear how it will treat these differences in risk management rules.

Finally, as applied to many chemicals under their conditions of use, a single risk determination is not accurate. It would be difficult, if not impossible, for the Agency to implement them fairly and transparently. Single risk determinations of the chemical substance would deprive the regulated

community of adequate notice about what EPA's decision means with respect to specific conditions of use of the chemical (do they or do they not present unreasonable risk?) and whether/how EPA would address those differences in risk management regulations.

B. EPA's Proposed Approach to Workplace Exposure and Regulation

1. Uncontrolled Worker Exposure

Another of EPA's proposed revisions – its mandatory prohibition of consideration of use of personal protective equipment (PPE) in any risk evaluation – will produce more single risk determinations of "presents unreasonable risk" that are not based on accurate workplace conditions. In fact, exclusion of consideration of actual PPE use practices would likely result in an unreasonable risk determination for every chemical to be evaluated under TSCA Section 6. This, in turn, would produce extremely restrictive regulations of workplace exposure to TSCA chemicals in the follow-on risk management rules.[13] This outcome-determinative requirement has already been demonstrated in nine "whole chemical" risk determinations EPA has made since June 2022,[14] as well as in EPA's inclusion of highly conservative Existing Chemical Exposure Limits (ECELs) in recently proposed risk management rules to address these risk determinations.

Further, based on EPA's blanket "no PPE" assumption, ACC has serious concerns about EPA's ability to make science-based decisions with regard to workplace exposures to TSCA chemicals. As an initial matter, EPA lacks OSHA's expertise in occupational safety and health and industrial hygiene practices and its proposal to prohibit any consideration of the use of PPE as part of its consideration of workplace conditions of use in any risk evaluation is not based in fact, and therefore is arbitrary. Next, and most importantly, while Congress in 2016 included "workers" in the statutory definition of the new term, "potentially exposed or susceptible subpopulations," Congress did not significantly change TSCA Section 9(a) to suggest EPA had primacy over OSHA in determining workplace exposure requirements, as EPA's proposed assumption would suggest. Section 9 continues to require EPA to coordinate with other federal agencies and other EPA program offices with respect to TSCA decisions, but it does not grant TSCA primacy over the broad standards and regulations under the Occupational Safety and Health Act. Accordingly, Congress' intention to keep the authority to regulate working conditions with OSHA should govern here. Congress did not intend TSCA to entirely supplant regulation of workers under OSHA, and EPA's attempt to usurp this authority with its proposed mandatory prohibition against consideration of PPE should fail under the non-delegation doctrine.

Because OSHA maintains the exclusive regulatory authority to ensure safe working conditions by developing rules and regulations governing occupational safety and health practices, EPA must defer to that authority, where relevant, in evaluating work exposures to existing TSCA chemicals. This includes accounting for the regulatory requirements and controls that have

[13] Moreover, not collecting information on industry usage or assessing the efficacy of PPE in the evaluation phase will hinder EPA's ability to understand and develop workplace chemical protection programs (WCPPs). This could potentially result in EPA issuing unnecessary bans before fully understanding whether existing workplace controls, including PPE, would necessitate such a ban.

[14] *See* 87 Fed. Reg. 38747 (June 29, 2022); 87 Fed. Reg. 54491 (Sept. 6, 2022); 87 Fed. Reg. 67901 (Nov. 10, 2022); 87 Fed. Reg. 76481 (Dec. 14, 2022); 87 Fed. Reg. 77596 (Dec. 19, 2022); 87 Fed. Reg. 77603 (Dec. 19, 2022); 87 Fed. Reg. 79303 (Dec. 27, 2022): 88 Fed. Reg. 1222 (Jan. 9, 2023): 88 Fed. Reg. 48249 (July 26, 2023).

already been put in place by OSHA to protect workers, including the use of PPE and other health and safety mechanisms. Failure to consider these controls is an overstep of authority by EPA, and will drive unnecessarily conservative regulations in the workplace that do not accurately reflect current working conditions.

Finally, EPA's assumption of no PPE use, even when mandated by OSHA, means the Agency is looking well beyond the scope of the law into unlawful misuse of chemical substances. If PPE use is mandated by law, then enforcement of that requirement should be carried out by the law under which it is mandated. EPA should not be assuming another law is not followed and then adding more regulatory burden than is necessary based on this assumption.

2. EPA needs to establish an independent, transparent, and public process for development of occupational exposure limits intended to be applied in conjunction with TSCA Section 6(a) risk management.

EPA requested public comment on how the Agency can provide a transparent and detailed basis for the proposed ECELs derived from the risk evaluation process.[15]

As part of risk management action under TSCA Section 6(a), EPA has proposed to limit occupational exposures by establishing an occupational exposure limit it refers to as an ECEL in proposed risk management rules for chrysotile asbestos,[16] methylene chloride,[17] perchloroethylene,[18] carbon tetrachloride,[19] and trichloroethylene.[20] Based on what is known to date regarding EPA's development of ECELs, these exposure limits do not meet the requisite standards to use "best available science" and apply the "weight of the scientific evidence" in regulating existing chemicals. As a result, EPA's process for developing ECELs has resulted, and will continue to result, in exposure limits that are artificially low, not representative of existing working conditions, and unnecessarily stringent and difficult to achieve.

EPA describes the ECEL as a risk-based performance standard to eliminate unreasonable risk presented by inhalation exposures and it is described as an 8-hour time-weighted average (TWA) concentration of the chemical substance in monitoring samples of the personal breathing zone of all persons reasonably likely to be exposed to the chemical substance.[21] EPA's application of the ECEL is one requirement of a WCPP that includes a number of prescribed requirements. EPA states in the proposed chrysotile asbestos risk management rule:

> Requirements to meet an ECEL would not include requirements for specific engineering or administrative controls; rather, the ECEL is a performance-based exposure limit that would allow regulated entities to determine how to most effectively meet the ECEL based on what works best for their workplace, while

[15] 88 Fed. Reg. at 74316.
[16] 87 Fed. Reg. 21706 (Apr. 12, 2022).
[17] 88 Fed. Reg. 28284 (May 3, 2023).
[18] 88 Fed. Reg. 39652 (June 16, 2023).
[19] 88 Fed. Reg. 49180 (July 28, 2023).
[20] 88 Fed. Reg. 74712 (Oct. 31, 2023).
[21] *See* Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA), 87 Fed. Reg. 21706 (Apr. 12, 2022).

following the hierarchy of controls to the extent feasible (e.g., preferential use of methods which prevent generation or release of asbestos in the workplace rather than relying on respiratory protection to meet the ECEL; see Unit IV.B.1, Exposure Controls).[22]

Prior to the proposed chrysotile asbestos risk management rule in April 2022, EPA had not provided any public information on the asbestos ECEL, offered any opportunity to comment on the ECEL, or conducted external consultation or peer-review of the ECEL with experts in occupational exposure limit development. In fact, EPA did not make information detailing the development of the ECEL publicly available until the spring of 2022, even though it had been developed earlier.

Further, EPA's ECEL values have been routinely based on outdated data and conservative values generated by EPA's Integrated Risk Information System (IRIS) program, resulting in exposure limits that are overly restrictive and not representative of workplace conditions. For instance, EPA's December 2020 ECEL for Occupational Use of Methylene Chloride, published subsequent to the final risk evaluation, provides an illustrative example. EPA set the ECEL for methylene chloride at 2 ppm, which represents "the concentration at or below which an adult human would be unlikely to suffer adverse effects if exposed for a working lifetime, including susceptible subpopulations." In deriving the ECEL, EPA used a 17.2 mg/m^3 human equivalent concentration (HEC) value from the initial 2011 methylene chloride IRIS assessment, which was obtained directly from a 1988 study in rats and therefore was not based on recent, peer-reviewed data related to worker exposures to methylene chloride. Although EPA stated that its methodology and inputs for the ECEL were derived from the June 2020 Final Risk Evaluation for methylene chloride, which claims to use the IRIS value merely "as a starting point," and that "EPA also evaluated other studies published since the publication of previous analyses," the 2020 Final Risk Evaluation also ultimately utilized the same value from the same rat study relied upon by the IRIS assessment. It is difficult to see how reliance on a 35-year-old study to develop exposure limits for modern-day workplace conditions would meet the standard for "best available science" and how materially relying on one decades-old study is consistent with "weight of the scientific evidence."

It is also important to note that for many years, EPA has been issuing TSCA section 5(e) Consent Orders for pre-manufacture notices (PMNs) for new chemical substances that require "that potentially exposed employees of the Company must wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health."[23] EPA has never subjected its NCEL development process to public comment or peer review. However, the NCEL is specific to the individual company that is the subject of the consent order that can work directly with EPA to implement appropriate exposure controls within the context of the company's occupational safety and health program and based on feasibility of implementation. The same level of cooperative occupational exposure limit

[22] 87 Fed. Reg. at 21718.

[23] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemical-exposure-limits-under.

development and implementation has not been afforded to companies impacted by EPA risk management rulemaking.

a. The proposed risk evaluation process will not inform risk management.

As noted above, because EPA proposes to codify its policies where:

- EPA will make a single determination as to whether the chemical substance presents an unreasonable risk of injury to health or the environment [§ 702.37 (f)(1)] and
- the Agency will not consider, as part of the unreasonable risk determination, exposure reduction based on assumed use of PPE by workers [§ 702.37 (f)(2)]

These proposals, however, if codified in the rule, mean that subsequent risk evaluations will fail to yield useful information for the purposes of risk management. EPA's practice has been to conduct a baseline occupational exposure assessment that assumes continuous uncontrolled exposure to the subject chemical substance. While such a scenario is theoretically possible, it is extraordinarily unlikely to occur as a practical matter based on practice and experience. It would assume, for example, that employees would voluntarily continue to subject themselves to chemical exposures with no PPE even where the exposure itself has an unpleasant smell or is uncomfortable. There is no reasonable basis to assume this human behavior; no factual basis to assume this behavior, and in fact this assumption is not only inconsistent with actual practice and experience it also cannot be reconciled with applicable best available science - the discipline of behavioral science.[24] Further, EPA should be evaluating these scenarios as they actually exist in the workplace, meaning that, if OSHA regulations require the use of PPE for the industry/condition of use being evaluated, EPA should evaluate potential chemical exposure with regard to those existing regulatory controls. Part of the value of a risk evaluation is for EPA to identify practices (preferably existing practices) where conditions of use do not pose unreasonable risk so that those practices can be used as a benchmark, in the event that risk management action be necessary.

b. EPA should review publicly available occupational exposure limits as part of the risk evaluation.

EPA should review publicly available occupational exposure limits (OELs) that may be currently applied by relevant manufacturers, distributors, users and disposers of chemicals in commerce in the United States. Doing so would be consistent with EPA's obligation to consider all "reasonably available information" in the risk evaluation process, which includes any information that EPA possesses or can reasonably generate, obtain and synthesize for use, considering its deadlines for prioritizing and evaluating risks.[25] The extent to which a publicly available OEL may be integrated into occupational safety and health (OSH) practices for a particular condition of use is relevant to potential determination where unreasonable risk *does not occur*. Given that EPA intends to make a single unreasonable risk determination, it is equally

[24] EPA defines "science" and "scientific" to be "expansive terms that refer to the full spectrum of scientific endeavors, e.g., basic science, applied science, engineering, technology, economics, social sciences, and statistics." U.S. EPA Scientific Integrity Policy at 2.
[25] *See* 40 C.F.R. § 702.3.

important, when possible, that it identify those circumstances under which a chemical substance is used with *no unreasonable risk*.

c. EPA should establish an occupational exposure limit development process that is independent of the risk evaluation.

ACC recommends that EPA conduct an independent, transparent, and public process for development of an OEL **following release of the draft risk evaluation but before the risk evaluation is finalized**. As part of that process EPA should consider current OSH practices under reasonable assumptions of workplace exposure (i.e., various controls used, including PPE) for each condition of use as part of the risk evaluation.

