Ad Hoc Downstream Users Coalition

Via Docket Submission

December 14, 2023

Assistant Administrator Michal Freedhoff
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Ad Hoc Downstream Users Coalition's Comments on the Environmental Protection Agency's Proposed Rule: Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act ("TSCA"); Docket No. EPA-HQ-OPPT-2023-0496

Dear Dr. Freedhoff:

We appreciate this opportunity to submit comments on behalf of the Ad Hoc Downstream Users Coalition ("Coalition") regarding the Environmental Protection Agency's ("EPA's") proposal to amend procedures for chemical risk evaluations under TSCA.[1] The risk evaluation program is a critical component of chemical regulation in the United States and has far-reaching consequences for the supply chain, including our members and the public. Other federal agencies, state agencies, and even the international community often cite EPA risk evaluation as the basis for their own regulatory actions. For these reasons, it is crucial that EPA adopt procedures resulting in accurate evaluations that reflect existent exposures and industry standards for worker protections and that identify uses that pose low or no risk, as well as those that may pose an unreasonable risk in the absence of risk mitigation controls to the extent necessary. We ask that EPA consider our comments and make the requested amendments to the final rule.

The Coalition is comprised of trade associations that represent a broad cross-section of U.S. industry, representing well over a thousand companies that manufacture (including import), process, or use chemical substances subject to TSCA. Members of the Coalition commenting on this proposed rule include the Alliance for Automotive Innovation ("Auto Innovators"), the American Coatings Association ("ACA"), American Forest & Paper Association ("AF&PA"), MEMA, the Vehicle Suppliers Association, the Plastics Industry Association ("PLASTICS"), the Toy Association, and the U.S. Tire Manufacturers Association ("USTMA").[2]

[1] Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74292 (proposed Oct. 30, 2023).

[2] From the manufacturers producing most vehicles sold in the U.S. to autonomous vehicle innovators to equipment suppliers, battery producers and semiconductor makers – Alliance for Automotive Innovation represents the full

auto industry, a sector supporting 10 million American jobs and five percent of the economy. Active in Washington, D.C. and all 50 states, the association is committed to a cleaner, safer and smarter personal transportation future. www.autosinnovate.org.

ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services. ACA's membership represents over 90 percent of the total domestic production of paints and coatings in the country.

AF&PA serves to advance a sustainable U.S. pulp, paper, packaging, tissue and wood products manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative — Better Practices, Better Planet 2020. The forest products industry accounts for approximately four percent of the total U.S. manufacturing GDP, manufactures nearly $300 billion in products annually and employs approximately 950,000 men and women. The industry meets a payroll of approximately $55 billion annually and is among the top 10 manufacturing sector employers in 45 states.

MEMA, the Vehicle Suppliers Association, is the leading trade association in North America for motor vehicle and mobility suppliers, parts manufacturers, and remanufacturers. It has been the voice of the automotive and commercial vehicle supplier industry since 1904. Its more than 1,000 members are Stronger by Association.

The Plastics Industry Association (PLASTICS) is the only organization that supports the entire plastics supply chain, including Equipment Manufacturers, Material Suppliers, Processors, and Recyclers, representing over one million workers in the $548 billion U.S. industry. PLASTICS advances the priorities of our members who are dedicated to investing in technologies that improve capabilities and advances in recycling and sustainability and providing essential products that allow for the protection and safety of our lives. Since 1937, PLASTICS has been working to make its members and the seventh largest U.S. manufacturing industry, more globally competitive while supporting circularity through educational initiatives, industry-leading insights and events, convening opportunities and policy advocacy, including the largest plastics trade show in the Americas, NPE2024: The Plastics Show.

The Toy Association is the North America-based trade association for the toy sector; our membership includes more than 950 businesses – from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs – all involved in bringing safe, fun toys and games to children. The toy sector is a global industry of more than US$90 billion annually, and our members account for more than half this amount, and approximately 90% of North American toy sales by dollar volume. Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard, and it serves as a model for other countries looking to safeguard the health and safety of their citizens with protective standards for children. The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.

USTMA is the national trade association for tire manufacturers that produce tires in the U.S. Our 13 member companies operate 58 tire-related manufacturing facilities in 17 states and generate over $27 billion in annual sales. We directly support more than a quarter million tire manufacturing U.S. jobs – totaling almost $20 billion in wages. USTMA advances a sustainable tire manufacturing industry through a commitment to science-based

Together, these associations speak for thousands of their respective manufacturers and companies that are involved along each portion of the consumer and commercial product supply chains.

The Coalition shares core values on TSCA implementation that include support for a single federal approach to preempt redundant, state-by-state regulatory actions. We also share a common interest in providing accurate and current use and exposure information about how the chemicals that EPA reviews are used in our members' products, both domestically manufactured and imported, to inform EPA's prioritization designations and risk evaluations. Moreover, the Coalition appreciates and supports EPA's proposal to provide a draft scope as early as feasible in the process, assuming that this does not replace any of the current public comment opportunities but rather adds an additional one. The Coalition has advocated for the early identification of chemicals undergoing risk evaluation and supports EPA's proposal to identify the individual conditions of use that will be part of risk evaluations at the time of the prioritization decision.

