



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

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Thank you for your letter of 25 September 2019 regarding the harmonised classification of titanium dioxide (TiO<sub>2</sub>) and the 14<sup>th</sup> adaptation to technical and scientific progress (ATP) of the Classification, Labelling and Packaging (CLP) Regulation. Your letter to Commissioner Jourová was forwarded to Commissioner Vella, within whose competence the subject matter of your letter falls, who has asked me to reply on his behalf.

In the first place, please kindly note that the 14th ATP to the CLP Regulation was already adopted on 4 October. Following the entry into force of the alignment Omnibus Regulation (Regulation (EU) 2019/1243) on 26 July, the form of the draft act changed from 'Commission Regulation' subject to the Regulatory Procedure with Scrutiny, to 'Commission Delegated Regulation'. This legal act was presented for a final consultation at the meeting of Competent Authorities on REACH and CLP (CARACAL) on 18 September, as you also mention in your letter. Based on that consultation, as well as on all previously received comments, including TBT comments, the Commission concluded that the proposed classification is the most balanced one and proceeded with the adoption of the Commission Delegated Regulation.

Please also note that 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 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 scientific opinion by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA), which had concluded that TiO<sub>2</sub> should be classified as a substance suspected of causing cancer (carcinogenic Category 2) by inhalation, 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, the REACH Committee discussed the draft Commission Regulation in February and March 2019.

Moreover, with regard to your concern that TiO<sub>2</sub> classification will have negative effects on the European chemical industry and the circular economy, please note that the classification under CLP does not entail in itself any automatic restriction or banning of products containing TiO<sub>2</sub>. Thus, when a substance is subject to harmonised classification only labelling and packaging obligations are triggered. It is not excluded that the classification of substances according to CLP may have consequences on other legislation (e.g. product specific legislation). However, as the CLP classification is based only on a scientific assessment of the hazardous properties of a substance, those potential consequences cannot be addressed under the CLP but must be addressed under those other pieces of legislation. It should also be emphasised that the most significant consequences occur for substances classified as carcinogen category 1, rather than category 2.

In addition, regarding the impact assessment to which you refer in your letter, please note that the Commission considers that such impact assessment is not necessary, either in the framework of the harmonisation of classification in general or in the context of the 14th ATP in particular. The CLP Regulation does not stipulate any obligation to perform an impact assessment in the process of harmonised classification according to Article 37 of the Regulation. More importantly, and regardless of any such obligation, it is considered that the benchmark criterion of 'significant impacts', which is normally required for an impact assessment to take place, is not relevant for the harmonised classification of substances under the CLP Regulation. Indeed, the impacts in CLP Regulation of a new classification are related mainly to labelling and packaging. Thus, as previously mentioned, when deciding on the harmonised classification of a substance, any decision on harmonised classification should solely rely on the hazardous properties of the substance, in line with the nature and the spirit of the CLP Regulation, and not on the assessment of any potential impacts in other legislation. Such potential downstream consequences of classification should be assessed in the corresponding pieces of legislation or they are considered to have been assessed when those pieces of legislation were adopted.

Finally, 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,

*(e-signed)*  
Kęstutis Sadauskas