The OEL development process should include a retrospective analysis of all existing current global OELs, to the extent feasible. The analysis would include various processes for development of health-based OELs, and risk policy decisions to assure that regulatory-adjusted OELs are feasible for the subject regulated community. It would be valuable for EPA to compare the elements of its developed OELs to those of other authoritative bodies to assist in broader understanding of where similarities and differences exist and the basis for differences.

d. EPA should develop a guidance document that articulates its OEL development approach.

EPA appears to believe that its hazard characterization process for the risk evaluation is sufficient for application in development of an OEL. Unfortunately, the ECEL process, which appears to apply EPA's process for development of a reference dose or a reference concentration, is not in its current form fit-for-purpose for TSCA Section 6(a) risk management. [26] For example, in the Methylene Chloride risk evaluation,[27] EPA used benchmark dose modeling to derive the human equivalent concentration (first percentile; $HEC_{1st\%ile}$) as a point of departure for chronic inhalation exposure. The $HEC_{1st\%ile}$ was used in the derivation of the methylene chloride ECEL. EPA goes on to state that "A BMDL, considered to be equivalent to a NOAEL(C) was calculated from Nitschke et al. (1988a) and therefore an UF of 1 is applied."[28] That is, the Benchmark Dose Lower Confidence Limit (BMDL) is equivalent to No Observed Adverse Effect Level concentration (NOAEL(C)), which is a threshold concentration below which there are no observed adverse effects in animals and therefore, no observed adverse effects are expected in humans at the $HEC_{1st\%ile}$. Moreover, additional uncertainty factors (the margin of exposure) and other conservatisms are built in so EPA has high confidence that "an adult human would be unlikely to suffer adverse effects if exposed for a working lifetime."[29] Consequently, the chronic non-cancer ECEL for methylene chloride effectively represents a "no risk" situation, which goes beyond the mandate of TSCA that it apply the provisions of Section 6(a) "to the extent necessary

[26] https://www.epa.gov/risk/review-reference-dose-and-reference-concentration-processes-document.
[27] U.S. Environmental Protection Agency. Risk Evaluation for Methylene Chloride (Dichloromethane, DCM). EPA Document# EPA-740-R1-8010 (June 2020). Available at https://www.epa.gov/sites/default/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf.
[28] Id. at 307.
[29] U.S. Environmental Protection Agency. Existing Chemical Exposure Limit (ECEL) for Occupational Use of Methylene Chloride (Dec. 10, 2020). Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0465-0021.

so that the chemical substance or mixture no longer presents" an unreasonable risk of injury to health or the environment.[30] EPA has not yet identified what constitutes "**reasonable risk**." That is, the conditions under which exposure constitutes a risk greater than "zero" but where the likelihood of suffering adverse effects is low but acceptable. Given that *total exposure* is a function of frequency, duration and magnitude of exposure, and EPA calculates the ECEL assuming continuous (8-hours per day) lifetime exposure (260 days per week for 40 years) at the ECEL, there is a lot of latitude to apply an occupational exposure limit (when necessary) that accounts for true exposures that are likely to be less than continuous and less than a 40-year lifetime. Any OEL development by EPA should serve to reduce **unreasonable** risk as required by the statute, not eliminate all risk.

e. EPA should establish a regulatory-adjusted OEL along with each health-based OEL (ECEL) it develops and describe its distinction between the two.

EPA's ECELs are generally based on the most sensitive overall effect – typically as observed in animal studies - and represents the concentration at which an individual, including a member of a potentially exposed or susceptible subpopulation (i.e., infants, children, pregnant women, workers, or the elderly), would be unlikely to suffer adverse effects if exposed for a working lifetime. The uncertainty factors applied also tend to be higher than those applied by other occupational health agencies and professional organizations. EPA often selects more conservative/less severe effects as the points of departure (e.g., early biomarkers of effect) for the ECEL, which add additional safety buffer to the ECEL. Under EPA's current process, these values have been routinely generated based on outdated data and resulted in exposure limits that are unnecessarily overly restrictive.

Moreover, the chronic ECEL assumes continuous exposure for an entire working lifetime, which, in many circumstances, may not accurately reflect worker exposure to that particular chemical. For instance, in the case of chrysotile asbestos, the inhalation unit risk upon which the ECEL is based includes additional conservative assumptions of a 40-year working lifetime exposure period starting at age 16. These assumptions are contrary to available data from the Bureau of Labor Statistics[31] and the Employee Benefit Research Institute[32] and with the Agency's own assumptions of exposure duration under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA, or Superfund). [33]

Further, while there is no question the ECELs proposed by EPA are highly protective, it is not clear they are entirely appropriate for every condition of use considered. In many cases, the worker population is less susceptible than the general population because it does not include infants, children or the elderly. Additionally, workers who may be health compromised are less likely to be active in the workforce. Perhaps more importantly, workplace exposures within specific COUs and even subcategories of COUs vary depending on the specific task, with some tasks conducted for short periods of time (i.e., less than a full shift) or only intermittently.

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[30] 15 U.S.C. § 2605(a).
[31] https://www.bls.gov/news.release/tenure.nr0.htm
[32] https://www.ebri.org/content/trends-in-employee-tenure-1983-2018
[33] U.S. Environmental Protection Agency. Framework for Investigating Asbestos-Contaminated Superfund Sites. OSWER Directive 9200.0-68 (Sept. 2008). Available at https://semspub.epa.gov/work/HQ/175329.pdf.

Moreover, job functions often will change throughout a worker's career; thus, potential chemical exposures will vary during that time.

Consequently, in risk management EPA should apply occupational exposure limits that consider real-world circumstances for the conditions of use where unreasonable risks are being managed. As noted above, EPA has never defined what constitutes unreasonable risk in the context of TSCA Section 6(a)(4)(A)'s requirement "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation" or for the purposes of risk management. And while one might expect that risk evaluation *unreasonable risk* would be the same as risk management *unreasonable risk*, the fact that risk evaluation makes a single determination and risk management is conducted on a condition of use by condition of use basis suggests they are quite different. In fact, the single unreasonable risk determination is based on an exposure scenario of continuous uncontrolled use for a working lifetime. Many workplaces will utilize standard industrial hygiene practices that consider hazard recognition and a variety of exposure controls.

In cases where EPA feels it is necessary to establish an occupational exposure limit for the purposes of risk management, it should adjust its health-based OEL to account for the differences in its highly conservative approach to risk determination compared to the realities of the potentially regulated conditions of use. It should also apply the statutorily required considerations of:

- effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
- the costs and benefits of the proposed and final regulatory action
- the cost effectiveness of the proposed regulatory action

to arrive at a regulatory-adjusted OEL that represents the most effective regulatory outcome.

f. EPA's OEL development process should be established with support from external experts, including EPA's Science Advisory Committee on Chemicals (SACC).

EPA should establish an OEL development process that includes experts in occupational exposure limit development from inside EPA, inside other government agencies, including OSHA and NIOSH, and among other expert bodies, such as the American Congress of Government Industrial Hygienists, the American Industrial Hygiene Association, and the Occupational Alliance for Risk Science (OARS) Workplace Environmental Exposure Levels (WEELs) Committee. Further, EPA should utilize the expertise of the SACC, the committee authorized under TSCA to provide "independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated by TSCA" and which includes individuals with "specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations." This internal and external collaboration with experts would help ensure that EPA's OEL process is based on the "best available science" and results in exposure limits that are accurate and appropriately protective.

Furthermore, to promote transparency in the process and adequate input from the regulated community, the OEL developed by this process and these experts should be made available for public comment before being finalized and should be subject to peer review if EPA is unable to convene a sufficiently robust body.

C. EPA's Proposed Revisions Aimed at Regulating Combined Exposures to TSCA Chemicals are Inappropriately Outcome Determinative

EPA's proposed changes designed to address "combined exposures" to TSCA chemicals, in conjunction with EPA's proposal to include "all" conditions of use in the risk evaluation scopes, and single risk determinations on the chemical substance, would elicit more single "unreasonable risk determinations" of TSCA chemical substances — without any differentiation in the chemical's risk, based on the chemical's conditions of use.

In particular, EPA's proposed revisions with respect to categories, aggregate exposure, cumulative risk assessment, and overburdened communities will significantly increase the complexities and uncertainties in TSCA risk evaluations even though EPA has previously cautioned of uncertainties and biases in multi-chemical risk assessments.[34,35] The broadening of the definition of potentially exposed or susceptible subpopulations (PESS) in particular expands the number of sub-populations that may have higher sensitivity, exposure, and risk. In other words, absent clear and consistent criteria for inclusion in a PESS sub-group, sub-group composition could be continually expanded or contracted, inviting inconsistent and unpredictable results. Subsequent regulatory actions could be invalidated as arbitrary.

1. Aggregate Exposure Assessments:

While EPA admits there is no mandate in TSCA to conduct aggregate exposure assessments, EPA declares it may do so "at its discretion."[36] EPA has proposed several changes to the rule to provide a foundation for **considering** aggregate exposure in each risk evaluation and then conducting aggregate exposure assessments, "as supported by the science,"[37] to address combined exposures to TSCA chemicals in risk evaluations.

EPA has proposed the following changes to support the Agency's commitment to conducting cumulative (multi-chemical, multi-exposure pathways, for now, with eventual inclusion of non-chemical stressors) assessments in TSCA risk evaluations, particularly for assessing chemical risks to "overburdened communities:"

- adding "overburdened communities" to broaden the definition of PESS;

[34] U.S. Environmental Protection Agency. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA/630/R-00/002 (Aug. 2000, at 76. Available at https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533.
[35] U.S. Environmental Protection Agency. Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity (Jan. 14, 2002), at 27. Available at https://www.epa.gov/sites/default/files/2015-07/documents/guidance_on_common_mechanism.pdf.
[36] 88 Fed. Reg. at 74305.
[37] Id.

- changing the rule's definition of "aggregate exposure" so that it can be used to assess exposure for a population, not just an individual;
- adding a mandatory consideration of "aggregate exposures" in risk evaluations[38];
- declaring a chemical substance and a "category" of chemical substances are equivalent; and
- the Preamble's specific discussion of cumulative risk.

Redefining aggregate exposure in this way would impose an unreasonable burden on the regulated entities.

2. Cumulative Risk

Cumulative risk assessment is not mandated by the statute. TSCA risk evaluations must, however, meet the scientific standards for use of best available science (BAS) and weight of the scientific evidence (WOSE). Since cumulative risk assessment (CRA) potentially encompasses both chemical mixtures and non-chemical stressors, and both of these fields continue to evolve, EPA should address cumulative risk assessment by guidance instead of by rulemaking. Guidance is more adaptable to updating and change than rulemaking. Guidance can (and should) be developed with opportunities for meaningful stakeholder involvement and can (and should) be subject to external peer review, as was the case for EPA's February 2023 Draft Principles for Cumulative Risk Assessment Under TSCA (EPA 740-P-23-001). [39]

The status of the Draft Principles is unclear, especially in light of this rulemaking. The Executive Summary of the SACC report stated "There was confusion and a general lack of definition for how the "Principles" document would provide a strategy that would provide scientific clarity regarding the available evidence, how specifically that evidence would be evaluated, and how decisions would be made in quantifying risk for decision making."[40] These fundamental issues need to be addressed before EPA can begin to consider how future advances will be incorporated in TSCA risk evaluations.

EPA acknowledged in the Draft Principles that "TSCA does not explicitly require EPA to conduct CRAs" but went on to state that "for some substances undergoing risk evaluation, the best available science may indicate that the development of a CRA is appropriate to ensure that any risks to human health and the environment are appropriately characterized." A similar comment and rationale are provided in the Preamble to this proposed rule. While EPA recognized the best available science standard, it did not recognize its own guidance documents related to multi-chemical risk assessment, which are clear that "The uncertainties and biases for even a small number of chemical components can be substantial."[41,42.] These guidance documents, as well as ACC's comments that "It is perhaps counter-intuitive, but casting a wide net to expand the

[38] See proposed 40 C.F.R. § 702.39(d) ("EPA **will** consider aggregate exposures to the chemical substance…" (emphasis added)).
[39] Available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/cumulative-risk-assessment-under-toxic-substances.
[40] https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0067.
[41] Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures, at 76.
[42] Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity, at 27.

common chemical group (CCG) to the maximum possible size will actually result in poorer assessments due to the potential to introduce bias and increase uncertainty" [43] are clear that increasing the number of chemicals in an assessment tends to decrease scientific robustness by increasing uncertainty and bias.