I. Executive Summary.

The Coalition appreciates the opportunity to comment on the EPA's proposed rule to amend the risk evaluation process. We support EPA's goal of strengthening the already robust framework for conducting risk evaluations under TSCA presented in the 2017 final risk evaluation framework rule ("2017 Final Rule").[3] However, many of the modifications in this proposal appear to contravene the bipartisan approaches passed by Congress in the Lautenberg Chemical Safety Act (LCSA) and, in reality, weaken the sound science approaches found in the 2017 Final Rule. Of utmost concern are the following aspects of EPA's proposal:

- **EPA must retain the definition of best available science**. There is value in retaining this definition as it provides a framework within which to determine the relevance and quality of the information and data that EPA relies upon in its risk evaluations and subsequent risk management activities. In the absence of such criteria, studies, data, and information that may not be fit for purpose could be used in an inappropriate manner and result in a flawed risk evaluation. EPA's proposal uses this term 44 times in the preamble and in the proposed rule, demonstrating its importance to the overall procedural framework. EPA has not shown how the current definition fails to provide the flexibility that EPA desires to take advancements in science into account. In contrast, these comments document several reasons for its continued use.

public policy advocacy. Our member company tires make mobility possible. USTMA members are committed to continuous improvement of the performance of our products, worker and consumer safety and environmental stewardship.

[3] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726 (July 20, 2017); codified at 40 C.F.R. Part 702, Subpart B.

- **EPA must retain the definition of weight of scientific evidence.** EPA should integrate all lines of evidence, including mechanisms of action, when conducting weight of scientific evidence determinations in TSCA risk evaluations.

- **We do not support the proposed word change to the peer review provision.** The phrase "or portions thereof" is not sufficiently explanatory with the continued need to require peer review of the draft risk evaluation for each chemical by the Scientific Advisory Committee on Chemicals ("SACC"). Important information could be missed. Comprehensive reviews of each risk evaluation are not duplicative of each other.

- **EPA needs to recognize OSHA-mandated use of personal protective equipment ("PPE") in risk evaluations**. The agency should assume that OSHA requirements are being met unless there is substantial evidence to the contrary. Statements in the rule itself that codify never assuming the use of PPE are a disservice to science and the public. The proposed rule does not align with the statute in this respect. EPA is charged by law to consider reasonably available evidence and information supplied by industry and incorporate a totality of the "circumstances" associated with each condition of use of a chemical into the risk evaluation.

- **EPA should stop use of the whole chemical approach and continue to acknowledge conditions of use that do not contribute to an unreasonable risk determination.** Determining that a chemical is an unreasonable risk must go hand-in-hand with accurately conveying those conditions of use that do not contribute to the risk, in whole or part, along with those that do. Workforces and communities also benefit from assurances of safety. Conditions of use that are unlikely to contribute to unreasonable risk determinations, such as replacement parts and articles, should be distinguished from others in the risk evaluation and in risk management. The statute directs EPA to use a heightened standard of review for replacement parts and articles. The proposed rule must include this heightened standard.

II. The Coalition Supports Keeping the Definition of Best Available Science.

The Coalition supports keeping the definition of "best available science" in this rule. We think EPA made the right decision in 2017 to finalize the risk evaluation procedural rule with a codified definition at 40 C.F.R. § 702.33 for "best available science." That decision was deliberative, after receiving and assessing extensive public comment, and it recognizes that this definition instills important procedural guard rails on how EPA must conduct risk evaluations.

By comparison, we find EPA's rationale for removing this definition to be vague and unconvincing. The Coalition is concerned that this aspect of EPA's proposal will seriously undermine public confidence in the risk evaluation process. In light of the regulatory flexibility the current definition offers, we are puzzled by EPA's explanation that removing the definition

will allow the agency to "remain flexible to changing science and approaches."[4] The existing definition states:

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

The above definition summarizes a number of general preconditions (reliable, unbiased, accordance with sound and objective practices), and references the use of supporting studies and data collected by "accepted methods or best available methods." All of these terms accommodate advancements in science. Next, the definition incorporates five discretionary science considerations verbatim from the statute itself (TSCA section 26(h)).

EPA does not identify precisely how this existing definition will hinder EPA's flexibility in conducting risk evaluations in the future. EPA generally offers that "EPA believes codifying a definition of "best available science" in the Risk Evaluation procedural rule is unnecessary and potentially problematic as it could limit the Agency's ability, flexibility, and mandate to incorporate the best available science into TSCA risk evaluations."[6] However, the only non-discretionary components of the existing definition of "best available science" are that it must

[4] 88 Fed. Reg. at 74309.

[5] 40 C.F.R. § 702.33.

[6] 88 Fed. Reg. at 74309.

be reliable, unbiased, and conducted in accordance with sound and objective practices. These are concepts which are important guideposts for any scientific advancements. EPA has not explained how any of them would prevent EPA from doing its job or lead to problematic application during the risk evaluation process. The definition does not prescribe that data be from within a certain time period, or of a certain type or protocol. The definition is meant to provide a framework for using studies conducted with scientific integrity that can be relied upon for purposes of risk evaluation. We ask EPA to clarify specific examples of how application of the existing definition of "best available science" will hinder EPA's flexibility in conducting risk evaluations in the future.

a. Moving TSCA's Best Available Science Considerations as Proposed Loses Their Effectiveness.

The Coalition does not support EPA's proposal to move the five considerations in the statute for best available science into the risk evaluation process requirements at Section 702.37(a)(2). The proposed rule states:

> EPA will document that the risk evaluation is consistent with the best available science and based on the weight of the scientific evidence. Considerations for determining best available science shall include, but are not limited to, the following as applicable:
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> (i) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
> (ii) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
> (iii) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
> (iv) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
> (v) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.[7]

In particular, the introductory paragraph is extremely problematic. First, it appears to propose to further supplement the five statutory considerations in some non-transparent way ("Considerations . . . shall include, but are not limited to"). Second, the proposed language appears to overstep the Agency's authority by even implying that these considerations can be

[7] 88 Fed. Reg. at 74321.

ignored ("shall include . . . as applicable"). Third, we respectfully submit that this language removes an important level of certainty that the current definition provides that best science practices will be used.

b. Reliance on General Agency Guidance is Not a Suitable Replacement for a Defined Term.

