



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

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

Brussels,  
ENV.B.2/Ares(2019)

[REDACTED]  
Association of the Chemical Industry of the Czech Republic

Dear [REDACTED]

Thank you for your letter of 21 February 2019 regarding the harmonised classification of titanium dioxide (TiO<sub>2</sub>) and the 14<sup>th</sup> adaptation to technical progress (ATP) of the Classification and Labelling (CLP) Regulation. Commissioner Jourová has asked us to reply on her behalf. Please accept our apologies for the delay in replying to you.

In September 2017, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) concluded that TiO<sub>2</sub> 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 TiO<sub>2</sub> as “possibly carcinogenic to humans”.

We are well aware of the concerns raised by Member States and the industrial sectors producing or using TiO<sub>2</sub>. 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. It was observed during those meetings that the opinion of RAC was largely supported. Taking into account the comments received following the June 2018 meeting with the Member State competent authorities (CARACAL meeting) and the September and December 2018 REACH Committee meetings, in February and March 2019 the REACH Committee discussed a draft Commission Regulation amending the CLP Regulation for the purposes of its adaptation to technical and scientific progress, which included TiO<sub>2</sub>. In view of the upcoming entry into force of the alignment Omnibus Regulation, the Commission will continue the discussion in the framework of the CARACAL meeting, before deciding on the adoption of a draft Commission Delegated Regulation.

Moreover, the Commission services are fully aware of the proposals made by different stakeholders and Member States, including the Czech Republic, to only address the issue under the workers protection legislation, through the establishment of EU occupational exposure limits (OELs). However, the concerns with TiO<sub>2</sub> - although mainly, but not

exclusively, a workers protection issue - pertain also to consumers, and, importantly, to the self-employed, where occupational health and safety (OSH) legislation is not applicable and where CLP would provide the necessary information to initiate the necessary actions to ensure protection. It is important to know that CLP provides information on hazardous properties of substances and mixtures and on basic safety measures to be taken (e.g. wear gloves) while other pieces of legislations (e.g. REACH, OSH) provide more detailed risk management measures to deal with specific hazard properties identified under CLP. Harmonised classification and labelling according to CLP not only has a direct effect on workers, self-employed professionals and consumers, it also has an indirect effect as it is the basis for the development, in particular by industry, of more detailed or case-specific risk management measures under REACH and OSH. Therefore, the Commission believes that the CLP Regulation is the relevant legal instrument to address the overall human health concern related to TiO<sub>2</sub> that can be complemented by more specific legislation, including workers protection legislation.

Yours sincerely,

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