TSCA requires that risk evaluations be done in accordance with the best available science and be completed within aggressive statutory deadlines, which inherently limit the scope and complexity of a cumulative risk evaluation. In order for cumulative risk evaluations to be done in accordance with the requisite timeliness and scientific robustness, the need for a cumulative risk assessment should first be established as part of problem formulation.

3. Grouping

EPA's principal considerations for grouping chemicals for inclusion in a cumulative risk assessment are toxicologic similarity and evidence of co-exposure over a relevant timeframe. This approach would likely cast such a wide net of chemicals and COUs that assessments would become impossible to complete on time and even when completed, would be so compounded with uncertainties and biases that the best available science standard cannot be met. Current experience with grouping chemicals such as flame retardants and PFAS, for example, highlights the complexities associated with grouping.[44] To address those concerns, ACC recommends consideration of a common MOA, together with consideration of sentinel exposures, TTCs, and 10% cutoffs to right-size the CCG.

For non-chemical stressors, the scientific foundation necessary for cumulative risk needs to be developed. ACC is funding research in this area and applauds EPA for convening a Science Advisory Board on Cumulative Impacts Research and for funding research in this area.[45]

4. Potentially Exposed and Susceptible Subpopulations (PESS) and Overburdened Communities

EPA proposes expanding the definition of PESS to include "overburdened communities" because:

> by specifically including overburdened communities in the regulatory definition of PESS, the Agency believes that this action would assist EPA and others in determining the potential exposures, hazards and risks to overburdened communities associated with existing chemicals a part of a TSCA risk evaluation.

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[43] https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0918-0030.

[44] *See* National Academies of Sciences, Engineering, and Medicine. 2019. A Class Approach to Hazard Assessment of Organohalogen Flame Retardants. Washington, DC: The National Academies Press. https://doi.org/10.17226/25412 and
NASEM Workshop on Federal Government Human Health PFAS Research, October 26-27. Board on Environmental Studies and Toxicology (2020). https://www.nap.edu/read/26054/chapter/1.

[45] Project Title: A Comprehensive Review and Appraisal of Frameworks, Methods, Metrics, and Data Used in Assessments of Communities with Environmental Justice Concerns
https://www.americanchemistry.com/chemistry-in-america/research/long-range-research-initiative-lri/current-projects

> The proposed inclusion of overburdened communities among the PESS considered in a chemical risk evaluation would also enable the Agency to design appropriate risk management approaches to address the unreasonable risk that the Agency may determine is presented by a chemical, including any unreasonable risk that is disproportionately borne by communities with environmental justice concerns.[46]

EPA states that "'Overburdened communities' may include various populations or communities in the United States that potentially experience disproportionate environmental harms and risks or multiple burdens from chemical exposure." However, EPA does not state how it will identify and substantiate the population(s) that comprise an "overburdened community" even though how that identification is done will likely determine what constitutes "overburdened community." Since EPA's definition of "overburdened community" cannot be separated from how that overburdened community is identified, and since EPA provides no methodology for how that will be determined, EPA's definition of "overburdened communities" is arbitrary.

EPA should recognize that data, methods, and guidance are needed before Cumulative Impact Assessment (CIA) can be used by EPA, not only for TSCA, but for any regulatory action under any statute. This is consistent with EPA's previous statement that "To support federal, state, tribal, and community decision-making, ORD must strengthen the scientific foundation for assessing cumulative exposures, impacts, and risks through existing and new methods, tools, data, and monitoring."[47] However, the larger question of whether EPA should use CIA in TSCA risk evaluations at all remain*s*. TSCA is a risk-based statute, and risk can only be assessed once causality has been determined. CIAs should not assume causality and should not be used as a means for EPA to circumvent what would likely be highly complex and quantitative risk evaluations for chemical and non-chemical stressors.

In addition to adding "overburdened communities" to PESS, EPA is also broadening its interpretation of "greater susceptibility" and "greater exposure." Again, it is not clear how EPA will identify these populations, and as stated above, the methodology used to identify many of these populations will likely determine what populations are included in these definitions. EPA should therefore state how each of these populations will be identified if EPA criteria do not already exist. EPA should not assume that socioeconomic status in particular or pre-existing disease, lifestyle factors, etc. in general are necessarily "effect modifiers" that intensify the adverse effects of a particular chemical. EPA should instead also acknowledge the potential for no interaction or for confounding of exposure or effect. Importantly, there are precedents for EPA doing exactly this. For example, in the Integrated Science Assessment (ISA) for Lead (Pb), EPA discusses analyses of socioeconomic status as a confounder for nervous system effects[48]. Similarly, in the ISA for particulate matter, EPA discusses analyses of the potential for confounding by co-pollutants.[49]

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[46] 88 Fed. Reg. at 74320.

[47] U.S. Environmental Protection Agency. Cumulative Impacts Research: Recommendations for EPA's Office of Research and Development (Sept. 2022). Available at https://www.epa.gov/system/files/documents/2023-05/CUMULATIVE%20IMPACTS%20RESEARCH-FINAL%20REPORT-EPA%20600-R-22-014A%20%2812%29.PDF.

[48] U.S. Environmental Protection Agency. Integrated Science Assessment for Lead (2013).

[49] U.S. Environmental Protection Agency. Integrated Science Assessment for Particulate Matter (2019).

D. EPA's Proposed Deletion of the Regulatory Definitions of "Best Available Science" and "Weight of the Scientific Evidence" Would Undermine the Scientific Foundation of TSCA Risk Evaluations

EPA proposes to delete the definitions of "best available science" (BAS) and "weight of the scientific evidence" (WOSE) from the current framework rule. Maintaining definitions for these key terms is essential to provide the public and regulated community with an understanding of the considerations that will guide Agency decision-making on the regulation and/or prohibition of existing TSCA chemicals.

1. Best Available Science

The definition of "best available science" in the current risk evaluation framework rule at § 702.33[50] is necessary and must be retained for the following reasons:

- The definition itself is not redundant with TSCA Section 26(h). While the five factors enumerated in the best available science definition at § 702.33 are the same as are described in § 26(h), the text of the definition is not. Furthermore, if the definition of best available science at § 26(h) were truly redundant with § 702.33, there would be no need for EPA to propose its removal at § 702.33, as it would arguably make no difference.
- This definition of the best available science at § 702.33 is necessary to hold EPA accountable. EPA is clear that part of the reason for eliminating the definition is that it limits EPA's "flexibility." It is very concerning that EPA considers being held to the existing definitional standard that includes "use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)" as limiting. For example, does EPA now intend to propose that it may need to use unsound and non-objective scientific practices? Studies developed by non-accepted methods? Methods that are not the best available? Among other things, if the existing definition and description of "best available science" is removed, this may be

[50] *Best available science* means science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable:
(1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
(2) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
(3) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
(4) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
(5) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

interpreted as EPA no longer needing to evaluate the scientific literature it uses in the risk evaluation for methodological quality. The benefit of retaining this definition is that EPA is clearly directed in § 702.33 to consider "[t]he degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented." Alternatively, if EPA has legitimate concerns regarding the scope of the "best available science" definition, it should provide proposed alternative text for the definition, rather than seeking to eliminate it altogether.

- EPA's policies, procedures, and guidance are not necessarily in accordance with best available science and even when they are, do not carry the weight of a rule. EPA's policies, procedures, and guidance could be out of date and fail to be in accordance with the best available science.

2. Weight of the Scientific Evidence:

EPA states:

> In the 2017 Final Rule, EPA defined the [weight of the scientific evidence (WOSE)] as ''a systematic review method, applied in a manner suited to the nature of the 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 and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.'' 40 CFR 702.33. The Agency believes this definition is problematic and inconsistent with typical risk assessment practice and is therefore proposing to eliminate the definition from the regulatory text—instead relying on long-established Agency guidance documents to guide weight of scientific evidence analyses under TSCA."[51]

These guidance documents do not specifically incorporate systematic review principles, with the exception of the 2022 ORD Staff Handbook for Developing IRIS Assessments. While the IRIS approach does describe the application of systematic review in WOSE, the approach does not encompass full evaluation of risk, conditions of use, and exposure, which are critical aspects of TSCA risk evaluations. EPA should provide a detailed description of the WOSE approach to be used in TSCA risk evaluations.

Systematic review (SR) methods help ensure that data are identified, evaluated, and integrated to support overall conclusions. WOSE approaches are generally characterized by the process of first synthesizing findings within different lines of evidence (e.g., animal, human, and mechanistic studies) and then integrating across these lines of evidence to determine the answer to a research question.[52] WOSE analyses can be conducted without systematic review; however, employing systematic review methods and protocols minimizes the risks of 'cherry picking' studies, and enhances transparency and robustness. While it may be correct that systematic

[51] 88 Fed. Reg. at 74310-11.

[52] Lynch, H. N., Mundt, K. A., Pallapies, D., & Ricci, P. F. (2022). Lost in the woods: Finding our way back to the scientific method in systematic review. *Global Epidemiology*, *4*, 100093. https://doi.org/10.1016/j.gloepi.2022.100093

review and weight of the evidence are not the same, most experts and agencies applying the systematic review methods for chemical risk assessment encourage the application of systematic review principals to WOSE for the purposes of enhancing transparency and ideally, objectivity (see for example, WHO, 2021). As stated in Lynch et al.[53]:

> While the application of "weight of evidence" methods varies across frameworks, it generally is interpreted as the process of first synthesizing within different lines of evidence (e.g., animal, human, and mechanistic studies) and then integrating across these lines of evidence to determine the answer to a research question [4]. Weight of evidence is employed within SRs, but when used as a standalone method, **it does not necessarily include a similarly structured system for planning the review and collecting information. Suter et al. [27],[54] for example, contrast "weight of evidence" with SR methods and propose a model for integrating them**.[emphasis added]

In other words, the current best practice in SR is to include WOSE evaluations within broader SR frameworks to help ensure that hazard identification conclusions and ultimately toxicity value derivation is based on objective and reproducible methods for arriving at these conclusions, the same way the literature search and selection processes are objective and reproducible. Whether or not EPA maintains the WOSE definition, EPA will still need to integrate diverse bodies of epidemiological, experimental animal, and mechanistic evidence to arrive at conclusions on potential hazards. While this process will always inherently involve scientific judgment, the risk in removing a clear definition of WOSE is that EPA will not be held to a specific scientific standard of WOSE, and thus the conclusions of any individual assessment may vary by differing applications of scientific judgment. In a high-level narrative WOSE, as proposed in the amended rule, the exact reasons for a hazard determination likely would not be easily understandable or reproducible.

As noted in the table below adapted from Suter et al. 2020 (Table 1), using SR principles within the WOSE process allows for clearer causal assessment, including frameworks that describe how a given causal descriptor was derived. Additionally, without clearly defining how EPA will use systematic review when integrating evidence to arrive at hazard conclusions, there is a risk that there will be no clear mechanism to directly link study biases and overall study quality identified in the study evaluation phase into overall conclusions on a chemical's hazard. The more appropriate course of action would be for EPA to retain the definition but clarify that systematic review methods should be employed in the WOSE process.

[53] Id.

