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From: To:	European Commission Delegations
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Subject:	Commission Delegated Regulation (EU) …/…of 4.10.2019 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 - Non-Paper by the Commission to the Permanent Representations of Member States on the Harmonised Classification of Titanium Dioxide (TiO2)

Delegations will find in the Annex the Non-Paper by the Commission concerning the above Delegated Act as requested by Delegations at the Attaché s Meeting of the Working Party on Technical Harmonisation on 8 November 2019.

Non-Paper to Permanent Representations of Member States on the harmonised classification of TiO2

Introduction

In the course of the Council Working Party on Technical Harmonisation (Dangerous Substances-Chemicals) on 8 November 2019, Commission and Member States have held discussions regarding a few substances amongst which titanium dioxide (TiO2), more specifically on their harmonised classification and labelling under the 14th Adaptation to Technical and Scientific Progress (ATP) to the CLP Regulation. It was the first time that a Commission Delegated Regulation had been adopted for CLP as the former ATPs had been subject to the regulatory procedure with scrutiny, since they had been adopted before the entry into force of the recent Omnibus Regulation[1].

The Commission wishes to highlight again the importance of harmonised classification and labelling for both human health and the environment.

The need for harmonised substance classification to protect human health and the environment

One of the main aims of CLP is to ensure a high level of protection of human health and the environment. Harmonised classification on the basis of RAC opinions[2] allows a more thorough and independent assessment of hazards compared to self-classification by industry. Applying the harmonised classification and labelling (CLH) process to the substances of highest concern also ensures that those substances are labelled and packaged in an appropriate and harmonised way. Although a detailed benefits analysis of the CLH process in general and of a harmonised classification for a specific substance in particular is difficult to carry out, it can reasonably be expected that a correct classification and labelling resulting from the CLH process improves the quality of information on hazards and risks of substances and subsequently users' safety when handling the substances. In addition, benefits for health of consumers and workers and for the environment may derive from measures triggered by downstream legislation linking specific risk management measures to CLP classification.

[1] 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 198/241, 25.7.2019, p.241).

[2] Opinions adopted by the Risk Assessment Committee at the European Chemicals Agency (ECHA), based on which the Commission adopts harmonised classification and labelling under CLP.

Substances with a harmonised classification are listed in Annex VI to CLP. There is a legal obligation under Article 37(5) CLP for the Commission to include, without undue delay, [new or revised] classifications (entries) in Annex VI on the basis of the scientific assessment carried out by the Committee for Risk Assessment (RAC). The 14th ATP to CLP introduces new or modified harmonised classifications for 28 substances, amongst which more than 10 are classified as CMRs (carcinogenic, mutagenic or toxic for reproduction). Examples are cobalt (CMR - most relevant for workers protection) and diisohexyl phthalate (toxic for reproduction - most relevant for consumers as it can be found in consumer products). Methylmercuric chloride and several pesticides have also been classified as CMRs.

The classification process of TiO2

Introduction

The RAC opinion on TiO2 was adopted in September 2017 and was subsequently transmitted to the Commission. While the Member State that submitted the classification dossier to RAC had proposed to classify TiO2 as a presumed carcinogen (Carcinogen Category 1B), RAC concluded in their opinion that a classification as a suspected carcinogen (Carcinogen Category 2) was warranted.

The harmonised classification of TiO2 was discussed in expert group meetings (meetings of Competent Authorities on REACH and CLP - CARACAL) several times as well as in an expert meeting dedicated especially to the classification of TiO2 in April 2018. On the basis of the discussions held and input received during these meetings, the Commission developed its draft legal text, which was subsequently discussed several times in the regulatory committee (REACH Committee) as an act subject to the regulatory procedure with scrutiny.

Following the entry into force of the alignment 'Omnibus Regulation' (Regulation (EU) 2019/1243) 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'. The draft delegated act was presented for a final consultation at the CARACAL meeting on 18 September 2019. Based on that consultation, as well as on all previously received comments, including comments received through the World Trade Organisation Technical Barriers to Trade notification (WTO – TBT), the Commission concluded that the proposed classification was the most balanced one and proceeded with the adoption of the Commission Delegated Regulation.

