



EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate B - Circular Economy & Green Growth
Director

 Ref. Ares(2019)37356 - 07/01/2019

DIRECTORATE-GENERAL
INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Directorate D- Consumer, Environmental and Health Technologies
Director

Brussels,
ENV.B.2/Ares(2018)

Mr Jan van der Meulen, Managing Director, CEPE
Mr Alexandre Dangis, EuPC
Dr Roger Doome, Secretary General, IMA-Europe
Mr Philip Bruce, Managing Director, FEICA
Mr John Dixon, Director Regulatory Affairs, FPE
Mr Gustavo Gonzalez-Quijano Secretary General, COTANCE
Ms Beatrice Klose, Secretary General, INTERGRAF
Dr Martin Kanert, Executive Manager, EuPIA
Mr Antonio Caballero González, General Secretary, EMO
Mr Mauro Scalia, Director Sustainable Businesses, EURATEX
Dr Alberto Arnavas, Director General, EFCC
Ms Patrizia di Mauro, Secretary General, UNIEP
Mr Bjoern-Markus Sude, Director, I&P Europe
Ms Susan Hancock, Secretary General, ATIEL
Dr Wilhelm Rauch, Business Manager, IVC

Dear Madam,
Dear Sir,

Thank you for your letter of 29 November 2018 regarding the harmonised classification of titanium dioxide (TiO₂) and its downstream consequences. Commissioners Vella and Bieńkowska have asked us to reply on their behalf.

In September 2017, the Risk Assessment Committee of the European Chemicals Agency (ECHA) concluded that TiO₂ should be classified as a substance suspected of causing cancer by inhalation. This is in line with the conclusion of the International Agency for Research on Cancer (IARC), a World Health Organisation agency, which categorised TiO₂ as “possibly carcinogenic to humans”.

We are well aware of the concerns raised by the industrial sectors producing or using TiO₂. For that reason, the Commission services concerned have dedicated ample time to the discussion of the matter with Member States and stakeholders in several meetings since November 2017, among which a dedicated meeting of experts on 23 April 2018 to discuss the matter in more detail. During that meeting, the opinion of ECHA’s Risk Assessment

Committee (RAC) was largely supported. In addition, the question of the scope of the CLP Regulation (EC) No 1272/2008 and whether particles of poor solubility and low toxicity (PSLT) – such as TiO₂ – and particle toxicity should be covered under that Regulation was discussed at length. The outcome was that particle toxicity can be considered an intrinsic property and should be considered as such under the CLP Regulation. As RAC only assessed TiO₂ particles, the harmonised classification only applies to TiO₂. This is without prejudice to the other poorly soluble low toxicity (PSLT) particles which may exhibit similar properties but in line with the CLP Regulation remain subject to self-classification.

The Commission is committed to ensuring a high level of protection of human health, as this is one of the objectives of the CLP Regulation. The Commission services are fully aware of the proposal made by some Member States to only address the issue under the workers protection legislation. However, as you know, TiO₂ is not only used in an industrial context but consumers and professional workers can also be exposed to that substance. Therefore, the Commission believes that the CLP Regulation is the relevant legal instrument to address the overall human health concern related to TiO₂ that can be complemented by specific legislation like workers protection legislation or product specific legislation, such as for cosmetic products.

The most recent discussion with stakeholders took place at a meeting with the Member States competent authorities (CARACAL meeting) on 12 June 2018, where – following the above mentioned expert meeting in April 2018 – the Commission services concerned presented a draft text to include TiO₂ in Annex VI to the CLP Regulation. For mixtures, this draft limited the classification to those mixtures containing TiO₂ and placed on the market in the form of a powder. This would significantly limit the number of mixtures to be labelled. The draft also contained provisions on information to consumers in particular on the hazard properties of some dusts or droplets that may be emitted under specific conditions of use of mixtures containing TiO₂ (*e.g.* spray application of paints).

Following these considerations, the Commission services are preparing the follow-up, taking into account the comments received following the June CARACAL meeting and the September REACH Committee meeting. In December 2018, the REACH Committee has discussed a draft Regulation amending the CLP Regulation for the purposes of its adaptation to technical and scientific progress. Further discussion on the harmonised classification of TiO₂ has taken place in that framework. It is expected that the REACH Committee will vote on the Draft Regulation in February 2019.

We would like to remind you that under the Cosmetics Regulation (see Commission Regulation (EU) 2016/1143), the use of small particles of TiO₂ in cosmetics is restricted as their use in spray products cannot be considered safe for the consumers.

Please note that the classification process set out in the CLP Regulation is purely hazard based. If following such hazard assessment it is concluded that a substance is carcinogenic, it should be classified as such. Downstream legal or socio-economic considerations are not part of that process. They should be considered in the framework of the various downstream legislations. However, please note that harmonised classification as carcinogenic Category 2 by inhalation, as proposed by RAC, will normally not lead to automatic bans under downstream legislation (contrary to a harmonised classification as Carcinogenic Category 1A or 1B in some cases).

Regarding downstream consequences of the possible classification on waste, please note that the Commission services are looking into the possibilities to mitigate any unwanted and unjustified consequences under the waste legislation.

Yours sincerely,

Kęstutis Sadauskas
Director
DG Environment

Carlo Pettinelli
Director
DG Internal Market, Industry,
Entrepreneurship and SMEs