

Brussels, XXX
[...] (2022) XXX

COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

The objectives of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) are to ensure (i) a high level of protection of human health and the environment, and (ii) the free movement of substances, mixtures and certain articles. These objectives are fulfilled, *inter alia*, by establishing hazard classes and their criteria for classification of substances and mixtures at EU level. Article 53(1) of Regulation (EC) No 1272/2008 empowers the Commission to adjust and adapt Articles 6(5), 11(3), 12, 14, 18(3)(b), 23, 25-29 and 35(2) second and third subparagraph and Annexes I to VIII so as to bring them into line with technical and scientific progress.

The need to insert new hazard classes and their criteria into the CLP Regulation for its adaptation to technical and scientific progress has been recognised by its inclusion as one of the primary commitments under the chemicals strategy for sustainability, which is a building block of the European Green Deal, for the protection of consumers, vulnerable groups and workers from the most harmful chemicals and for the target of zero chemical pollution in the environment.

Experience and scientific knowledge gained in the identification of substances under Regulation (EC) No 1907/2006 as substances of very high concern due to their endocrine disrupting properties highlight the need to introduce new hazard classes in Regulation (EC) No 1272/2008 to ensure a high level of protection for human health and the environment. Similar experience in the identification of substances with persistent, bioaccumulative and toxic properties (PBT) and very persistent, very bioaccumulative properties (vPvB) under Annex XIII to Regulation (EC) No 1907/2006 has triggered the same need to introduce new hazard classes. Substances having probable serious effects on the environment due to their persistent, mobile and toxic (PMT) and very persistent, very mobile (vPvM) properties also require the introduction of the respective hazard classes. Based on deliberations and consultations of scientific experts, the criteria and accompanying hazard statements as laid down in the Annexes to this delegated regulation appropriately reflect the development of scientific knowledge in these fields.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

2.1. Consultations of relevant expert group and ad hoc discussions in its subgroup

Pursuant to Article 53a(4) of Regulation (EC) No 1272/2008, experts designated by each Member State were consulted in the relevant expert group ‘Competent Authorities for Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) and Classification, Labelling and Packaging (CLP) (CARACAL)’ according to the rules of the Interinstitutional Agreement on Better Law-Making of 13 April 2016¹. In accordance with points 10 and 11 of the Annex to that Agreement, the European Parliament and the Council have received all documents related to those discussions and could send experts to the meetings of the CARACAL expert group.

¹ OJ L 123, 12.5.2016, p. 1.

Stakeholders were consulted in the CARACAL expert group in accordance with point 6 of the Annex to that Agreement. The progress and updates on the definition and criteria for new hazard classes were presented and discussed at the following ad hoc CARACAL meetings: CARACAL meeting of 30 September 2021 on PMT, vPvM and PBT, vPvB substances, and CARACAL meeting of 14 December 2021 on New Hazard Classes, More than One Constituent Substances (MOCS) and Self-classification.

Scientific criteria included in the Annexes to this Regulation follow, in addition, discussions in meetings of CARACAL's Subgroup on Endocrine Disruptors held on 2 July 2020, 7 February 2020, 19 October 2020, 22 March 2021, 13 September 2021 and 24 February 2022, and meetings of ECHA's PBT Expert Group held on 28 May 2021 and 28 June 2021. At all these meetings, stakeholder representatives were present.

The final consultations of the CARACAL expert group on this draft Delegated Regulation were held on [placeholder] 2022 and [placeholder] 2022.

2.2. Consultations during the impact assessment process

In accordance with point 13 of the Interinstitutional Agreement on Better Law-Making of 13 April 2016, the Commission carried out an impact assessment for review of the CLP Regulation composed of the legislative proposal and this delegated regulation. This impact assessment includes an analysis of impacts of inserting new hazard classification criteria given the significant economic, environmental and social impacts.

The Commission's Regulatory Scrutiny Board conducted a quality check of the impact assessment, evaluating it positively with some reservations to be addressed in the final version of the impact assessment.

As part of the impact assessment process concerning the revision of the CLP Regulation, the Commission held (a) an **open public consultation** and (b) a **targeted stakeholder survey** on a number of issues. Feedback on the new hazard classes was received as part of those consultation tools.

a) Open public consultation

The Commission launched the open public consultation on the revision of the CLP Regulation (Regulation (EC) No 1272/2008 on the classification, labelling, and packaging of substances and mixtures) on 9 August 2021 for a period of 14 weeks ending on 15 November 2021².

