EUROPEAN
COMMISSION

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[1].

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.

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

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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[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.

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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).

(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

EUROPEAN
COMMISSION

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ANNEX

ANNEX

to the

Commission Delegated Regulation

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

ANNEX

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

(1) Part A is amended as follows:

(a) Section 1.1 is replaced by the following:

‘1.1 Importers and downstream users placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.’;

(b) Section 2.3 is replaced by the following:

‘ 2.3. In the case of mixtures placed on the market for industrial use only, submitters may opt for a limited submission, as an alternative to general submission requirements, in accordance with Section 3.1.1 of Part B, provided that a rapid access to additional detailed product information is available in accordance with Section 1.3 of that Part.’;

(c) Section 4.1 is replaced by the following:

‘ 4.1 A single submission, hereinafter 'group submission', may be provided for more than one mixture where all the mixtures in a group have the same classification for health and physical hazards.’;

(d) Section 4.3. is replaced by the following:

‘ 4.3. By way of derogation from Section 4.2, a group submission shall also be allowed where the difference in the composition between different mixtures in the group only concerns perfumes, provided that the total concentration of the differing perfumes contained in each mixture does not exceed 5 %.’;

(e) in Section 5.1, the third subparagraph is replaced by the following:

‘ By way of derogation from the second subparagraph, a new UFI shall not be required for mixtures in a group submission containing perfumes provided that the change in the composition only concerns those perfumes or the addition of new perfumes.’;

(f) Section 5.2 is replaced by the following:

‘ 5.2. The submitter shall print or affix the UFI on the label of the hazardous mixture or, alternatively, on the packaging in close proximity to the label.

In the case of mixtures which are not packaged, the UFI shall be indicated in the Safety Data Sheet or be included in the copy of the label elements referred to in Article 29(3), as applicable.

The UFI shall be preceded by the acronym "UFI" in capital letters followed by a colon (“UFI:”) and it shall be clearly visible, legible and indelibly marked.’;

(g) Section 5.3 is replaced by the following:

‘ 5.3 By way of derogation from the first subparagraph of Section 5.2, in the case of mixtures supplied for use at industrial sites, the UFI may alternatively be indicated in the Safety Data Sheet.’;

(2) Part B is amended as follows:

(a) in Section 1.1, the second subparagraph is replaced by the following:

‘The complete trade name(s) of the mixture shall be provided, including, where relevant, brand name(s), name of the product and variant names as they appear on the label, without abbreviations and enabling its specific identification.’;

(b) Section 1.2 is replaced by the following:

‘ *1.2. Details of the submitter and contact point*

The name, full address, telephone number and e-mail address of the submitter shall be provided and, if different, the name, full address, telephone number and e-mail address of the point of contact to be used for obtaining further information relevant for emergency health response purposes.’;

(c) Section 1.3 is replaced by the following:

‘ *1.3. Telephone number and e-mail address for rapid access to additional product information*

In the case of a limited submission as laid down in Section 2.3 of Part A, a telephone number and an e-mail address shall be provided at which rapid access to detailed additional product information relevant for emergency health response purposes is available in the language provided in Section 3.3 of Part A. The telephone number shall be accessible 24 hours per day, 7 days per week.’;

(d) in Section 2.4, the third indent is replaced by the following:

‘ – the pH, if available, of the mixture as supplied, or, where the mixture is a solid, the pH of an aqueous liquid or solution at a given concentration. The concentration of the test mixture in water shall be indicated. If the pH is not available, the reasons shall be given;’

(e) in Section 3.1, the third and fourth subparagraphs are replaced by the following:

‘ By way of derogation from the second subparagraph, in a group submission, perfume components in mixtures shall be present in at least one of the mixtures.

For group submissions where the perfumes vary between the mixtures contained in the group, a list shall be provided of the mixtures and the perfumes they contain, including their classification.’;

(f) Section 3.1.1 is replaced by the following:

‘ 3.1.1. Requirements for mixtures for industrial use

In the case of a limited submission as laid down in Section 2.3 of Part A, the information to be submitted on the composition of a mixture for industrial use may be limited to the information contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006, provided that additional information on the composition is available on request for rapid access in accordance with Section 1.3.’;

(g) the heading to Section 3.2 is replaced by the following:

‘ *Identification of mixture components*’;

(h) in Section 3.2, the following paragraph is inserted before Section 3.2.1:

‘ A mixture component is either a substance or a mixture in mixture.’;

(i) in Section 3.2.2, the second subparagraph is replaced by the following:

