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**Brussels, 29 October 2019**
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**COVER NOTE**

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| From: | Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director |
| date of receipt: | 29 October 2019 |
| To: | Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union |
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| Subject: | COMMISSION DELEGATED REGULATION (EU) …/... of 29.10.2019 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 |

Delegations will find attached document C(2019) 7611 final.

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EUROPEAN
COMMISSION

Brussels, 29.10.2019
C(2019) 7611 final

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

**of 29.10.2019**

**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**

(Text with EEA relevance)

# 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 streamlined 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 certain workability concerns, 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. The Commission is currently looking into these issues, and once solutions will have been developed, any ensuing changes to the new rules will need to be made 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[1].

Furthermore, the initiative was published for feedback during the period 22 July 2019 to 19 August 2019 under the title "Hazardous substances – rules on information to be provided for an emergency health response (update)" (http://ec.europa.eu/info/law/better-regulation/initiatives/isc-2019-04397_en). The public feedback received can be summarised as follows.

The Commission received 109 comments from individuals and organisations, mostly associated with the chemical industry and mainly located in Europe.

More specifically, the vast majority of comments was submitted by industrial stakeholders (87% of the comments came from either companies, or business organisations/associations) whilst comments submitted by other entities made up 13% in total (5% - EU citizen, 1% - public authority, 1% - trade union and 6% - other).

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

The deferral of the first compliance deadline from 1 January 2020 to 1 January 2021 was very much welcomed, and there was a broad consensus that such a deferral is needed due to the workability concerns outlined above.

Concerns were also expressed regarding the workability issues as such, which are however not addressed by the initiative published for feedback, but are being dealt with separately.

Many comments regarded the amendment of Section 5.2, Part A of the Annex providing for the alternative to print or affix the unique formula identifier (UFI) on the packaging in close proximity to the label instead of on the label itself. It was argued that explicit reference should be made to "inner packaging" instead of "packaging" only, as otherwise it would be required to put the UFI on every packaging layer according to Article 33 of Regulation (EC) No 1272/2008 without any additional benefit to emergency health response as outer packaging will most likely not be available in case of a poisoning incident. The Commission has taken-up this suggestion and Section 5.2, Part A of the Annex now refers explicitly to "inner packaging". An additional subparagraph was added to specify that where the inner packaging is either in such a shape or so small that it is impossible to affix the UFI on it, the submitter may print or affix the UFI on an outer packaging in close proximity to the label.

Concerning the second subparagraph of Section 3.2.2, Part B of the Annex on the information on the substances contained in a mixture in mixture (MIM), it was highlighted that this amendment would potentially increase the administrative burden for submitters. If a mixture to be notified in a Member State contains a MIM which itself has not been notified in that specific Member State, then the MIM needs to be identified by means of the compositional information contained in the Safety Data Sheet and any other known components. In case the MIM has been notified, it suffices to include the UFI of the MIM in the notification of the final mixture. According to the comments received the provisions in Section 3.2.2., Part B would require different notifications for the same mixture in case the MIM has been notified in some Member States and not in others.

While the Commission is of the view that this problem needs to be tackled, a solution could rather be found by adjusting the relevant IT tools than by amending the legal text. For example, the availability of UFIs for a certain Member State could be checked before the actual submission is made or the submission tools could allow the introduction of both variants in the submission format, i.e. to provide the UFI of the MIM and the SDS data.

Moreover, comments were also raised that this proposed change would require submitters to communicate upstream in the supply chain in order to verify whether a MIM has already been notified in a certain Member State, i.e. whether the UFI is available in that Member State. The Commission believes that this amendment would actually lower the administrative burden of submitters given that IT systems would immediately verify whether a UFI is available in a certain Member State and thus supply chain communication would not be needed.

In conclusion, the comments received in the framework of the public consultation have been taken into account concerning Section 5.2, Part A of the Annex and the reference to "inner packaging". Regarding the comments raised on MIMs as outlined above, the problem will be tackled through IT solutions rather than an amendment of the legal text.

## 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.

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

**of 29.10.2019 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**

(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 1907/2006[2], 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[3] 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 also 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.

(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

[2] OJ L 353, 31.12.2008, p.1.

[3] 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).

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, 29.10.2019

*For the Commission*
*The President*
*Jean-Claude JUNCKER*