[54] Suter, G., Nichols, J., Lavoie, E., & Cormier, S. (2020). Systematic Review and Weight of Evidence Are Integral to Ecological and Human Health Assessments: They Need an Integrated Framework. *Integrated Environmental Assessment and Management*, 16(5), 718–728. https://doi.org/10.1002/ieam.4271

Table 1. Comparison of attributes of Classic Systematic Review, Classic Weight of Evidence, and an integrated approach (Adapted from Suter et al., emphasis added)

Attribute	Classic SR	Classic WoE	Integrated SR & WoE
Emphasis	Transparent and unbiased assembly of information	Hypothesis best supported by available information	Scientific rigor while accommodating many situations
Generality of results	General applicability (e.g., the chemical is a carcinogen)	General or case-specific (e.g., the chemical caused this cancer cluster)	General or case specific
Institutions	Institutions specify methods and compile results (e.g., Cochrane)	None; users define methods	Some government agencies recommend for specific applications
Consistency	Consistent methods within fields	Diverse methods even within fields	Consistent framework with diverse options
Sources of information	Published experiments from literature	Literature, purposive studies and models, data bases, etc.	Any type of information
Types of evidence	One per assessment or, if more than one, assessed separately	Usually more than one	Usually more, because most questions cannot be answered with only one type
Implications of evidence	One type of study with one implication	Multiple types of evidence have different implications for hypotheses	Usually multiple types of inferences
Meta-analysis	Standard inferential method	Seldom used	Encouraged when appropriate
Causation	Not an issue because the experiments that answer the question are inherently causal	Causal inference from heterogeneous evidence that seldom experimentally answers the assessment question	Recommends distinct assessment to establish causation and then use the causal relationship to make predictions.
Role of rating	Used to express risk of bias or other qualities, but not for inference	Implied by the concept of weighting but seldom employed	Recommended for transparency of weighting evidence and drawing inferences
Role of expertise	Expertise needed but latitude minimized by detailed methods and statistical inference	Expert knowledge and judgment are essential and explicit	Expert knowledge and judgment are essential and explicit
Tools	Software tools for literature searching, screening search results, and extracting information	No known software tools for automating steps in environmental assessments	Software tools for literature search, screening and extraction.

Finally and perhaps most importantly, Section 4 of the proposed rule suggests that EPA intends to increase efficiency in systematic review by adjusting the depth of the evaluation for different conditions of use, stating that while EPA must consider the full spectrum of COUs, "not all of those conditions of use will warrant the same level of evaluation."[55] EPA explicitly states that "Efficiencies may be gained in similarly tailoring approaches to peer review and/or systematic review."[56] While systematic review often requires a substantial level of effort and time to complete, the systematic review process as applied to TSCA can be made more efficient in certain steps (e.g., literature identification) while still keeping with the principles of review. However, without clearly defining when and where "streamlining" is allowed in the risk

[55] 88 Fed. Reg. at 74300.
[56] Id.

evaluation process, there may be inconsistency across different risk evaluations developed by different EPA and EPA contractor teams.

In the current proposal, while EPA proposes elimination of the definition of WOSE, it retains reference to systematic review at § 702.37(a)(6)(2): "EPA will apply systematic review and/or systematic approaches to reviewing reasonably available information that are objective, unbiased, and transparent." ACC supports application of systematic review methods with these goals; however, current systematic review guidance often focuses on the early steps of systematic review (e.g., literature searches and data quality metrics) but does not provide sufficient detail on evidence integration which is the critically important step to determine the data and information that is fit for use in risk evaluations. For this reason, EPA must retain the definition of WOSE to ensure this key piece is not lost. EPA should also clarify the status of the current TSCA systematic review guidance.

E. Statutory Construction and Legislative Intent Do Not Support EPA's Proposed Revisions

The overly broad mandates for EPA to scope "all" conditions of use and yet to make a single risk determination on a chemical substance as a whole (rather than on the chemical substance under its conditions of use), misinterpret the statutory language and Congressional intent of Sections 6(a), 6(b)(4)(A), 6(b)(4)(B), 6(b)(4)(D), 6(b)(4)(F), 6(i), and 18, and the scientific standards of Section 26, (in particular Section 26(i)'s requirement for EPA to make a Section 6 science-based decisions based on the weight of the scientific evidence.)

Congress required EPA under Section 6(b)(4)(B) to establish a process rule for conducting risk evaluations **in accordance with Section 6(b)(4)(A)**, which requires EPA to determine "whether" a chemical presents unreasonable risk "under the conditions of use" of the chemical. Under TSCA Section 6(b)(4)(F)(i), in conducting risk evaluations, EPA must integrate available information "on hazards and exposures for the conditions of use of the chemical substance." Congress also established two types of risk determinations: "presents unreasonable risk" and "does not present unreasonable risk." Both types of risk determinations must be made in accordance with Section 6(b)(4)(A) – which (again) includes the phrase "under the conditions of use."

Congress was not ambiguous or silent as to the process by which it wanted EPA to conduct risk evaluations, and that the risk evaluation process must include an evaluation of different conditions of use that are relevant to that particular chemical. TSCA Section 6(b)(4)(A) expressly instructs EPA to begin the risk evaluation process by defining the "conditions of use" to be considered in the risk evaluation in a published scoping document. Specifically, Section 6(b)(4)(D) states: "not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator ***expects to consider***." (emphasis added). If Congress intended for "all" conditions of use to be evaluated, it would not have instructed EPA to scope the conditions of use that it "expects to consider" for any given chemical.

The TSCA risk evaluation provisions must be read together and in context. For example, why would Congress require the Agency to develop, as a first step in risk evaluation, a scoping document that sets forth the "conditions of use" that it "expects to consider," only to have EPA make a single risk determination on the whole chemical, without regard to specific conditions of use? Further, why would Congress require EPA (at Section 6(b)(4)(F)), in conducting risk evaluations, to "integrate" available information on hazards and exposures for the conditions of use of the chemical substance, only to have EPA make a single risk determination of the chemical substance as a whole, i.e., without accounting for the chemical's hazards and exposures for the chemical's different conditions of use? Finally, why would Congress require that EPA ultimately make a risk determination for the chemical based on the conditions of use identified in the scope, if it intended that the risk determination would cover the whole chemical, regardless of the specific uses? EPA's proposed changes are at odds with what Congress intended when it took up the difficult task of developing a systematic process for evaluating existing TSCA chemicals' hazards and their exposures under the chemical's conditions of use and then regulating the chemical under those conditions of use determined to "present unreasonable risk."

EPA's proposal to include "all" conditions of use in the risk evaluation also runs counter to TSCA's preemption provision which explicitly references and relies on the specific conditions of use outlined in published scope document in determining when federal preemption applies. Specifically, TSCA states that federal preemption applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 6(b)(4)(D)."[57] Additionally, TSCA's exception to preemption provision also explicitly references the scope document, allowing as an exception to preemption, agency action that "imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance and addresses the same hazards and exposures, ***with respect to the same conditions of use as are included in the scope of the risk evaluation*** published pursuant to section 6(b)(4)(D)."[58] If Congress intended for "all" conditions of use to be evaluated in the scope of the risk evaluation, it would not have specifically singled out only those conditions of use that are to be identified in the scope when discussing preemption. Rather, it would have likely imposed a blanket preemption on all conditions of use associated with the particular chemical.

In sum, EPA's proposed revisions to the framework rule are inconsistent with the plain meaning of the relevant statutory provisions of TSCA and Congressional intent. They also ignore the context of the rest of the statute. EPA's two key proposed mandates – "all" conditions of use must be in the scope of every risk evaluation and EPA must make a single risk determination on the chemical substance as a whole at the end of the risk evaluation – up-end Congress's understanding of the need for science-based risk evaluations based on the specific conditions of use that are relevant to the particular chemical, to lead to understandable and workable risk determinations.

F. EPA's Reliance on the 2019 Decision by the 9th Circuit Court of Appeals Is Misplaced

[57] 15 U.S.C. § 2617(c)(2).
[58] 15 U.S.C. § 2617(d)(1)(A)(iii)(II)(aa) (emphasis added).

EPA's reliance on the 2019 decision by the Ninth Circuit Court of Appeals[59] to support the Agency's proposed revisions to the risk evaluation framework rule is misplaced. The court upheld most aspects of the 2017 risk evaluation framework rule. The court did not make any judicial findings related to petitioners' challenge of the 2017 rule's provisions on conditions of use and risk determinations. Instead, the court determined the petitioners' claims were either not justiciable or not ripe.[60] Therefore, the court's characterization is dicta and does not support EPA's re-interpretation of the statute to impose either a mandatory requirement for EPA to include "all" conditions of use in the scopes of all risk evaluations or a mandatory requirement for "single" risk determinations at the end of every risk evaluation.

Further, although EPA claims to have "authority" to make these revisions in light of what it perceives as the 2017 rule's "ambiguous" provisions, EPA does not have authority to impose arbitrary requirements that lead to arbitrary regulatory outcomes. EPA's proposed changes fail to consider the context of the rest of the statute and taken as a whole, these revisions would produce arbitrary risk determinations and ultimately arbitrary risk management decisions stemming from those.

II. Interpretation of TSCA's Provisions on Risk Evaluations

A. EPA's Key Proposed Revisions Are Based on Interpretations of the Statute which Run Afoul of the Rules of Statutory Construction.

Congress provided EPA authority under TSCA to scope what conditions of use of a priority chemical to include in a risk evaluation. Congress provided EPA authority to make more than one risk determination on a chemical, in order to make clear which conditions of use of the chemical needed regulation and which did not.

Congress gave EPA authority under TSCA to address categories of chemicals, and to consider aggregate exposure in risk evaluations, but Congress did not mandate consideration of these concepts. Congress gave EPA authority under TSCA to address certain exposure pathways already regulated under other environmental statutes under its jurisdiction and authority to address workers, if relevant to a chemical's conditions of use in the scope of the risk evaluation. With EPA's proposed key mandates on "all" conditions of use and a "single" risk determination, however, EPA is essentially mandating consideration of aggregate exposure from combined exposures to chemicals in all risk evaluation and regular development of risk evaluations of categories of chemical.

Requiring consideration of all of these concepts in each risk evaluation would make it difficult, if not impossible. for EPA to meet the scientific standards of TSCA Section 26 and for EPA to meet the statutory deadlines.

1. EPA's proposed changes to the scoping requirements of the 2017 TSCA risk evaluation framework rule depend on statutory interpretations which misconstrue the plain meaning of the statute.

[59] *Safer Chemicals, Healthy Families v. U.S. Environmental Protection Agency*, 943 F.3d 397 (9th Cir. 2019).
[60] 88 Fed. Reg. at 74293-94.

In EPA's lengthy discussion of its reasoning for its proposed change to the scoping requirements,[61] it argues that the Agency **lacks discretionary authority to exclude <u>any</u> conditions of use from the scopes of TSCA risk evaluations.**[62]

To support its "lack of discretionary authority" argument, EPA re-interprets the phrase "as determined by the Administrator" in Section 3(4)'s statutory definition of "conditions of use" and the phrase "expects to consider" in the scoping provision at Section 6(b)(4)(D) in very narrow ways. These re-interpretations are not compelling on their face, either when viewed from a plain meaning of the phrases themselves or in the context of what scoping is designed to achieve in TSCA risk evaluations. To put a fine point on its re-interpretations, EPA states that its lack of authority prohibits it from including even those conditions of use not expected to be significant contributors to risk. EPA provides specific examples: that it cannot exclude byproducts, impurities within articles, equipment leaks, climate changes that could lead to changes in chemical exposures, exposure pathways already assessed and regulated under other laws under EPA's jurisdiction, etc. Without any discretionary authority to exclude any conditions of use, EPA makes the assertion that the statute requires the Agency to include **all** conditions of use and **all** exposure routes and pathways in the scope of each risk evaluation.

EPA also asserts, however, that, pursuant to the phrase "as determined by the Administrator" in the Section 3(4) definition of "conditions of use," it "retains authority" to exercise its judgment to determine whether a particular circumstance of a condition of use is in fact "intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of" (i.e., whether it actually falls within the definition of a condition of use[63]). The Agency explains that it retains this authority largely in order to exclude conditions of use that are "unsubstantiated, speculative or otherwise not likely to occur."[64] But this very narrow view of the Agency's role in determining what is and is not a condition of use, however, is not supported by a plain reading of Section 3(4).