The Commission received 625 responses from four types of stakeholders: companies and business associations; EU and non-EU citizens; public authorities; and civil society (all other stakeholders). Responses were mainly received from companies and business associations (45%) and from EU and non-EU citizens (39%) and civil society (12%). Of the responses from businesses, almost 69% were from SMEs, while 30% were from large companies. A

² https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals_en

total of 144 position papers were uploaded. In terms of geographical distribution, most responses were received from France (28%) and Germany (20%).

The results show that opinions on the introduction of new hazard classes varied significantly between different stakeholder groups.

All stakeholders agreed that it was either ‘important’ or ‘very important’ for them to know if a chemical is either ‘an endocrine disruptor with adverse effects on human health’, ‘an endocrine disruptor with adverse effects on the environment’, ‘Persistent, bio-accumulative and toxic’ and ‘Persistent, mobile and toxic’. Business associations and companies were the least likely to rate the need for knowledge of adverse effects as ‘very important’, but they still on average rated these aspects as ‘important’. 65% of respondents stated that they would be ready to pay 10-50% more for alternative products not containing such chemicals.

Civil society, public authorities and citizens were in favour of ‘a sub-categorisation for chemicals with a high level of certainty on their endocrine-disrupting properties’, taking the view that there should be a distinction between endocrine disruptors for human health and the environment, as well as a distinction between proven and suspected endocrine disruptors. 63% of companies and business associations were, however, not in favour of making a distinction between proven and suspected endocrine disruptors.

The favoured label, chosen by 34% of respondents, for chemicals identified as toxic to reproduction and as an endocrine disruptor according to the planned criteria was: ‘May cause infertility or damage to the unborn child; May cause endocrine-related adverse effects on human health’.

72% of respondents agreed that criteria for PBT (Persistent, Bioaccumulative and Toxic) and vPvB (very Persistent and very Bioaccumulative) in Annex XIII of REACH should be introduced in the CLP Regulation. Most respondents (69% overall) did not believe that a category for suspected PBT (and one for suspected vPvB) was necessary.

As regards PMT (Persistent, Mobile and Toxic) and vPvM (very Persistent and very Mobile) categories, the responses varied across the different stakeholder groups. While 75% of companies and business associations did not consider such categories necessary, 79% of civil society, 62% of citizens and 53% of public authorities did.

26% stated that the World Health Organization’s definition and criteria for endocrine disruptors should be taken over word for word in the EU CLP criteria, while an equal percentage of 26% believed it was necessary to further refine the World Health Organization’s definition and criteria and/or existing criteria for plant protection and biocidal products in order to develop the CLP criteria.

All stakeholder categories responded in the majority that environmental toxicity should be part of the toxicity criterion (74% of respondents overall), and 100% of public authorities were of that view.

Companies and business associations expressed repeated support that any of the new hazard classes referred to above should only be introduced in Regulation (EC) No 1272/2008 as an implementation measure of the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS).

b) Targeted stakeholder consultation

The targeted stakeholder consultation on CLP was open for 6 weeks from 10 November to 22 December 2021. The purpose of the consultation was to gather expert advice from Member

States' authorities and national CLP helpdesks, academia, NGOs, and duty holders. A total of 167 responses and 39 position papers were received.

Analysis of the responses to the targeted stakeholder consultation showed that supporters of the introduction of new hazard classes believed that the initiative would reduce exposure to hazardous chemicals and lead to safer workplaces, to substitution by better and safer alternatives, and to better control of hazardous chemicals.

However, the analysis also showed that business entities and associations were mostly not in favour of introducing new hazard classes. Those stakeholders argued that such introduction would lead to potential information overload in hazard communication, distort the level playing field of international trade, and lead to cost increases for various activities. Those stakeholders also expressed their concerns about potential overlaps of the new hazard classes with existing ones for classification and labelling, together with the concern that Regulation (EC) No 1272/2008 is not the proper means for addressing endocrine disrupting properties, which refer to a mode of action rather than a hazard. Counterarguments put forward highlighted that in fact endocrine disruptors affect various organisms in very different ways; endocrine disruption should therefore be considered as an intrinsic (hazardous) property and hence qualifies as a hazard.

Other commentators pointed to the fact that properties such as persistency and mobility are not necessarily related to hazards, i.e., they do not automatically mean that a chemical is hazardous. Some written responses from CARACAL members, however, highlighted that the combination of specific properties, e.g., very persistent and very mobile or persistent, mobile and toxic, pose a threat to drinking water sources. Such combinations of properties increase the chances of chemicals passing through natural and artificial barriers in wastewater treatment facilities.

