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 (Text with EEA relevance)

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

(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[(1)], 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[(2)] 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/11. (See end of Document for details)*

(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, 29 October 2019.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/11. (See end of Document for details)*

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. Instead of including the UFI in the supplemental information on the label, the submitter may opt to print or affix it on the inner packaging located with the other label elements.

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 located with the other label elements on an outer packaging.

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.;

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(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 email address of the submitter shall be provided and, if different, the name, full address, telephone number and email 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. *Name, telephone number and email 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 name, a telephone number and an email 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