With respect to the phrase "the Administrator expects to consider" in Section 6(b)(4)(D), EPA similarly obfuscates a plain reading of the scope provision with a circular explanation.[65] EPA concludes that the Agency "no longer believes" that this phrase "gives the Agency broad discretion to choose among conditions of use that it will include in a risk evaluation of a chemical substance."[66] The Agency's interpretation is forced and not convincing. Rather, as discussed above, if Congress intended for "all" conditions of use to be evaluated, it would be

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[61] Id. at 74296-301.
[62] With one exception: legacy disposals, based on the 9th Circuit Court of Appeals decision on that question.
[63] 88 Fed. Reg. at 74298.
[64] Id. Further, EPA omits that EPA negotiators suggested it would be better to proceed with the proposed and final rules on the covered chemicals to avoid delay.
[65] Id. ("Likewise, the instruction in TSCA section 6(b)(4)(D) for the Agency to – during the scoping phase – identify the conditions of use it "expects to consider" in a risk evaluation is best read as directing the Agency to identify the uses and other activities that it has determined constitute the conditions of use of the chemical substance, while acknowledging that the Agency's expectations at the scoping phase may not always align perfectly with the conditions of use actually considered and assessed in draft and final risk evaluations.")
[66] Id.

counter-intuitive to have instructed EPA to scope the conditions of use that it "expects to consider" for any given chemical.

On their face, both phrases support EPA's authority to determine what conditions of use **to include** in the scope of risk evaluation. EPA's reliance on the 9th Circuit's discussion of the "categorical exclusion" of "legacy disposal" does not undermine EPA's general authority –based on EPA's judgment and facts -- to determine what conditions of use to include in the scope of a risk evaluation. EPA's attempt to characterize its authority as simply "choosing" among conditions of use, without factual support, is disingenuous. Essentially, EPA's re-interpretation of these two provisions is an attempt to de-couple the two provisions rather than reading them in the context of each other and the rest of the statute.

EPA also asserts that it "believes" its interpretation is more consistent with Congressional intent. It finds that intent in a Congressional Record paragraph about an EPA technical discussion with congressional negotiators concerning three risk assessments (TCE, NMP and MC) that were completed prior to passage of the TSCA amendments, but which EPA noted "were not conducted across all conditions of use." This statement by EPA in this context is not dispositive. The particular discussion EPA cited was not about Section 6(b)(4)(D) and what must be in or out of scope of risk evaluations. Instead, it was specific to discussions about Section 26(l)(4) Chemical Substances with Completed Risk Assessments on these three final risk assessments which were published prior to enactment.[67]

EPA also declares that the Agency's "lack of discretion" is "implied" in the entirety of the U.S. Senate Congressional Record for June 7, 2016. Yet EPA fails to point to specific language supporting this claim,[68] while ignoring another statement that is on point but contrary to EPA's claim about Congressional intent. The Republican legislative manager of the TSCA bill, Senator Vitter, stated:

> 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 that the Agency will address in its evaluation of the priority chemical.** This assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law's strict deadlines.[69]

Planning, scoping, and problem formulation are not only good practice in risk assessment, but they are also EPA policy and facilitate the identification and proper consideration of data quality. These planning phases also provide an opportunity for risk assessors and managers, and other stakeholders to consider the context in which the risk assessment is being conducted and the purpose(s) for which the results will be used. They are the first steps in EPA's 2014 Framework

[67] *See* 162 Cong. Rec. at S3518-19.
[68] 88 Fed. Reg. at 74317, Ref. 11.
[69] 162 Cong. Rec. at S3519 (emphasis added).

for Human Health Risk Assessment to Inform Decision Making, as depicted in Figure 1.[70] This document emphasizes the importance of planning and scoping, as well as importance for EPA's data quality objectives and the 2001 Data Quality Act.[71]

Moreover, scoping allows the agency to focus its resources, and focus reviews on conditions of use that are more likely to present unreasonable risk:

> It is worthwhile to note that organizations are usually faced with finite resources and time to conduct their assessments; thus, not only are there scientific drivers that demand improved quality but also the realization that resources must be used efficiently. The extent of documentation needs to be balanced by resources and priorities, particularly when the timeliness of the response is critical. The mere presence of a substance in the environment does not necessarily mean that it poses a threat to human health or to the environment; thus, an approach that considers exposure early in the process can better focus resources on those stressors that pose exposure scenarios of concern.[72]

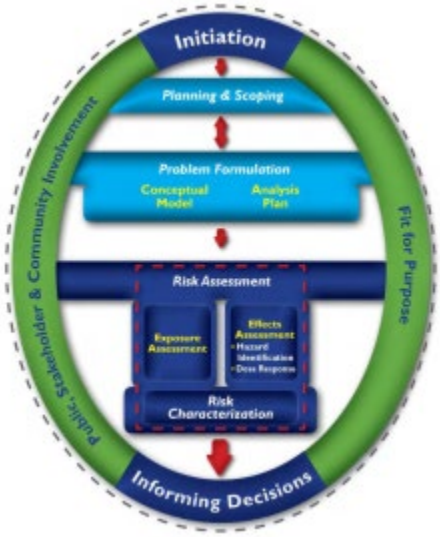

Figure 1. Figure Reproduced from EPA's 2014 *Framework for Human Health Risk Assessment to Inform Decision Making.*

Scoping and problem formulation are considered best practices across systematic review frameworks.[73] In 2021, the World Health Organization (WHO) released a general framework for systematic review, which drew from available frameworks across the globe and was internationally peer reviewed. This framework highlighted the importance of developing the scope within the problem formulation step, and emphasized the overall importance of problem formulation, stating:

[70] U.S. Environmental Protection Agency. Framework for Human Health Risk Assessment to Inform Decision Making. EPA/100/R-14/001 (April 2014), at 7.
[71] Id. at 10.
[72] Fenner Crisp PA, Dellarco VL. (2016). Key elements for judging the quality of a risk assessment. *Environ Health Perspect* 124:1127–1135. http://dx.doi.org/10.1289/ehp.1510483.
[73] See Ref. 53.

> A rigorous, well planned problem formulation process is a **major factor** in ensuring that an assessment project yields a successful result. It helps ensure that a systematic review targets, in a **resource-efficient way**, the critical information needed for informing risk management decisions, and helps ensure that the results of the review process are credible. [74]

TSCA's scope provision sets a deadline for EPA to publish the scope of the risk evaluation to be conducted, "including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations **the Administrator expects to consider**…."[75] As the initial component of a risk evaluation, scoping works to focus the risk evaluation of the chemical substance. Focusing the evaluation will increase efficiency and decrease delays caused by the requirements of systematic review (note, for example, that individual study quality evaluation of hazard, use, and exposure data is very time-intensive). As noted in the WHO framework, "Narrowing the scope to one or two questions that are critical to decision-making is an effective way of reducing resource requirements while preserving maximum rigour."[76] By proposing to require "all" conditions of use be included in the scope, EPA is effectively negating the whole purpose of the scoping component of a risk evaluation.

EPA's claim to lack authority to exclude conditions of use from the scope but retain authority to determine whether a circumstance of a condition of use meets the Section 3(4) definition, is a disjointed interpretation of these two statutory provisions. Why would EPA narrow its authority to focus the risk evaluation through the scope, since that is the purpose of scoping? Why would EPA have authority to determine if a circumstance does or does not meet the definition of conditions of use, but no authority to exclude any condition of use from the scope in the first place? What problem is EPA trying to solve with this mandate to scope all conditions of use into each risk evaluation? Is EPA implying that the prior Administration's risk evaluations were short on conditions of use? If so, that is not supported by facts. The original, final risk evaluations on the first 10 chemicals addressed most conditions of use for each of the first ten chemical substances evaluated.

EPA's re-interpretation of several provisions of TSCA mandating a significant broadening of the scope of every TSCA risk evaluation, is inconsistent with the plain meaning of the TSCA statute. EPA's re-interpretations of these provisions in its proposed rule are not supported by Congressional intent.

2. The Agency's proposal mandating a "single" risk determination at the end of every risk evaluation "reads out" the meaning of several other provisions of TSCA.

TSCA Section 6(b)(4)(A) requires that EPA shall conduct risk evaluations "to determine **whether** a chemical substance presents an unreasonable risk of injury to health or the

[74] WHO (World Health Organization). Framework for the use of systematic review in chemical risk assessment (2021) (emphasis added). Available at https://apps.who.int/iris/handle/10665/347876.
[75] 15 U.S.C. § 2605(b)(4)(D) (emphasis added).
[76] WHO. Framework for the use of systematic review in chemical risk assessment, at 10.

environment…under the conditions of use." (emphasis added). In 2017, EPA interpreted this provision to mean that where the risk evaluation revealed that some COUs present unreasonable risk and some COUs did not present unreasonable risk, that the Agency could issue more than one risk determination of the chemical substance at the conclusion of the risk evaluation, to clearly account for these differences under different conditions of use of the chemical. EPA is now proposing to revise that approach by mandating that that in every risk evaluation, the Agency must issue only a single risk determination of a chemical substance as a whole.

EPA contends, however, that risks of the chemical under its conditions of use will continue to be assessed in the risk evaluation and accounted for in the single risk determination. But EPA does not clearly explain how it would achieve this outcome. Instead, EPA attempts to refute industry's earlier claims in comments on the Agency's revised risk determinations for HBCD, PV29, TCE, and others, that the Agency had "read out" the "under the conditions of use" language of Section 6(b)(4)(A), as well as the "in accordance with Section 6(b)(4)(A)" language laid out in Sections 6(a), 6(b)(4)(B), 6(c), 6(i) and 18. EPA appears to be suggesting that because none of these provisions specifically include the "under conditions of use" language, that the statute supports its interpretation mandating single risk determinations of chemical substances, without regard to conditions of use. This argument is specious, given the "in accordance with Section 6(b)(4)(A)" language throughout the statute.

To provide further support for its proposed requirement for a "single" risk determination of a chemical substance in every risk evaluation, EPA characterizes the current risk evaluation rule's risk determinations as "use by use" risk determinations. This characterization is both inaccurate and misleading. The Section 6(b)(4)(A) phrase "under the conditions of use" modifies the phrase "whether a chemical substance presents an unreasonable risk of injury to health or the environment." The two phrases cannot be read independent of the other, despite EPA's declarations that the risk determination must be of the substance, not the conditions of use. In much of its discussion of its rationale for a "single" risk determination, EPA fails to cite the 6(b)(4)(A) language "under the conditions of use."

Contrary to EPA's claims, Section 6(i)'s final agency action requirements would be read out of the statute under EPA's "single" risk determination requirement. Section 6(i) paragraphs (1) and (2) make clear that two types of risk determinations under Section 6(b)(4)(A) can be made (of the chemical under the conditions of use) at the end of each risk evaluation. These are: Section 6(i)(1) determinations that a chemical substance **does not present** an unreasonable risk of injury to health or the environment under the conditions of use; and Section 6(a) determinations that a chemical substance **presents** an unreasonable risk under the conditions of use. Because EPA does not include "under the conditions of use" language in Section 6(b)(4)(A) whenever it focuses on the first part of that paragraph, EPA argues that it mandates a single risk determination of the chemical substance in each risk evaluation, ignoring when there are differences in risk presented by a chemical under some of the chemical's conditions of use.

Similarly, Section 18(a)(1)(B)'s state-federal relationship provisions regarding federal preemption would also be "read out" under EPA's interpretation requiring a single risk determination of a chemical substance. What States can and cannot do (in terms of regulating chemicals) is dependent on whether a chemical or specific conditions of use are **determined not**

to present unreasonable risk at the end of the risk evaluation, or whether a final risk management rule places restrictions on various uses of a chemical **determined to present unreasonable risk**. If EPA can only make a single risk determination, the preemption that would otherwise apply to no unreasonable risk determinations at the end of risk evaluation is invalidated. This violates basic canons of statutory construction, such as the enacted purposes canon, a bedrock element of statutory interpretation, and the harmonious reading canon. Further, if Congress had intended for a single risk determination to be made with respect to TSCA chemicals, it would not have limited preemption to only those conditions of use that are identified within the "scope of the risk evaluation."

Under the rules of statutory construction, an interpretation of certain statutory provisions that reads out other provisions of the same statute is invalid. EPA has failed to consider its proposed change mandating single risk determinations in the context of the rest of the statute.

3. EPA's Rationales for Its Proposed Revisions to the Risk Evaluations Procedures Are Not Supported by Legislative History.