2.3. Stakeholders' feedback of the draft delegated act following publication on the 'Have Your Say' portal (public feedback mechanism)

[placeholder]

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal act amends Regulation (EC) No 1272/2008. The legal basis of this delegated act is Article 53(1) of Regulation (EC) No 1272/2008.

This Regulation takes the form of a Commission Delegated Regulation. In light of the empowerment in Article 53(1) of Regulation (EC) No 1272/2008, it is appropriate to adapt Part 3 and Part 4 of its Annex I, Part 1 of its Annex III, and Part 1 of its Annex VI to technical and scientific progress via delegated act, in accordance with Article 290 of the Treaty on the Functioning of the European Union.

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amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 1907/2006¹, and in particular Article 53(1) thereof,

Whereas:

- (1) Parts 2 to 5 of Annex I to Regulation (EC) No 1272/2008 contain harmonised criteria for the classification of substances, mixtures and certain articles in hazard classes and in differentiations of those hazard classes and set out provisions on how those criteria are to be met as well as the corresponding labelling requirements. Part 3 of Annex I to Regulation (EC) No 1272/2008 contains criteria on health hazards and Part 4 of that Annex contains criteria on environmental hazards.
- (2) The European Green Deal² sets out the goal to better protect human health and the environment as part of an ambitious approach to tackle pollution from all sources and move towards a toxic-free environment.
- (3) The need to establish a legally binding hazard identification of endocrine disruptors, based on the definition established by the World Health Organization in 2002³ and building on criteria already developed for plant protection products⁴ and biocidal

¹ OJ L 353, 31.12.2008, p. 1.

² Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – The European Green Deal (COM(2019) 640 final, 11 December 2019).

³ WHO/IPCS (World Health Organization/International Programme on Chemical Safety), 2002. Global assessment on the state of the science of endocrine disruptors (WHO/PCS/EDC/02.2), https://apps.who.int/iris/bitstream/handle/10665/67357/WHO_PCS_EDC_02.2.pdf.

⁴ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

products⁵, and to apply it across all Union legislation, is highlighted in the Commission's Communication 'Chemicals strategy for sustainability towards a toxic-free environment'⁶. That Communication also points to the need to include new hazard classes and criteria in Regulation (EC) No 1272/2008 in order to fully address environmental toxicity, persistency, mobility and bioaccumulation.

- (4) The Commission has conducted an impact assessment on the addition of new hazard classes and criteria in Regulation (EC) No 1272/2008, which encompassed an open public consultation, as well as a stakeholder consultation. The Commission has also consulted the European Chemicals Agency's expert group on persistent, bioaccumulative and toxic chemicals, the competent authorities for REACH and CLP (CARACAL), as well as the subgroup on endocrine disruptors of that expert group, on the new hazard classes and criteria for classification and labelling of substances and mixtures, and has taken into account their scientific advice.
- (5) Based on experience and increased scientific knowledge gained in identifying substances as substances of very high concern due to their endocrine disrupting properties as well as in identifying substances as PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative), PMT (persistent, mobile, toxic) and vPvM (very persistent, very mobile) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁷, it is necessary to adapt Regulation (EC) No 1272/2008 to technical and scientific progress by introducing new hazard classes and criteria. The scientific criteria against which available evidence for classification in those hazard classes are to be assessed should reflect the current state of the science.
- (6) Substances and mixtures with endocrine disrupting properties pose a concern to public health and the environment. It has been proven that endocrine disruption can lead to certain disorders in humans, among others birth defects, developmental, reproductive or neurodevelopmental disorders, cancer, diabetes and obesity, and that those disorders have a high and increasing incidence in both children and adults. It has also been demonstrated that endocrine disrupting properties can negatively affect animal populations.
- (7) Experience shows that substances and mixtures with PBT or vPvB properties represent a very high concern. They do not easily break down in the environment and tend to accumulate in living organisms across the food web. Accumulation of those substances in the environment is difficult to reverse, as the emission does not readily cease by lowering their concentration, and the effects of this accumulation are often difficult to predict in the long-term. Moreover, certain PBT and vPvB substances

⁵ Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council. OJ L 301, 17.11.2017, p. 1.

⁶ Chemicals Strategy for Sustainability, COM(2020) 667 final.

⁷ 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).

which undergo long-range transport have the potential to contaminate remote pristine areas. Once those substances are released into the environment, exposure to them is difficult to reverse, which leads to cumulative exposure of both animals and humans via the environment.

