



The European Commission  
Brussels, Belgium

**Via US TBT Inquiry Point**

April xx, 2020

Re: Comments from the Toy Association Regarding The European Union's Reply to U.S. Government and Industry Comments on Notification G/TBT/EU/629 on the Draft Commission Regulation Amending, for the Purposes of Its Adaptation to Technical and Scientific Progress, Regulation (EC) No. 1272/2008

Dear Sir/Madam:

We are writing in response to the European Union's ("EU") March 6, 2020 reply to comments it received from the United States and U.S. industry groups regarding notification G/TBT/EU/629 on the Draft Commission Regulation Amending, for the Purposes of Its Adaptation to Technical and Scientific Progress, Regulation (EC) No. 1272/2008 of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures and Correcting Commission Regulation (EU) 2018/669 ("the CLP regulation"). We understand that the regulation was adopted on October 4, 2019 and is expected to go into effect in October 2021.

The Toy Association and the North American toy industry recognize and support the EU's priority of ensuring that consumers have access to toys of the highest quality while safeguarding human health and safety against potential hazards such as those presented by the unsafe use of titanium dioxide. In fact, The Toy Association and the North American toy industry have been global leaders in toy safety for decades. The Toy Association continues to work with medical experts, governments, consumers, and industry to provide technical input to ensure that toy safety standards keep pace with innovation and potential emerging issues.

We would like to thank the EU for considering and responding to comments from U.S. industry groups, including those of The Toy Association. We appreciate the EU's clarification of the scope of the CLP regulation's provisions related to titanium dioxide and its likely impact on imported toys. However, we do not believe that our concerns were adequately addressed. We continue to believe the EU's titanium dioxide provisions of Annex II, Clause III(3) of the revised Toy Safety Directive, 2009/48/EC ("TSD CMR Restriction") are unwarranted, inconsistent with international safety standards, and are a violation of the EU's obligations with regard to Technical Barriers to Trade, as they are only

tenuously related to product safety and more stringent than required to accomplish their intended purpose. The provisions will also create unnecessary and costly trade and market interruptions, as discussed below.

We appreciate that the EU has clarified that classification as a category 2 carcinogen under the European Commission's Toy Safety Directive does not prohibit the use of titanium dioxide in toys under certain conditions, in particular, in concentrations equal to or smaller than 1%, or if they are inaccessible to children in any form, including through inhalation, when the toy is used as intended or in a foreseeable way, bearing in mind the behavior of children, or if their use, following an evaluation by the relevant Scientific Committee, is found to be safe, in particular in view of exposure, and is permitted by a Commission Decision. However, the TSD CMR Restriction would apply this content limit to liquid and solid mixtures where no potential for inhalation exists. We therefore urge a derogation from this limit for such toys.

We further recognize that even if a derogation is issued, the CLP regulation requires certain packaging and labeling warnings on toys with titanium dioxide in powder form containing 1% or more of respirable particles (with aerodynamic diameter equal to or smaller than 10  $\mu\text{m}$ ) and or with mixtures in powder form containing 1% or more of titanium dioxide that is in the form of or incorporated in particles with aerodynamic diameter  $\leq 10 \mu\text{m}$ . We also understand that liquid mixtures (e.g. play cosmetics such as viscous makeup) as well as solid mixtures, presumably such as in clay and slime, will require a mandatory warning label although they are not subject to classification. This will of course concern and confuse consumers and negatively impact retail sales, because of and despite the lack of any risk of inhalation.

While we recognize that it is possible that some uses of titanium dioxide could present a risk to health, such as in the case of respirable small particles, the potential risk of titanium dioxide in toys is exceedingly remote, and we believe the restrictions on toys are an unintended consequence of what may well be an appropriate action for such consumer products. This inert mineral has widespread safe uses, including in paints, coatings, printing inks, plastics, cosmetics, food-and feedstuffs, textiles, rubber and pharmaceuticals. In toy manufacturing, titanium dioxide is typically used in plastics, rubber, paints, clays, slimes, and coatings. There is no reasonable risk of inhalation with such uses, and there is no sound scientific basis to regard the use of titanium dioxide as hazardous in such applications. For this reason, we continue to believe that the Toy Safety Directive's regulation of titanium dioxide as a category 2 carcinogen when used as in the toy industry does not advance consumer health or safety. As such, the Toy Safety Directive's inclusion of titanium dioxide as a category 2 carcinogen remains more stringent than necessary to accomplish its intended purpose, which we reiterate is a violation of the EU's WTO obligations regarding Technical Barriers to Trade.

Furthermore, the CLP regulation's requirement that toys containing more than 1% titanium dioxide product labeling include safety warnings is unnecessary and out of proportion to any potential risk posed by the substance. Titanium dioxide as used in toy manufacture is generally used in viscous liquid or solid forms and is not respirable in such forms. The requirement to label toys with a warning of potential carcinogenicity would not enhance public safety because titanium dioxide cannot be inhaled when used in paints, clays, or as otherwise used in the toy industry and thus the potential risks of inhalation in such uses (certainly not to the point of lung overload, the EU's postulated mechanism of action to initiate carcinogenicity) are exceedingly remote. The use of warning labels in a case when there is minimal, if any, foreseeable risk can have the effect of diminishing the effectiveness of product label warnings in general, diverting from serious and significant risks.



Inspiring Generations of Play

1200 G Street NW • Suite 200 • Washington, DC 20005  
t. 202.459.0353 • e. [info@toyassociation.org](mailto:info@toyassociation.org)

Finally, we note that the CLP regulation labeling requirement is inconsistent with international standards on classification and labeling schemes such as the UN Globally Harmonized System, which does not provide for the labeling of titanium dioxide in a fashion provided for by the CLP regulation. For all the foregoing reasons, this labeling requirement must not be applied to such toys.

We appreciate the opportunity to provide our comments to the EU's reply and the EU's consideration of them on this important issue. Please do not hesitate to contact me if you should have questions or would like further information from me. I can be reached at [akaufman@toyassociation.org](mailto:akaufman@toyassociation.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Alan P. Kaufman", with a long horizontal flourish extending to the right.

Alan P. Kaufman  
Senior Vice President, Technical Affairs