

**REPLY FROM THE EUROPEAN UNION TO THE COMMENTS RECEIVED FROM  
AUSTRALIA REGARDING NOTIFICATION**

**G/TBT/N/EU/629**

**DRAFT COMMISSION REGULATION AMENDING, FOR THE PURPOSES OF ITS  
ADAPTATION TO TECHNICAL AND SCIENTIFIC PROGRESS, REGULATION (EC) No  
1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON  
CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES  
AND CORRECTING COMMISSION REGULATION (EU) 2018/669**

The European Union (EU) would like to thank the Australian authorities for their comments on the 'Draft Commission Regulation amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2018/669' concerning the 14<sup>th</sup> adaptation to technical and scientific progress ('ATP') of the Classification, Labelling and Packaging ('CLP') Regulation<sup>1</sup>.

The EU would like to inform the Australian authorities that the 14<sup>th</sup> ATP of the CLP Regulation was adopted on 4 October 2019. Following the entry into force of the alignment Omnibus Regulation (Regulation (EU) 2019/1243<sup>2</sup>) on 26 July 2019, the form of the notified draft legal act changed from 'Commission Regulation' subject to the Regulatory Procedure with Scrutiny to 'Commission Delegated Regulation'. This draft legal act was presented for a final consultation at the meeting of Competent Authorities on REACH<sup>3</sup> and CLP (CARACAL) on 18 September 2019. Based on that consultation, as well as on all previously received comments, including TBT comments, the EU concluded that the proposed classification is the most balanced one and adopted the Commission Delegated Regulation.

Please note the following, with regard to the issues that were raised in the above-mentioned comments:

With regard to the claim that the classification may create unnecessary obstacles to international trade for TiO<sub>2</sub> and for products containing TiO<sub>2</sub>, please note that the

---

<sup>1</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1), available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R1272-20191201>

<sup>2</sup> Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (OJ L 198, 25.7.2019, p. 241), available at <https://eur-lex.europa.eu/eli/reg/2019/1243/oj>.

<sup>3</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1), available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20191030>

classification of TiO<sub>2</sub> under the CLP Regulation does not in itself restrict the placing on the market of TiO<sub>2</sub>-containing products. When a substance is subject to harmonised classification, labelling and packaging obligations are triggered.

It is not excluded that the classification of substances according to the CLP Regulation 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 Regulation but must be addressed under those other pieces of legislation, which often take into account harmonised classification according to the CLP Regulation in the framework of a risk assessment. It is to be noted that the most significant consequences occur for substances classified as carcinogenic category 1, rather than category 2.

Thus, whether and to which extent a product will be affected by the harmonised classification and labelling of TiO<sub>2</sub> according to the CLP Regulation will depend, first, on the type of product. Classification and labelling applies to substances and mixtures only, not to articles.

Moreover, it is only the respirable particles of TiO<sub>2</sub> (with an aerodynamic diameter equal to or smaller than 10 µm) that will be classified as suspected carcinogens. Classification in the case of a mixture will depend on the latter's content, i.e. it will be classified only if it is in powder form and contains 1% or more of TiO<sub>2</sub> particles with an aerodynamic diameter equal to or smaller than 10 µm. Liquid mixtures (e.g. paints) as well as solid mixtures will not have to be classified, but only the addition of a warning on the label will be mandatory. That labelling obligation has been considered necessary, as liquid and solid mixtures, which do not fulfil the criteria for classification, may still display hazards similar to the hazards of classified mixtures when they are in a specific form (droplets or dust).

Please note also that the CLP Regulation provides that if, following a hazard assessment, it is concluded that a substance is carcinogenic, it shall 'normally be subject to harmonised classification and labelling'. 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 (carcinogenic Category 2) 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'.

Moreover, please note that the EU is fully aware of and has assessed proposals that were made by different stakeholders to address the issue under workers' protection legislation, through the establishment of EU harmonised occupational exposure limits (OELs). While the concerns with TiO<sub>2</sub> are mainly a workers' protection issue, they are not exclusively so, since they also pertain to consumers and, importantly, to the self-employed, who are not covered by occupational health and safety legislation and for whom the CLP Regulation would provide the necessary information to initiate any actions needed to ensure protection. Therefore, the EU is of the opinion that the CLP Regulation is the relevant legal instrument to address the overall human health concerns related to TiO<sub>2</sub> that can be complemented by more specific legislation, including workers' protection legislation.

For all the above mentioned reasons, the EU considers that the harmonised classification of TiO<sub>2</sub> contained in the above-mentioned ATP is fully justified, proportionate and not trade restrictive.

Following its adoption on 4 October 2019, the 14<sup>th</sup> ATP of the CLP Regulation was published in the Official Journal of the European Union of 18 February 2020<sup>4</sup> and entered into force 20 days after its publication. It will be applicable as of 1 October 2021<sup>5</sup> but may be applied as of the entry into force on a voluntary basis.

The EU would like to thank the Australian authorities once again for providing comments on the notified draft and hopes that the responses conveyed sufficiently clarify the issues raised.

\*\*\*

---

<sup>4</sup> Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation (OJ L 44, 18.2.2020, p. 1), <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1586275372795&uri=CELEX:32020R0217>

<sup>5</sup> Corrigendum to Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation (Official Journal of the European Union of L 44 of 18 February 2020) (OJ L 51, 25.2.2020, p. 13), <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1586275372795&uri=CELEX:02020R0217-20200218>