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)

n-Methylpyrrolidone (NMP) (Docket ID EPA-HQ-OPPT-2016-0743)

Methylene Chloride (MC) (Docket ID EPA-HQ-OPPT-2016-0742)

Trichloroethylene (TCE) (Docket ID EPA-HQ-OPPT-2016-0737)

August 1, 2022

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I. Executive Summary

The draft revised risk determinations for perchloroethylene (PCE), n-methylpyrrolidone (NMP), methylene chloride (MC) and trichlorethylene (TCE) were published in the Federal Register on June 30, July 1, July 5, and July 7, 2022, respectively. In each of these draft revisions, EPA has taken a "whole chemical approach" to risk determination instead of making risk determinations for these chemical substances under their individual conditions of use (COUs).[1,2,3,4] Each of these drafts also reflects the assumption that personal protective equipment (PPE) is not used in the workplace, and therefore, EPA does not consider PPE in these draft revised risk determinations.

EPA has not adequately supported its decision to implement a whole chemical approach in these chemicals' risk determinations or its decision to not assume use of PPE for industrial and commercial uses. In applying these two policies, EPA is ignoring its own evaluation of available data and analysis of these TSCA chemicals under their conditions of use when it suits EPA's purposes. Application of these policy decisions then, is arbitrary. ACC's comments express several key concerns with the approaches that EPA applied to each of these chemicals' draft revised risk determinations which need to be addressed by the Agency, including:

Whole Chemical Approach

- EPA has made changes in key language of these draft revised risk determinations regarding the whole chemical approach. These changes make EPA's whole chemical approach even more arbitrary in its application than originally conceived and they give EPA the ability to broaden the number of conditions of use the Agency can use to justify its whole chemical approach.
- The Agency has not adequately supported its proposal to implement a whole chemical approach.
- The approach is inconsistent with TSCA and EPA's own risk evaluation regulations. A single "whole chemical" unreasonable risk determination, when there are conditions of use that the

[1] Perchloroethylene (PCE); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, 87 Fed. Reg. 39085 (June 30, 2022).
[2] N-Methylpyrrolidone (NMP); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, 87 Fed. Reg. 39511 (July 1, 2022).
[3] Methylene Chloride; Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, 87 Fed. Reg. 39824 (July 5, 2022),
[4] Trichloroethylene (TCE); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, 87 Fed. Reg. 40520 (July 7, 2022).

Agency has determined *do not* present an unreasonable risk, ignores the possibility of "no unreasonable risk" determinations for a chemical under its conditions of use.

- The approach is neither science-based nor risk-based and does not meet the science requirements of TSCA Section 26.
- The approach is arbitrary, and lacks clarity, principles, and criteria.
- The approach will have substantial adverse impacts on the regulated community as well as on the credibility of both EPA and OSHA regulations.

Assumption of No PPE

- Assumptions regarding the lack of use of PPE are inconsistent with TSCA's requirements that EPA determine whether a chemical presents an unreasonable risk under the chemical's "conditions of use."
- These assumptions do not comply with TSCA's Section 26 requirements that TSCA risk evaluations be consistent with best available science and based on weight of the scientific evidence.
- These assumptions are inconsistent with the Occupational Safety and Health Act's statutory and regulatory requirements.
- Addressing PPE (and other OSHA requirements) only in the risk management rule, and not as part of the conditions of use in the risk evaluation, will have significant potential impacts, including the potential for duplicative and inconsistent requirements.

Because EPA has not provided a science-based, reasoned explanation for these changes, EPA should withdraw these draft revised unreasonable risk determinations, and should correct the scientific and procedural errors in them. In addition, EPA should provide an opportunity for public comment on the whole chemical and no PPE policy decisions before applying these changes to any other chemical substances.

II. EPA's changes to key language in these risk determinations makes EPA's whole chemical approach more arbitrary in its application and gives EPA greater ability to broaden the conditions of use it can use to justify its whole chemical approach.

EPA's justification and support for its implementation of a whole chemical approach and a "no assumption" of PPE in its draft revisions to the risk determinations for perchloroethylene (PCE), n-methylpyrrolidone (NMP), methylene chloride (MC) and trichloroethylene (TCE) are largely identical to one another. These solvents are pivotal inputs to many critical supply chains such as for semiconductors, high-capacity batteries, refrigerants, and much more. For example, chlorinated solvents are critical to the compliance with the American Innovation and Manufacturing (AIM) Act which directs EPA to address hydrofluorocarbons (HFCs) with high global warming potentials (GWPs).[5] The vast majority of the next

[5] https://www.epa.gov/climate-hfcs-reduction

generation low GWP solutions are manufactured from these feedstocks. Products made from these solvents are critical in making semiconductor and other electronics applications, as well as defense, medical products, foam insulation and fire protection.

Except for the chemical-specific information about hazards to human health and/or the environment and lists of conditions of use (COUs), EPA's language in the Federal Register (FR) notices on these chemical substances and their draft revised risk determinations are the same. For this reason, ACC is addressing EPA's draft revisions to the risk determinations of each of these chemicals in this single set of comments. These comments will be filed in the dockets for each of the chemicals.

Without explanation, EPA has changed some of the key language it has been using for the last year to describe how it will implement a "whole chemical" approach in certain risk determinations going forward. This language change first appeared in the **final** revised risk determination for HBCD, published on June 29, 2022.[6] The change was also included in FR notices and draft revisions to the risk determinations for PCE, NMP, MC and TCE. It is **different** from key language EPA used in its **draft** revisions to the risk determinations for HBCD and PV29.[7] EPA does not discuss why it uses this new language in the HBCD final risk determination or in these four chemicals' draft revised risk determinations. This change is significant, however, because it arguably makes EPA's "whole chemical" approach more arbitrary in its application and it gives EPA the ability to broaden the conditions of use that it chooses to justify a "whole chemical" approach for these chemicals, and others in the future.

A. EPA's use of the new term "substantial amount" of conditions of use to justify application of a whole chemical approach is vague and will result in arbitrary and inconsistent risk determinations.

To justify its use of a whole chemical approach in the **draft** HBCD revised risk determination, EPA states,

> Since the chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, **the Agency's risk findings and conclusions encompass the majority of those conditions of use**, and the Agency is better positioned to achieve its TSCA objectives for HBCD when issuing a whole chemical determination for HBCD, EPA concludes that the Agency's risk determination for HBCD is better characterized as

[6] Cyclic Aliphatic Bromide Cluster (HBCD); Revision to the Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, 87 Fed. Reg. 38747 (June 29, 2022).
[7] Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, 86 Fed. Reg. 74082 (December 29, 2021); Colour Index Pigment Violet (PV29); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, 87 Fed. Reg. 12690 (March 7, 2022).

> a whole chemical risk determination rather than condition-of-use-specific risk determinations."[8]

ACC's comments on the HBCD draft revised risk determination[9] strongly criticized EPA's lack of scientific support for this justification for a "whole chemical" approach and for failing to address obvious questions about the scientific integrity of EPA's whole chemical approach. Specifically, ACC asked "What is EPA's science basis for concluding that a 'majority' of individual COU unreasonable risk determinations warrant a whole chemical unreasonable risk determination?"[10]

EPA's response to comments on the HBCD draft revised risk determination does not provide additional scientific support for its claim, but merely repeats the claim above,[11] while also providing an example distinguishing a "majority" of conditions of use from a "single" condition of use.[12] EPA also includes a statement about the six conditions of use in the HBCD risk evaluation that "drive" the unreasonable risk, therefore justifying a whole chemical approach.[13]

In its **final** risk determination for HBCD, however, EPA states:

> Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation **and a substantial amount of the conditions of use** drive the unreasonable risk**,** it is therefore appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk.[14]

EPA has replaced its "majority" of conditions of use concept with a new "substantial amount" of conditions of use concept to decide when a "whole chemical" approach is appropriate. This "substantial amount" of COUs concept is repeated in the draft risk determinations for PCE, NMP, MC, and TCE.

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[8] Draft Revised Unreasonable Risk Determination for HBCD, Document ID EPA-HQ-OPPT-2019-0237-0095, Section 5.1.1, pp. 2-3, lines 81-87 (emphasis added).
[9] ACC Comments on EPA's Revised TSCA Risk Determination for HBCD (March 4, 2022), Comment ID EPA-HQ-OPPT-2019-0237-0119.
[10] *Id.*, p. 10.
[11] Cyclic Aliphatic Bromide Cluster (HBCD); Revision to Toxic Substances Control Act (TSCA) Risk Determination, Response to Public Comments (June 2022), Document ID EPA-HQ-OPPT-2019-0237-0124, p. 7.
[12] "For instance, circumstances in which an unreasonable risk determination is potentially driven by a single condition of use that does not impact or intersect with other evaluated uses (such as a single consumer use of a substance out of a wide range of other manufacturing, processing and consumer uses evaluated, for example) may warrant different treatment than circumstances in which the majority of the chemical substance's conditions of use contribute to unreasonable risk, and the Agency might adopt different approaches to the risk determinations in those particular instances." *Id.*, p. 7.
[13] "In the case of HBCD, six of the twelve conditions of use drive the unreasonable risk and the chemical-specific properties cut across the conditions of use within the scope of the risk evaluation; therefore, the risk determination for HBCD is better characterized by the whole chemical approach." *Id.*, p. 11. It is not clear how six out of twelve conditions of use constitutes a majority.
[14] Final Unreasonable Risk Determination for HBCD (June 2022), Document ID EPA-HQ-OPPT-2019-0237-0125, Section 5.1.1, pp. 2-3 (emphasis added).

