

Brussels, **XXX**  
[...] (2019) **XXX** draft

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

**of **XXX****

**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**

(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**

According to Article 45(1) of the CLP Regulation, Member States' appointed bodies shall receive information from importers and downstream users on the hazardous chemical mixtures they place on the market. Commission Regulation (EU) No 2017/542 amended the CLP Regulation (EC) No 1272/2008 by adding an Annex harmonising the information to be provided relating to emergency health response (“**Annex VIII**”). Annex VIII was adopted in March 2017 and was intended to become applicable on 1 January 2020.

The Commission is proposing an amendment to Annex VIII before its applicability date that would contain uncontentious clarifications of the text, so as to allow a more streamline interpretation of the text, improve internal coherence and mitigate some unintended consequences made apparent only after the adoption of the Annex.

The Commission is also proposing an amendment of the first compliance deadline (identical with the applicability date of Annex VIII) from 1 January 2020 to 1 January 2021 given that there have been calls for more extensive amendments to Annex VIII before its applicability date, for reasons of workability concerns. The Commission has examined the workability for all sectors, as certain workability issues of Commission Regulation (EU) 2017/542 were identified, such as the effects of high variability in mixture composition due to the natural origin of components, the difficulty of knowing the exact composition of products in cases involving complex supply chains, and the impact of multiple suppliers of mixture components with the same technical properties and hazards. Once solutions how to address these workability issues will have been developed, any ensuing changes will need to be made to the new rules before the first compliance date. A postponement of the first compliance deadline would allow Member States and ECHA to be ready in time and allow industry to comply with Annex VIII by the deadline.

### **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 Agreement on Better Law-Making of 13 April 2016<sup>1</sup>.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The legal act amends Regulation (EC) No 1272/2008. The legal bases of this delegated act are Article 45(4) and Article 53(1) of Regulation (EC) No 1272/2008.

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<sup>1</sup> OJ L 123, 12.5.2016, p. 1.

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

of **XXX**

**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**

(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/EEFC and 1999/45/EC, and amending Regulation (EC) No 1907/2006<sup>2</sup>, and in particular Articles 45(4) and 53(1) thereof,

Whereas:

- (1) Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) 2017/542<sup>3</sup> 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 amendments are expressed to apply from 1 January 2020, but importers and downstream users are only required to start complying with the new rules in stages, according to a series of compliance dates depending on the use for which a mixture is placed on the market. The first such compliance date is 1 January 2020.
- (2) After adoption of Regulation (EU) 2017/542, several drafting suggestions were made during discussions with national authorities and other stakeholders with a view to facilitating implementation of the new rules introduced by that Regulation and clarifying their meaning. The new rules introduced by that Regulation should therefore be amended to allow for a more streamlined interpretation of them, to improve internal coherence and to mitigate some unintended consequences that have only become apparent since adoption of that Regulation. In particular, since the unique formula identifier (UFI) may need to be updated frequently, the new rules should provide for the UFI to be shown either on the label of the hazardous mixture or on its packaging in close proximity to the label. Article 31(5) of Regulation (EC) No 1272/2008 already includes the option of putting all the label elements on the packaging rather than on a label. In addition, Article 29(3) of Regulation (EC) No 1272/2008 addresses the situation where a mixture is supplied without any packaging.

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<sup>2</sup> OJ L 353, 31.12.2008, p.1.

<sup>3</sup> 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).

- (3) In addition to the drafting suggestions, national authorities and other stakeholders have raised certain issues concerning the workability of the new rules introduced by Regulation (EU) 2017/542, for example the effects of high variability in mixture composition due to the natural origin of components, the difficulty of knowing the exact composition of products in cases involving complex supply chains, and the impact of multiple suppliers of mixture components with the same technical properties and hazards. Once any solutions needed to address these issues have been developed, any resulting changes to the new rules will have to be made before the first compliance date when importers and downstream users are required to start complying with the new rules as regards mixtures for consumer use. It is therefore appropriate to defer the first compliance date from 1 January 2020 to 1 January 2021 in order to allow sufficient time to develop the necessary solutions and make any necessary changes to the new rules. This postponement does not affect the need for Member States to have their systems operational in good time before 1 January 2021 in order to allow importers and downstream users sufficient time to prepare for their submissions before that date.
- (4) Regulation (EC) No 1272/2008 should therefore be amended accordingly.
- (5) The date of application of this Regulation should be deferred in order to align it with the date of application of Regulation (EU) 2017/542,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

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

- (1) in Article 25, paragraph 7 is replaced by the following:

‘7. Where under Annex VIII the submitter creates a unique formula identifier, it shall be included in the supplemental information on the label in accordance with the provisions of section 5 of Part A of that Annex.’;
- (2) in Article 29, the following paragraph is inserted:

‘4a. Where under Annex VIII the submitter creates a unique formula identifier, the submitter may, instead of including it in the supplemental information on the label, opt to show it in another way permitted by section 5 of Part A of that Annex.’;
- (3) Annex VIII is amended as set out in the Annex 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*.

It shall apply from 1 January 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission  
The President  
Jean-Claude Juncker*

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