EUROPEAN
COMMISSION

Brussels, 31.8.2020
C(2020) 5758 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 31.8.2020

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures in order to improve the workability of information requirements related to emergency health response

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

According to Article 45(1) of Regulation (EC) No 1272/2008, Member States' appointed bodies shall be responsible for receiving information from importers and downstream users on the hazardous chemical mixtures they place on the market. Commission Regulation (EU) 2017/542 amended Regulation (EC) 1272/2008 by adding an Annex harmonising the information to be provided relating to emergency health response ("Annex VIII")[1].

Annex VIII was adopted in March 2017. After adoption, Member States and industry stakeholders called for amendments of Annex VIII before its compliance date, for reasons of serious workability concerns[2]. The Commission services commissioned a study to assess the legitimacy of the claims and the impact on duty holders and concluded that an amendment of Annex VIII was indeed necessary. The amendment would constitute a second amendment to the Regulation, after the adoption of Regulation (EU) 2020/11, which deferred the compliance date for mixtures for consumer use and aimed at a more streamlined interpretation of the rules, improving internal coherence and mitigating some unintended consequences that had only become apparent since the adoption of Regulation (EU) 2017/542.

The Commission is now proposing to add paragraph (8) to Article 25 as well as to amend Annex VIII of Regulation (EC) 1272/2008 in order to solve the workability issues.

In line with the empowerments given under Regulation (EC) No 1272/2008, amended through Regulation (EU) 2019/1243, and in particular Article 53c thereof, the Commission shall adopt a separate delegated act in respect of each power delegated to it. Since powers delegated for the amendment of Article 25 and Annex VIII are different, the Commission is proposing two separate delegated acts.

This proposed act contains the amendment of Annex VIII and addresses the concerns raised, i.e. the difficulty or impossibility of knowing the exact composition of products in cases where raw materials with highly variable or unknown composition are used, where multiple suppliers are being used for components that are stored in the same recipient, or where complex supply chains are involved, as well as the impossibility to know in advance which exact bespoke mixtures will be placed on the market.

This proposed act introduces a general solution with the concept of an interchangeable component group ('ICG'), as well as more sector specific solutions for gypsum, ready mixed concrete, cement and fuels and bespoke paints.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Pursuant to Article 53a(4) of Regulation (EC) No 1272/2008, experts designated by each Member State were consulted in the relevant expert group CARACAL (Competent Authorities for REACH and CLP (E02385)) according to the rules of the Interinstitutional

[1] OJ L 78, 23.3.2017, p. 1–12.

[2] Notably the difficulty or impossibility of knowing the exact composition of products in cases where raw materials with highly variable or unknown composition are used, where multiple suppliers are being used for components that are stored in the same recipient, or where complex supply chains are involved.

Agreement on Better Law-Making of 13 April 2016[3]. This included also members of the European Association of Poison Centres and Clinical Toxicologists (EAPCCT).

Furthermore, the initiative was published for feedback during the period 12 May 2020 – 9 June 2020 under the title "Hazardous chemicals - updated requirements for submitting information to poison centres" (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12384-Amending-requirements-for-information-for-poison-centers). The public feedback received can be summarised as follows.

The Commission received 21 comments from individuals and organisations, almost all associated with the chemicals industry and mainly located in Europe.

More specifically, the vast majority of comments was submitted by industrial stakeholders (95% of the comments came from either companies, or business organisations/associations) whilst comments submitted by other entities made up 5% in total.

Overall, commentators very much welcomed the proposed act and mentioned that the general and sector specific solutions provided are workable.

The vast majority of the comments concerned a request to postpone the first compliance date of 1 January 2021 stipulated in Commission Delegated Regulation (EU) YYYY/XXX *[C(2020)5758]*. The reasons provided were the large numbers of mixtures claimed to have to be notified, the delay of the adoption of this act compared with the original timeline due to COVID-19 and the ensuing impossibility to adopt this act before the non-transmission period of the European Parliament and the Council during a certain period in summer[4], the concern that the necessary IT tools developed by ECHA to which industry needs to adapt their systems may not be ready in time and the concern that the IT systems of the Member States may suffer from potential security breaches if not ready in time.

The Commission does not intend to postpone the compliance date of 1 January 2021 for the following reasons: The European Chemicals Agency ("Agency") developed and published the submission format as per Part C of Annex VIII already in April 2019. Further, the Agency developed and established a searchable database which is operational since November 2019.

Concerning the readiness of the Member States' IT systems, the preparation for their access to the searchable database is going according to plan for all Member States that have opted to use the searchable database of the Agency. Member States only get access to the searchable database if they fulfil all security requirements, so the concerns regarding security breaches are unfounded.