EPA has proposed significantly different procedures for the TSCA risk evaluation framework rule than those that were finalized in 2017. EPA has apparently done so in order to achieve other objectives that go well beyond what Congress intended when it adopted the amendments to TSCA in 2016. EPA's proposed mandates work in conjunction with EPA's other proposed changes with respect to categories of chemicals, "overburdened communities," aggregate exposure and even cumulative risk assessment. These proposed changes aim to use TSCA to address, as a matter of course, combined exposures to TSCA chemicals to protect "over-burdened communities."

This broadening of the focus of the 2016 TSCA amendments runs counter to Congress's concerns about the ability of EPA to make progress on the huge task Congress had established in the amendments: "to systematically evaluate more chemicals than ever before."[77] Congress provided EPA the discretion to determine which conditions of use to include in the scope of risk evaluations in order to ensure the risk assessments were focused on chemicals and their conditions of use that raise the greatest potential for risk – and to ensure that EPA could do the job put before them.[78]

Congress did anticipate consideration of potentially exposed or susceptible subpopulations in **some** risk evaluations, as determined by EPA and if relevant to a risk evaluation. But it did not mandate consideration of "all" conditions of use involving PESSs, in all risk evaluations, nor did it include the proposed (and undefined) term "overburdened communities" in the list of types of PESSs in the statute. Congress mentioned the term "aggregate exposure" once in the statute, at Section (b)(4)(F), but only to make clear that in conducting risk evaluations EPA must describe any aggregate exposures that were considered and the basis for that consideration. Congress did not require consideration of aggregate exposure as EPA has proposed in §702.39(d)(8).

[77] 162 Cong. Rec. at S3520.
[78] *See* id. at. S3519.

If Congress had intended to require EPA to include "all" conditions of use in the scope of each evaluation and "all" the circumstances under which a chemical is manufactured, distributed, used or disposed of, it would have used the phrase "under all conditions of use" instead of the phrase "under the conditions of use." If Congress had intended EPA to make "single" risk determinations on a chemical substance as a whole, rather than more accurate risk determinations of the chemical under its conditions of use, it would have so stated. If Congress had intended EPA to address combined exposures to chemicals on a regular basis to address PESSs or "overburdened communities" it would have said so. Congress developed a bipartisan compromise largely aimed at evaluating a backlog of the tens of thousands of TSCA's grandfathered existing chemicals, and to do so under aggressive statutory deadlines. These proposed revisions impose very different requirements than what the statute says on its face, and what Congress meant by them. Given the enormous undertaking of the TSCA amendments, Congress did not envision that EPA would greatly expand the requirements -- before even one risk management rule on one chemical had even been finalized.

The legislative history of the TSCA amendments does not support EPA's proposed revisions to the risk evaluation framework rule. These proposed changes, taken together, would be so complex and time-consuming to implement that they will significantly slow implementation of the 2016 TSCA revisions.

4. EPA Downplays Other Provisions in the TSCA Statute That Were Designed to Focus EPA's Efforts in Order to Enable the Agency to Make Risk Determinations within Statutory Deadlines. EPA has failed to consider its proposed revisions in the context of other TSCA provisions.

EPA's proposed revisions to TSCA's risk evaluation framework rule make clear that its objectives behind its proposal are aimed at expanding TSCA to **require** protection of workers and "overburdened communities" from combined exposures to chemicals. EPA relies in large part on Executive Order 13990 as the basis for addressing overburdened communities. Its "no PPE" assumption has been designed purposefully to achieve more stringent regulations in the workplace.

EPA disregards the bipartisan 2016 amendments' objectives of making their ambitious requirements for a more systematic, science-based process to evaluate and regulate TSCA's grandfathered, existing chemicals, based on their conditions of use. EPA's proposed revisions disregard the 2016 TSCA provisions to help focus EPA's efforts so that the enormous undertaking could be achieved over time.

TSCA provisions which were designed to focus EPA's risk evaluation efforts on chemicals substances that presented the greatest potential for unreasonable risk include the following:

- requirements for EPA to update the TSCA Inventory;
- requirements for EPA to prioritize chemicals as either Low Priority or High Priority for risk evaluations;
- authority for EPA to scope risk evaluations on conditions of use that have the greatest potential for unreasonable risk;

- authority for EPA to make two types of risk determinations – unreasonable risk and no unreasonable risk – for chemicals under their conditions of use;
- aggressive statutory deadlines for completing the risk evaluations and issuing risk management rules to regulate chemicals that presented unreasonable risk under those conditions of use **that EPA had scoped into the risk evaluation;** and
- to do all of this in accordance with the statute's scientific standards of best available science and weight of the scientific evidence.[79]

EPA's arguments that its proposed revisions were contemplated by Congress are not compelling. Instead, its proposed mandates and other changes broadening TSCA would up-end the balance that Congress was striving for in 2016.

5. There are other more reasonable interpretations of TSCA's risk evaluation requirements that EPA should consider as an alternative to its proposed revisions.

The better interpretation of TSCA is that EPA has authority to identify what conditions of use to include in the scope of each risk evaluation and authority to make risk determinations that are based on the chemical's conditions of use. To put it plainly, a risk-based determination must be made on a condition of use basis, since each use has its own exposure and thus its own risk. The two cannot be de-coupled if a risk determination is to be risk-based. The better interpretation of TSCA is for case-by-case considerations of the more scientifically challenging topics of aggregate exposure from combined exposures and risk evaluations of categories of chemicals.

III. Administrative Procedure Act Considerations

A. EPA's Proposed Revisions May Run Afoul of the Administrative Procedure Act Requirements for Reasonable Regulations

EPA contends in its preamble that its proposed changes are "authorized" by its interpretation of TSCA's risk evaluation provisions. But "in accordance with statutory authority" is only one requirement that regulations must meet under the Administrative Procedure Act (APA). Agency regulations must also be reasonable – not arbitrary, capricious, or an abuse of the Agency's discretion.

Requiring every scope of every risk evaluation to address "all" conditions of use of a chemical while at the same time requiring EPA to make a single risk determination of the chemical substance, without regard to different risks under "all" the different conditions of use, raises questions about how EPA will make these "single" risk determinations without being arbitrary.[80]

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[79] *See* id. at S3519-22.

[80] EPA experimented with its new "whole chemical" policy in nine chemical risk determinations over the last two years (a single risk determination would be based first on findings that a "majority" of the chemical's COUs presented unreasonable risks; and then changing that to a "substantial number" of the chemical's COUs presented unreasonable risk). But here, EPA concluded that the "better interpretation" is simply to assert that the Agency has authority to make a single risk determination on the chemical substance itself. EPA does not explain how it will

In the preamble to its proposed revisions, EPA makes several comments about the Agency's authority to make certain decisions and take certain actions within the risk determinations. For example, EPA states:

> Although EPA previously found ambiguity in TSCA section 6(b)(4)(A), it now believes that a better reading of the statute in light of its content and structure (and other reasons described in this paragraph) is that it requires EPA **to simultaneously evaluate all conditions of use** of a chemical substance.[81]
>
> A determination that a chemical substance presents an unreasonable risk does not mean that the entirety or whole of that chemical's uses – or even a majority of uses – presents unreasonable risk. Rather, **EPA may determine that a chemical substance presents an unreasonable risk based on risk associated with even a single condition of use.** [82]
>
> EPA generally expects every risk determination to identify which conditions of use are – or are not – **significant contributors to EPA's determination that the risk** presented is unreasonable.[83]
>
> …in exercising EPA's authority under TSCA section 6(a) to ensure that "the chemical substance…no longer presents such risk**, EPA may regulate conditions of use that do not themselves contribute to unreasonable risk for a given chemical**.[84]

Taken together, these statements indicate that EPA is considering multiple inconsistent approaches to making single risk determinations and suggest the arbitrary nature of EPA's decision-making with respect to its risk determinations.

There is no TSCA requirement for a risk management "framework" rule, so EPA would apply its proposed single risk determinations on a case-by-case basis. How EPA will address the complexity of a single risk determination in each risk management rule is unclear. With greater complexity in the risk evaluations will come greater uncertainties about the risks presented. In turn, EPA will use "default" assumptions in risk management that will likely produce overly conservative risk management decisions in more cases than not. In fact, EPA's proposal appears to have been designed to reach default, overly conservative results. EPA's proposal for the risk evaluation rule, as well as the case-by-case risk management decisions that will flow from it, suggest EPA's regulations of chemical substances under TSCA may prove to be arbitrary.

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determine whether a chemical substance – as a whole -- presents or does not present unreasonable risk when there are some conditions of use of the chemical that according to the risk evaluation analyses clearly fall onto one side of unreasonable risk or the other.

[81] 88 Fed. Reg. at 74302 (emphasis added).

[82] Id. (emphasis added).

[83] Id. at 74303 (emphasis added).

[84] Id. (emphasis added).

B. EPA's proposed revisions to the risk evaluation rule also raise issues under the Administrative Procedure Act about the adequacy of notice to the regulated community.

The regulated community may not know at the end of the risk evaluation process, with its "single" risk determination, which conditions of use ultimately might be regulated, and which might not. By only including a single risk determination on the chemical substance, independent of the chemical's conditions of use, EPA is not providing meaningful notice to stakeholders at the end of the risk evaluation process about what to expect in risk management of the chemical substance. Stakeholders must wait for EPA to publish a proposed risk management rule, one year after the risk determination, to know whether risk management actions might be proposed for those conditions of use of interest to stakeholders. EPA may even regulate "no unreasonable risk" conditions of use.

Lack of notice will also mean that stakeholders will not know what information, if any, that the Agency might need to make sound risk management decisions. The greater complexities of the risk management rules that would result from EPA's proposed changes to the risk evaluation framework rule would also make it more difficult, if not impossible, for the regulated community to meet the compliance deadlines for risk management rules.

IV. The Science Standards of TSCA

The Best Available Science and Weight of the Scientific Evidence Standards Required under Section 26 of TSCA Will be Difficult for EPA to Meet Under These Proposed Revisions.

The proposed revisions to the risk evaluation framework rule would broaden and increase the complexity of the risk evaluations to such an extent that raise serious questions about whether EPA's risk determinations made under these two proposed revisions could ever meet the "best available science" (BAS) and "weight of the scientific evidence" (WOSE) scientific standards of the statute.

EPA has failed to persuasively support the scientific merits of its proposed revisions to the rule. EPA has merely stated, with conclusory reasoning, that these revisions meet BAS and WOSE. Section 26(h) and (i) require more with respect to science-based decisions made under Section 6 – which includes both risk determinations and risk management rules. TSCA amendments directed EPA to establish procedures for conducting "risk evaluations" of TSCA's existing chemicals. Under the requirements of Section 6(b)(4)(F), risk evaluations must integrate and assess available information on the "hazards" of a chemical and the "exposures" for the chemical's conditions of use. Risk determination is a component of the risk evaluation. A single risk determination of a chemical substance as a whole, ignores the "condition of use" requirement laid out in Section 6(b)(4)(A) and 6(b)(4)(F). Chemicals may be determined to present unreasonable risk under some conditions of use and no unreasonable risk under others. A single risk determination of the chemical without regard to conditions of use makes a mockery of what Congress intended in the TSCA amendments of 2016 and arguably takes EPA back to

making decisions based only on the inherent hazards of a chemical, not both hazard and exposures under the conditions of use. This does not meet the scientific standards of Section 26. Further, EPA is not practiced in conducting aggregate exposure assessments or cumulative risk assessments. Both raise serious scientific challenges. EPA's proposed revisions to address combined exposures for all conditions of use of a chemical for thousands of TSCA chemicals with multiple conditions of use for all exposure routes and pathways would be impossible. Using TSCA risk evaluations to regularly evaluate the combined exposures to "overburdened communities" and cumulative risk for categories of chemicals would be scientifically challenging and complex. EPA's proposed revisions would make it much more difficult for EPA's risk evaluations to meet the Section 26 standards. This in turn would further delay TSCA implementation.

V. Process Concerns

A. EPA's proposed revisions to the risk evaluation rule will produce complexities in the risk evaluations that will create serious inefficiencies and resource problems for the Agency.