The Coalition does not agree with EPA that it is sufficient for the agency to rely upon general agency guidance and interpretations of "best available science" instead of the current definition.[8] EPA's guidance is not always up-to-date, and it is often difficult for the agency to keep pace with scientific developments and update its guidance. Also, guidance documents may be changed without the same level of significant public input or recourse as a notice and comment rulemaking. EPA specifically cites to EPA's Information Quality Guidelines. Chapter 6.4 outlines how EPA has adapted and applied the principles for "best available science" developed under the Safe Drinking Water Act ("SDWA") Amendments of 1996. There appears to be few substantive differences between the term "best available science" as defined in 40 C.F.R. § 702.33 and the concepts in this section of the guidance document. That said, EPA is not proposing to update this guidance to specify that these principles apply to Section 6 of TSCA. In addition, there is a significant difference between a codified definition and guidance. As EPA is well aware, regulations are to be followed, while guidance is discretionary. The public can rely upon codified definitions that require EPA adhere to them. Reliance on guidance documents removes the public's ability to have the same level of scrutiny on agency actions.

EPA acknowledges "that 'best available science' is an integral component of section 6 risk evaluations."[9] The agency uses the term "best available science" no less than forty-four times in the preamble of this proposed rule and in the proposed rule itself. That alone is a strong indication of the need to maintain the words that define its use in TSCA risk evaluations. EPA codified this definition in response to comments by the regulated community and interested parties on the proposed rule. Specifically, commentors were concerned that the lack of a definition would lead to confusion, that the application of the term to the risk evaluation process would not be transparent, and lead to overall greater uncertainty in the process. EPA agreed at that time that the definition it adopted would "increase clarity and transparency" in the process.[10] Eliminating the definition removes the transparency and clarity established by the 2017 Final Rule. Its removal from Part 702 is contrary to the stated intent of Administrator Regan for the agency to operate in a "fishbowl" environment, providing the public with full transparency regarding EPA decision-making.[11]

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[8] 88 Fed. Reg. at 74309.

[9] 82 Fed. Reg. at 33731.

[10] *Id*.

[11] Michael S. Regan, *Message to EPA Employees - Transparency and Earning Public Trust in EPA Operations* (Apr. 12, 2021), https://www.epa.gov/aboutepa/administrator-michael-regan-message-epa-employees-transparency-and-earning-public-trust.

We appreciate that since the implementation of the amendments to TSCA, EPA has learned and developed efficiencies related to the risk evaluation program. However, this aspect of EPA's proposal is simply a case of "cutting off one's nose to spite one's face" – an expression used to describe a needlessly self-destructive overreaction. We think removing this definition damages the integrity of the program in the long term. The definition serves as a standard for weighing the appropriateness of the new procedures that EPA proposes to undertake and provides a framework within which to determine the relevance and quality of the information and data that EPA relies upon in its risk evaluations and subsequent risk management activities. In the absence of such criteria, studies, data, and information that may not be fit for purpose could be used in an inappropriate manner and result in a flawed risk evaluation. The proposal to remove this definition seems like avoidable "re-work" on the part of the agency. Maintaining it will further underscore the agency's commitment to the kind of comprehensive, scientific risk evaluations that EPA is trying to achieve through this rulemaking. EPA should be proud to be both the caretaker and implementer of the best definition of "best available science" in the world today.

c. <u>The Reasons for Having this Definition Remains Valid.</u>

The Coalition supports the 2017 Final Rule determination to define best available science.[12] The rationales from that rule all appear to carry forward into this proposal. They include the following:

- The law requires that EPA operate in a manner that is consistent with the best available science and make decisions based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).[13]
- Data sets may change but the definition of this term can accommodate changing science.[14]
- The term has a number of different meanings, making it more important to define them in this rule so the public knows which definition would be applied.
- The definition is a "cornerstone" of risk evaluations under TSCA, and a definition is necessary to alleviate potential confusion in implementation of these requirements.
- The definition is consistent with agency policy to define only those terms in the statute (e.g., aggregate exposure, conditions of use, pathways, etc.).
- The definition will instill confidence, increase transparency, and provide the public with assurance that EPA will adhere to the requirements of the statute.
- EPA determined that "best available science" is an integral component of section 6 risk evaluations.
- The definition is consistent with the current approach already used Agency-wide, while also acknowledging the specific standards under TSCA.

[12] 82 Fed. Reg. at 33731.

[13] Id. at 33727.

[14] Id. at 33731 for reference to this supporting rationale and those that follow.

- Changes from the prior proposed rule include the addition of EPA's commitment to using the best available science and a weight of the evidence approach.[15] The definition implements the change announced in the 2017 Final Rule.
- EPA uses best available science elsewhere in the rule to ensure that the use of guidance documents that may have been developed under another statute would be compliant with the various requirements of section 26 of TSCA. Proposed § 702.37(a)(1) retains this reference.[16]
- EPA uses best available science elsewhere in the rule to document that the risk evaluations are consistent with the term. Proposed 702.37(a)(2) retains this use.[17]
- EPA uses best available science elsewhere in the rule to evaluate hazard and exposure data in a manner consistent with the section 26 science standards.[18] Proposed § 702.39(e)(2) retains this reference.[19]
- EPA uses best available science elsewhere in the rule in conducting "fit-for-purpose" risk assessments. EPA determined that technically sound risk determinations can be made under the current definition of best available science, through a combination of diverse types of information and methods approaches. EPA proposes to retain a "fit-for-purpose" approach in the proposed rule and the flexibility permitted by the current definition to use different approaches remains unchanged. [20]