- (8) PMT and vPvM substances pose concerns as, due to their high persistence together with their low adsorption potential and mobility, they can enter the water cycle, including drinking water, and spread over long distances. Many PMT and vPvM substances are only partly removed by wastewater treatment processes and can even break through the most advanced purification processes at drinking water treatment facilities. Such incomplete removal coupled with new emissions mean that the concentration of those PMT and vPvM substances in the environment increase over time. Once released into the environment, exposure to PMT and vPvM substances is difficult to reverse, which leads to cumulative exposure of both animals and humans via the environment. Any effects from this exposure are unpredictable in the long-term.
- (9) In light of the increased scientific knowledge and experience gained in identifying endocrine disruptors for human health and the environment as well as PBT, vPvB, PMT and vPvM substances and mixtures, it is appropriate to introduce hazard classes for those substances and mixtures and the corresponding scientific criteria to identify them.
- (10) The level of evidence as regards endocrine disrupting properties may be of different scientific strength. It is therefore appropriate to create two categories of endocrine disruptors: known or presumed endocrine disruptors (category 1) and suspected endocrine disruptors (category 2), both for human health and for the environment.
- (11) When developing guidance on the application of the endocrine disruptor criteria, the European Chemicals Agency can benefit from the experience gained from the implementation of legislation on plant protection products and biocidal products and other scientific justifications, in order to provide guidelines that clarify which effects not leading to chronic outcomes for human health and the environment could fall outside the definition of 'adverse effect'.
- (12) The intrinsic properties of PBT and vPvB substances and mixtures display similarities, but they differ substantially with regard to the toxicity criterion. It is therefore appropriate to create two separate hazard classes, each with its own criteria, while establishing common rules for the scientific assessment of the intrinsic properties related to persistency and bioaccumulation.
- (13) The intrinsic properties of PMT and vPvM substances and mixtures display similarities, but they differ substantially with regard to the toxicity criterion. It is therefore appropriate to create two separate hazard classes, each with its own criteria, while establishing common rules for the scientific assessment of the intrinsic properties related to persistency and mobility.
- (14) In order to allow for adequate classification of substances and mixtures as PBT and vPvB, whether or not registered under Regulation (EC) No 1907/2006, the existing criteria for identification of PBT and vPvB substances set out in Section 1 of Annex XIII to Regulation (EC) No 1907/2006 should be included in Regulation (EC) No 1272/2008. In this regard, any introduction of hazard categories for PBT and vPvB in Regulation (EC) No 1272/2008 would not be appropriate in view of the high level of scientific strength of the evidence required to fulfill the PBT and vPvB criteria -

which mirror those so far laid down in Annex XIII to Regulation No 1907/2006. Moreover, the screening information laid down in that Annex, to be considered when screening for P, vP, B, vB and T properties, serves a different purpose than hazard identification and classification. In addition, the development of criteria for further hazard categories based on that screening information would lead to overclassification and significant overlaps with existing environmental classification. Therefore, it would not be appropriate to introduce additional hazard categories for PBT and vPvB in Regulation (EC) No 1272/2008.

- (15) The classification criteria for M/vM relate, in particular, to the log K_{oc} (soil adsorption coefficient) value. The K_{oc} value is the organic carbon-water partition coefficient and reflects the ability of a substance to be adsorbed on the organic fraction of solid environmental compartments such as soil, sludge and sediment, and is therefore inversely related to the substances' potential of entering into ground water. It is therefore appropriate to assess the mobility criterion against the log K_{oc} value of a substance, a low K_{oc} implying a high mobility.
- (16) Providing for new hazard classes entails introducing those classes with their name, their respective hazard statements and their respective hazard category codes. It is therefore necessary to include those hazard classes, hazard statements and category codes in Annexes I, III and VI to Regulation (EC) No 1272/2008.
- (17) To ensure that suppliers of substances and mixtures have time to adapt to the new classification and labelling provisions, the application of the obligation to classify and label substances and mixtures in accordance with this Regulation should be deferred. Substances and mixtures which are already placed on the market before the end of that deferral period, should be allowed to continue being placed on the market without being re-classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.
- (18) In line with the transitional provisions set out in Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the new classification and labelling provisions before the date of application of the obligations to classify and label substances and mixtures in accordance with this Regulation.
- (19) Regulation (EC) No 1272/2008 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1272/2008 is amended as follows:

- (1) Annex I is amended as set out in Annex I to this Regulation;
- (2) Annex III is amended as set out in Annex II to this Regulation;
- (3) Annex VI is amended as set out in Annex III to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.
Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

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