Significantly, the new phrase "substantial amount of the conditions of use" is even more vague than EPA's original articulation of a "majority" of conditions of use. It arguably provides EPA broader flexibility to make risk determinations however it chooses – whether to use a whole chemical approach or to make condition-of-use based risk determinations. It will depend on how EPA chooses to interpret the phrase "substantial amount."

This type of flexibility to determine when there is a "substantial amount" of COUs is not science-based. This is inconsistent with TSCA's Section 26's requirements that Section 6 decisions, based on science, meet "best available science" and "weight of the scientific evidence" requirements. EPA's reliance upon this vague notion of "substantial amount," therefore, does not satisfy the requirement that EPA support its revised decisions with "reasoned explanation."[15]

This language change reveals the arbitrary nature of EPA's "whole chemical" approach. It underscores ACC's position that unreasonable risk determinations of a TSCA chemical substance under each of its specific conditions of use is a more accurate way to make these decisions – as well as representing a better interpretation of TSCA (see Section III below). While EPA argues that the "whole chemical" approach to risk determinations is "permissible" (under its strained reading of the law), that does not make it sensible. Even the name "whole chemical" is a misnomer. For example, in each of the risk evaluations for PCE, NMP, MC and TCE, EPA found that certain conditions of use of these chemicals did NOT present unreasonable risk. EPA has not proposed changing the underlying analyses in Section 4 of the risk evaluations that supported those risk determinations.[16] Yet EPA plans to withdraw these chemicals' Section 6(i)(1) "no unreasonable risk" orders, and, presumably, address these conditions of use that EPA has determined are safe during risk management.

B. EPA does not explain what it means by the phrase "conditions of use that drive unreasonable risk," arguably giving EPA the ability to broaden its claim that enough COUs justify a "whole chemical" approach.

EPA's new articulation of when it is appropriate to use a whole chemical approach includes a second phrase which EPA has failed to explain, and which raises additional concerns.

As noted above, the draft revision to the HBCD risk determination uses the phrase, "the Agency's risk findings and conclusions **encompass** the majority of those conditions of use."[17] But the final risk

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[15] *E.g.*, PCE Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39086.
[16] *See* EPA Releases Draft Revised Risk Determination for Perchloroethylene for Public Comment (June 30, 2022), available at https://www.epa.gov/chemicals-under-tsca/epa-releases-draft-revised-risk-determination-perchloroethylene-public-comment; EPA Releases Draft Revised Risk Determination for n-Methylpyrrolidone for Public Comment (July 1, 2022), available at https://www.epa.gov/chemicals-under-tsca/epa-releases-draft-revised-risk-determination-n-methylpyrrolidone-public; EPA Releases Draft Revised Risk Determination for Methylene Chloride for Public Comment (July 5, 2022), available at https://www.epa.gov/chemicals-under-tsca/epa-releases-draft-revised-risk-determination-methylene-chloride-public; EPA Releases Draft Revised Risk Determination for Trichloroethylene for Public Comment (July 7, 2022), available at https://www.epa.gov/chemicals-under-tsca/epa-releases-draft-revised-risk-determination-trichloroethylene-public-comment.
[17] Draft Revised Unreasonable Risk Determination for HBCD, Section 5, p. 3, lines 82-83 (emphasis added).

determination for HBCD uses the phrase "a substantial amount of the conditions of use **drive the unreasonable risk**."[18] The phrase **"drive the unreasonable risk"** is used throughout the FR notice announcing the final revised risk determination for HBCD, as well as in the draft revised risk determinations and FR notices for PCE, NMP, MC and TCE that are the subject of these comments. EPA does not explain what it means for conditions of use to "drive the unreasonable risk." This term is not used anywhere in the TSCA statute or the Risk Evaluation Rule.[19]

In the PCE, NMP, MC and TCE FR notices, however, it is also clear that this phrase is **not** used to replace the TSCA Section 6(b)(4)(A) language requiring EPA to conduct risk evaluations to determine whether a chemical substance "presents" an unreasonable risk under the conditions of use. In EPA's draft revisions to these risk determinations, the phrase "drive the unreasonable risk" is **not** applied to the "chemical substance." Instead, it is only applied to the phrase "a substantial amount of the conditions of use." It is not clear what EPA means by using this phrase only in this context. Whatever EPA's purpose for using this phrase, however, it arguably gives the Agency broad ability to re-characterize certain "presents no unreasonable risk" COUs as COUs that "drive" the unreasonable risk – and hence increase the number of COUs EPA might need to justify a "whole chemical" approach in the risk determination. This outcome is also consistent with EPA's discussion of its risk management authority in its proposed revisions to the risk determinations:

> EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address unreasonable risk. For instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities are not unreasonable risk drivers.[20]

In sum, EPA's shifting articulation of its "whole chemical" approach is impermissibly vague.

III. EPA has not adequately supported its decision to implement a whole chemical approach in the risk determinations for PCE, NMP, MC and TCE.

The whole chemical approach as applied by EPA to date is arbitrary in its application; reliant upon a reading of certain TSCA provisions in isolation, inconsistent with the statute as a whole and Congressional intent; and without regard to other provisions that would be rendered superfluous by the "whole chemical" approach. The whole chemical approach to TSCA risk determinations is misguided public policy that will mislead the public, the marketplace and state regulators.

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[18] Final Unreasonable Risk Determination for HBCD, Section 5, pp. 2-3 (emphasis added).
[19] *See* 40 C.F.R. Part 702, Subpart B.
[20] Draft Revised Unreasonable Risk Determinations for PCE (Document ID EPA-HQ-OPPT-2016-0732-0117), NMP (Document ID EPA-HQ-OPPT-2016-0743-0118), MC (Document ID EPA-HQ-OPPT-2016-0742-0120), TCE (Document ID EPA-HQ-OPPT-2016-0737-0131), Section 5, p. 3.

The 2016 TSCA amendments were designed to ascertain whether TSCA chemicals present unreasonable risk under the chemical substance's COUs, and where they did, to impose a range of risk management controls on those chemical-specific COUs to the extent necessary so that they did not continue to present unreasonable risk. TSCA chemicals are important building block chemicals for industrial, commercial, and consumer uses, hence, the importance of consideration of the conditions of use of these substances.

One of the predominant early principles that emerged in the debates on the TSCA amendments was that chemicals should be "safe for their intended uses." This principle recognized that both the inherent toxicity of a chemical *and* the likely exposures under its COUs must be evaluated to determine whether a chemical presents risks to humans and the environment. The principle of "safe for intended uses" was expanded during the 8-year legislative debate to the concept of "intended, known or reasonably foreseen conditions of use."[21] The term "conditions of use" was defined in the statute to cover the "circumstances" or activities of the manufacture, processing, distribution in commerce, use, or disposal of TSCA chemicals. These circumstances determine what "exposure scenarios" specific to the chemical's COUs the Agency should include in TSCA risk evaluations. In the risk evaluation, the Agency would integrate exposure scenario information with data on the chemical's inherent "hazards" (e.g., potential to cause cancer or non-cancer effects in humans, toxicity to aquatic life). The TSCA amendments made clear that requirements for conducting risk evaluations include consideration of a chemical's "hazards and exposures for the conditions of use" and "the likely duration, intensity, frequency and number of exposures under the conditions of use."[22]

Previously, EPA made multiple "risk determinations" for each of these chemical substances under each of these chemicals' multiple COUs. A risk determination's coverage was clear because each risk determination was specifically associated with a chemical substance's COUs that were scoped in the risk evaluation. Under the Agency's proposed whole chemical approach, as applied to PCE, NMP, MC and TCE, if a "substantial amount" of the COUs the Agency includes in its risk evaluation are found to "drive" the unreasonable risk, the Agency proposes to make only one risk determination: a whole chemical determination of unreasonable risk.

A. The whole chemical approach is inconsistent with TSCA and its implementing regulations.

1. TSCA Section 6 is predicated on the Agency making determinations of both "unreasonable risk" and "no unreasonable risk" for the "conditions of use" for each chemical substance.

By essentially removing consideration of individual COUs from the risk determination, the whole chemical approach is inconsistent with the risk evaluation process described in TSCA Section 6. TSCA

[21] TSCA Section 3(4) defines "conditions of use" 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).
[22] *See* 15 U.S.C. §§ 2605(b)(4)(F)(i) and (iv).

Section 6(b)(4)(A) requires that EPA risk evaluations determine "*whether* a chemical substance presents an unreasonable risk…under the conditions of use."[23] In conducting a risk evaluation, EPA must "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance" and "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use."[24] Section 6(b)(4) contemplates risk determinations of both "unreasonable risk" and "no unreasonable risk" for a chemical substance based on the chemical's inherent hazards and the chemical's exposures under the COUs. The concept of "whole chemical" is not mentioned in the TSCA statute.

