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Page: 1/2

Committee on Technical Barriers to Trade

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EUROPEAN UNION – TITANIUM DIOXIDE: REGULATION (EC) NO 1272/2008 (CLP REGULATION), ANNEX VI, PART 2

STATEMENT BY THE EUROPEAN UNION TO THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE
13 – 15 NOVEMBER 2019

The following communication, dated 13 November 2019, is being circulated at the request of the delegation of the European Union.

1. And thank you to the Delegations of the United States, Mexico, Canada, the Russian Federation, Australia, Japan and New Zealand for their comments on the draft Regulation on hazard classification of several substances, including cobalt and titanium dioxide, amending the EU Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation).

2. Titanium dioxide and cobalt have been included in the 2018 Adaptation to Technical and scientific Progress (ATP) amending the CLP Regulation. Several discussions on the classification of cobalt and TiO₂ and the classification of mixtures containing TiO₂ have taken place in the expert group for REACH and CLP ("CARACAL") and in the regulatory committee (the REACH Committee). In addition, a full-day meeting of the CARACAL SubGroup was organised, dedicated to a discussion of the classification of TiO₂. A draft Commission Regulation was discussed in the REACH Committee of February and March 2019. Taking into account the upcoming change of the legal procedure for the adoption of amendments to the CLP Regulation, the 14th ATP to CLP was adopted by the Commission on the 4 October 2019. The Council and the European Parliament will have two months objection period following the adoption and transmission of the measure. The proposed classification of cobalt and TiO₂ is based on the Risk Assessment Committee's (i.e., RAC, one of the scientific committees of the European Chemicals Agency) opinion as well as on the comments received and concerns expressed by the Member States and stakeholders.

3. With regard to TiO₂, only the respirable particles of TiO₂ (diameter smaller than 10 µm) will be classified as suspected carcinogen. In addition, the introduction of a note is proposed to limit the classification of mixtures to the ones placed on the market in powder form with a diameter smaller than 10 µm and if they contain 1% or more of such small TiO₂ particles. Liquid mixtures (e.g. paints) as well as solid mixtures will not have to be classified. For such non-classified mixtures, the addition of a sentence on the label is proposed: 'Warning! Hazardous respirable droplets/dust may be formed when sprayed/used. Do not breathe spray or mist/dust).

4. The downstream legal consequences of the classification of TiO₂ as a carcinogen Category 2 remain limited in our view. The most significant consequences occur for substances classified as carcinogen category 1, rather than category 2. Substances classified as carcinogens category 1 are normally directly banned in cosmetics, toys, pesticides and REACH for consumer uses. However, for carcinogens category 2, there are no such significant direct consequences. More specifically, with regard to the legislation on plant protection products, biocidal products, food additives, contaminants, water and pharmaceuticals, there would be no or minor consequences. Regarding other legislation, the use of TiO₂ could continue under certain conditions (e.g. granting of authorisation, exemption, demonstration of safe use): this is the case for food contact materials, plastic food contact materials, toys, feed additives, cosmetics and EU Ecolabel. Finally, waste containing TiO₂ would be classified as hazardous only if it was in powder form and TiO₂ exceeded

the above-mentioned concentration limit, so that the impact under waste legislation would also be limited.

5. With regard to cobalt, the Commission believes that the classification as carcinogen for all routes of exposure as advised by RAC is in line with the CLP Regulation as well as the UN GHS (UN Globally Harmonized System of Classification and Labelling of Chemicals). However, the Commission considered that the method that was used to determine the Specific Concentration Limit of 0.01% should be assessed in order to discuss if the method is relevant for inorganic compounds like TiO₂. The proposed entry in Annex VI to CLP for cobalt is without such specific limit and the generic limit of 0.1% will therefore be applied.

6. The EU would like to reassure the TBT Committee that all comments sent by WTO Members have been distributed to Member States and they have been and will be duly taken into account by the Commission and Member States in the decision-making process for the formal adoption of a RAC opinion. Finally, the EU would like to stress that ECHA's RAC committee took into account in its scientific assessment all available data, including the information submitted during the public consultation period. Review of a RAC opinion is only possible if new scientific information is available.