‘Information on the substances contained in a MIM shall be provided in accordance with the criteria of Section 3.2.1, unless the submitter does not have access to information on the full composition of the MIM. In the latter case, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI, if available and if the appointed body has received the information on the MIM in a prior submission. In absence of a UFI or if the appointed body has not received the information on the MIM in a prior submission, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and the compositional information contained in the Safety Data Sheet of the MIM and any other known components, as well as the name, e-mail address and telephone number of the MIM supplier.’;

(j) Section 3.2.3 is replaced by the following:

‘ 3.2.3. Generic product identifiers

By way of derogation from Sections 3.2.1 and 3.2.2, the generic product identifiers “perfumes” or “colouring agents” may be used for mixture components used exclusively to add perfume or colour, where the following conditions are met:

– the mixture components are not classified for any health hazard,

– the concentration of mixture components identified with a given generic product identifier does not exceed in total:

(a) 5 % for the sum of perfumes; and

(b) 25 % for the sum of colouring agents.’;

(k) Section 3.3 is replaced by the following:

‘ *3.3. Mixture components subject to submission requirements*

The following mixture components shall be indicated:

(1) mixture components classified as hazardous on the basis of their health or physical effects which:

– are present in concentrations equal to or greater than 0.1 %;

– are identified, even if in concentrations lower than 0.1 %, unless the submitter can demonstrate that those components are irrelevant for the purposes of emergency health response and preventative measures;

(2) mixture components not classified as hazardous on the basis of their health or physical effects which are identified and present in concentrations equal to or greater than 1 %.’;

(l) Section 3.4 is replaced by the following:

‘ *3.4. Concentration and concentration ranges of the mixture components*

Submitters shall provide the information laid down in Sections 3.4.1 and 3.4.2 with regard to the concentration of the mixture components, identified in accordance with Section 3.3.’;

(m) in Section 3.4.1, the title of Table 1 is replaced by the following:

‘**Concentration ranges applicable to hazardous components of major concern for emergency health response**’;

(n) Section 3.4.2 is replaced by the following:

‘ 3.4.2. Other hazardous components and components not classified as hazardous

The concentration of the hazardous components in a mixture that are not classified for any of the hazard categories listed in Section 3.4.1 and of the identified components not classified as hazardous shall be expressed, in accordance with Table 2, as ranges of percentages in descending order by mass or volume. As an alternative, exact percentages may be provided.

By way of derogation from the first subparagraph, for perfume components that are not classified or only classified for skin sensitisation Category 1, 1A or 1B or aspiration toxicity, submitters shall not be required to provide information on their concentration, provided that their total concentration does not exceed 5 %.

Table 2

Concentration ranges applicable to other hazardous components and components not classified as hazardous

Concentration range of the component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 - < 100	20 % units
≥ 10 - < 25	10 % units
≥ 1 - < 10	3 % units
>0 - < 1	1 % units’;

(o) Section 3.5 is replaced by the following:

‘ *3.5. Classification of mixture components*

The classification of mixture components for health and physical hazards (hazard classes, hazard categories and hazard statements) shall be provided. This includes the classification for at least all substances referred to in Point 3.2.1 of Annex II to Regulation (EC) No 1907/2006 on requirements for the compilation of Safety Data Sheets. In the case of a MIM identified by means of its product identifier and its UFI in accordance with Section 3.2.2. of Part B, only the classification for health and physical hazards of the MIM shall be provided.’;

(p) in Section 4.1, the title of Table 3 is replaced by the following:

‘**Variations of the concentration of components requiring a submission update**’;

(q) in Section 4.1, the final subparagraph is replaced by the following:

‘When the perfumes in a group submission change, the list of mixtures and the perfumes they contain as required in Section 3.1. shall be updated.’;

(3) Part C is amended as follows:

(a) Section 1.2 is replaced by the following:

‘**1.2. Identification of the mixture and of the submitter**

Product identifier

– Complete trade name(s) of the product (in case of group submission, all product identifiers shall be listed)

– Other names, synonyms

– Unique Formula Identifier(s) (UFI)

– Other identifiers (authorisation number, company product codes)

Contact details of the submitter and, where applicable, contact point

– Name

– Full address

– Telephone number

– E-mail address

Contact details for rapid access to additional product information (24 hours/7 days). Only for limited submission.

– Name

– Telephone number (accessible 24 hours per day, 7 days per week)

– E-mail address’

(b) in Section 1.3, the list of “Additional information on the mixture” is replaced by the following:

‘ *Additional information on the mixture*

– Colour(s)

– The pH, if available, of the mixture as supplied, or, where the mixture is a solid, the pH of an aqueous liquid or solution at a given concentration. The concentration of the test mixture in water shall be indicated. If the pH is not available, the reasons shall be given;

– Physical state(s)

– Packaging (type(s) and size(s))

– Intended use (product category)

– Uses (consumer, professional, industrial)’.