TSCA Sections 6(i)(1) and (2), which define final agency action for purposes of judicial review, also contemplate risk determinations of both unreasonable risk and no unreasonable risk.[25] Section 6(i)(1) requires EPA, when it determines a chemical substance *does not present* an unreasonable risk under Section 6(b)(4)(A) (i.e., "under the conditions of use"), to issue an order which will be considered final agency action. Section 6(i)(2), however, provides, when EPA determines a chemical substance *presents* an unreasonable risk under Section 6(b)(4)(A), the final Section 6(a) risk management rule is considered final agency action. TSCA Section 6, therefore, contemplates the potential for two types of risk determinations. A single whole chemical unreasonable risk determination, when there are COUs that the Agency has determined do not present an unreasonable risk, ignores the possibility of "no unreasonable risk" determinations for a chemical substance under its conditions of use. In fact, in each of the draft revised risk determinations for PCE, NMP, MC and TCE, EPA declares it will withdraw those "no unreasonable risk" orders that became effective when the risk evaluations were finalized.[26]

TSCA gives EPA three years to complete a risk evaluation to allow for a detailed, scientific-based evaluation of the COUs.[27] The whole chemical approach ignores the factors that go into the risk evaluation, pursuant to Section 6(b)(4)(F), and the risk determination, pursuant to Section 6(b)(4)(A). Instead, the whole chemical approach pushes the time intensive COU risk evaluation and determination into the much shorter risk management rule phase.[28] Further, this approach does not give confidence to the regulated community and the public that uses that EPA has determined are safe and do not pose an unreasonable risk will be allowed to continue.

2. The whole chemical approach impermissibly renders parts of the statute superfluous.

It is "a cardinal principle of statutory construction" that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or

[23] 15 U.S.C. § 2605(b)(4)(A) (emphasis added).
[24] 15 U.S.C. § 2605(b)(4)(F)(i) and (iv).
[25] 15 U.S.C. § 2605(i)(1), (2).
[26] *E.g.*, PCE Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39086.
[27] 15 U.S.C. § 2605(b)(4)(G).
[28] *See* 15 U.S.C. § 2605(c)(1).

insignificant."[29] The whole chemical approach, however, renders parts of the statute that relate to no unreasonable risk determinations superfluous.

In addition to Section 6, other sections of TSCA rely on the Agency issuing no unreasonable risk determinations. For example, TSCA Section 18(a)(1)(B)(i) preempts state and local actions to prohibit or restrict the manufacture, processing, distribution in commerce, or use of chemical substances for which EPA has made no unreasonable risk determinations under Section 6(i)(1).[30] The whole chemical approach, in which the Agency would not make no unreasonable risk determinations that would be subject to preemption, makes Section 18(a)(1)(B)(i) superfluous.

Moreover, TSCA Section 19 establishes the procedure and standard for judicial review of, among other things, no unreasonable risk determination orders issued under Section 6(i)(1).[31] Again, the whole chemical approach makes the provisions applicable to judicial review of no unreasonable risk determination orders issued under Section 6(i)(1) superfluous.

Congress could not have intended for TSCA Section 6 to be interpreted such that sections of the statute have no meaning.

B. The whole chemical approach is inconsistent with EPA's Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act ("Risk Evaluation Rule").

The TSCA Amendments required EPA to establish a process by rule to conduct risk evaluations in accordance with TSCA Section 6(b)(4)(A) (i.e., "under the conditions of use"). The Risk Evaluation Rule promulgated under TSCA contemplates that EPA will make a risk determination for each condition of use:

> *As part of the risk evaluation*, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment *under each condition of uses* [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.[32]

That the rule provides for determinations to be made in single or multiple decision documents allows EPA to reach different determinations on different conditions of use at different points in time.

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[29] *Duncan v. Walker*, 533 U. S. 167, 174 (2001) (internal quotation marks omitted).
[30] 15 U.S.C. § 2617(a)(1)(B)(i). *See* also 15 U.S.C. § 2617(c)(3) (defining scope of preemption to include "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final agency action the Administrator takes pursuant to" Section 6(a) or 6(i)(1).).
[31] 15 U.S.C. § 2618.
[32] 40 C.F.R. § 702.47 (emphasis added).

Other provisions of the Risk Evaluation Rule envision that EPA will base "unreasonable risk" determinations on an analysis of COUs. For instance, 40 C.F.R. § 702.41(a)(9) states:

> EPA will complete the risk evaluation of the chemical substance addressing all of the conditions of use within the scope of the evaluation. However, EPA may complete its evaluation of the chemical substance under *specific conditions of use*…at any point following the issuance of the final scope document and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk…EPA will follow all of the requirements and procedures in this Subpart when it conducts its evaluation of the chemical substance under any *individual or specific conditions of use*. (emphasis added)

Similarly, the Risk Evaluation Rule provides that EPA will consider COUs when making final determinations of no unreasonable risk:

> A determination by EPA that the chemical substance, *under one or more conditions of use* within the scope of the risk evaluation, does not present an unreasonable risk…will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order.[33]

The Risk Evaluation Rule does not support EPA's proposed whole chemical approach.

C. EPA has not provided a reasoned explanation of its decision to revise the PCE, NMP, MC and TCE risk determinations to implement the whole chemical approach.

In each of the FR notices on these four chemicals, EPA makes broad, conclusory statements for taking a whole chemical approach (e.g., to "ensure the public is protected from unreasonable risk from chemicals in a way that is supported by science and the law;"[34] to "ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment;"[35] and because "the 'whole chemical' approach to determining unreasonable risk to health is 'permissible' under EPA's statutory obligations under TSCA 6(b)(4) and the implementing regulations."[36]) None of these statements, however, is a reasoned explanation for the Agency's decision to apply the whole chemical approach to these risk determinations.

EPA also asserts an administrative flexibility rationale for taking a whole chemical approach.[37] Missing from each of these four FR notices, however, were two examples EPA had provided in the HBCD and PV29 draft revised risk determinations of how it might exercise its flexibility under this approach: where

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[33] 40 C.F.R. § 702.49(d) (emphasis added).
[34] *E.g.*, NMP Draft Revision to TSCA Risk Determination, 87 Fed. Reg. 39511.
[35] *Id*. at 39512.
[36] *Id*. at 39514.
[37] *Id*. ("The Agency expects that this case-by-case approach will provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances.").

a single COU, "that does not impact or intersect" with other evaluated uses, drives an unreasonable risk determination, a whole chemical approach might not be warranted; but where a "majority" of a substances' COUs contribute to unreasonable risk, the whole chemical approach might be warranted.[38] In ACC's comments on these earlier FR notices, ACC suggested that these two examples seemed to indicate that EPA did not intend to consistently apply the whole chemical approach, even in similar circumstances. ACC raised other questions related to EPA's examples in its comments on those earlier draft revised risk determinations.[39] EPA did not answer these questions in its response to public comments that accompanied the final revised risk determination for HBCD. Instead, EPA simply re-iterated its broad authority to regulate existing chemicals and implement a process to conduct risk evaluations.[40] Since EPA has not answered ACC's questions about how the Agency will implement its whole chemical approach, it has failed to show that its administrative flexibility rationale for the whole chemical approach meets the requirement for a reasoned explanation for EPA's change.

EPA states in the FR notices and in the draft revised risk determinations that a screening approach to assess potential risks from the air and water pathways is being conducted separately for several of the first 10 chemicals and that if the results suggest there is additional risk, EPA will determine if the risk management approaches contemplated for that substance will protect against the risks or if the risk evaluation will need to be formally supplemented or revised.[41] Any supplemental analyses for the risk evaluations that have the potential to influence the risk management rules must be made available for public comment.

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[38] PV29 Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 12693 ("For instance, circumstances in which an unreasonable risk determination is primarily driven by a single condition of use that does not impact or intersect with other evaluated uses (such as for example, a single consumer use of a substance out of a wide range of other manufacturing, processing and consumer uses evaluated) may warrant different treatment than circumstances in which the majority of the chemical substance's conditions of use contribute to unreasonable risk, and the Agency might adopt different approaches to the risk determinations in those particular instances. EPA anticipates that this flexibility will better serve TSCA's objectives by helping ensure that EPA is best positioned to present, and initiate risk management to address, chemical specific unreasonable risk determinations. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.").

[39] ACC Comments on EPA's Revised TSCA Risk Determination for HBCD ("What approach is applied when there is more than one COU that drives the risk determination but less than a 'majority' of COUs? When does a COU 'impact and intersect' with another COU and how does that differ from a COU 'contributing' to unreasonable risk? What constitutes a 'majority' of COUs, and what would prevent addition of low probability, or hypothetical COUs, such that a 'majority' finding could be reached in an arbitrary manner?"); *see also* ACC Comments on EPA's Revised TSCA Risk Determination for PV29 (April 21, 2022), Comment ID EPA-HQ-OPPT-2016-0725-0081.

[40] HBCD Revision to TSCA Risk Determination, Response to Public Comments, p. 7.

[41] PCE Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39087; NMP Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39513; MC Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39826; TCE Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 40522.

D. The whole chemical approach is neither science-based nor risk-based and does not meet the science requirements of TSCA Section 26.

1. EPA broadly characterizes its whole chemical approach as a reasonable, science-based alternative to the "condition-of-use specific" risk determination but has not supported its "science-based" claim.

