REPLY FROM THE EUROPEAN UNION TO THE COMMENTS RECEIVED FROM THE UNITED STATES 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 United States (US) authorities for their comments of 7, 8 and 11 February, and 8 March 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 US 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.

[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

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

Cobalt

- With regard to the potential impact on imports into the EU of stainless steel and stainless articles containing 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. cutlery or other stainless steel articles). Thus, the creation of anxiety and confusion would not be justified.
- Whether and to which extent a product will be affected by the harmonised classification and labelling of cobalt according to CLP will depend, first, on the type of product. Some substances and mixtures which are 'in the final state and for the final user' are excluded from the scope of CLP (e.g. food additives) and are covered by product specific legislation. Moreover, the classification in the case of a mixture will depend on the latter's content. Only if a mixture contains ≥0.1% of cobalt will it be classified as carcinogenic category 1B (except if other substances in the mixture would trigger such classification).
- 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 cannot be addressed under the CLP Regulation but must be addressed under those other pieces of legislation.
- In addition, regarding claims that the classification for all routes of exposure is overly conservative, it should be mentioned that the EU relies on the scientific opinion of the European Chemical Agency's (ECHA) Risk Assessment Committee (RAC). RAC has advised classification for all routes of exposure, based, amongst others, on the information available in the dossier and in the course of the public consultation. Such classification is in line with the CLP and the UN Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS), in particular the wording 'In certain instances, route-specific classification may be warranted, if it can be conclusively proved that no other route of exposure exhibits the hazard' of Section 3.6.2.1 of Annex I to the CLP, which is in line with the UN GHS (see Table 3.6.2 of GHS). Thus, in the case of cobalt, a potential re-examination of the classification as regards routes of exposure can only be considered if new and relevant data from scientific studies becomes available, which would conclusively demonstrate absence of carcinogenic effects from oral or dermal routes of exposure. In view of the time needed for such test results to become available, there is no scientific and legal justification to exclude any specific route of exposure at this point in time.
- The EU confirms that all relevant scientific evidence, including epidemiological studies, have been assessed and taken into account by RAC following a weight of evidence approach and on the basis of an expert judgment.
- The EU considered that the method that was used to determine the Specific Concentration Limit of 0.01% should be assessed in order to discuss if it can

be used for inorganic compounds such as cobalt. The adopted entry in Annex VI to CLP for cobalt is without such specific limit; instead, the generic concentration limit of 0.1% is applied as long as no new information warranting a specific concentration limit becomes available.

- The EU has proposed for adoption at OECD level a new method to assess bio-elution of metals in gastric fluid. The method estimates the bio-accessibility of the metals contained in materials. This information could then be used for the classification of e.g. alloys in accordance with article 12(b) of CLP.

TiO2

- With regard to the claim that the classification would raise unjustified barriers to trade in products containing TiO2, the EU would first like to refer the US to the reply above concerning cobalt. Thus, the classification under CLP 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 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.
- Moreover, in accordance with the harmonised classification, only TiO2 in powder form containing 1% or more of respirable particles (with aerodynamic diameter equal to or smaller than 10 µm) will be classified as suspected carcinogen. In addition, the classification of mixtures will be limited to those in powder form containing 1% or more of TiO2 that is in the form of or incorporated in particles with aerodynamic diameter ≤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.
- With regard to toys containing TiO2, in accordance with the Toy Safety Directive (Directive 2009/48/EC[4]), substances classified as carcinogenic category 2 may in principle not be used in toys. However, these substances may still be used in toys if they are present in concentrations equal to or smaller than the relevant CLP concentrations (in this case: 1%), or if they are inaccessible to children in any form, including through inhalation, when the toy is used as intended or in a foreseeable way, bearing in mind the behaviour of children, or if their use, following an evaluation by the relevant Scientific Committee, is found to be safe, in particular in view of exposure, and is permitted by a Commission Decision.
- Moreover, regarding the claim made that there is no evidence that TiO2 causes cancer in humans, please note that the classification is in line with the

[4] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p.1), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009L0048-20181126

conclusion of the International Agency for Research on Cancer (IARC), a World Health Organisation agency, which categorised TiO2 as 'possibly carcinogenic to humans'. In addition, as a response to the claim that interspecies differences exist between rats and humans, questioning the extent to which test results in rats can be extrapolated to humans, in the RAC opinion it was emphasised that the experimental and human evidence currently available does not conclusively exclude a carcinogenic potential or hazard of TiO2 in humans. It should also be noted that under the Cosmetics Regulation (see Commission Regulation (EU) 2016/1143[5]) the use of TiO2 (nano) in cosmetics is already restricted, as its use in spray products cannot be considered safe.

- Finally, the question of the scope of the CLP Regulation and of whether PSLT particles and particle toxicity should be covered under that Regulation has been discussed at length. The outcome was that particle toxicity can be considered an intrinsic property and should be considered as such under the CLP Regulation. Other substances with PSLT particles may also exhibit similar properties to TiO2. Nevertheless, since no harmonised classification is adopted for other PSLT particles, these remain subject to self-classification at present and the harmonised classification only applies to TiO2 particles.

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

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[5] Commission Regulation (EU) 2016/1143 of 13 July 2016 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 189, 14.7.2016), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1143&from=EN