Regarding the delay caused by COVID-19 and the ensuing impossibility to adopt this act before the non-transmission period of the co-legislators in a certain period in summer, the Commission estimates that it amounted to approximately two and a half months. In the view of the Commission, this however does not warrant a postponement of the compliance date.

The feedback pointed out that a significant number of mixtures need to be notified as of 1 January 2021. It should be taken into account that Annex VIII merely harmonises the submission format and that the submission obligations under Article 45 are already applicable since Regulation (EC) 1272/2008 entered into force. A transitional period until 1 January 2025 for already notified mixtures under the existing national systems is foreseen under Regulation (EU) 2017/542, so mixtures already placed on the market can benefit from it.

[3] OJ L 123, 12.5.2016, p. 1.
[4] OJ L 123, 12.5.2016, p. 1.

Commentators welcomed in particular the introduction of the ICG concept under Section 3.5., Part B of Annex VIII.

It was proposed to remove the five components limit under letter (c), second subparagraph of Section 3.5. of Part B given that for both the acute hazards (corrosion/irritation, aspiration) and the chronic hazard (skin sensitisation), the rationale for a five-component limit is not clear. The expert group consulted and quoted above discussed the same matter and reached the conclusion that the five component limit was needed as a counterbalance to the alleviated set of criteria for components classified for these hazard classes to be grouped in an ICG, compared to the set of criteria stipulated in the first subparagraph of Section 3.5 of Part B. Indeed, whereas in the first subparagraph all components grouped in an ICG need to have the same hazard classification and technical function, this is not required under the second subparagraph. The increase in uncertainty for poison centres through alleviation of the conditions needed to be balanced by the introduction of a limit to the number of components that can be grouped in an ICG.

A further comment regarded the change of the wording from "toxicological profile" to "toxicological properties" under the third indent of letter (a), first subparagraph of Section 3.5. of Part B, in order to avoid confusion with the meaning of the term 'toxicological profile' that is used in other, international regulatory frameworks. The expert group consulted and quoted above discussed the same matter and concluded to change the wording which is now introduced in the legal text.

Further, commentators proposed to clarify that the first and second subparagraph of Section 3.5. of Part B apply alternatively and suggested to insert the wording "alternatively" at the beginning of the second subparagraph of Section 3.5. of Part B. The expert group consulted and quoted above discussed the same matter and reached the conclusion that the proposed wording emphasises more clearly that it concerns and alternative option, and agreed to add this wording which is now introduced.

Moreover, it was suggested to insert the caveat "where applicable" for the pH requirement under letter (b), second subparagraph of Section 3.5. of Part B due to the fact that a pH can only be measured in aqeous mixtures. The expert group consulted and quoted above discussed the same matter and reached the conclusion to add this wording which is now introduced.

Stakeholders very much welcomed the solution under Section 3.6. of Part B for mixtures complying with a standard formula as specified in Part D (cement, gypsum binder, ready mixed concrete) and suggested to the Commission to consider an extension of this solution to other sectors. Given the lack of evidence on the need for a simplification for other sectors, the Commission currently does not consider to expand this solution.

The fuels sector very much welcomed the specific solution for fuels under Section 3.7. of Part B. A suggestion was made to delete the wording "until a more suitable solution is found" in Recital (5) of this act describing the derogation for fuels to submit the information contained in the safety data sheet, as well as any other known information on the products' chemical composition. Considering the uncertainty that the simplification provided to the sector will provide poison centres with the optimal level of information, the Commission is of the view that the wording in Recital (5) should be kept in case a more suitable solution will be available in the future.

The summary of comments on bespoke paints is provided under Commission Delegated Regulation (EU) YYYY/XXX *[C(2020)5758]*.

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 45(4) of Regulation (EC) 1272/2008.

For the readers' convenience, this version of Annex VIII entirely repeals and replaces the previous version.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) 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) 1907/2006[5], and in particular Article 45(4) thereof,

Whereas:

(1) Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) 2017/542[6] to add certain requirements for the submission of information relating to emergency health response and for the inclusion of a 'unique formula identifier' in the supplemental information provided on the label of a hazardous mixture. The requirements were amended by Commission Delegated Regulation (EU) 2020/11[7]. Importers and downstream users are required to start complying with the requirements in stages, according to a series of compliance dates depending on the use for which a mixture is placed on the market

(2) Concerns have been raised by various industry sectors regarding the workability of the emergency health response information requirements in certain cases, notably with regard to the difficulty of knowing the exact composition of mixtures in cases where raw materials with a highly variable or unknown composition are used in the manufacture of the mixture, in cases where toxicologically very similar components supplied by multiple, different suppliers are used together in the same production line, or in cases involving complex supply chains. Concerns have also been raised, in the case of bespoke mixtures, about the impossibility of knowing in advance which exact bespoke mixtures are to be placed on the market.