EPA asserts that since the "chemical specific properties" (identified for PCE, NMP and MC as benchmark exceedances for multiple COUs that span across most aspects of the chemical's lifecycle and irreversible health effects; benchmark exceedances are also mentioned for TCE, but not irreversible health effects)[42] "cut across the conditions of use," EPA's risk findings and conclusions encompass a substantial amount of those COUs. EPA, however, provides no scientific support for this claim, stating simply:

> Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, a substantial amount of the conditions of use drive the unreasonable risk; therefore, it is appropriate for the Agency to make a determination for [PCE, NMP, MC and TCE] that the whole chemical presents an unreasonable risk.[43]

EPA appears to be only evaluating identified hazard under the whole chemical approach, based upon the chemical-specific properties. This approach ignores TSCA's requirements to 1) consider, where relevant, the likely duration, intensity, frequency, and number of exposures under the COUs, pursuant to Section 6(b)(4)(F)(iv); and 2) to describe the weight of scientific evidence supporting the exposure description for the COUs, pursuant to Section 6(b)(4)(F)(v).

In the proposed revised determination, EPA does not clarify the role of differential levels of exposure associated with any specific COUs of PCE, NMP, MC or TCE as required by TSCA Section 6(b)(4)(F)(iv). Further, EPA's use of "irreversibility of effects" as a unique criterion of effects is a departure from historic EPA risk assessment practice which would unnecessarily undermine the integrity of EPA risk assessments under TSCA and other statutes.[44] Simply asserting that these "chemical specific properties cut across the conditions of use within the scope" of these risk evaluations does not make it so. Without a more in-depth explanation, EPA's rationale for its whole chemical approach is not science-based.

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[42] PCE Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39088; NMP Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39514; MC Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39827; TCE Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 40523.

[43] *Id.*

[44] EPA's human health risk assessments are already protective for "irreversible health effects," as they are based on safe levels of exposure to a substance in the most sensitive sub-populations for appropriate routes and durations of exposure. Indeed, the vast majority of risk assessments done across the Agency are based on effects that the Agency does not consider to be reversible (*e.g.*, cancer, systemic effects, target organ effects, etc.). As such, implementing a criterion of "irreversibility of effects" would unnecessarily undermine the integrity of EPA risk assessments under TSCA and other statutes.

EPA has not addressed several other questions about the scientific integrity of EPA's whole chemical approach. Specifically:

- What is EPA's science basis for concluding that a "substantial amount" of individual COU unreasonable risk determinations warrant a whole chemical unreasonable risk determination?
- How will EPA treat the COUs that it determines do not present an unreasonable risk?
- Does EPA plan to use its whole chemical approach when a "substantial amount" of a chemical's scoped COUs are found NOT to present unreasonable risk? If not, why not?
- On page 1 of the revised Unreasonable Risk Determinations for PCE, NMP, MC and TCE, EPA discusses its consideration of COUs considered "singularly or in combinations with other exposures." EPA claims it did not aggregate exposures to estimate risks to these chemicals, but has EPA done so without fully describing it, as required by TSCA §6(b)(4)(F)(ii)?

EPA does not address these and other questions about its conclusions, either with respect to the risk determinations or its consideration of whole chemical risk determinations for other TSCA chemicals in the future. In sum, EPA has not supported its claim that its whole chemical approach to risk determinations is science-based and has provided no science-based support for why a "substantial amount" of COUs should trigger a whole chemical unreasonable risk determination.

2. Risk determinations under TSCA Section 6 must be consistent with best available science and weight of the scientific evidence under Section 26(h) and 26(i). EPA has not satisfied these requirements in its proposed whole chemical risk determination approach.

Risk determinations are science-based decisions under TSCA Section 6. Therefore, they are subject to Section 26(h)'s requirements for these decisions to be "consistent with best available science" and Section 26(i)'s requirement that these decisions be based on the "weight of the scientific evidence."[45] In the Risk Evaluation Rule, EPA defines best available science as "science that is reliable and unbiased."[46] The Risk Evaluation Rule further states that "[u]se of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices…" and includes a series of considerations including, "[t]he 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."[47]

In a June 2021 press release, EPA describes its proposed whole chemical approach as a "policy change" or a new "policy direction" which it plans to apply on a chemical-specific, case-by-case basis "in a

[45] 15 U.S.C. §§ 2625(h) and 2625(i).
[46] *See* 40 C.F.R. §702.33.
[47] *Id.*

surgical manner."[48] In the draft revised risk determinations for PCE, NMP, MC and TCE, EPA "proposes that the appropriate approach to these determinations is to make an unreasonable risk determination for [PCE, NMP, MC and TCE] as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation."[49] Yet, EPA does not include any discussion of its treatment of the "no unreasonable risk" COUs in this "whole chemical" approach. EPA's focus is purely on "unreasonable" risk determinations.

EPA also does not articulate how its whole chemical risk determinations for these four chemical substances meet the Section 26 requirements of best available science. A whole chemical determination of unreasonable risk that is based only on a "substantial amount" of COUs and ignores those COUs that EPA has determined present "no unreasonable risk," is not an accurate representation of these chemical substances under all of their conditions of use (which EPA scoped into the risk evaluation), much less scientifically based. Moreover, EPA does not state what "sound and objective science practices" it is using in making its whole chemical unreasonable risk determinations. The Agency does not articulate to what extent it has used "technical procedures" to support a single risk determination that only reflects a "substantial amount" of the COUs that were evaluated in the risk evaluation. Consequently, EPA does not explain how this whole chemical approach is consistent with best available science.

EPA mentions TSCA's Section 26(i) requirement that EPA's decisions be based on the weight of the scientific evidence, but merely recites what it considered in the existing risk characterization of these chemicals.[50] The Risk Evaluation Rule's definition of "weight of scientific evidence"[51] requires more, including that EPA "integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." EPA's whole chemical approach to the PCE, NMP, MC and TCE risk determinations cannot be described as a "systematic review method" that evaluates streams of evidence and integrates that evidence based on strengths, limitations, and relevance. EPA's whole chemical approach can only be described as vague, subjective, and inaccurate method to communicate hazard and does not meet the TSCA Section 26 science standards required for TSCA Section 6 decisions, including risk determinations.

3. EPA's "whole-chemical" approach is not risk-based and will produce misleading, non- science-based decisions about TSCA chemicals.

EPA's whole chemical approach undermines TSCA's statutory requirements for risk-based decision-making. Risk is a function of both hazard and exposure. Risk determinations should be driven by the risk

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[48] *See, e.g.*, News Release, EPA Announces Path Forward for TSCA Chemical Risk Evaluations (June 30, 2021); available at https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations; 87 Fed. Reg. at 39087; 87 Fed. Reg. at 39513; 87 Fed Reg. at 39826; 87 Fed Reg. at 40522.
[49] EPA's Draft Revised Unreasonable Risk Determinations for PCE, NMP, MC and TCE, Section 5.1.1.
[50] *See, e.g.*, 87 Fed. Reg. at 40521; Draft Revised Unreasonable Risk Determination for TCE, Section 5.1.1.
[51] 40 C.F.R. §702.33 (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.").

characterization's integration of hazard and exposure data and information, which are specific to the chemical substance under its various COUs.

Under TSCA Section 6(b)(4)(F)(i), EPA must "integrate" available information on hazards and exposures for the conditions of use of the chemical substance; and under Section 6(b)(4(F)(iv) in conducting risk evaluations EPA must take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substances. These two requirements are consistent with Section 6(b)(4)(A)'s requirement that EPA conduct risk evaluations (which include risk determinations) to determine *whether* a chemical substance, under the COUs which EPA chooses to scope into the risk evaluation, presents an unreasonable risk – or not.

EPA would determine that a TSCA chemical presents unreasonable risk across the board when the risk characterization identifies only some uncertain "amount" of the chemical's COUs as presenting unreasonable risk. The whole chemical approach ignores EPA findings of "no unreasonable risk" for the chemical in exposure scenarios under other COUs. The whole chemical approach "reads out" of EPA's risk determination those COUs that do *not* present unreasonable risk. This approach results in regulating and communicating on the basis of an incomplete understanding of a chemical's actual risk.

E. EPA's whole chemical risk determinations for PCE, NMP, MC and TCE lack clarity, principles, and criteria demonstrating the arbitrary nature of the whole chemical approach.

1. EPA has provided no principles or criteria by which it will determine when to take a whole chemical approach in TSCA risk determinations.

In its June 30, 2021 announcement of its plan to use a whole chemical approach in revisions to some of its risk evaluations, EPA declared that it "will continue to assess and analyze each condition of use, but then the agency plans to make the determination of unreasonable risk just once for the whole chemical when it is clear the majority of the conditions of use warrant one determination."[52] In the FR notices and proposed revisions to the risk determinations for PCE, NMP, MC and TCE, the Agency confirmed that it was not re-assessing these chemical substances under their COUs and not changing EPA's risk characterizations in Section 4 of their 2020 risk evaluations. It was simply changing their "condition of use based" risk determinations to whole chemical determinations. The reasons for this change, however, are not transparent.

EPA has not identified any threshold principles or criteria by which it will decide *whether* to take a whole chemical approach in a risk determination. EPA appears to give itself unbridled flexibility to decide when to apply a whole chemical approach and when not. It merely states it will make "surgical" decisions on a "case by case" basis.

