REPLY FROM THE EUROPEAN UNION TO THE COMMENTS RECEIVED FROM PHILIPPINES 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 Philippines 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 Philippines 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 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.

Please note the following, with regard to the issues that were raised in the above-mentioned comments and represented the stakeholders' views on this issue, as mentioned therein.

With regard to the claim that the classification may have serious implications for international trade for TiO2, please note that the classification under the CLP Regulation does not in itself restrict the placing on the market of TiO2-containing products. When a substance is subject to harmonised classification, labelling and packaging obligations are triggered for that substance and for certain mixtures

[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.

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 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.

Moreover, the most significant consequences occur for substances classified as carcinogenic category 1, rather than category 2. Substances classified as carcinogenic category 1 are normally directly banned in cosmetics, toys, pesticides and REACH for consumer uses. However, for carcinogens category 2, there are no such significant direct consequences. More specifically, with regard to the legislation on plant protection products, biocidal products, food additives, contaminants, water and pharmaceuticals, there would be no or minor consequences. Regarding other legislation, the use of TiO2 could continue under certain conditions (e.g. granting of authorisation, exemption, demonstration of safe use): this is the case for food contact materials, plastic food contact materials, toys, feed additives, cosmetics and EU Ecolabel.

The EU legislator has considered that restricting the use of carcinogenic substances in other products is warranted in view of the protection of human health. Such restrictions – as well as the labelling and packaging obligations mentioned before – affect EU companies and third country companies alike and therefore cannot qualify as barriers to trade.

Regarding the claim that the classification is unfounded and is not commensurate with expert opinions, it should be mentioned that the EU relied on the scientific opinion by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). In September 2017, RAC concluded that TiO2 should be classified as a substance suspected of causing cancer (carcinogenic Category 2) by inhalation. For their opinion, RAC took into account all reliable and adequate scientific evidence that was available, in a weight of evidence assessment. The resulting opinion of RAC 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’.

Moreover, harmonised classification of TiO2 will not trigger hazard classification of other substances designated as ‘poorly soluble particles of low toxicity’ (PSLTs). Since no harmonised classification is adopted for these other PSLT particles, they remain subject to self-classification at present and the harmonised classification only applies to TiO2 particles.

Finally, with regard to the alternative proposals focused on managing the perceived occupational exposure risk, the EU is fully aware of proposals that were made to only 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.

Following its adoption on 4 October 2019, the 14th ATP of the CLP Regulation was published in the Official Journal of the European Union 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.

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

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[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:02020R0217-20200218