

November 16, 2025

European Commission
EU-TBT Enquiry Point
Unit GROW A3
Avenue d'Auderghem 45
1000 Bruxelles
Belgique

VIA U.S. TBT enquiry point

RE: Notification G/TBT/N/EU/1157 – Products Containing intentionally added microplastics

Dear Sir/Madam:

The Toy Association is the North American-based trade association; our membership includes more than 900+ 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 within the global marketplace.

Toy safety is the top priority for the toy industry and our Association, and we have been global leaders in advancing physical and chemical toy safety for decades, including through our work on the ASTM F963 Toy Safety Standard. ASTM F963, as incorporated in the U.S. Code of Federal Regulations (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 for several non-toy categories, and its consensus process ensures consideration of stakeholder viewpoints, innovation in product design and data-supported emerging hazards.

The Toy Association would like to thank the European Commission for the opportunity to submit comments on the proposed revisions to the synthetic polymer microparticles requirements under REACH, and respectfully offer this input on behalf of our members, via the World Trade Organization's Technical Barriers to Trade (WTO TBT) network.

Our comments focus on the changes proposed to the established derogation under Paragraph 5, point (c) of Entry 78 of Annex XVII of Regulation (EC) No 1907/2006 (REACH), which was adopted less than two years ago. The implementation of Entry 78 has already created significant compliance challenges for manufacturers and trade partners, due in part to the lack of clear guidance and the absence of a transitional period. For example, guidance was not available at the time of entry into force, and subsequent changes to that guidance further complicated compliance planning. Unfortunately, this newly proposed amendment by the European Union appears to exacerbate these issues and further frustrates the application of the current derogation. In response, we would like to raise the following specific concerns, which we believe represent barriers to trade:

- **The proposal includes no transitional period.** Following the hardship caused by the immediate applicability of Entry 78, it is surprising and concerning to see a similar approach repeated with this proposed amendment. The proposal applies only a 20-day implementation period after publication, at store shelf level. Products that have already been legally placed on the market — or are in transit to the EU — will be rendered non-compliant without warning and without a means for responsible economic

operators to adapt, even if the change were to have been clearly defined. This will result in significant and unnecessary disruption across the supply chain and may result in the destruction of safe and compliant products. This approach appears inconsistent with Article 2.12 of the WTO TBT Agreement, which requires Member States to allow a "reasonable interval" between publication and entry into force of technical regulations, so that producers—especially those in exporting countries—have sufficient time to adapt.

Further, compressed timelines for implementation lead to increased risks to consumers since responsible manufacturers who conform to the regulatory environment will be negatively affected by having to remove safe and compliant product from the market, at significant cost, while conversely, the opportunity widens for potential counterfeit and noncompliant products to fill the void in the marketplace.

- **Unclear scope and need for guidance.** The amendment introduces a new condition requiring the end use of certain products to have a "duration of one year or longer" for the derogation to apply¹. This terminology is unclear, without explanation as to how this duration should be defined or measured in practice, and only limited information as to the basis for the change. Many products, such as toys, are likely to be used or retained for more than a year, even if this is not the case for every instance of use for such product. Nor are examples provided of which products may fall inside or outside the scope of the derogation. Further, the proposed text does not clarify examples of concern "where the solid matrix is frequently removed or replaced". Conceptually, it is unclear where a solid matrix containing the synthetic polymer microparticles could even be "frequently removed or replaced" from a product.

This lack of clarity will make implementation extremely difficult for both enforcement authorities and businesses. In accordance with Article 2.9.2 of the TBT Agreement, sufficient information must be provided on the products to be covered by the proposed technical regulation, to enable stakeholders to assess the potential trade impact of a measure. At this stage, further clarification — ideally in the form of a staff working document or implementation guidance, with input from all stakeholders — is essential prior to any implementation of the proposed change and, it is our hope that this guidance will also provide the missing background and detail to support the basis for these changes.²

- **Proportionality and environmental impact.** The impact from this change would see safe derogated products immediately considered to be noncompliant and therefore having to be corrected all through the EU supply chain. Toys are not a significant contributor to the distribution of microplastics in the environment, and this revision, as presented, will require economic operators to reassess and revise products far beyond the intended effect, especially without clear guidance. With the continued uncertainty of the impacted product, this amendment would likely result in a widespread withdrawal and unnecessary disposal of many products across the EU market and supply chain. This will immediately create far more waste than the rule intends to prevent. This outcome raises questions about proportionality. The potential for negative environmental and trade impacts to outweigh the regulatory benefit could render the measure more trade-restrictive than necessary, in violation of TBT Article 2.2.

¹ European Commission - amending Annex XVII to Regulation (EC) No 1907/2006 - synthetic polymer microparticles – Website: https://members.wto.org/crnattachments/2025/TBT/EEC/25_06123_01_e.pdf - see point (2)

² European Commission - amending Annex XVII to Regulation (EC) No 1907/2006 - synthetic polymer microparticles – Text with EEA relevance - Website: https://members.wto.org/crnattachments/2025/TBT/EEC/25_06123_00_e.pdf, see item 4: "This derogation was not meant to apply to intended end uses of short duration, where the solid matrix is frequently removed or replaced, so that the incorporation of the synthetic polymer microparticles in the solid matrix is short-lived, because this would be contrary to the objective of emission minimisation."

- **Recommended Action.** We respectfully urge the European Commission to consider the following actions to mitigate the unintended trade and environmental consequences of this amendment:
 1. Postpone the adoption of the changes to Paragraph 5, point (c) until the scope of the derogation has been clearly defined. This could be supported by the publication of a staff working document including examples of affected and unaffected products, which can then form the basis for formal implementation guidance.
 2. Introduce a suitable transitional period — for example, a period of two years — ensuring that the amendment applies only to products first placed on the market after that period.

Additionally, we acknowledge that other elements of the amendment — particularly the clarifications related to medicinal products, veterinary medicinal products, and product and process-oriented research and development — may be needed urgently. As a practical solution, we propose that the proposed amendment prioritize only those elements, while the revision to Paragraph 5(c) is deferred until further clarification is available.

Conclusion

The Toy Association is grateful for the opportunity to provide comment and to share our concerns related to the European Union's proposed changes to the existing derogation, which we fear will create confusion across industry, lead to disruptions within the supply chain and introduce unintended consequences for the marketplace and environment, as described herein. As such, we respectfully request that the Commission reconsider its proposal, to allow for clarification and a suitable transition period. Should you have any questions regarding our concerns, please do not hesitate to contact me or my colleague Joan Lawrence. I can be reached at jhuxley@toyassociation.org, and Ms. Lawrence can be reached at jlawrence@toyassociation.org.

Sincerely,



Jos Huxley
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The Toy Association
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About The Toy Association and the toy industry:

The Toy Association is the North American based trade association; our membership includes more than 900+ 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.

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 protect 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.