[52] News Release, *supra* note 48. Between the June 2021 news release and EPA's publication of the final revised risk determination for HBCD, EPA changed its articulation of "when" a whole chemical approach will be warranted.

EPA's articulation of how it has decided that a whole chemical approach is "appropriate" for PCE, NMP, MC and TCE risk determinations is largely identical in each of their FR notices. EPA first declares the whole chemical approach is appropriate for each of these chemicals "because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle…)" for the health of [workers, occupational non-users, consumers, and bystanders (w/exception of PCE)] and the "irreversible health effects" of each of these chemicals (except TCE) associated with exposures to the chemicals. Then, EPA states that "Because these chemical-specific properties "cut across the conditions of use" within the scope of the risk evaluation, a "substantial amount" of COUs "drive the unreasonable risk." Finally, EPA concludes, "therefore, it is appropriate for the Agency to make a determination" for each of these chemicals that "the whole chemical presents an unreasonable risk."[53]

EPA's explanation of when it is appropriate to make a whole chemical determination, and when it is not, is not supported in any meaningful, much less scientific way. As articulated, EPA's whole chemical determinations will produce inconsistent results. EPA's application of whole chemical determinations for PCE, NMP, MC and TCE, therefore, are arbitrary.

Despite EPA's statements implying the whole chemical approach will be the "exception" rather than the rule, there is nothing in these four FR notices or EPA's revisions to the risk determinations of PCE, NMP, MC or TCE that establishes any science-based criteria for EPA's application of a whole chemical approach in future TSCA risk evaluations. Without development of principles and criteria, which must be satisfied on a case-by-case basis before EPA could apply a whole chemical approach, EPA could unduly influence TSCA risk determinations based on considerations other than the best available science. Principles and criteria on the application of this approach, consistent with TSCA's framework, are essential to the credibility of this approach.

2. EPA has not made clear how a whole chemical risk determination will impact risk management rules.

EPA does not discuss how the whole chemical approach will impact the risk management rules for these substances. How will EPA address COUs that it finds in the risk characterization to present no unreasonable risk? Will they be included in the rule even though no risk management is needed? Will they be regulated only if they are impacted by COUs that present unreasonable risk? TSCA Section 6(b)(4)(F) provides specific requirements for EPA to evaluate the existing conditions of use during the risk evaluation. Failing to finalize that analysis in the risk evaluation phase by COU, in accordance with Section 6(b)(4)(A), creates additional ambiguity and uncertainty during the risk management rule process.

EPA must be more transparent about its plans with respect to TSCA risk management rules that result from whole chemical risk determinations. At a minimum, EPA should: a) not apply risk management

[53] PCE Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39088; NMP Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 39514; and TCE Draft Revision to TSCA Risk Determination, 87 Fed. Reg. at 40523. EPA does not explain the phrases: "cut across the conditions of use;" "substantial amount;" or "drive the unreasonable risk."

rules to COUs for which rules are not necessary and are not contemplated by TSCA Section 6(i)(1); and b) issue "no unreasonable risk" determinations by order for a chemical's COUs in accordance with TSCA Section 6(i)(1).

F. EPA's whole chemical approach will have substantial impacts.

1. The whole chemical approach to risk determinations undermines TSCA's risk-based decision-making framework.

A whole chemical risk determination of "unreasonable risk" is effectively a return to TSCA before the 2016 amendments, when a chemical's hazard assessment and hazard characterization drove EPA's decisions about the chemical without any consideration of exposure under their "conditions of use." Chemicals were simplistically described as either "toxic" or not, based on lab studies, not in real world condition-of-use circumstances. The whole chemical approach would produce the same result as the pre-2016 approach by ignoring certain of a chemical's COUs and the exposures and populations associated with those uses when those COUs present NO unreasonable risk. The whole chemical approach to risk determinations would artificially increase the number of unreasonable risk determinations made under TSCA. It gives EPA broad authority to determine that a "whole chemical" presents an unreasonable risk because the chemical has certain specific properties that "cut across" multiple conditions of use within the scope of the risk evaluation, and therefore a "substantial amount of COUs "drive" the unreasonable risk.

2. Whole chemical risk determinations could lead to non-science-based market impacts and arbitrary regulations.

A single "unreasonable risk" determination for a chemical overall will likely be interpreted by the public and the marketplace as a declaration that the substance is toxic in all circumstances, regardless of exposure and PPE use. Expectations could be raised that the substance will be completely banned from commerce. If EPA makes a whole chemical risk determination, but EPA's risk management rules provide "nuanced" risk management controls for such "whole chemicals," the public could be confused.

The marketplace could react similarly to these whole chemical determinations. The marketplace will likely not wait for EPA's risk management rule. The marketplace will likely begin the process of "product de- selection" of a chemical as soon as EPA makes a whole chemical determination of unreasonable risk for a chemical. When the European Union's REACH program's hazard-based framework labeled chemicals as "substances of very high concern" (SVHCs), European manufacturers noted that the European marketplace began de-selection of products containing these substances well before the EU regulated them. This could occur with whole chemical determinations of unreasonable risk, even if there are conditions of use – including many beneficial uses – that EPA has characterized as presenting no unreasonable risk.

If EPA applies its whole chemical approach broadly, industrial manufacturers' and users' ability to innovate could be seriously harmed. This result would be counter to Congress' intent that the US exercise its authority over chemical substances "in such a manner as not to impede unduly or create unnecessary

economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."[54]

State legislatures and regulatory agencies, similarly, would not wait for EPA's risk management rules to act. States could move to propose arbitrary regulations, such as outright bans of these chemicals as soon as EPA's "whole chemical" unreasonable risk determination is finalized.

The impact of EPA's whole chemical approach could ripple through the public's perception, the marketplace, innovation within industry, and state regulation.

G. Conclusion on the Whole Chemical Approach

ACC opposes EPA's whole chemical approach to risk determinations as described in the FR notices for the reasons discussed above. EPA has not provided a reasoned explanation for this change in its implementation of TSCA risk determinations. EPA should withdraw its whole chemical approach because EPA's TSCA risk determinations should be risk-based, incorporate COUs, and consider TSCA's "risk-based" decision- making framework generally. Risk determinations also must comply with TSCA Section 26's best available science and weight of the scientific evidence requirements. EPA's decisions must be consistent with other requirements under TSCA, such as the processes for making and implementing "no unreasonable risk" determinations and the requirements for developing risk management rules. The proposed whole chemical approach as applied to these chemicals, is arbitrary, will mislead the public, the marketplace, and state regulators. The approach does not meet TSCA's science and risk-based standards.

If, however, EPA decides to retain the whole chemical approach, the Agency should:

- Review this approach in the context of TSCA's risk-based decision-making framework for risk evaluation of COUs and requirements for risk management rules that build upon the COU determinations.
- Develop principles and criteria that would determine when a whole chemical approach could be used, and when it should not be used.
- After reviewing the whole chemical approach in light of ACC's concerns and recommendations, provide the public another opportunity to comment on EPA's review of its proposed whole chemical approach to risk determinations.
- Clarify in public communications about whole chemical risk determinations that a whole chemical determination of unreasonable risk does not mean that certain uses of the chemical cannot continue; they simply must meet EPA's risk management requirements. EPA might

[54] 15 U.S.C. § 2601(b)(3).

consider a different name for this approach to avoid the public and the media's misunderstanding of these decisions.

IV. EPA has not adequately supported its decision to <u>not</u> assume use of PPE in TSCA risk determinations.

A. Introduction

In the FR notices for PCE, NMP, MC and TCE, EPA proposes to apply a "no assumption of PPE" in their risk determinations. Although the notices are specific to these risk determinations, EPA implied in the revised risk determination for HBCD that its proposed "no assumption of use of PPE" approach may be used in future TSCA risk determinations involving occupational exposure.[55]

EPA declares in each of these notices that it "does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practice is sufficient to address the risk, applicable to all potentially exposed workers, or consistently and always properly applied."[56] The Agency then explains that "going forward, EPA intends to make its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE."[57] In other words, EPA proposes to assume for risk determinations there is little or no compliance with OSHA — despite the fact that employers must comply with all applicable OSHA standards.

In both the notices and the draft revised risk determinations, EPA distinguishes *the* appropriateness *of evaluating* levels of risk present in occupational exposure scenarios (both with and without PPE mitigation measures) *from the inappropriateness of making the risk determination based on the assumption of PPE.* In the draft revised risk determinations, EPA states it is "appropriate to *evaluate* the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency,"[58] but EPA makes clear that this information merely "can help inform" EPA's potential risk management actions.[59]

Under its "no PPE assumption," EPA would treat the Occupational Safety and Health Act's (OSH Act) requirements for PPE and other OSHA mandatory standards in industrial workplaces as irrelevant in TSCA risk determinations. EPA would treat PPE only as a "tool" for risk management rather than as part of a chemical's COU which should factor into the chemical's risk determination. This approach is

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[55] *See* 86 Fed. Reg. at 74086; *see also* News Release, *supra* note 48 ("EPA is therefore revisiting the assumption that PPE is always used in occupational settings when making risk determinations for a chemical. Instead, the agency plans to consider information on use of PPE, or other ways industry protects its workers, as a potential way to address unreasonable risk during the risk management process.").
[56] 87 Fed. Reg. at 39089; 87 Fed. Reg at 39515; 87 Fed. Reg. at 39828; 87 Fed. Reg. at 40524
[57] *Id.*
[58] Draft Revised Unreasonable Risk Determinations for PCE, NMP, MC and TCE, Section 5.2.4 (emphasis added).
[59] *Id.*

inconsistent with TSCA's requirements to consider conditions of use and Section 26's scientific standards.