III. The Coalition Supports Keeping the Definition of "Weight of Scientific Evidence."

The Coalition supports keeping the definition of "weight of scientific evidence" in this rule. Again, we think EPA made the right decision in 2017 to finalize the risk evaluation procedural rule with a codified definition at 40 C.F.R. § 702.33 for this term. That decision was deliberative, after receiving and assessing extensive public comment, and it recognizes that this definition also instills important procedural guard rails. We oppose replacing the definition of "weight of scientific evidence" by relying on general agency guidance documents.[21]

Our concerns and considerations here are similar to that above: EPA's rationale for eliminating this definition lacks transparency, in that the agency has not demonstrated that the

[15] 82 Fed. Reg. at 33742.

[16] *Id.* at 33739. EPA states: "The scope of each risk evaluation will identify those guidance documents that the Agency expects to utilize to inform the risk evaluation. EPA will use the guidance only to the degree that it represents the best available science appropriate for the particular risk evaluation." *See also* 88 Fed. Reg. at 74321.

[17] 88 Fed. Reg. at 74321.

[18] 82 Fed. Reg. at 33742

[19] 88 Fed. Reg. at 74322.

[20] 82 Fed. Reg. at 33739-40; 88 Fed. Reg. at 74296, 746298, 74299, 74300, 74301, 74310, 74311, 74321.

[21] 88 Fed. Reg. at 74311.

"weight of scientific evidence" definition has limited or impacted the legitimacy of the risk evaluation process. In the proposed rule, EPA states that the existing definition is "problematic and inconsistent with typical risk assessment practice."[22] EPA points to the NASEM report, *The Use of Systemic Review in EPA's Toxic Substances Control Act Risk Evaluations*, which stated concerns with the manner in which the term "weight of scientific evidence" was defined in terms of a separate and critical concept, "systemic review."[23] However, EPA rejects the recommendation to simply refine the definition to distinguish its role.[24] Instead, EPA proposes to eliminate the definition altogether and rely on four guidance documents that describe the "weight of scientific evidence" assessment. In this regard, the proposed rule is contrary to and fails to implement NASEM's recommendations. NASEM's report highlights how undefined terms and processes can result in compromising the integrity of the risk evaluation process:

> The committee found that transparency of the entire risk evaluation process is compromised across all of its elements. Neither clear questions nor protocols have been developed for the systematic reviews. Consequently, the review process is not documented from its start, and clarity is lacking when the review is finished and published. Overall, the committee found that the lack of information and details about the specific processes used for the identification of evidence reduced confidence in the findings. The OPPT processes and practices are not consistent with the standard of practice for systematic review.[25]

As underscored by the NASEM report, the need to provide transparency to the public regarding the risk evaluation process persists, regardless of the identified weaknesses in the existing definition.

EPA should not relegate important scientific terms like this one to guidance. As EPA recognized in 2017, defining this term provides for "confidence, increase[s] transparency, and provide[s] the public with assurance[s] that EPA will adhere to the requirement of the statute."[26] The term "weight of the scientific evidence" is defined at 40 C.F.R. § 702.33 as follows:

> Weight of the scientific evidence means a systematic review method, applied in a manner suited to the nature of evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify

[22] *Id*. at 74310.

[23] *Id*. at 74311.

[24] NASEM notes that changing a definition can be difficult and suggests that at a minimum EPA adopt a specific term to describe the weight of the scientific evidence throughout the evaluation integration step. *See* National Academies of Sciences Engineering and Medicine, *The Use of Systematic Review in EPA's Control Act Risk Evaluations*, 54 (The National Academies Press, 2021). https://doi.org/10.17226/25952.

[25] *Id*. at pp. 6-7.

[26] 82 Fed. Reg. at 33731.

> and evaluate each stream of evidence, including strengths, limitations, and relevance of each study to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

Again, we strongly urge EPA to maintain this definition rather than striking it from existence. Additional rationales for continuing to include this definition in the final rule include many of those documented immediately above in the prior section of these Comments. In the area of unintended consequences, doing away with the definition would demonstrate disregard for the process that swayed EPA to invest in defining this term just six years ago. Surely, this is not EPA's intent. At that time, EPA agreed that inclusion of the term would provide "transparency to the public regarding the processes for how the Agency reviews scientific information used in risk evaluations without stifling scientific advances."[27] We continue to agree with that conclusion.

IV. The Coalition Supports Comprehensive Peer Review for Each Risk Evaluation.

The Coalition commends and appreciates EPA's historical commitment to peer review in the TSCA program. However, we do not support this proposed modification. We are concerned that the proposed rule change in this area demonstrates less commitment to "peer review" and will have a chilling effect on public confidence in EPA's work product. Peer review is a critical component of the TSCA regulatory process; to allow discretion as to what sections of a risk evaluation would undergo peer evaluation would undermine the very purpose of this integral scientific step. While some information in a risk evaluation may have undergone previous peer review, it is the complete evaluation and how each piece of information is applied that must be reviewed by appropriate peer reviewers. We urge EPA to maintain public trust by continuing the established process of comprehensive peer review for every chemical risk evaluation. Current regulation states:

> The EPA Peer Review Handbook (2015), the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin), and other available, relevant and applicable methods consistent with 15 U.S.C. 2625, will serve as the guidance for peer review activities. *Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A).*[28]

The proposed rule moves this provision to 40 C.F.R. § 702.41 and reduces the requirement in the last sentence above to conduct peer review ("Peer review will be conducted . . . ") to a mere expectation, as follows:

> EPA *expects that* peer review activities on risk evaluations conducted pursuant to 15 U.S.C. 2605(b)(4)(A), *or portions thereof*, will be consistent with the applicable peer review policies, procedures, guidance documents, and methods pursuant to

[27] *Id*. at 33733.

