REPLY FROM THE EUROPEAN UNION TO THE COMMENTS RECEIVED FROM NEW ZEALAND 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 New Zealand authorities for their comments submitted to the EU TBT Enquiry Point, concerning the 14th adaptation to technical and scientific progress ('ATP') of the Classification, Labelling and Packaging ('CLP') Regulation[1].

The EU would like to inform the New Zealand authorities that the 14th 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[2]) on 26 July 2019, the form of the notified draft 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[3] 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. This act was published in the Official Journal of 18 February 2020[4] and entered into force 20 days after its publication. It will be applicable as of 1 October 2021[5] but may be applied as of the entry into force on a voluntary basis.

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[1] 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.

[2] 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.

[3] 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.

[4] 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), available at https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1586275372795&uri=CELEX:32020R0217

[5] 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), available at https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1586275372795&uri=CELEX:32020R0217

Please also note the following remarks, with regard to the issues that were raised in your comments:

First, the EU would like to draw the attention of the New Zealand authorities to the revised legal text of the adopted Commission Delegated Regulation, compared to the draft version to which the New Zealand authorities refer in their comments. In the adopted Regulation, Note 10 has been added to Annex VI to the CLP Regulation: according to this Note, 'The classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1% or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 μm'. In addition, the statements on the labels of non-classified TiO2-containing mixtures are as follows in the adopted Regulation: liquid mixtures containing 1% or more of titanium dioxide particles with aerodynamic diameter equal to or below 10 μm shall bear the EUH211 statement 'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist'. Solid mixtures containing 1% or more of titanium dioxide shall bear the following EUH212 statement: 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust'. In addition, liquid and solid TiO2-containing mixtures not intended for the general public and not classified as hazardous that are labelled with EUH211 or EUH212, shall bear statement EUH210.

With regard to the concern of the New Zealand authorities that TiO2 classification would unduly restrict trade in goods containing titanium dioxide, please note that one of the aims of the CLP Regulation is to protect human health. It should be mentioned that the classification under the CLP Regulation does not entail in itself any automatic restriction or banning of products containing TiO2. When a substance is subject to harmonised classification, labelling and packaging obligations are triggered for that substance and any mixture containing it, but not for articles. 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 classification under the CLP Regulation 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. It should also be added that the most significant consequences occur for substances classified as carcinogenic category 1, rather than category 2.

It should be mentioned that the classification process set out in the CLP Regulation is purely hazard-based. The EU relied on the scientific opinion by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). For their opinion, RAC took into account all reliable and adequate scientific evidence that was available, in a weight of evidence assessment. If, following such hazard assessment, it is concluded that a substance is carcinogenic, it shall 'normally be subject to harmonised classification and labelling', in accordance with Article 36(1) of the CLP Regulation. Thus, in September 2017, RAC concluded that TiO2 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 TiO2 as 'possibly carcinogenic to humans'.

Furthermore, regarding the justification of the labelling requirement applying to liquid and solid mixtures, it should be noted that, as some hazardous dust or droplets could be formed during the use of the mixtures containing TiO2, it is necessary to inform the users of the precautionary measures that need to be taken to minimise the hazard for human health.

Finally, with regard to potential less trade-restrictive alternatives, the EU is fully aware of and has assessed proposals that were made to address the issue under workers' protection legislation, through the establishment of EU harmonised occupational exposure limits (OELs). While it is clear that the concerns with TiO2 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. Overall, the EU believes that the CLP Regulation is the relevant legal instrument to address the overall human health concern related to TiO2 that is complemented by more specific legislation, including workers' protection legislation.

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

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