B. EPA's proposal not to rely on "intended, known or reasonably foreseen" use of PPE in these risk determinations is inconsistent with TSCA's requirements that EPA determine whether a chemical presents an unreasonable risk under the chemical's "conditions of use."

EPA's proposal not to assume use of PPE in the PCE, NMP, MC and TCE TSCA risk determinations is inconsistent with TSCA's Section 6(b)(4) risk evaluation requirements relating to "conditions of use." Section 6(b)(4)(A) requires that EPA conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant in the risk evaluation by the Administrator, *under the conditions of use."*[60] TSCA Section 3(4) defines "conditions of use" 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."[61] The proposal also fails to "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use" pursuant to TSCA Section 6(b)(4)(F)(iv). Further, ignoring the use of PPE ignores the requirement to "describe the weight of scientific evidence for the identified hazard and exposure" pursuant to Section 6(b)(4)(F)(v). Instead of describing the weight of scientific evidence, EPA ignores the use of industrial hygiene data, as required by OSHA, to evaluate engineering and administrative controls and then the use of PPE as an additional layer of protection.

In the revised risk determinations for PCE, NMP, MC and TCE, EPA proposes to discount certain "known or reasonably foreseen" circumstances of manufacturing under OSHA's mandatory requirements and instead to rely upon only one condition of use – one in which PPE is *not* required, used, or complied with. EPA justifies its decision by declaring, "it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements."[62]

By assuming PPE is not used in any COU, EPA is ignoring OSHA comprehensive, industry-specific, standards which OSHA-regulated employers and employees must meet. These require employers to assess whether hazards present in their workplace necessitate the use of PPE and, if so, to provide the types of PPE that would protect them from these hazards; to communicate the decision to the employees; to select PPE that properly fits affected employees; to verify the performance of the hazard assessment;

[60] 15 U.S.C. § 2605(b)(4)(A) (emphasis added).
[61] 15 U.S.C. §2602(4) (emphasis added).
[62] 87 Fed. Reg. at 39089; 87 Fed. Reg. at 39515; 87 Fed. Reg. at 39828; 87 Fed. Reg. at 40524

and to certify compliance with these requirements. Failure to consider these OSHA industry-specific standards is particularly arbitrary when an entire COU is governed by the OSHA standards.

Among other things, these OSHA-required assessments of hazards in the workplace through industrial hygiene evaluations have resulted in employers implementing engineering controls to reduce exposures such that PPE would not be needed or required.[63] Where engineering controls are not feasible, or provide inadequate protection, PPE is required.[64] In addition to these OSHA requirements, employers have implemented industry or sector work practices for industrial hygiene such as requiring PPE for certain identified tasks as an additional layer of protection. EPA's proposal also ignores that OSHA standards require employer and employee compliance with these standards and that OSHA has authority to enforce them.

Instead, EPA characterizes these "known or reasonably foreseen" COUs in OSHA-regulated facilities as dismissible "assumptions" for purposes of TSCA risk determinations. In its proposal, EPA would treat existing PPE not as part of the workplace "condition of use" that is factored into the risk determination (even though it is characterized in the risk evaluation itself), but simply as a "tool" that EPA would apply in risk management. Therefore, EPA's risk determination does not evaluate the COUs at industrial facilities which must meet OSHA's mandatory standards, requirements, and hierarchy of controls.

EPA asserts that it "does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practice is sufficient to address the risk, applicable to all potentially exposed workers, or consistently and always properly applied."[65] This statement, however, ignores the OSH Act's purpose, its "general duty clause" for employers and employees, and its hazard communication standards, which are intended to apply to all workers.[66] The existence of those OSHA standards has and does lead to widespread usage.

EPA's proposal to assume no PPE use unless there is 100% compliance by all workers, at all times, under OSHA is unreasonable.

In addition, neither TSCA's definition of "potentially exposed or susceptible subpopulation,"[67] nor the Section 6(b)(4) risk evaluation requirements specify protection of "all" individuals in a potentially exposed or susceptible subpopulation.

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[63] 29 C.F.R. § 1910.119(e).
[64] 29 C.F.R. § 1910.119(f).
[65] *Id.*
[66] The General Duty Clause, Section 5(a)(1) of the OSHA Act, 29 U.S.C. 654(a)(1), applies where there is no standard that applies to the hazard and the employer's own employees are exposed to the alleged hazard. Any hazard for which a Section 5(a)(1) citation/violation is issued to an employer must be reasonably foreseeable.
[67] "The term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." 15 U.S.C. § 2602(12).

When PPE is specifically required under OSHA, it is an integral part of the COUs of manufacturing and processing.[68] PPE is required and utilized as an additional layer of protection. Therefore, under TSCA's requirements that risk determinations be made based upon reasonably available information about a chemical's "conditions of use," EPA should consider PPE and other applicable OSHA standards and practices as part of the COUs in TSCA risk evaluations, including in the risk determinations of those COUs. EPA's proposal would disregard the integral role of PPE under these specific COUs.

C. EPA's proposed change regarding assumptions about compliance with OSHA standards, including PPE, does not comply with TSCA's Section 26 requirements that TSCA risk evaluations be consistent with best available science and based on weight of the scientific evidence.

TSCA Sections 26(h) and 26(i) require EPA to make decisions in Section 6 risk evaluations consistent with "best available science" about whether a chemical's inherent hazards, together with its exposures under the chemical's COUs, present unreasonable risk. EPA's decisions in its risk evaluation must also be based upon the "weight of the scientific evidence." These Section 26 requirements are applicable to risk evaluations involving workplace COUs when workers are relevant to the risk evaluation. As EPA notes, TSCA risk determinations are part of the risk evaluation,[69] so EPA's risk determinations must also be consistent with the best available science and based on the weight of the scientific evidence. EPA's proposal would allow evaluation and characterization of risks to include consideration of use of PPE but would disallow "assumptions" of PPE and other OSHA requirements from consideration in the risk determinations. This is contrary to requirements in TSCA Section 26 and Section 6(b)(4)(F)(v).

1. EPA should rely upon experts in industrial hygiene, including OSHA and NIOSH.

Industrial hygiene (IH) is a long-standing profession with established workplace hazard recognition, evaluation, and control measures.[70] In order for risk evaluations to meet TSCA Section 26's scientific standards, risk assessors and others involved in evaluating and approving the assessments of workplace risks must meet well-established IH training and certification requirements.[71] The education, training, and certification requirements for a practicing IH are rigorous. IH practices are multidisciplinary and require expertise to integrate the required inputs in order to accurately assess the complexities of workplace hazards and develop risk mitigation measures.

To understand whether current worker protection from exposure to chemicals is consistent with best available science, EPA must consult the expertise of industrial hygienists, including OSHA and NIOSH,

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[68] *See, e.g.*, 29 C.F.R. §§ 1919.132-1910.140.
[69] 87 Fed. Reg. at 39088; 87 Fed. Reg. at 39513; 87 Fed. Reg. at 39826; 87 Fed. Reg. at 40522. *See also* 40 C.F.R. §702.47.
[70] *See* https://www.osha.gov/sites/default/files/training-library_industrial_hygiene.pdf
[71] *See* http://www.abih.org/become-certified

to determine whether it can rely upon OSHA controls on exposure as consistent with "best available science" and based upon weight of the scientific evidence.

In its proposed revision "not to assume" PPE in the risk determination and to address PPE only in the risk management rule, however, EPA says it "will" consult with, and "*intends* to strive for consistency with applicable OSHA requirements...."[72] Consistent with TSCA Section 26, EPA should commit to incorporating the expertise of OSHA and other industrial hygienists about current, science-based protection of workers in the workplace. Failure to recognize IH standards that implement OSHA requirements does not comply with the Section 26(h) mandate for EPA to utilize "measures, methods, protocols, methodologies or models, employed in a manner consistent with the best available science."

2. EPA should coordinate with OSHA to ensure risk management decisions are based on best available science.

EPA has not indicated how it will coordinate and consult with OSHA on Section 6 risk management rules under Section 9. TSCA Section 9(a)(6) requires consultation between EPA and OSHA to avoid duplicative requirements,[73] but EPA's assertions that it "will" consult with OSHA and that it will "strive" to be consistent with applicable OSHA requirements and industry practices suggest that such consultation has not occurred. EPA should ensure it is consistent with OSHA's hierarchy of controls approach, which includes long-standing risk management strategies employed by industry, such as engineering controls and industrial hygiene practices, in addition to PPE use. If it does not, EPA's proposed risk management rules involving PPE controls to protect workers from chemical exposures will not be supported by "best available science" and "weight of the scientific evidence."

D. EPA's rationale for its "no assumption of PPE" in risk evaluations is inconsistent with the OSH Act's statutory and regulatory requirements.