[28] 40 C.F.R. § 702.45 (emphasis added).

> guidance promulgated by Office of Management and Budget, EPA, and in accordance with 15 U.S.C. 2625(h) and (i).[29]

Again, we are concerned that the proposed wording eliminates EPA's commitment to peer review altogether, rather than simply reducing the potential for redundant reviews of particular sections of the risk evaluation.

a. <u>How Science Approaches are Applied to Each Chemical Warrants Peer Review.</u>

EPA notes that "it is expected that specific approaches may be used repeatedly, after due consideration of complexity, novelty, and prior peer review. That is, there may be situations when repeated peer review is not warranted."[30] Within the preamble EPA indicates that peer review could be limited to "portions or sections that constitute unreviewed influential information."[31] However, the proposed rule goes further than clarifying "what peer review will be conducted" in those cases.[32] Regardless of the maturity of the approach, how the approaches are applied to a specific chemical warrants peer review.

With this in mind, we propose the following change in the wording (in italics below) for this provision in the regulation:

> EPA expects that peer review activities on risk evaluations conducted pursuant to 15 U.S.C. 2605(b)4(A) will be consistent with the applicable peer review policies, procedures, guidance documents, and methods pursuant to guidance promulgated by Office of Management and Budget, EPA, and in accordance with 15 U.S.C. 2625(h) and (i). *Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A) and may be additionally conducted on unreviewed, revised portions thereof.*

We think this proposed definition avoids duplicative or redundant peer review for the same chemical, while maintaining the integrity and equality of peer review among different chemicals subject to risk evaluation. We believe this language better expresses and continues EPA's "commit[ment] to using peer review in the development of TSCA risk evaluations."[33]

b. <u>The Proposed Change of Approach May Foreclose the Discovery of Important Information.</u>

Again, our Coalition commends EPA for upholding the pillar of peer review and those dedicated individuals who have served as peer reviewers for EPA. The peer review process has

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[29] 88 Fed. Reg. at 74323 (emphasis added).

[30] *Id*. at 74308.

[31] *Id*.

[32] *Id*. at 74307.

[33] *Id*.

contributed significantly to the risk evaluation process. By EPA's own account, peer review successfully identified that 1,4-dioxane exposures in products was missing from the scope of that risk evaluation.[34] If EPA's rubric of foregoing peer review of matured scientific approaches had been applied in that case, the opportunity to make this kind of important contribution would have been lost. By conducting peer review, EPA was able to identify an additional exposure and assess any associated unreasonable risk. Peer review helps EPA to fulfill its risk evaluation objectives. Further, the process itself does not cause any undue burden or delay to EPA meeting its deadlines for conducting risk evaluations.

The peer review process elevates EPA's ability to provide robust risk evaluations. When risk evaluations are subject to peer review the comments and recommendations all contribute to a better analysis and interpretation of the data. These outcomes are better for EPA, the general population, and the regulated community. Additionally, it is well understood that the peer review process is a useful tool to not only evaluate the scientific data but to identify potential technical issues within the draft materials. Ultimately, this saves time and money. EPA's Peer Review Handbook (2015) states that one of the benefits of peer review is that "by ensuring a sound basis for decisions, cost savings are likely to be realized because decisions are less likely to be challenged."[35]

V. The Coalition Supports Comprehensive Risk Evaluations and Balanced Consideration of Worker Protection Information, Scoping, and Other Agency Statutes.

The Coalition supports robust and comprehensive risk evaluations. We support a single federal approach to risk evaluation and risk management of chemicals to preempt redundant, state-by-state regulatory actions. Such an approach favors the kind of comprehensive inclusion of conditions of use EPA is seeking to ingrain in the rule. With respect to the scope of the risk evaluation, other agency statutes, and worker protection, we think EPA's approach has been too far-reaching and overly simplistic. It is not enough to simply decide whether or not to "assume" that risk evaluations must be comprehensive every time, that the agency should or should not "assume" to include or exclude circumstances regulated by other agency statutes, or "assume" that PPE is or is not used or foreclose the agency's ability to make risk determinations through orders at some earlier stage in the overall process. And in all cases, EPA should adopt a balanced and objective approach that takes reasonably available and verifiable information into account.

a. Retaining the Flexibility in the Statute on the Scope of Risk Evaluations.

While we urge EPA to continue to strive for comprehensive risk evaluations, the Coalition agrees with other commenters that EPA has – and should maintain – discretion under TSCA to

[34] *Id*. at 74308. This example is provided solely to demonstrate the usefulness of peer review. It is not intended as an endorsement of the associated policy determinations.

[35] U.S. EPA, *Peer Review Handbook (4th Edition)* (EPA/100/B-15/001), Sec. 1.2.2 (Science and Technology Policy Council 2015). https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015.

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

> The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the Agency is given the discretion to determine the conditions of use considered in the scope that the Agency will address in its evaluation of the priority chemical.[36]

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

b. EPA's Assumption of No Use of PPE Must End.

The Coalition is concerned that worker protection practices are being given shallow treatment by EPA. EPA should not "assume" these practices do not exist. The reality is that they do exist, often are mandated by OSHA, and are the primary means by which EPA should be assessing and protecting workers under TSCA. Industry is providing valuable information to EPA in TSCA submissions – under penalty of perjury – of their workplace protection practices. The agency's failure to truly understand, acknowledge and utilize this information in risk evaluations *in a balanced manner* is arguably the most frustrating aspect of EPA's implementation of the Lautenberg Amendments to TSCA.