A balanced proposal – scope of the classification of TiO2 and of mixtures containing TiO2

As stated above, throughout the many discussions that were organised, several arguments were raised in favour of and against the harmonised classification of TiO2. Very clear and strong arguments in favour of harmonised classification under CLP were: (i) the legal obligation for the Commission to follow up on a RAC opinion and (ii) the obligation to inform people (consumers, workers and self-employed workers) about the hazards of the products they use. This element of hazard communication through labelling is essential in the protection of human health and the environment under CLP. It should be noted that hazard communication through labelling reflects the outcome of a scientific assessment (by RAC in this case) and should not take into account any use or exposure-related considerations.

On the other hand, it was argued that the toxicity caused by TiO2 is of a particular nature, i.e. it concerns particle toxicity. Only when particles can be respired and reach the lower regions of the lung can toxicity arise. It was questioned to what extent such particle toxicity should be covered under CLP and it was argued that a direct translation of the substance identity in the RAC opinion would not reflect the fact that the concern is related only to respirable particles.

Considering it essential not to deprive users of chemicals of information on their hazards, the Commission concluded it was necessary to proceed with the classification, albeit in an adapted form, in order to address the concerns expressed with regard to the nature of the toxicity caused by TiO2.

The final entry for TiO2 in Annex VI to CLP as adopted, therefore, looks as follows:

At substance level, only TiO2 in the respirable form (TiO2 particles with an aerodynamic diameter ≤ 10 µm) will be classified as a suspected carcinogen,

For mixtures containing TiO2, a similar consideration with regard to respirability was taken into account (if the mixture cannot be respired, *a fortiori* any TiO2 contained in the mixture cannot be respired):

- only mixtures in powder form containing ≥ 1% of TiO2 which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 µm will be classified as suspected carcinogen,

- liquid mixtures (e.g. paints) containing such respirable particles of TiO2 will not be classified,

- solid mixtures containing such respirable particles of TiO2 will not be classified.

In order to address the situation where liquid mixtures containing ≥ 1% of respirable TiO2 particles (such mixtures would not have to be classified) are used in such a way that small droplets are formed that are respirable, a labelling requirement was added:

'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist'.

A similar warning statement was introduced for solid mixtures containing ≥ 1% of respirable TiO2 particles:

'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'

The alignment of the Commission's adopted classification of TiO2 with RAC's conclusion

It has been claimed that the classification of TiO2 is unfounded and not commensurate with expert opinions. It should be noted, however, that the Commission relied on the scientific opinion of 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. 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'. Moreover, with regard 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. In addition, it should be noted that under the Cosmetics Regulation (see Commission Regulation (EU) 2016/1143) the use of TiO2 (nano) in cosmetics is already restricted as its use in spray products cannot be considered safe.

In its opinion, RAC concluded that TiO2 is a suspected carcinogen only in case of inhalation. In the legal act, this was transposed by specifying that only TiO2 in the powder form needs to be classified, if the particle size of the substance has an aerodynamic diameter ≤ 10 μm. In other words, based on input from scientific experts, the Commission translated the concept of respirability into a specific value for the particle diameter. This would also facilitate enforcement.

It should be noted that the RAC opinion did not provide any advice on how mixtures containing TiO2 should be classified, as the mandate of RAC is limited to assessing substance hazards only. Any derogations or requirements relating to mixture classification can therefore not be in contradiction with the RAC opinion.

Should particle toxicity be covered by CLP at all?

It has been claimed that the effects on the lung that lead to the adopted harmonised classification are non-substance specific or not intrinsic to TiO2, but are rather a dust effect (commonly called particle toxicity) and should therefore not be covered under CLP.

Indeed, TiO2 has been associated to a group of substances designated as 'poorly soluble particles of low toxicity' or PSLTs. These substances are chemically inert and thus show low toxicity based on conventional biochemical mechanisms. However, PSLTs have been shown to be able to overwhelm clearance mechanisms in the lung, thereby leading to chronic inflammation and eventually to the possibility of cancer. 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. The fact that not all dusts or particles are necessarily carcinogens demonstrates that there is still a substance-specific element at play in any toxicity exerted.

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.

What level of protection will the classification provide?

The formal adoption of RAC's scientific conclusion in the CLP Regulation will increase the level of protection of human health. It will oblige industry, *inter alia*, under the REACH Regulation, to perform a risk assessment for workers and consumers exposed to this substance, thus allowing the identification of risk management measures to reduce any identified risk for human health.

Could a better level of protection not be achieved with other regulatory measures (occupational health and safety legislation, dust limit values)?