1. EPA's rationale is not consistent with the OSH Act or OSHA's implementation of the law.

OSHA regulates worker exposure to chemicals through a variety of broad statutory and more specific regulatory provisions, as well as industry practices that have been built upon the OSH Act's framework. All workers are protected by the OSH Act's General Duty clause[74] and all workers who handle chemicals are protected by OSHA's Hazard Communications standard. In proposing "no assumption" of PPE in risk determinations, EPA discounts OSHA's statutory and regulatory framework. The comprehensive requirements under the OSH Act and OSHA's regulations include:

- **The OSH Act's Purpose**. The purpose of the OSH Act is "to assure *so far as possible* every working man and woman in the Nation safe and healthful working conditions and

[72] 87 Fed. Reg. at 39089; 87 Fed. Reg. at 39515; 87 Fed. Reg. at 39828; 87 Fed. Reg. at 40524.
[73] 15 U.S.C. 2608(a)(6).
[74] 29 U.S.C. § 654.

to preserve our human resources."[75] The Act list a series of actions to achieve that purpose, including: encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions; and authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce.[76]

The OSH Act contemplated implementation through regulatory actions by OSHA, but also through workplace-specific actions by employers and employees, to reduce occupational hazards and to "institute and perfect" existing programs for providing safe and healthful working conditions. These provisions anticipated employer and employee development of workplace-specific engineering controls, industrial hygiene practices, and compliance with same; as well as compliance with OSHA's regulatory standards to protect workers from exposures to specific chemicals and application of a hierarchy of controls to reduce exposures to chemical hazards.

- **Compliance and Enforcement.** Compliance with the OSH Act is achieved through a combination of activities which OSHA performs and activities which the employer performs. Section 8 of the OSH Act authorizes OSHA to conduct inspections and investigations of any workplace where work is performed by employees for an employer.

  This section also requires employers to keep records of their activities to meet the requirements of the OSH Act.[77] Section 10 of the OSH Act includes the procedures for OSHA's enforcement of OSH Act statutory and regulatory requirements.[78]

- **OSHA's Standards.** OSHA's standards generally prescribe a variety of mandatory requirements for assuring "safe and healthful" workplaces in businesses affecting interstate commerce. The mandatory requirements of OSHA's standards, which are relevant to EPA's proposal, include, but are not limited to:

  OSHA's Hazard Communication Standard (29 C.F.R. § 1910.1200)
  OSHA's Hazard Communication Standard addresses worker education and training. "This occupational safety and health standard is intended to address comprehensively the issue of classifying the potential hazards of chemicals and communicating information concerning hazards *and appropriate protective measures* to employees, and to preempt any legislative or regulatory enactments of a state, or political subdivision of a state, pertaining to this subject." The standard also states: "The measures employees can take to protect themselves from these hazards, including specific procedures the employer has

[75] 29 U.S.C. § 651(b) (emphasis added).
[76] *Id.*
[77] 29 U.S.C. § 657.
[78] 29 U.S.C. § 659.

implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used."

Personal Protective Equipment (29 C.F.R. §§ 1910.132-1910.140)
This standard requires the employer to "assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE)." If such hazards are present, or likely to be present, the employer must:

- Select, and have each affected employee use, the types of PPE that will protect the affected employee from the hazards identified in the hazard assessment;
- Communicate selection decisions to each affected employee;
- Select PPE that properly fits each affected employee; and
- Verify that the required workplace hazard assessment has been performed through a written certification that identifies the workplace evaluated; the person certifying that the evaluation has been performed; the date(s) of the hazard assessment; and, which identifies the document as a certification of hazard assessment.

Training (29 C.F.R. § 1910.132(f)(1))
This standard requires the employer to "provide training to each employee who is required by this section to use PPE," including:

- When PPE is necessary;
- What PPE is necessary;
- How to properly don, doff, adjust, and wear PPE;
- The limitations of the PPE; and
- The proper care, maintenance, useful life, and disposal of the PPE.

The standard also requires that each affected employee demonstrate an understanding of the training and the ability to use PPE properly before being allowed to perform work requiring the use of PPE. When the employer has reason to believe that any affected employee who has already been trained does not have the required understanding and skill, the employer must retrain the employee. Retraining is also required when circumstances render training obsolete, *e.g.*, changes in the workplace, and changes in types of PPE to be used.

Personal Protective Equipment Standards for Specific Types of Protection. These standards provide both general and specific requirements for PPE designed to protect different exposure routes. Standards potentially relevant to the protection of workers who handle chemical substances include Eye and Face Protection (29 C.F.R. § 1910.133), Respiratory Protection (29 C.F.R. § 1910.134), and Hand Protection (29 C.F.R. § 1910.138).

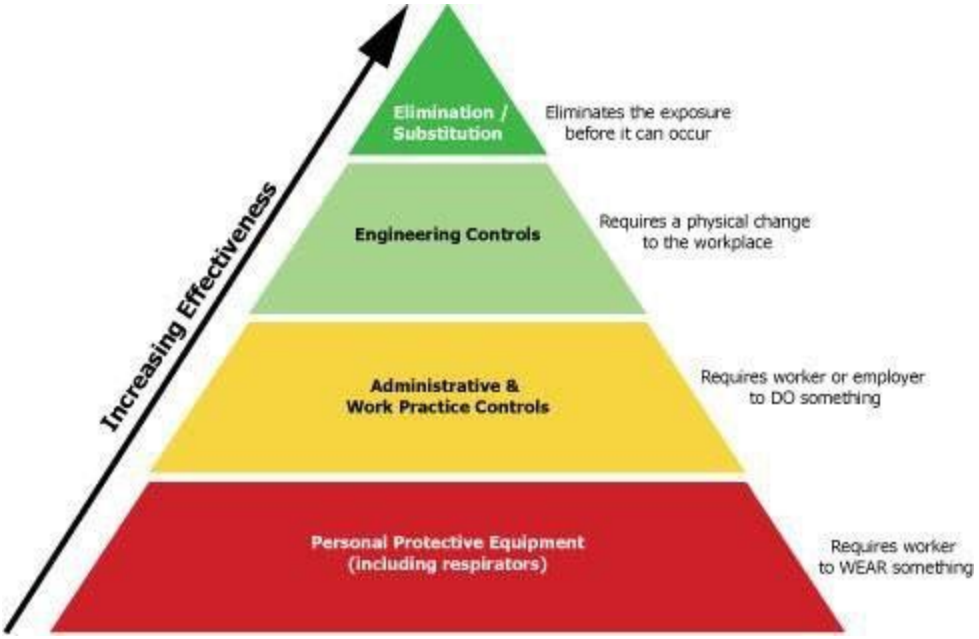
OSHA's Exposure Limitations and other Guidelines

OSHA exposure limitations and other guidelines also help determine what PPE is required to protect workers. These include:

- **OSHA's Permissible Exposure Limits (PELs)**. PELs are OSHA-enforceable legal limits, applicable in general industry (29 C.F.R. § 1910.1000), shipyard employment (29 C.F.R. § 1915.1000), and construction (29 C.F.R. § 1926.1101). OSHA has developed PELs for about 400 substances. Employers must comply with these where employees are potentially exposed to certain chemical hazards.
- **NIOSH's Recommended Exposure Limits (RELs):** The National Institute for Occupational Safety and Health (NIOSH) recommends guideline, not enforceable, occupational exposure limits. The RELs are included in the NIOSH Pocket Guide to Chemical Hazards,[79] which presents key information and data in abbreviated tabular form for 677 chemicals or substance groupings.
- **Other organization's guidelines** that assist in control of occupational health hazards, *e.g.,* ACGIH Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs);[80] California OSHA PELs;[81] and American Industrial Hygiene Association's (AIHA) Workplace Environmental Exposure Levels (WEELs)[82] subsequently managed by the Toxicology Excellence for Risk Assessment (TERA) Occupational Alliance for Risk Science (OARS) (https://tera.org/OARS/). Global evaluations such as the EU Committee for Risk Assessment (RAC) and the German MAK Commission can also be considered. Some industries also develop occupational exposure limits for chemicals ensure worker safety at their facilities.

Hierarchy of Controls on Exposures:
It is OSHA's long-standing policy that elimination/substitution of exposure to a hazard, before it can occur, is the most effective type of control to protect workers. Where that cannot be done, engineering and work practice controls are the primary means to reduce employee exposure to toxic chemicals, where feasible. Respiratory protection is required to be used if engineering or work practice controls are infeasible or while engineering controls are being implemented.[8378] OSHA uses a hierarchy of controls (see illustration below) as a means of determining how to implement feasible and effective controls.[84]

[79] https://www.cdc.gov/niosh/npg/default.html
[80] https://www.acgih.org/science/tlv-bei-guidelines/
[81] https://www.dir.ca.gov/title8/5155table_ac1.html
[82] https://www.aiha.org/get-involved/aiha-guideline-foundation/weels
[83] https://www.osha.gov/chemical-hazards.
[84] https://www.osha.gov/chemical-hazards/controlling-exposure



> At OSHA regulated facilities, when effective engineering controls are not feasible, or while they are being implemented, employers must provide appropriate PPE at no cost to workers, provide appropriate training and education regarding its use, and ensure that workers use it properly.[85]

EPA ignores that OSHA requires employers to review the chemical hazards in the workplace and to require employees to use appropriate PPE where needed to protect them from chemical exposures via inhalation, ingestion, direct injection, dermal and/or eye exposures. EPA ignores that most employers subject to OSHA comply with OSHA's requirements to provide PPE and train their employees how to use it. EPA ignores that OSHA inspects and investigates facilities to enforce PPE and other OSHA requirements.

