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November 7, 2025

Nancy B. Beck, Ph.D.
Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

RE: Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA) (EPA Docket No. EPA-HQ-OPPT-2025-0260)

Dear Principal Deputy Assistant Administrator Beck,

The Toy Association would like to thank the Environmental Protection Agency (EPA) for the opportunity to submit comments on the proposed revisions to the TSCA Risk Evaluation framework. These comments are provided on behalf of The Toy Association and its 900+ members, representing manufacturers, importers, designers, retailers, inventors, and toy safety testing labs, all working to ensure safe play for children and families.

Toy safety is our industry's number one priority, and we have been global leaders in advancing physical and chemical toy safety for decades. ASTM F963, as incorporated in 16 CFR 1250 pursuant to the Consumer Product Safety Improvement Act (CPSIA), is recognized as one of the world's premier toy safety standards. Its comprehensive requirements have been emulated globally for toys and several non-toy categories, and its consensus process ensures consideration of stakeholder viewpoints, innovation in product design and data-supported emerging hazards.

Our comments address opportunities outlined by EPA to effectively adjust the Risk Evaluation Framework to align with the intent laid down by Congress with the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the Lautenberg Act), improving the process by which chemicals are assessed without impacting safety and EPA's stated purpose to protect human health and the environment while also fostering economic prosperity and growth,

Summary

The Toy Association supports EPA's aim to enhance the efficiency and transparency of the Risk Evaluation Framework. While the toy industry is not a primary user or handler of raw chemicals, like many other consumer product industries it is a downstream user of the materials that are made available by the chemical industry and as such, is an interested party in the existing chemical review process subject to TSCA Section 6(b). The toy industry relies on the availability of safe and effective polymers in order to produce the safe and reliable toys upon which American consumers depend. The 2024 rule on the TSCA Risk Evaluation framework that codified the 2021 policy changes has led to significant concerns that risk evaluations of 'building

block' chemicals will result in unrealistically excessive restrictions on the supply of the polymers that depend on those specific chemicals, especially under the broad 'whole chemical' approach, limiting EPA's ability to effectively focus its efforts on the areas of actual concern.

Proposed Updates to Risk Evaluation Framework

The Toy Association supports the proposal to restore EPA's discretion to focus mandated risk evaluation work on the specific circumstances that may result in unreasonable risk, and exclude certain conditions of use (COUs) and exposure pathways that are not relevant or applicable in the supply chain, especially with the singular 'whole chemical' risk determination that is currently applied.

The Toy Association welcomes the restoration of an emphasis on tailored evaluations that focus on relevant risks, along with the intent to return to condition-specific risk determinations.

We respectfully request EPA also consider the important position that the Lautenberg Act provides with regard to preemption for the "hazards, risks, and uses or conditions of use" included in the scope of the risk evaluations carried out by EPA. Since such preemption is triggered when EPA finds that a chemical does or does not present unreasonable risk, a COU that is determined not to be relevant or applicable should be listed in the risk evaluation as not presenting unreasonable risk, so that it maintains the preemption coverage; a COU that is not listed would fall outside of the scope of Federal preemption. Federal preemption under TSCA is essential to ensure a uniform approach to chemical management nationwide. Without comprehensive and inclusive EPA risk evaluations, states may enact individual, and sometimes conflicting, chemical regulations—creating a patchwork of requirements that can confound industry compliance, increase costs, and potentially impede access to important products. In light of this consideration, we respectfully urge EPA to continue to conduct comprehensive risk evaluations, retain discretion to exclude conditions of use under certain conditions, such as when the use is already regulated by other environmental statutes, and keep low-risk conditions of use in the mix under a "fit for purpose" risk evaluation approach.

Similarly, when EPA makes a determination that articles¹ do not contribute to unreasonable risk as part of a risk evaluation, we respectfully ask EPA to also consider including a reference in the final rule for the chemical stating that articles are out of scope. For example, as was noted with the 2024 rule relating to methylene chloride (MeCl), concerns were raised by commenters that it was not clearly defined whether articles were applicable under the final rule or not².

Changes to Occupational Exposure Considerations

The Toy Association agrees with EPA's proposed position that the exclusion of the use of personal protective equipment (PPE) from the occupational exposure assessment is "unnecessarily confusing, limits what EPA can consider in making an unreasonable risk determination beyond the statutory prohibition on considering non-risk factors"³ and contradicts TSCA Section 26(k)⁴ which requires EPA to consider reasonable available information in making risk evaluation decisions, including hazard and exposure information pertaining to conditions of

¹ As defined in 40 CFR 751.5

² [Response to public comments: Regulation of Methylene Chloride under TSCA Section 6\(a\)](#)

³ FR Vol. 90, No. 182, p 45704 referring to the proposal to amend 40 CFR 702.39(f)(2) related to PPE usage.

⁴ 15 USC §2625(k)

use. Restoring the recognition of factors that significantly address real-world exposure conditions will result in more accurate and realistic risk determinations.

Aggregate Exposure Assessment Adjustments

The Toy Association recognizes that aggregate exposure assessments may be applicable in certain circumstances, and agrees with EPA's proposal that it is not necessary for justification to be made for the absence of such assessments and that such assessments should be made at EPA's discretion as and when appropriate.

Definitions and Terminology

The Toy Association agrees that clearly defined definitions increase the consistency and reliability of risk evaluations since uncertainty and inconsistency in the application of terminology can significantly increase the burden that regulated entities face. As such, The Toy Association supports the inclusion of definitions for 'best available science' and 'weight of scientific evidence' in the final rule.

Conclusion

The Toy Association welcomes EPA's proposals to review the TSCA Risk Evaluation framework, and to address the concerns raised regarding the need to streamline the process and reexamine the changes implemented in the 2024 rule. The proposed revisions will help to align the rule more closely with the original intent of the statute, and will ensure that EPA will be able to carry out risk evaluations in an effective and efficient manner in order to meet its mission and important role.

The Toy Association welcomes the opportunity for continued collaboration on regulatory policy. Please do not hesitate to reach out to discuss further if we can assist with additional clarification on any of the points raised in this submission.

Sincerely,



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About The Toy Association and the toy industry:

The Toy Association is the North America-based trade association; our membership includes more than 800 businesses, from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs, and all members are involved in bringing safe & fun toys and games to children. The toy sector is a global industry of more than US \$90 billion worldwide annually, and our members account for more than half of this amount.

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 that has been adopted as a mandatory toy safety standard for all toys sold in the U.S. under the Consumer Product Safety Improvement Act (CPSIA) in 2008. It also serves as a model for other countries looking to protect the health and safety of their citizens with protective standards for children. The 2023 revision to ASTM F963 was accepted

by the Commission and came into force in April 2024. The Toy Association continues to work with medical experts, government, consumers and industry to provide technical input to ensure that toy safety standards keep pace with innovation and potential emerging issues.

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.