It has been claimed that appropriate occupational health and safety controls are adequate to protect public and workers' health and safety in relation to potential TiO2 exposure. The Commission is fully aware of proposals that were made by different stakeholders to only address the issue of TiO2 hazard and exposure under workers protection legislation, through the establishment of an EU harmonised occupational exposure limit (OEL). However, while concerns with TiO2 are mainly a workers protection issue, they are not exclusively so. The issue also pertains to consumers, and, importantly, to the self-employed, who are not covered by occupational health and safety legislation. In those cases, CLP would provide the necessary information to initiate the required actions to ensure protection. It is important to know that CLP provides information on hazardous properties of substances and on basic safety measures to be taken (e.g. wear gloves), while other pieces of legislation (e.g., REACH, OSH) provide more detailed risk management measures to deal with specific hazard properties identified under CLP. Overall, the Commission believes that the CLP Regulation is the relevant legal instrument to address the overall human health concern related to TiO2 that can be complemented by more specific legislation if necessary, including workers protection legislation.

What is the Commission's assessment of the socio-economic impact of the classification of TiO2 as a suspected carcinogen?

The question has been raised by some Member States and industry stakeholders to perform an impact assessment of the harmonised classification and labelling of TiO2. The Commission considers that such impact assessment is not necessary, whether in the framework of the harmonisation of classification in general or in the context of the 14th ATP in particular. The CLP Regulation does not stipulate any obligation to perform an impact assessment in the process of harmonised classification according to Article 37 of the 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 solely rely 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.

Having said that, in order to address the concerns expressed by various stakeholders, the Commission did a qualitative assessment of the consequences of classification of TiO2 as a suspected carcinogen on various pieces of downstream legislation. The outcome of that review is described in the following section.

Potential downstream consequences of classification of a substance as a suspected carcinogen: waste and sectoral legislation

It is a known fact that the most significant downstream legal consequences occur for substances classified as carcinogen category 1 (known or presumed carcinogen), rather than category 2 (suspected carcinogen). Nevertheless, also for suspected carcinogens certain downstream consequences may be expected.

Substances classified as carcinogens category 1 are normally directly banned in cosmetics, toys, pesticides and in chemicals for consumer use. In contrast, 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.

After contacting other services responsible for these downstream pieces of legislation, and after research conducted, it is estimated that the number of mixtures placed on the market to be classified as carcinogenic will be limited.

With regard to the possible consequences on waste classification, the Commission developed an update of the guidance on waste classification[3] to cover the specific case of waste containing TiO2, to be discussed with national experts, which will state that – in analogy to classification of mixtures containing TiO2 under CLP - only waste in powder form containing 1% or more respirable particles of TiO2 (≤ 10 µm) will be classified as suspected carcinogen.

More generally, on the question to what extent classification of TiO2 will hamper the circular economy, in addition to the amendments to the guidance on waste classification referred to above, it should be noted that even if waste containing TiO2 is classified as hazardous, this does not prevent it from being recycled. In other words, classification of waste per se does not necessarily impact the circular economy.

[3] *Commission notice on technical guidance on the classification of waste*, C/2018/1447, OJ C 124, 9.4.2018, p. 1–134

Substance evaluation under REACH

The claim has been made that since TiO2 is the subject of substance evaluation under REACH, the outcome of the process should be awaited before any decision on classification under CLP is taken. It should be noted, however, that the tests proposed to be conducted in the context of substance evaluation will take several years to be finalised. Thus, the Commission sees no scientific or legal justification to wait for such information before concluding on the classification of TiO2. If the information resulting from the substance evaluation could be of impact on the harmonised classification, a proposal to change the existing classification can be submitted by a Member State in accordance with Article 37 of CLP.

Problem of extending the deadline due to the specific case of CTPHT

Due to an administrative oversight, the old harmonised classification and labelling of one substance (pitch, coal tar, high-temp. (CTPHT)), will enter into application on 1 December 2019, with the result that the classification currently in force will be erroneously replaced by the original harmonised classification and labelling. The 14th ATP corrects this error. If the 14th ATP does not apply in a timely manner, it will mean that manufacturers, importers and downstream users will have to classify, label and package the substance CTPHT, and mixtures containing it, in accordance with the original classification (i.e. carcinogen category 1B, instead of the current classification as carcinogen category 1A (stricter than 1B), Mutagen category 1B and Toxic for reproduction category 1B). This will potentially also trigger unwanted consequences on other pieces of legislation (e.g. product specific legislation, workers protection legislation, etc.) which refer to the CLP classification. In general, it is expected to affect the current level of protection of human health and the efficient functioning of the internal market.