3. EPA has not provided a reasoned explanation to support its proposal on PPE.

EPA's rationale for its proposed "no assumption of PPE" in risk determinations is not a reasoned explanation. EPA states that the Agency does not "believe" that PPE is "sufficient to address the risk, applicable to *all* potentially exposed workers, or consistently and *always* properly applied," and that it "cannot assume that *all* facilities have adopted these practices for the purposes of making the TSCA risk determination."[86]

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[85] *Id.*
[86] 87 Fed. Reg. at 39089; 87 Fed. Reg. at 39515; 87 Fed. Reg. at 39828; 87 Fed. Reg. at 40524 (emphasis added).

EPA has not provided reasonably available data or information to support its "belief" concerning the insufficiency of PPE at OSHA regulated facilities. EPA cites no records of widespread non-compliance with OSHA requirements by employers who manufacture, process, distribute, use, or dispose of TSCA chemicals generally or PCE, NMP, MC or TCE specifically. EPA cites no data or information showing chemical industry workers largely refuse the PPE they are provided by their employers. EPA cites no data that workers are universally being harmed because they do not use PPE. In addition to the regulatory requirements listed above, the OSH Act's General Duty Clause applies to all employers who can be cited for exposing their employees to reasonably foreseeable hazards.

EPA's proposals could inadvertently create regulatory confusion and overlapping requirements when attempting to protect workers through a whole chemical determination for these chemicals and risk management rules that would apply to all workplaces involving any of these chemicals within the scope of the risk evaluation, including workplaces that are already subject to OSHA. In other words, if this proposed approach to PPE is applied broadly in all future TSCA risk evaluations, EPA would treat already regulated OSHA employers and employees and non-OSHA regulated employers and employees as operating under identical conditions of use, requiring identical risk management controls and subject to identical enforcement.

The Risk Evaluation Rule requires EPA to base its risk evaluations on reasonably available information.[87] EPA has not met that requirement with respect to sufficiency of PPE in the risk determinations on PCE, NMP, MC or TCE.

E. Addressing PPE (and other OSHA requirements) only in the risk management rule, not as part of the conditions of use in the risk evaluation, has significant potential impacts.

If EPA adopts and applies the "no PPE" assumption to all TSCA risk determinations going forward, it will have serious impacts on the regulated community as well as on the credibility of both EPA and OSHA regulations:

- **A Modification in TSCA's Focus from Risk-Based Determinations to Assumption-based Risk Management:** In the context of addressing worker exposure to chemicals in TSCA risk evaluations and risk determinations, EPA's proposal would modify TSCA's focus from the science-based decision making in the risk evaluations and the risk determinations, as required by TSCA Sections 6 and 26, to default assumption-based decision-making in risk management rules.
- **Duplicative, Inconsistent and Costly Requirements:** TSCA risk management rules might impose costly requirements that are either duplicative of or inconsistent with those that OSHA has already imposed on employers and employees in OSHA-regulated businesses affecting interstate commerce.

[87] *See* 40 C.F.R. §702.41(b).

- **Lack of Transparency about Risk Management Rules:** EPA's proposal is not transparent about its plans for implementation of this proposed change in the risk management rule itself. How will EPA require PPE in the risk management rules? Is EPA coordinating with OSHA and/or the regulated community to determine how PPE is used in a COUs? Will EPA incorporate into the Risk Management Rule a requirement that COUs comply with OSHA regulatory requirements? Will EPA establish a single PPE control on all workplaces, whether OSHA regulated or not? Or will EPA require a range of controls depending on what worker protection is already in place, where there is need and where not?
- **Bad Public Policy:** It is bad policy for one federal agency to assume – without supporting data or information -- that another federal agency has not been complying with and enforcing laws under its jurisdiction. EPA's proposal ignores OSHA's standards and OSHA's expertise in protecting workers.
- **OSHA's Jurisdiction Would Be Threatened:** Although Congress provided EPA additional authority to protect workers (as a potentially exposed or susceptible subpopulation) from exposures to TSCA chemicals through TSCA regulations, nothing in the statute or its legislative history suggests Congress wanted EPA to displace OSHA's primacy in assuring safe and healthful workplaces. Yet EPA's proposal suggests EPA believes it has broad authority to make TSCA regulatory decisions about PPE in the workplace whether or not these decisions are consistent with OSHA's standards and regulations and industrial practice over the years. OSHA should retain primary jurisdiction in regulating the workplace and enforcing workplace health and safety standards and EPA should coordinate with OSHA pursuant to TSCA Section 9.
- **EPA's Resources Will Be Challenged:** EPA lacks the expertise and the resources to regulate *all* workplaces involving potential TSCA chemical exposures and to enforce those requirements. TSCA's risk evaluation and risk management rule process was not intended, or structured, to replace OSHA's workplace regulations. EPA's small risk evaluation and risk management teams for each chemical, and all COUs of that chemical, do not have the resources, expertise, or time to replace OSHA's regulatory infrastructure that has been developed over decades of notice and comment rulemaking. Workplaces subject to OSHA, as described above, have developed engineering and administrative controls to comply with such standards. Employees have been trained on standard operating procedures detailing how specific tasks must be taken to safely operate the engineering controls. Hazard assessments, built upon industrial hygiene monitoring, have been developed for each task to implement PPE as an additional layer of protection. Industrial hygiene standards are also followed to confirm the ongoing effectiveness of the engineering controls. Again, EPA should coordinate with OSHA pursuant to TSCA Section 9.
- **Unintended Consequences:** If EPA's proposal is adopted, the Agency will need to develop clear, accurate communications materials to explain EPA's new approach to PPE

to the already OSHA-regulated community. A rushed approach to regulating the workplace could implement PPE requirements in a manner not consistent with existing best practices developed under OSHA and other industrial standards, leading to unintended consequences that undermine EPA's objectives for protecting workers. For example, there are specific fit-testing requirements in place that must be built into any new regulations. Also, unwarranted PPE requirements could lead to, for example, heat exhaustion; in some cases, the inability to effectively preform basic tasks because of utilizing chemical gloves when not needed or creating an increased trip hazard if respirators are required at all times.

F. Alternative Recommendation for EPA's Consideration

ACC recommends that EPA take a different approach to addressing the protection of workers as a potentially exposed or susceptible subpopulation under TSCA.

- EPA should consider more targeted ways to address its concerns about the subpopulation of workers who are *not* covered by OSHA standards because they are self-employed individuals or public sector workers not covered by their State plan. A more targeted approach would allow EPA to consider different workplace conditions of use in the risk evaluation and risk determination, leading to risk management rules that are targeted to address the chemical substance under COU-specific determinations of unreasonable risk.
- EPA should develop risk evaluations and make risk determinations on the basis of reasonably available information that meets TSCA's Sections 6 and 26 standards, not on the basis of assumptions that PPE is "always" or "never" used in the workplace. This information would form the basis for risk determinations of either no unreasonable risk or unreasonable risk of the chemical under its workplace COUs and inform risk management rules.
- Rather than assume either "PPE" or "no PPE" in TSCA risk determinations, EPA should seek to support its risk determinations with available information from industry/businesses about their current worker exposure controls and the efficacy of those controls. During the scoping process of a TSCA risk evaluation. EPA should request information from the affected industry and businesses – both OSHA-regulated and non-OSHA regulated -- about the worker protection practices that are in place at their facilities to reduce chemical exposures to workers.
- EPA should work with OSHA during the scoping phase about information OSHA might provide EPA about compliance by employers and employees at facilities with mandatory OSHA requirements. If warranted, EPA and OSHA could also discuss improved enforcement of OSHA requirements. EPA should consult with NIOSH and OSHA regarding PPE specifically and other hierarchy of controls generally. EPA should also consult with NIOSH and OSHA about ways EPA could improve its own industrial hygiene expertise.

- In light of TSCA's best available science and weight of the scientific evidence requirements, risk management requirements should also be targeted, depending on whether they apply to OSHA-regulated businesses or non-OSHA regulated businesses.
- EPA could consider the European approach to COUs for the workplace, *e.g.*, where industrial activities have ongoing engineering controls and strong industrial hygiene systems, including PPE and monitoring; professional users of chemicals have some PPE but not necessarily engineering controls with IH programs; and essentially "consumer" uses of chemicals have no PPE.
- When unreasonable risk is found under a chemical's workplace COUs, risk management requirements (whether new for non-OSHA regulated businesses, or additional for OSHA regulated businesses) should materially contribute to reducing the risk to workers so that it is not unreasonable. The hierarchy of controls (elimination/substitution, engineering, administrative/work practice, PPE) should be applied until the risk is not unreasonable.
- EPA should consider as a potential risk management action, where warranted by specific COUs' risk evaluations, the establishment of federally enforceable training/certification for self- employed individuals, or public sector workers not covered by a state plan.
- EPA should base its risk management requirements on OSHA standards.

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Because EPA has not provided a science-based, reasoned explanation for these changes, EPA should withdraw the draft revised risk determinations on PCE, NMP, MC and TCE and provide a reasoned explanation for its proposed changes. At a minimum, EPA should provide an opportunity for public comment before applying these changes to any chemical substance.