Our members feel quite strongly that the TSCA risk evaluations conducted to-date turn a blind eye to the vast majority of industry employers that are subject to these legal requirements and take these important steps to protect their workforce. The Occupational Safety and Health Act of 1970 ("OSH Act") applies to private sector employers with more than nine employees and workers in all states and U.S. territories.[37] As EPA has observed, there are limited employers not regulated by the OSH Act, some sectors are covered by other federal safety standards, and some companies may not be complying or be ineffective in doing so. However, EPA's narrow and single-minded emphasis on discrete sectors that are not under OSHA authority, cases of noncompliance, and the ineffective use of PPE is unbalanced and

[36] 162 *Cong. Rec.* S3519 (daily ed. June 7, 2016), https://www.congress.gov/114/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf.

[37] U.S. Department of Labor: Occupational Safety and Health Administration, *Worker's Rights* (OSHA 3021-02R) (2023). https://www.osha.gov/sites/default/files/publications/osha3021.pdf.

ignores the flexibility elsewhere in the statute to address these concerns. For example, it may be possible to address these discrete sectors as separate worker susceptible subpopulations in a risk evaluation if EPA has data to support risk concerns. Alternatively, the conditions under which these discrete sectors are exposed could rise to the level of separate conditions of use. We urge EPA to consider these sectors as subcategories within this designated category and evaluate them separately from OSHA regulated sectors.[38] However, in the majority of cases, EPA has or can be provided with reasonably available and verifiable information on the use of PPE. TSCA does not require EPA to recognize the circumstances associated with these groups without also recognizing the compliant circumstances of others.

c. The Use of PPE is Part of the Circumstances Under which a Chemical is Manufactured, Processed, Distributed, Used, and Disposed.

The Coalition respectfully submits that TSCA requires consideration of the totality of "circumstances" associated with actual conditions of use, including the use of PPE documented in industry comments. More specifically, EPA is tasked with evaluating the "conditions of use" defined as:

> the *circumstances*, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.[39]

EPA's proposed approach is not consistent with the important phrasing in the statutory definition above for the agency to consider the "circumstances" associated with "conditions of use."

EPA's exercise of judgment should be guided by the dictionary meaning of "circumstances" which is "the sum of essential and environmental factors (as of an event or situation)."[40] Here, if there is information on the record concerning the use of PPE, EPA's exercise of judgement should include a balanced consideration of the PPE as part of the circumstances for the condition of use. Industry has provided numerous public comments

[38] Again, non-compliance at regulated workplaces should be a high priority for enforcement. Basing risk evaluations on lack of compliance does not change the behavior of bad actors. Instead, an unreasonable risk determination based upon noncompliance creates bias against compliant employers. Workers who are not covered by existing safety standards, or who are employed by noncompliant employers, or are subject to ill-fitting PPE may be considered a "susceptible subpopulation." This group has "greater susceptibility or greater exposure" than the general population. As "greater susceptibility" is not a defined term, EPA can interpret it to include workers who are exposed due to a lack of workplace protections. EPA should reserve statements on the identification of noncompliance and direct these concerns to the appropriate offices for enforcement. Imposing more rules on noncomplying companies raises the stakes but is no guarantee of compliance and is not a sufficient basis to ignore the vast majority of companies who seek to comply with the law.

[39] 15 U.S.C. § 2602(4); 40 C.F.R. § 702.33 (emphasis added).

[40] Circumstances, Merriam-Webster.com Dictionary, Merriam-Webster, https://www.merriam-webster.com/dictionary/circumstance#:~:text=%3A%20the%20sum%20of%20essential%20and,%3A%20state%20of%20affairs%20%3A%20eventuality.

related to occupational safety practices[41] demonstrating "known" use involving employment of PPE measures. In addition, OSHA requirements should be considered an adopted practice unless there is data to indicate otherwise. In the face of this reasonably available information, it is not reasonable for EPA to make risk determinations based upon "circumstances" that largely consist of hypothetical, worst-case scenarios when reasonably available information on the use of PPE is provided. Rather, industry information on workplace protections is precisely the kind of "circumstance" that Congress wants EPA to considered as part of conditions of use that are "intended, known, or reasonably foreseen."

EPA states in the proposed rule that it believes it has authority to "exercise judgment in making its determination as to whether a particular *circumstance* is intended, known, or reasonably foreseen, and therefore falls within the definition of a 'condition of use' for a particular chemical."[42] However, within this framework, EPA is required to consider "reasonably available information"[43] in determining "whether the risks posed by a specific high priority substance are reasonable in the circumstances of exposure and use."[44] We do not think the phrase "as determined by the Administrator" permits EPA to rule out the use of PPE at the risk evaluation stage.[45]

d. Considering PPE Does Not Conflate the Risk Evaluation and Risk Management Phases.

As a Coalition, we respectfully express our grave concern with EPA's pendulum swings on worker protection. This procedural rule should aim for balance. We suggest these specific changes to the language for § 702.39(f)(2) to reflect a more balanced and objective practice (suggested text indicated with italics):

> In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information, including known and reasonably foreseen circumstances *where use*

[41] 88 Fed. Reg. at 74304.

[42] *Id*. at 74298 (emphasis added).

[43] Defined as information "that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." 40 C.F.R. § 702.33

[44] 162 *Cong. Rec.* S3522 (daily ed. June 7, 2016).

