REPLY FROM THE EUROPEAN UNION TO THE COMMENTS RECEIVED FROM CANADA 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 Canadian authorities for their comments of 8 February 2019 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 14th adaptation to technical and scientific progress ('ATP') of the Classification, Labelling and Packaging ('CLP') Regulation[1].

The EU would like to inform the Canadian 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 legal act changed from 'Commission Regulation' 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 proceeded to adopt the Commission Delegated Regulation.

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

[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), 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), 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), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20191030

Cobalt

- With regard to the potential disruption of trade of cobalt-containing stainless steel products, as well as of nickel that contains cobalt, please note that the classification under the CLP Regulation does not in itself restrict the placing on the market of cobalt or cobalt-containing products. When a substance is subject to harmonised classification, only labelling and packaging obligations are triggered for that substance and any mixture containing it, but not for articles (e.g., stainless steel articles). It is not excluded that the classification of substances according to the CLP Regulation may have consequences under 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 must be addressed under those other pieces of legislation.

- With regard to the Better Regulation impact assessment to which you refer in your comments, please note that the EU position is that an impact assessment, in the framework of the harmonisation of classification in general and of the 14th ATP in particular, is not necessary. The CLP Regulation does not stipulate any obligation to perform an impact assessment in the procedure for harmonised classification under Article 37 of the CLP 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, when deciding on the harmonised classification of a substance, any decision on harmonised classification should rely solely 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.

TiO2

- With regard to the claim that the classification would have a significant and negative impact on trade in products containing TiO2, the EU would first like to refer the Canadian authorities to the reply above concerning cobalt. Thus, the classification under the CLP Regulation does not entail in itself any automatic restriction or banning of products containing TiO2. While consequences under other pieces of legislation are not excluded, please note that the most significant consequences occur for substances classified as carcinogens category 1, rather than category 2. Substances classified as carcinogens category 1 are normally directly banned in cosmetics, toys and pesticides and under 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.

- Moreover, in accordance with the harmonised classification, only the respirable particles of TiO2 (aerodynamic diameter equal to or smaller than 10 µm) will be classified as suspected carcinogens. In addition, the classification of mixtures will be limited to the ones placed on the market in powder form containing 1% or more of TiO2 that is in the form of or incorporated in particles with aerodynamic diameter equal to or below 10 µm. Liquid mixtures (e.g. paints) containing 1% or more of TiO2 particles with aerodynamic diameter equal to or below 10 µm as well as solid mixtures (the latter: unless they are in powder form) containing 1% or more of TiO2 will not have to be classified, but only the addition of a warning on the label will be mandatory.
- Regarding the claim of the Canadian authorities that TiO2 should first be assessed under the REACH Regulation, as part of a substance evaluation process: in view of the time needed for test results to become available in the context of that process, there is no scientific and legal justification to wait for such information before concluding on the classification of TiO2. If the information coming from the substance evaluation could lead to a change of the harmonised classification, a proposal to change the existing classification could be submitted by a Member State of the EU in accordance with article 37 of the CLP Regulation.
- Regarding the claim that impacted stakeholders had a limited possibility to provide input on the proposed classification, please note that a public consultation had been conducted by the European Chemicals Agency (ECHA) on the dossier for harmonised classification and labelling. Furthermore, the EU has worked in close consultation with EU Member State experts and the stakeholders representing various interests. The issue was discussed in the expert group for CLP, CARACAL, as well as in the expert meeting dedicated to the issue of TiO2 in April 2018. In addition, a consultation under the public feedback mechanism was conducted by the EU on the draft legal act containing the classification of TiO2. Finally, the EU has replied to several letters from and accepted meetings with industry associations on the specific topic of harmonised classification of TiO2 and possible consequences induced by requirements in other pieces of legislation. Overall, the proposed measure on the classification of titanium dioxide has followed all the necessary procedures for a harmonised classification proposal and the EU has made all efforts to address concerns raised by the industry throughout the process, taking into account the need also for protection of human health.

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