

## **25th Meeting of Competent Authorities for REACH and CLP**

### ***TDMA position on agenda item “Classification of TiO<sub>2</sub> and mixtures containing TiO<sub>2</sub>”***

#### **Introduction**

The manufacturers of Titanium Dioxide are grateful that the Commission has tabled this item on the agenda of the 25th Meeting of Competent Authorities for REACH and CLP, next 16 November 2017.

Last 14 September, the Committee for Risk Assessment (RAC) adopted its opinion on TiO<sub>2</sub>, recommending its classification as Category 2 - Suspected Carcinogen, by inhalation.

Ahead of this meeting, the Titanium Dioxide Manufacturers Association (TDMA) wanted to share its views on the challenges brought by the recommended classification of TiO<sub>2</sub> as suspected carcinogen by inhalation (cat. 2) and share a number of possible ways forward.

#### **Economic, environmental and regulatory impacts without any improvements to human health**

In our view, classifying TiO<sub>2</sub> as suspected carcinogen by inhalation (cat. 2) will have broad economic, environmental and regulatory impacts, while not improving the safety of European workers and consumers.

It would affect the jobs of millions of workers in Europe and beyond, in a wide range of industry sectors from paper, plastics, paints, cosmetics and automotive. It would threaten the billions of euros of value added to the EEA, across the industries using TiO<sub>2</sub> in their products.

These adverse socio-economic impacts would be highly disproportionate as the recommended classification is not expected to enhance human health benefits to consumers—who do not interact with inhalable forms of TiO<sub>2</sub>, or further protect workers - who are already protected by existing PPE measures.

Beyond socio-economic impact, it would heavily impact on EU wider policy objectives that the EU is promoting, notably a circular economy as many waste streams containing more than 1% TiO<sub>2</sub> would be deemed hazardous.

#### **Broader impact beyond TiO<sub>2</sub>**

This recommended classification of TiO<sub>2</sub> as suspected carcinogen by inhalation (cat. 2) has broad impact beyond the regulation of TiO<sub>2</sub>, as stated in the RAC opinion:

“RAC acknowledges that the carcinogenicity profile described for TiO<sub>2</sub> is not exclusively characteristic for TiO<sub>2</sub> but applies to a group of chemicals with similar toxicity profile addressed as “poorly soluble low toxicity particle”. The CLH report and this RAC Opinion concentrates on TiO<sub>2</sub> data and do not fully consider the data for other PSLT substances”.  
(see page 41, para 5)

Indeed, the effect seen with TiO<sub>2</sub> is not unique to this particular substance but is because TiO<sub>2</sub> is a dust, or “poorly soluble, low toxicity” substance (PSLT). The recommended classification of TiO<sub>2</sub> as suspected carcinogen by inhalation (cat. 2) therefore sets a precedent and may have regulatory consequences on other common particulate substances in the EU.

This raises questions about the suitability and appropriateness of CLH for addressing such a broad class of substances justly.

Attached you will find an executive summary of the expected socio-economic impacts of a harmonised classification of  $\text{TiO}_2$ <sup>1</sup> as suspected carcinogen by inhalation (cat. 2). The full report is available upon request.

#### **TDMA proposal**

In light of the broader issues described above, TDMA would like to put forward the following proposals:

1. A Working Group of Member States, ECHA, the Commission, NGO and industry experts to consider the appropriate mechanism for any regulation of PSLTs.
2. An interim derogation on the labelling requirement, should the RAC opinion be incorporated to the ATP before any outcomes of the PSLT working group or CoRAP review (on 2018 work programme) are available.
3. Undertake a Better Regulation Public Consultation for the European Commission and other interested stakeholders to better understand the real world implications of any decision before they are taken. There is ample precedent with the European Commission routinely undertaking such public consultations on Annex XIV listing of substances after the formal ECHA stage. For example, see Public Consultation of 16 September 2016 [here](#).
4. Pause the entry of  $\text{TiO}_2$  into ATP while considering steps 1, 2 and 3

In parallel, the members of TDMA have embarked on a 14m Euro science programme with the objective to answer remaining questions on our substance, including discussions on questions related to all forms of  $\text{TiO}_2$ , including surface treated nanoforms.

**END**

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<sup>1</sup> Draft final report prepared for the Titanium Dioxide Industry Consortium, 27 October 2017