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 (Text with EEA relevance)

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

(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 Article 45(4) and 53(1) thereof,

Whereas:

(1) In order to carry out their responsibilities, bodies appointed in accordance with Article 45(1) of Regulation (EC) No 1272/2008 need information about mixtures placed on the market and classified as hazardous on the basis of their health and physical effects. That information is submitted to appointed bodies at national level by importers and downstream users and it commonly includes product identification, hazard identification, composition information and toxicological information. Poison centres rely on information provided by those appointed bodies, and sometimes constitute such bodies themselves.

(2) The Commission carried out the review provided for by Article 45(4) of Regulation (EC) No 1272/2008, and its findings, which were based on thorough expert consultation, were published in January 2012. The review concluded that there is considerable variation in the current notification systems, data formats and country-specific requirements regarding the requested information in the Member States. This implies that importers and downstream users placing mixtures on the market in different Member States, need to provide multiple submissions and in different formats, regarding information that is often similar. The review also showed that this diversity leads to inconsistencies in the information available to medical personnel and the general public in cases of poisoning incidents in different Member States.

(3) The findings of the review were supported by a Commission costs and benefits study completed in March 2015[(2)], which confirmed that, in addition to improved health

response, the harmonisation of information to be provided to appointed bodies would lead overall to significant cost savings.

(4) The relevant stakeholders, such as the European Association of Poison Centres and Clinical Toxicologists (EAPCCT) have been consulted, in particular in the framework of the costs and benefits study and through a number of workshops.

(5) It is therefore appropriate to harmonise the information to be received by appointed bodies from importers and downstream users, as well as to establish a format for the submission of the information.

(6) It is necessary to specify which information needs to be submitted to an appointed body. This includes information regarding the identification of the mixture and of the submitter, the hazard identification and the mixture components. Due to the fact that mixtures' formulations can be subject to frequent slight modifications with little or no impact on the emergency health response to be provided, requiring information about the components of the mixture in exact percentages would be disproportionate. Therefore, as an alternative, concentration ranges may be submitted for mixture components. The width of those ranges should be determined on the basis of the health and physical effects of the mixture components and the relevance of the information for emergency health response.

(7) In view of the fact that mixtures classified as hazardous may also contain non-classified components that can nonetheless have adverse effects after unintended use (e.g. following ingestion), appointed bodies should have at their disposal information on the latter components where needed to formulate preventive or curative action.

(8) The format for the submission of the information should be harmonised in order to allow importers and downstream users operating in different Member States to use the same submission or submission format in different Member States. The submissions should be made electronically in a harmonised XML format maintained by the European Chemicals Agency and made available free of charge.

(9) In order to facilitate the transmission of information on the intended use of a mixture and to support the statistical analysis of related poisoning cases, a European product categorisation system should be developed by the European Chemicals Agency and used in the submission of information.

(10) According to a Commission costs and benefits study, poison centres and other appointed bodies have reported experiencing problems with the correct identification of the mixture concerned in up to 40 % of the calls they receive. This could lead to unnecessary overtreatment of patients and hospitalisation for precautionary reasons. Therefore, as part of the harmonisation of the information, it is necessary to require identification of a mixture by a unique alphanumeric code (unique formula identifier) to be affixed to the label.

(11) Most calls to poison centres and other appointed bodies concern accidental exposure to hazardous mixtures used by consumers and to a lesser extent by professionals. Only a small number of calls concern mixtures for industrial use, which are used in industrial installations. In addition, on industrial sites there usually is a greater knowledge of

the mixtures used and medical treatment is generally available. Therefore, importers and downstream users of mixtures for industrial use should be allowed to fulfil limited information requirements.

(12) In order to spread the necessary work of adapting the format for data submission, and to prioritise information provision where it is most needed, it is considered reasonable and proportionate to lay down a stepwise applicability of the new information requirements set by this Regulation according to the use of the mixture.