Many TSCA chemicals are building block chemicals. Many of them have hundreds if not thousands of conditions of use. It would be a gargantuan task for EPA to have to evaluate all conditions of use of a chemical substance in each TSCA risk evaluation (including conditions of use that are already regulated under other environmental statutes under EPA's jurisdiction or under other statutes such as OSHA) within the 3 and a half year (maximum) statutory deadline.

It would be a similarly gargantuan task for EPA to propose risk management rules based on a single unreasonable risk determination that includes "all" conditions of use of the chemical substance and then finalize them within two more years (with possibility of extension for two more years).

These revisions will make EPA's job more resource intensive and unnecessarily harder than Congress intended. This is why Congress developed a provision on "scoping" a risk evaluation in the first place: to give EPA the discretion to focus the risk evaluations on those conditions of use that presented the greatest potential for unreasonable risk. [85] EPA's proposed revisions requiring all conditions of use be in the scope (including conditions of use that are already regulated) negates the whole purpose of a "scope" for a risk evaluation, contradicting general practices of risk assessment.

EPA's proposed revisions to the existing risk evaluation framework rule will produce exceptionally complex risk evaluations and risk management rules that will create arbitrary regulatory decisions by the Agency.

At a minimum, the proposed revisions to the risk evaluation rule are premature, because it is not yet clear how these proposed revisions to the risk evaluation requirements will play out in risk management rules, since none has yet been finalized.

[85] 162 Cong. Rec. at S3519.

The current EPA may think its strained interpretations of the statute are warranted in order to protect "overburdened communities" against combined exposures to TSCA chemicals. But to require these outcomes under these interpretations in all risk evaluations, EPA is mandating such a huge broadening of its TSCA mission that it is setting itself and the TSCA program up for failure.

VI. Peer Review

A. Removing References to EPA's Peer Review Handbook (4th Edition 2015) and OMB's Information Quality Bulletin for Peer Review

EPA is proposing to "removing the reference to specific versions of guidance documents. The 2017 final rule specifically names the EPA Peer Review Handbook 4th Edition 2015 (Ref. 39) and OMB's Information Quality Bulletin for Peer Review (Ref. 40). While at the time of this proposed rule these documents were and still are applicable the Agency recognizes that these documents may be updated and/or their names modified and seeks to avoid confusion as to which guidance documents will be used. The Agency proposes at § 702.41 to refer instead to ''applicable peer review policies, procedures, guidance documents, and methods adopted by EPA and the Office of Management and Budget (OMB) to serve as the guidance for peer review activities."

While ACC recognizes that peer review policies may be updated with regard to editions and that the names may change, the benefit of specifying EPA and OMB guidance was a lack of ambiguity. If these references are removed, it may be unclear to EPA staff and stakeholders alike which policies, procedures, guidance documents, and methods from EPA and OMB are applicable to TSCA risk evaluations. As such, provision of clarity by EPA and OMB in some format may be required, particularly for stakeholders who have not been engaged in risk evaluation prior to the proposed update of the rule.

B. Peer Review of Portions of an Assessment

EPA states that "Rather than peer reviewing an entire risk evaluation, in adhering to applicable guidance, it may be appropriate for EPA to conduct peer review on only portions or sections that constitute unreviewed influential information. EPA also expects that a TSCA risk evaluation may use peer reviewed products (e.g., risk assessments, hazard assessments, models), or portions thereof, conducted by another EPA office or other authoritative body (e.g., state, national, or international programs), for which both the best available science and weight of scientific evidence standards were adhered to (see Unit III.I.1.). "

ACC does not agree that a "piecemeal peer review" of TSCA risk evaluations where peer review is limited only to elements of the risk evaluation that have not been previously peer reviewed by others in a manner that EPA thinks is in accordance with TSCA is appropriate. There is because a risk evaluation truly is greater than the sum of its parts and should therefore be reviewed holistically. This is especially salient with a "whole chemical" approach to risk evaluation. All elements of the risk evaluation (e.g. hazard assessment/characterization and dose-response assessment, exposure assessment/characterization, risk calculations/characterizations) interact

with the other elements to produce over-arching conclusions from the risk evaluation regarding unreasonable risk. Therefore, the totality of the risk evaluation must be considered in peer review.

C. EPA Must Conduct Full, Open Peer Review of All Elements of Draft Risk Evaluations

EPA has failed to provide a reasoned basis for diminishing the scope, quality, and transparency of peer review for highly influential TSCA risk evaluations. ACC's Formaldehyde Panel recently outlined in detail the statutory, regulatory, policy, and scientific justifications for EPA to conduct full, open, independent peer reviews of all elements of risk evaluations, as well as to fully address both public and peer reviewer comments.[86] TSCA Section 26(h) requires "best available science" including "independent verification or peer review of the information or the procedures, measures, methods, protocols, methodologies, or models." This independent validation depends on full, open peer review process with clear charge questions.

EPA has failed to acknowledge that the Agency considered and fully rejected limiting peer review in its final 2017 framework rule. This proposal fails to grapple with the numerous arguments made in support of this position:

> Accordingly, EPA has retained the provision from the proposed rule requiring peer review on all risk evaluations. Guidance on how peer review will be conducted will remain consistent with the EPA Peer Review Handbook. For clarity, EPA did move the peer review provision to its own section of the rule, as suggested by a commenter. EPA agrees with comments that peer reviewed evaluations will instill greater confidence and provide transparency to the process. EPA postulated in the proposed rule that there may be circumstances that may not necessitate peer review (e.g., where a chemical substance is found to not present an unreasonable risk or that findings are similar or the same as other jurisdictions (states or countries) that have reached similar conclusions based on the same information). Public comment presented arguments to why this is not appropriate. Although a substance may not present an unreasonable risk, the consequence of a "false negative" could be extremely problematic. For the second scenario where EPA's results may be similar to another jurisdiction's, commenters argued that it will also be necessary to peer review the evaluation. It would be necessary to make certain the best available science and weight of the scientific evidence approaches were used properly, as they may not have been required under the process by which the comparable evaluation was conducted. As such, EPA will require peer review on all risk evaluations.[87]

[86] https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0130.
[87] 82 Fed. Reg. at 33744.

In support of limited, piecemeal peer review, EPA indicates that "a TSCA risk evaluation may use peer reviewed products (e.g., risk assessments, hazard assessments, models), or portions thereof, conducted by another EPA office or other authoritative body (e.g., state, national, or international programs), for which both the best available science and weight of scientific evidence standards were adhered to."[88] However, a review of EPA peer review charge questions for recent IRIS assessments does not include a single example in which the peer reviewers were asked to comment on "best available science" or any of the Congressionally mandated standards under TSCA Section 26(h). In fact, EPA's air and pesticide programs have explicitly argued that EPA's IRIS assessment for formaldehyde do not constitute the "best available science," as ACC's recent comments on the Agency's Air Emission Reporting Requirements rule catalogue in detail.[89] EPA's 2017 explanation that, even in the case of EPA use of other peer reviewed risk assessments or models, the peer review will lack the right questions relevant to TSCA scientific standards still holds. The newly proposed regulatory text at § 702.41 providing for EPA flexibility to conduct peer review on the "portions" of risk evaluations is inappropriate and lacks a statutory basis. EPA has already noted in its 2017 framework rule preamble that no peer review would be "redundant" with TSCA scientific standards.

EPA has also begin turning to non-public, so-called "letter peer reviews" for some draft risk evaluations, noting in the proposal that "EPA has previously used this flexibility in the TSCA program and sought a letter peer review."[90] This decision is inconsistent with the need for independent validation under Section 26(h) of TSCA as well as EPA's Peer Review Handbook, which states that "[l]etter reviews by individual experts are more appropriate when a work product is not controversial, covers only a few disciplines, or when premature disclosure of a sensitive report to a public panel could cause harm to government or private interests."[91] EPA's Handbook contrasts these more limited reviews with panel reviews, arguing that: "panels are preferable for influential products because they tend to be more deliberative than individual letter reviews and the reviewers can help inform one another;" "Panels are valuable when the work product is complex and multidisciplinary"; and "Panel peer review meetings may be open to the public, with opportunities for public comment."

EPA should adopt standard, statutorily derived charge questions. In Section 26(h) of TSCA, Congress established standards for scientific quality that should be at the crux of any peer review. EPA asserts that it "will not seek peer review of any determination as to whether the risk is 'unreasonable,' which is an Agency policy determination,"[92] but this obscures the role clear Congress intended for independent validation of key methods and begs the question of what purpose peer review serves, if not to advise the Administrator in the context of Congressionally mandated standards for scientific quality and the use of the weight of scientific evidence. EPA also invokes the SACC to argue that there is no role for "advice and expert consultation" on

[88] 88 Fed. Reg. at 74308.
[89] https://www.regulations.gov/comment/EPA-HQ-OAR-2004-0489-0263.
[90] 88 Fed. Reg. at 74307.
[91] https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf, at 57.
[92] 88 Fed. Reg. at 74308.

"scientific and technical aspects of issues relating to the implementation" of the title for informing "unreasonable risk."[93] EPA should also strive to provide this legal context to peer review bodies, consistent with the best practices recommended by other organizations that have weighed in on improvements to the science advisory process at agencies like EPA.[94] This is consistent with framework guidance adopted by EPA in the context of setting National Ambient Air Quality Standards.[95]

All TSCA risk evaluations are "highly influential scientific assessments" or "influential scientific information" that should follow EPA and OMB peer review and information quality guidelines. EPA is required under the White House Office of Management and Budget's *Final Information Quality Bulletin for Peer Review*[96] to post on their web site a Peer Review Agenda[97] that includes all planned and ongoing "influential scientific information" developed by EPA and an attendant "Peer Review Plan," in part to provide the public an opportunity to comment on peer review timing as well as which peer review bodies will be engaged. These requirements are also discussed in detail in EPA's *Peer Review Handbook*. "Influential scientific information" is defined as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions."[98]

EPA appears to previously have shared ACC's view that this major risk evaluation is "influential science" for other TSCA risk evaluations, as the current Peer Review Agenda includes peer review plans for TSCA risk evaluations for perchloroethylene, carbon tetrachloride, asbestos, methylene chloride, NMP, and trichloroethylene (but not forthcoming evaluations for TCEP or formaldehyde).[99]

D. EPA Should Subject this Proposed Rule to Peer Review and Scientific Consultation, Consistent with TSCA Section 26 and the Environmental Research, Development, and Demonstration Authorization Act

Given the substantive scientific, technical, implementation, and methodological issues raised in the proposed rule, EPA should seek peer review and consultation, consistent with 42 U.S. Code § 4365(c) and 15 U.S. Code § 2625(o), with the U.S. EPA's chartered Science Advisory Board (SAB) and/or Science Advisory Committee on Chemicals (SACC) on the proposed rule. As discussed below, this review is strongly supported by Congressional requirements under the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) and Section 26 of TSCA. Failure to do so would mean that EPA's potential significant elimination of peer review processes for risk evaluations and more flexible approach

[93] Id..
[94] https://www.keystone.org/wp-content/uploads/2015/08/ResearchIntegrityRountableReport.pdf ("Panelists should be periodically reminded of the statutory requirements that govern the questions the panel is addressing.")
[95] https://www.epa.gov/sites/default/files/2018-05/documents/image2018-05-09-173219.pdf.
[96] https://cfpub.epa.gov/si/m05-03.pdf.
[97] https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.
[98] https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015.
[99] https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

to standards for best available science will have never been subject to feedback from an Agency peer review body and its expert members.

The SACC represents an appropriate forum for review of these dramatic changes in Agency interpretation of the scientific standards under TSCA. Section 26(o) of TSCA establishes the SACC "to provide independent advice and expert consultation… with respect to the scientific and technical aspects of issues relating to the implementation of this subchapter." Given the momentous changes in EPA's commitment to full, open peer review of all risk evaluations as well as the elimination of EPA's definitions of "best available science" and "weight of scientific evidence," the SACC is uniquely situated to examine the proposed rule.