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5 OJ L 353, 31.12.2008, p.1.

6 Commission Regulation (EU) 2017/542 of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response (OJ L 78, 23.3.2017, p. 1).

7 Commission Delegated Regulation (EU) 2020/11 of 29 October 2019 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards information relating to emergency health response (OJ L 6, 10.1.2020, p. 8).

(3) It is necessary to address the situation where different but toxicologically very similar components are used in a mixture, and where it is unknown which component is present in a particular mixture placed on the market at a given time. To ensure that the emergency health response requirements can be complied with properly in practice, importers and downstream users should be allowed to group toxicologically similar components of a mixture together in an interchangeable component group and provide information on the total concentration of those components present in the mixture, without having to specify their separate concentrations. In order to allow poison centres to formulate a suitable emergency health response, components should only be grouped in an interchangeable component group if their classification for health and physical effects is identical and if the hazards identification and the additional hazard information are identical for all possible combinations of the resulting final mixture incorporating those components. For components classified for certain hazard classes, it should also be necessary for them to have the same technical function and the same toxicological properties in order to be grouped.

(4) In order to address particular difficulties encountered by the gypsum, ready-mixed concrete and cement sectors and to allow them to comply with the emergency health response requirements without reducing the level of safety, it should be possible for emergency health response information relating to certain standardised mixtures within those three sectors to be submitted by reference to a standard composition. However, in order to allow poison centres to formulate a suitable emergency health response, this option should only be available in cases where the mixture classification does not change according to the mixture's composition within the concentration ranges specified in the standard formula, and where the information on composition is at least as detailed as the information contained in the mixture's safety data sheet, drawn up in accordance with Article 31 of Regulation (EC) No 1907/2006 ("safety data sheet"). In the event that the information contained in the safety data sheet is more detailed than the information on the composition in the standard formula, importers and downstream users should be required to notify the information in the safety data sheet instead.

(5) In order to address particular difficulties anticipated for certain fuels, and taking into account the facts that fuels placed on the market normally conform to a technical standard and that poison centres have communicated a low number of poisoning incidents with fuels, it should be possible, until a more suitable solution is found, to submit emergency health response information by reference to the information contained in the safety data sheet, as well as any other known information on the products' chemical composition.

(6) In order to satisfy customer demand for very specific paint shades, formulators are sometimes asked to formulate and supply paints on a bespoke basis at the point of sale. These bespoke paints could have an almost unlimited number of different compositions. Therefore, without any mitigating measures, compliance with the emergency health response requirements in Annex VIII to Regulation (EC) No 1272/2008 would require formulators of bespoke paints either to submit information and create unique formula identifiers (UFIs) in advance for an extremely large number of paints of all possible colour combinations, many of which might never be supplied in reality, or to postpone each supply until the information had been submitted and the UFI had been created. Either approach would place a disproportionate burden on the bespoke paints industry, in particular small and medium sized enterprises, without improving the level of safety significantly.

(7) Poison centres have not communicated a significant number of accidents related to paints. In light of the apparently lower risks compared to other mixtures, it is justified to allow a more flexible approach, as this would not be reducing the current level of safety.

(8) It is therefore appropriate to provide for the possibility to exempt bespoke paints from the notification obligations in Annex VIII and from the requirement to create a UFI. However, in that case, in order to allow poison centres to formulate a suitable emergency health response, the individual mixtures contained in bespoke paints should remain subject to all the requirements of that Annex. Alongside this Regulation, Commission Delegated Regulation (EU) YYYY/XXX *[OP: Please insert reference to the act amending Article 25 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on the classification, labelling and packaging of substances and mixtures as regards bespoke paints, C(2020)5758]* amends Article 25 of Regulation (EC) No 1272/2008 to add a new rule, in the case of bespoke paints for which no submission in accordance with Annex VIII has been made and no corresponding UFI has been created, requiring the UFIs of all the individual mixtures contained in the bespoke paint to be indicated on the label of the bespoke paint, together with the specific concentration of each such mixture with a UFI that is present in a concentration exceeding 5%.

(9) Given the number of changes to Annex VIII to Regulation (EC) No 1272/2008, it is appropriate to replace the whole Annex for the sake of legal clarity.

(10) Considering that the compliance date for mixtures for consumer and professional use of 1 January 2021 laid down in Annex VIII to Regulation (EC) No 1272/2008 is approaching, and that this Regulation enables all sectors to comply with that Annex, this Regulation should enter into force as early as possible.

(11) Regulation (EC) No 1272/2008 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex VIII to Regulation (EC) No 1272/2008 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day after 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, 31.8.2020

For the Commission
The President
Ursula VON DER LEYEN