(13) In order to ensure a smooth transition and avoid disproportionate costs, the submissions provided to appointed bodies before the date of application of this Regulation should remain valid for a certain time after this Regulation starts to apply. However, if significant changes in the formulation, product identifier or toxicology of the mixture occur in the meantime, a submission update pursuant to this Regulation should be required.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 54(1) of Regulation (EC) No 1272/2008,

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) In Article 25, the following paragraph 7 is added:

7. Where under Annex VIII the submitter creates a unique formula identifier, it shall be included on the label in accordance with the provisions of Section 5 of Part A of that Annex;

(2) Annex VIII is added 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, 22 March 2017.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/542. (See end of Document for details)*

ANNEX

ANNEX VIII

Harmonised information relating to emergency health response and preventative measures

PART A

GENERAL REQUIREMENTS

1. Application

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 2020.

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

1.3. Importers and downstream users placing on the market mixtures for industrial use within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2024.

1.4. Importers and downstream users having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) before the dates of applicability mentioned in Sections 1.1, 1.2 and 1.3 and which are not in accordance with this Annex, shall for those mixtures not be required to comply with this Annex until 1 January 2025.

1.5. By way of derogation from Section 1.4, if one of the changes described in Section 4.1 of Part B of this Annex occurs before 1 January 2025, importers and downstream users shall comply with this Annex before placing that mixture, as changed, on the market.

2. Purpose, definitions and scope

2.1. This Annex sets out the requirements that importers and downstream users placing mixtures on the market, hereinafter "submitters", shall fulfil in respect of the submission of information so that appointed bodies shall have at their disposal the information to carry out the tasks for which they are responsible under Article 45.

2.2. This Annex shall not apply to mixtures for scientific research and development and to mixtures for product and process oriented research and development as defined in Article 3(22) of Regulation (EC) No 1907/2006.

This Annex shall not apply to mixtures classified only for one or more of the following hazards:

(1) gases under pressure;

(2) explosives (unstable explosives and Divisions 1.1 to 1.6)

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

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with Section 5.3 of this Part and 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 Part B.

2.4. For the purposes of this Annex the following definitions shall apply:

(1) "Mixture for consumer use" means a mixture intended to be used by consumers;

(2) "Mixture for professional use" means a mixture intended to be used by professional users but not at industrial sites;

(3) "Mixture for industrial use" means a mixture intended to be used at industrial sites only.

Where mixtures have more than one use, the requirements for all relevant categories of use shall be met.

3. **Submission requirements**

3.1. Before placing mixtures on the market, submitters shall provide information relating to mixtures classified as hazardous on the basis of their health or physical effects to the bodies appointed under Article 45(1) (hereinafter "appointed bodies"), in the Member State or Member States where the mixture is placed on the market.

The submission shall contain the information laid down in Part B. It shall be submitted by electronic means in an XML format provided by the Agency and made available free of charge.

3.2. Where following receipt of a submission under Section 3.1 an appointed body makes a reasoned request to the submitter that additional information or clarification is necessary for that appointed body to carry out the tasks for which it is responsible under Article 45, the submitter shall provide the necessary information or clarification requested without undue delay.

3.3. The submission shall be in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

3.4. The intended use of the mixture shall be described in accordance with a harmonised product categorisation system provided by the Agency.

3.5. A submission update shall be made without undue delay when the conditions laid down in Section 4.1 of Part B are met.

4. **Group submission**

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 and belong to the same product category referred to in Section 3.4.

4.2. A group submission shall only be permitted when all mixtures in the group contain the same components (as identified in Section 3.2 of Part B), and for each of the components, the reported concentration range is the same for all mixtures (as provided in Section 3.4 of Part B).

4.3. By 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 or fragrances, provided that the total concentration of perfumes and fragrances contained in each mixture does not exceed 5 %.

4.4. In the case of a group submission, the information required in Part B shall be provided for each of the mixtures contained in the group where applicable.

5. **Unique formula identifier (UFI)**