



February 9, 2019

United States Technical Barriers to Trade Enquiry Point  
Standards Coordination Office (SCO)  
National Institute of Standards and Technology (NIST)

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**Re: 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;  
Reference: G/TBT/N/EU/629**

To Whom It May Concern:

The American Chemistry Council's Titanium Dioxide Stewardship Council (TDSC)<sup>1</sup> is pleased to provide these comments on the EC's World Trade Organization (WTO) Technical Barriers to Trade (TBT) notification of December 12, 2018 regarding proposed updates to the classification, labeling, and packaging (CLP) of substances of mixtures. Among the many updates in the proposed regulation is a provision to list titanium dioxide (TiO<sub>2</sub>) as a Class 2 carcinogen by inhalation.

TiO<sub>2</sub> is a naturally occurring, highly versatile white pigment used to confer brightness, opacity, and protection from damage caused by ultraviolet light in a wide array of applications, including paints, sunscreen, cosmetics, food, paper, plastics, and pharmaceuticals. U.S. producers directly export significant amounts of TiO<sub>2</sub> to the EU each year. For instance, over the last decade U.S. producers of TiO<sub>2</sub> have exported, on average, approximately 185,000 metric tons per year to the EU. With historical prices averaging over \$2,000 per metric ton, that amounts to at least \$370 million of annual exports that could be subject to the impacts of this proposed regulation. In addition, TiO<sub>2</sub> is a key component in cosmetics, paints and coatings, plastics and other products that are exported to the EU. The potential harm to those industries may significantly raise the annual trade impact to the U.S. For example, in 2016 the U.S. exported \$2.9 billion worth of cosmetics to the EU.

TDSC opposes the proposed classification for TiO<sub>2</sub> on the basis that it is disproportionate to the potential for harm from the substance. ECHA's Risk Assessment Committee (RAC) articulated significant questions in relation to the science underpinning the proposal, and there is

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<sup>1</sup> The members of TDSC are the Chemours Company, Cristal, KRONOS Worldwide, Tronox Limited, and Venator Materials.



no evidence that TiO<sub>2</sub> causes cancer in humans. TDSC believes the unjustified classification would create significant, unjustified technical barriers for imports of TiO<sub>2</sub> and TiO<sub>2</sub>-containing products to the EU. The proposal would create a detrimental precedent for treatment of other poorly soluble, low toxicity particulate substances (PSLTs) under the CLP regulatory framework. TDSC believes the proposal for TiO<sub>2</sub> classification should be withdrawn until other alternatives put forward by EU Member States are given thorough consideration. Our concerns are described in more detail below.

**1. The proposed classification would raise unjustified barriers to trade in products containing TiO<sub>2</sub>.** The proposed classification could be interpreted as automatically triggering provisions in other EU legislation restricting the use of TiO<sub>2</sub> in products, irrespective of the route of exposure. Specifically, TiO<sub>2</sub> could automatically be banned in the EU from its use in food contact materials, pharmaceuticals, cosmetics, and toys, even though the route of exposure the proposed classification seeks to address (inhalation) is not present. Restrictions on the use of TiO<sub>2</sub> in products where it cannot be inhaled are clearly unjustified barriers to trade. Furthermore, companies who make potentially affected products should not be burdened by the costly and time consuming process of seeking an exemption when the inhalation concern does not apply. In addition, the impacts of the proposed classification could disproportionately impact countries that export significant quantities of the affected goods to the EU.

**2. The proposed classification could set an inappropriate and unsupported precedent for classification and labeling of other particulate substances and could raise similar trade barriers.** TDSC believes the proposed regulation is inconsistent with the mandate of the CLP regulation, which is to focus on hazard properties intrinsic to a substance. Indeed, the hazard concern for TiO<sub>2</sub> is neither intrinsic nor unique to TiO<sub>2</sub>. It can apply to PSLTs more broadly. If applied consistently, all PSLTs would be classified the same way, which would raise additional barriers to trade in the form of unwarranted restrictions on products exported to the EU. Alternatively, if the proposed regulation is not applied to other PSLTs, TiO<sub>2</sub> would receive discriminatory treatment compared to potential TiO<sub>2</sub> alternatives, even though they are PSLTs as well. As described below, TDSC believes there are multiple potentially viable alternatives available that avoid these foreseeable complications.

**3. Regulatory measures are available to address the potential concerns without affecting trade.** The parties to the regulatory assessment of TiO<sub>2</sub> agreed that the relevant concern relates to occupational health and safety. The European Commission's TiO<sub>2</sub> technical meeting on April 23, 2018 concluded that concerns for consumers are negligible as it is unrealistic that consumers are exposed to the suspected inhalation hazard for powdered TiO<sub>2</sub>.<sup>2</sup>

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<sup>2</sup> "TiO<sub>2</sub> classification is mainly relevant in a worker environment. The risk for consumers is negligible given the very high levels of exposure that would be required, which are unrealistic under normal and foreseeable conditions." See minutes of the April 23, 2018 meeting as reported in *27th Meeting of Competent Authorities for REACH and CLP (CARACAL)*, CLP Open Session, June 12, 2018. Doc. CA/45/2018. The Commission clarifies that the conclusions were those of the participants in the April meeting, not the official conclusion of the Commission.

TDSC believes that the EC should more thoroughly explore proposed alternative regulatory options that, as we currently understand them, would address the occupational hazard concern without creating unnecessary barriers to trade. Such proposed alternatives include:

1. A proposal from Germany that would seek to find a harmonized approach to PSLTs with a focus on harmonized occupational safety and health legislation in Member States;
2. A joint U.K.-Slovenia proposal that would seek to use Annex II of the CLP to address particle toxicity shared by all PSLTs; and
3. The EC process of developing occupational health and safety measures for TiO<sub>2</sub> under the EU Directive on Chemical Agents at Work, which has already begun.

TDSC requests that the United States raise these concerns about the impacts of the proposed classification of TiO<sub>2</sub> with the EC and the EU Member States. The current proposal presents unnecessary and unwarranted trade restrictions in view of potentially more effective and proportionate regulatory alternatives. The EU should remove TiO<sub>2</sub> from the proposed regulation and more fully clarify legal and regulatory questions about the impacts of the proposed classification on affected sectors. In addition, the EU should give full consideration of the proposed alternatives. The alternatives are far less likely to be trade restrictive and could provide a more coherent European approach to the broader issue of managing exposure to PSLTs in dust.

Thank you for your consideration of these comments. Please feel free to contact me if you have any questions ([REDACTED]@americanchemistry.com).

Sincerely,

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[REDACTED], Chemical Products and Technology