EPA should also seek scientific advice from the EPA's chartered SAB in manner consistent with 42 U.S. Code § 4365(c). ERDDAA directs the EPA Administrator to establish a standing Science Advisory Board. Congress further required that "[t]he Administrator, at the time any proposed criteria document, standard, limitation, or regulation under… [TSCA]…, or under any other authority of the Administrator, is provided to any other federal agency for formal review and comment, shall make available to the Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based." Providing this information at the stage of interagency review and comment facilitates the Board providing "its advice and comments on the adequacy of the scientific and technical basis of the… regulation, together with any pertinent information in the Board's possession."[100]

While EPA appears to have engaged the SAB in the context of this proposal, along with numerous other regulatory actions,[101] this engagement was not consistent with ERDDAA and did not constitute meaningful consultation for three reasons. First, EPA briefed an SAB workgroup, as opposed to the chartered SAB. The former is not subject to critical requirements under ERDDAA and the Federal Advisory Committee Act. For example, the briefing materials for the SAB workgroup have not been made public. Second, this briefing did not include the preamble or text of the proposed rule or "relevant scientific and technical information… on which the proposed action is based" and took place months after the interagency process for the proposal started in late June.[102] Third, the SAB workgroup's recommendation was based on the involvement of the SACC despite EPA's now-apparent failure, as noted above, to engage this body on the proposed rule.

VII. Additional Requests for Comment

A. Consideration of Potential Climate-Related Risks in a Risk Evaluation

[100] 42 U.S.C. § 4365(c).
[101] https://sab.epa.gov/ords/sab/f?p=114:0:17206674413838:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1119.
[102] https://www.reginfo.gov/public/do/eoDetails?rrid=322111.

EPA does not currently address how it may consider climate-related risks in a risk evaluation in the framework rule. EPA should not change this. While Congress gave EPA some additional authority in the 2016 amendments of TSCA, Congress did not intend to sweep away and invalidate other federal statutes and programs with responsibility for air emissions and climate impacts. "More authority" is simply not equivalent to a Congressional grant of superseding authority over every other federal statute.

Policies and regulatory actions directed at addressing climate change are well beyond the scope and intent of TSCA. Legislative intent in fact sheds light on this: "EPA may not promulgate a rule under section 6 of TSCA" when the agency "already regulates that chemical through a different statute under its own control, like the Clean Air Act."[103]

We caution that the U.S. Supreme Court's recent decision in West Virginia v Environmental Protection Agency held that EPA did not have authority to issue a greenhouse gas emissions rule under the major questions doctrine, considering elements including whether the agency's action represents a "transformative" change in the agency's authority. Likewise, EPA recently denied a petition seeking to compel the Agency to use its TSCA regulatory authority to "phase out the production and importation and, as warranted, the processing, distribution, use or atmospheric disposal of certain chemical substances and mixtures" in September 2022. Stretching TSCA into a vehicle to mandate consideration of the potential climate impacts of chemicals as a matter of course in every risk evaluation would be similarly transformative, and not in a productive way.

The proposed rule continues a recent trend by EPA of trying to shoehorn climate policy into unsuitable statutory authorities and programs. Under the Administration's "All of Government" approach to climate policy, neither Congressional intent nor legislative authority are overruled by regulatory expediency, as reflected in the proposal's statement that "any risk management actions following any determination that a chemical substance presents unreasonable risk will result in needed public health and environmental protections that limit exposure to dangerous chemicals, and, where applicable, address the climate crisis and advance environmental justice."

EPA's challenge is not demonstrating that climate is a legitimate health or environmental crisis; rather, it is demonstrating that TSCA is a legitimate, appropriately designed, fit-for purpose, and reasonably anticipated legislative tool to address it. EPA's example scenario, in which "rising sea levels or extreme temperatures made worse by climate change were leading to regular and predictable changes in exposures associated with a given condition of use of a chemical substance," suggests it is not.[104] The potential for some hypothetical, future impact is not enough to let EPA restrict a chemical under TSCA.

Congress has given the Administration a wide range of legal, regulatory, and financial tools to address the myriad threats to human health and safety, climate and the environment, security, and the economy. It has provided a wide range of policy tools and resources to promote economic, social, occupational, and environmental interests as well, including, most recently the landmark Inflation Reduction Act and Bipartisan Infrastructure law. Among these, TSCA is one of the most

[103] 162 Cong. Rec. H3028 (daily ed. May 24, 2016) (statement of Rep. Robert Pittenger)
[104] 88 Fed. Reg at 74298.

complex and challenging when focused on its core mission alone. EPA should focus on implementing the law as intended rather than further complicating a program that is struggling to meet its legislative obligations. With respect to the essential role that chemistry plays in protecting the environment and mitigating climate change, these elements should be considered as part of the risk management process, including alternatives analysis, benefit-cost review, and alternatives assessment.

B. Proposed Changes to Process for Manufacturer-Requested Risk Evaluations

EPA's proposed changes would codify a number of policy approaches into the risk evaluation rule collectively make it perhaps fatally and permanently unattractive for a chemical manufacturer, going forward, to request EPA to perform a risk evaluation. These policy changes include the "no PPE" assumption, which may be factually invalid and readily debunked for a particular manufacturer (e.g., the manufacturer requesting the risk evaluation may have unequivocal evidence that proper PPE is being used by its worker base). These also include the approach mandating a single risk determination, which ties EPA's hands with respect to reaching a determination, at the end of the risk evaluation, that one or more of the conditions of use of the chemical do not present unreasonable risk, which would conclude the process for those conditions of use and act as a safety certification from the agency. The current reality – under the current framework rule – is that EPA is currently taking over five years to perform a risk evaluation and complete the risk management process. EPA is also charging significant fees to do this.

We note that even if EPA does nothing to change the existing framework rule, its current approach to risk evaluations including manufacturer-requested evaluations would also discourage these requests. EPA only received 4 requests for manufacturer requested risk evaluations since the 2016 amendments, and EPA's last acceptance of these was on December 8, 2020.[105] Since EPA announced and began implementing its new policy approaches to risk evaluation on June 30, 2021 that it now seeks to codify (e.g., no PPE, single chemical determination) no manufacturer has come forward to request an evaluation, so we are seeing real time the adverse effect of the policies. Here, EPA proposes to impose even more cost and burden on manufacturers requesting such reviews, including a requirement to research all conditions of use – even though those conditions of use may be unknown to the manufacturer, or may be uses the manufacturer does not support or sell into.

EPA has estimated in its Information Collection Request that with its proposed changes, it will receive not receive the maximum of five manufacturer requests per year, but only one. We believe this is misplaced. The number should be zero. EPA's proposed approach makes the process so unattractive and valueless as to be unusable. We do not see scenarios where a manufacturer would see value in paying a multi-million-dollar fee to initiate the process EPA describes.

[105] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-manufacturer-requested-risk-evaluations-under-tsca

We note further the impact of the new EPA fee rule on manufacturer requested risk evaluations and urge EPA to take this into consideration. In our view, EPA cannot and should not change fee schedules for these risk evaluations after a manufacturer request has been submitted and accepted in a punitive manner or a manner that increases expected and planned costs. This implicates basic due process principles of fair play and of course the reliance interest of the regulated entity on the procedural rules in place at the time a request was submitted. For example, the D4 request was granted in 2019 when the old fee rule was in place. But under the new fee rule, EPA substantially increased its estimate for a risk assessment to almost $10 million dollars. EPA should clarify that the submitters of the four pending manufacturer requests will not be retroactively, ex post facto subject to policy changes that adversely affect their reliance interests whether in the risk evaluation framework rule or elsewhere.

At a minimum, we urge EPA not to modify the manufacturer-requested review provisions and retain the current language in the existing framework rule.

C. Improving Engagement with Small Entities.

In the final page of the preamble for EPA's proposed rule, EPA "requests comment on general approaches or best practices for improving engagement with small entities" including "how to improve its outreach to the stakeholder community" and "education on the TSCA risk evaluation process for small entities."[106] EPA fails to include any approaches the Agency has deployed to engage small entities, nor proposes regulatory text to address these deficiencies. EPA also fails to include recommendations received by small entities to better engage them in the risk evaluation process.

In October 2023, a group of small business trade associations, including the American Feed Industry Association, American Home Furnishings Alliance, Catfish Farmers of America, Composite Panel Association, Kitchen Cabinet Manufacturers Association, and National Aquaculture Association, wrote to EPA seeking that EPA establish a small business panel, pursuant to the Small Business Regulatory Enforcement Fairness Act, for the forthcoming draft risk evaluation of formaldehyde.[107] Noting that many risk management decisions are pre-ordained by EPA's risk evaluation process, these groups requested "that this panel be held before completion of the draft risk evaluation, in order to inform the risk assessment, as well as to keep open regulatory options that would reduce small firm burdens." Unfortunately, EPA has not acted on this request. ACC believes EPA convening SBREFA panels ahead of risk evaluation is the best practice for improving engagement with small entities. In addition, and discussed in more detail below, meaningful interagency coordination on TSCA risk evaluation, including with agencies that coordinate more closely with small entities, is another avenue for better coordination and is consistent with Section 9 of TSCA and long-standing Executive Orders and OMB guidance.

In general, there must be better outreach from EPA to small businesses clearly explaining the impact that TSCA and risk evaluations can have on their supply chains. It should be clearly

[106] 88 Fed. Reg. 74316.
[107] https://nfda.org/Portals/0/HCHO%20SBREFA%20LETTER%20FINAL%2010-6-23.pdf.

explained that TSCA does not just regulate chemical manufacturers but can ban a chemical altogether, and result in loss of access to a supply chain, or price shocks. EPA must provide sufficient notice further explaining that the supply chains cannot wait until a risk management rule is proposed, as this is too far along in the process and will not provide enough time to adequately engage. EPA should consider options used by other federal agencies, including providing website information and outreach events.[108]

D. Other Missed Opportunities for Early EPA Engagement in the Risk Evaluation Process

EPA's proposed rule has also missed the opportunity to seek public comment and propose new regulatory text for existing statutory and regulatory requirements that EPA's TSCA risk evaluations have flouted. For example:

- Despite requirements under Section 9 of TSCA related to interagency coordination, Executive Order 12866, and long-standing OMB guidance on the need for interagency review of significant guidance and other non-regulatory actions, recent EPA draft and final risk evaluations and risk determinations have failed to go through an interagency process.[109] Several members of Congress from both parties have additionally supported the need for greater engagement with other federal agencies, including those with greater coordination with small entities, in the TSCA risk evaluation and IRIS assessment process.[110] Consistent with Section 9 of TSCA and Executive Order 12866, EPA should go through a formal interagency process led by the White House Office of Information and Regulatory Affairs, including consultation with the Department of Defense, Small Business Administration, U.S. Department of Agriculture, Food & Drug Administration, Department of Labor, and NASA, for all draft and final risk evaluations.
- EPA has also failed to include draft or final risk evaluations in its entries for the Office of Management and Budget's Unified Agenda of Regulatory Actions.[111] As a result, EPA has failed to provide required notification of draft and final TSCA risk evaluations to EPA's Science Advisory Board, pursuant to EPA's 2022 memorandum[112] and 42 U.S. Code § 4365(c).

VIII. Conclusion

[108] For example, see https://www.ftc.gov/business-guidance/small-businesses or https://www.fda.gov/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia?utm_medium=email&utm_source=govdelivery

[109] Based on a search at https://www.reginfo.gov/public/do/eoAdvancedSearch.

[110] https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0066; https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0065/attachment_2.pdf; https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0065; https://carey.house.gov/sites/evo-subsites/carey.house.gov/files/evo-media-document/RepCareyLettertoEPAAdminRegan.pdf; https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0061.

[111] Based on a review of 2021 – 2023 Unified Agendas: https://www.reginfo.gov/public/do/eAgendaMain.

[112] https://sab.epa.gov/ords/sab/r/sab_apex/files/static/v406/Science%20Supporting%20EPA%20Decisions.pdf.

EPA's proposed revisions discussed above are not authorized by the statute taken as a whole, are unworkable, could create due process problems with respect to lack of notice to potentially regulated entities, and are simply not reasonable to implement. They should be withdrawn. EPA should retain the existing framework rule as it was originally promulgated.