[45] While we reserve disagreement on EPA's authority to include or exclude conditions of use in the scope of the risk evaluation, we note that once a condition of use is included, EPA own statements align with the need to consider the totality of the circumstances associated with the condition of use. In this proposed rule, the agency states that the "statutory text and structure is that EPA does not have discretionary scoping authority, and that risk evaluations are to be conducted on the circumstances under which the chemical is known, intended and reasonably foreseen to be manufactured, processed, distributed in commerce, used, and disposed of (*i.e.,* activities that constitute the "conditions of use")." 88 Fed. Reg. at 74297.

> *of personal protective equipment is substantiated, and* where susceptible subpopulations of workers are exposed due to the absence ~~or ineffective use~~ of personal protective equipment. ~~EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination.~~ *For purposes of this paragraph, use of personal protective equipment is considered substantiated based upon reasonably available information provided through verifiable industry submissions and/or data obtained by EPA from other federal agencies. EPA will consider such substantiated use of personal protective equipment as part of the risk determination.*

We strongly disagree with EPA's proposed approach to state in this rule that *"EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination."* This language needlessly eliminates agency flexibility, to prevent there to be any ability to take PPE into account when making a risk determination. This simplistic approach may make EPA's job easier, but it is a deceptive practice that does not reflect actual protections in place to prevent exposures.

The Coalition urges EPA to acknowledge, and not preemptively exclude, the use of PPE information in making risk determinations under TSCA. We do not think it is possible for EPA to exclude consideration of PPE at the risk evaluation stage under TSCA's safety standard which states:

> The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.[46]

We trust that EPA can agree that the use of PPE cannot be excluded as a "non-risk" factor above, since PPE is designed to be protective against the risks of chemical exposure. Rather, PPE is classified as part of the "circumstances" that must be considered with each condition of use. Our alternative language above would provide clarity and certainty for the regulated community. Reference to ineffective use should be struck, as this is a subjective determination that goes to the need for proper training and is outside the norm. Again, EPA has other means by which to address this concern, such as improved enforcement, or identification as a separate susceptible subpopulation or a separate condition of use.

EPA's proposed rule even forecloses a limited case in which the agency indicates it would be able to take PPE into account. EPA explains this limited circumstance as follows:

> For example, where EPA has reasonably available information that substantiates use and effectiveness of PPE (e.g., information demonstrating that performance of

[46] 15 U.S.C. § 2605(b)(4)(A).

> a condition of use is impossible in the absence of PPE), EPA generally expects to take that information into account in the risk determination.[47]

In the language above, we are pleased that EPA distinguishes between "assumed" use (or non-use) of PPE and "reasonably available information. However, we disagree that TSCA sets the high bar of "impossible use" of a chemical without PPE *before* EPA can consider reasonably available information that demonstrates the use of PPE. Rather, we think our suggested language strikes a more balanced approach for EPA to take PPE into consideration when reasonably available and verifiable information demonstrates its use.

VI. EPA's Risk Communication and Determination Requirements for Conditions of Use.

The Coalition asks EPA to continue to identify conditions of use that do not contribute to the unreasonable risk finding for the chemical, on an individual or cumulative basis. It is imperative to our members that EPA and the rules governing risk evaluations do not lose sight of the individual conditions of use that are subject to evaluation. By making "a single risk determination of the chemical substance," EPA communicates to the public that the entire substance presents an unreasonable risk. Coalition members are concerned that this blanket approach to risk determinations will paint all manufacturers and processors of these chemicals as "bad actors" since EPA will not distinguish the conditions of use contributing to the determination. This will create confusion among the regulated community and public as to those conditions of use that influenced EPA's risk determination.

a. Procedural Needs for Communicating to the Public on Conditions of Use.

We think the process of risk evaluation, in which EPA considers the circumstances associated with each condition of use of the chemical, requires EPA to reach a conclusion for each condition with respect to whether it contributes to an unreasonable risk finding or not. For example, EPA states that an unreasonable risk determination may be made on a singular condition of use.[48] If there are 30 conditions of use for that chemical in total, in this example EPA would find that the chemical is not an unreasonable risk in 29, or most, of its uses.

In the preamble, EPA commits to "provide a rationale and explanation as to which conditions of use or exposure pathways are significant contributors to risk."[49] The proposed rule is silent on communications relating to those conditions of use that are *not* significant contributors or that do not contribute to the unreasonable risk determination in any way. Nevertheless, the Coalition greatly appreciates EPA's intent. EPA's statement acknowledges agency communications on conditions of use as a critical procedure in risk communication under TSCA. TSCA has become a highly watched area of regulatory law as EPA has undergone

[47] 88 Fed. Reg. at 74305.

[48] *Id*. at 74302.

[49] *Id*. at 74302-03.

risk evaluations on chemicals subject to litigation and legislation. It is important for the public to have clear information regarding the status of their uses following a risk evaluation.

EPA's current practice in the risk evaluation documents generally includes listings which conveys the conditions of use that significantly contribute to the unreasonable risk finding and those that do not. *The Coalition strongly urges EPA to continue this practice.*

Moreover, we think it is consistent with agency intent, current practice, and balanced risk communication to add the following language to the end of proposed section 702.37(a)(5) (suggested text indicated with italics):

> EPA will determine whether a chemical substance does or does not present an unreasonable risk after considering the risks posed under all of the conditions of use and, where EPA makes a determination of unreasonable risk, EPA ~~intends to~~ *will* identify the conditions of use that contribute to such determination~~.~~*, those that are not significant contributors to the risk, and those which do not contribute to the unreasonable risk determination. The two latter determinations will be final agency actions and invoke preemption.*

We urge EPA to capture this important additional procedural element in the rule itself due to the importance of risk communication, and to avoid miscommunication concerns. Since EPA must reach a determination on each condition of use, is currently communicating risk outcomes for each condition of use, and intends to continue to do so, we think this addition to the rule reflects current practice. We ask EPA to recognize the importance of risk communication by adding this language to the rule. In addition, EPA has not identified how or when a condition of use will qualify as a significant contributor to the risk determination. We urge EPA to provide further explanation of this point in the final rule. For example, as explained in a prior section of these comments, EPA must take reasonably available and verifiable information on workplace protection into account during the risk evaluation phase, and such information should be used to draw conclusions with respect to the relative contribution of a condition of use. Finally, in the interest of risk communication that is balanced, transparent and fair, we ask EPA to ensure that the procedures for risk evaluation include conveying information to the public on conditions of use that do *not* contribute to an unreasonable risk determination.

b. <u>Clarifying Certain EPA Policies on Conditions of Use that Do Not Contribute to Unreasonable Risk Determinations and Keep Early Determination Flexibility.</u>

The Coalition wishes to express its concerns with a statement in the preamble that the agency may regulate conditions of use that do not themselves contribute to unreasonable risk for a given chemical.[50] EPA should clarify and explain this statement. It appears to exceed the agency's authority under Section 6(a) to take such actions. Section 6(a) states:

[50] *See Id*. at 74303 which states "where a risk evaluation's underlying analysis suggests that particular use downstream in the supply chain is significantly contributing to unreasonable risk determination for the chemical substance, EPA's risk management actions need not apply only to the downstream use. EPA may, for example,

> (a)Scope of regulation
>
> If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture *to the extent necessary so that the chemical substance or mixture no longer presents such risk*.[51]

As stated above, risk management actions should be undertaken only "to the extent necessary" so that a chemical "no longer presents" an unreasonable risk. This language seems to preclude EPA's ability to implement its statement in the proposed rule to regulate conditions of use that do not present an unreasonable risk. If a use does not present an unreasonable risk, it would also not (or be unlikely to) contribute to the unreasonable risk. As a result, efforts to draw these conditions of use into the risk management phase make the action vulnerable to challenge under the substantial evidence standard of TSCA.

For example, Section 6 sets a different standard for the agency to regulate articles and replacement parts. EPA appears to be much more willing to fold those into their risk evaluations and restrict them than we think is permissible under TSCA. Coalition members are concerned that low exposures from chemicals in articles and replacement parts may be bundled with other conditions of use and subject to significant restrictions. Section 6(c)(2)(D) of TSCA specifically exempts replacement parts for complex durable goods and complex consumer goods unless it is found to contribute significantly to the risk. EPA must continue to distinguish amongst conditions of use. TSCA, as it pertains to replacement parts and articles, requires that EPA identify that condition of use as the significant contributor in order to regulate them. Accordingly, we ask EPA to confirm that it intends to uphold the regulatory standard for replacement parts and articles. We also request more guidance on how EPA intends to quantify which conditions of use are the significant contributors to the unreasonable risk.

Finally, the Coalition urges EPA to maintain agency discretion on "early determinations" to permit EPA to communicate on risk prior to the release of the final risk evaluation. We

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determine that elimination of the unreasonable risk requires regulation of the chemical's upstream manufacture, processing or distribution in commerce–even where the upstream activity itself does not directly result in the exposures that present the unreasonable risk." We think this statement applies to limited circumstances, such as eliminating the manufacture for the particular downstream use in question as an option should downstream workplace controls be found insufficient to remove the unreasonable risk. However, we do not agree that a comprehensive manufacturing ban or imposing workplace controls that are not required for those operations would be acceptable risk management actions in that case.

[51] 15 U.S.C. § 2605(a) (emphasis added).

appreciate EPA's explanation on this "early determinations" point,[52] and the role of Section 7 for early and immediate communications on risk findings. Here, a balanced approach also requires consideration of the need for early communications on conditions of use that do *not* contribute to the risk determination. There may be circumstances where EPA has enough data and compelling cause to make early notifications in this area to the public. Based on the length of the risk evaluation process, and the regulatory uncertainty that exists throughout, we think it is too early in the process to completely rule out the potential usefulness of early determinations. We think these determinations are permitted by the statute. Moreover, we think early determinations may significantly aid in risk communication under TSCA in the long term.

VII. Conclusion.

In closing, the Coalition supports a robust, comprehensive risk evaluation process that recognizes actual circumstances in which PPE is used for each condition of use, and which is based on best available science and weight of the scientific evidence. We strongly support retaining the definitions for best available science and weight of the scientific evidence in the rule. These definitions are needed due to the integral way in which EPA uses these terms in other parts of the rule to describe how it will conduct various parts of the risk evaluation. We think peer review should remain comprehensive. The way in which a method is applied to a particular chemical is not duplicative of when that method is applied to a different chemical and peer review should not be a selective exercise as a general rule. Important contributions could be missed in that case. The Coalition is concerned that EPA retain flexibility in the scope and circumstances the agency can consider in risk evaluations. We oppose aspects of this proposed rule that foreclose agency flexibility and ignore actual circumstances associated with conditions of use in the area of worker protection. We think there is a vital need for EPA to evaluate and distinguish among conditions of use, including articles and replacement parts, in their relative contribution to the risk determination. The Coalition urges the adoption of the risk communication procedure that we propose in these comments in recognition of the role of risk communication in this process.

Respectfully Submitted,

Alliance for Automotive Innovation
American Coatings Association
American Forest & Paper Association
MEMA, The Vehicle Suppliers Association
Plastics Industry Association
The Toy Association
U.S. Tire Manufacturers Association

[52] *See* 88 Fed. Reg. at 74301.