II

(Non-legislative acts)

REGULATIONS

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.

([1]) OJ L 353, 31.12.2008, p. 1.
([2]) Study to support the harmonisation of the information to be submitted to poison centres, according to Article 45 of Regulation (EC) No 1272/2008 (CLP Regulation), 3.3.2015.

(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

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 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)**

5.1. The submitter shall create a unique formula identifier, hereinafter UFI, by electronic means made available by the Agency. The UFI is a unique alphanumeric code that unambiguously links the submitted information on the composition of a mixture or a group of mixtures to a specific mixture or group of mixtures. The assignment of a UFI is free of charge.

A new UFI shall be created when a change in the composition of the mixture or group of mixtures fulfils one or more of the conditions foreseen in points (a), (b) and (c) of the fourth indent of Section 4.1 of Part B.

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

5.2. The submitter shall print or affix the UFI on the label of a hazardous mixture. The UFI shall be preceded by the acronym "UFI" in capital letters and it shall be clearly visible, legible and indelibly marked.

5.3. By derogation from Section 5.2, the UFI may in the case of hazardous mixtures for industrial use and for mixtures which are not packaged alternatively be indicated in the Safety Data Sheet.

6. **Formats and technical support for submission of information**

6.1. The Agency shall specify, maintain and update the UFI generator, the XML formats for submissions and a harmonised product categorisation system and make them available free of charge on its website.

6.2. The Agency shall provide technical and scientific guidance, technical support and tools facilitating the submission of information.

PART B

INFORMATION CONTAINED IN A SUBMISSION

1. **Identification of the mixture and of the submitter**

1.1. *Product identifier of the mixture*

The product identifier shall be provided in accordance with Article 18(3)(a).

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

In addition, the UFI(s) shall be included in the submission.

1.2. *Details of the submitter*

The name, full address, telephone number and email address of the submitter shall be provided. This information shall be consistent with the data provided on the label in accordance with Article 17(1)(a).

1.3. *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 telephone number and an email address for rapid access to additional detailed product information services shall be provided at which rapid access to detailed additional product information in the language provided in Section 3.3 of part A is available for appointed bodies during emergencies. The telephone number shall be accessible 24 hours per day, 7 days per week.

2. **Hazards identification and additional information**

This section sets out the information requirements related to the health and physical hazards of the mixture and the appropriate warning information associated with those hazards, as well as the additional information to be included in a submission.

2.1. *Classification of the mixture*

The classification of the mixture for health and physical hazards (hazard class and category) shall be provided in accordance with the classification rules in Annex I.

2.2. *Label elements*

The following label elements required in accordance with Article 17 shall be provided, if applicable:

— hazard pictogram codes (Annex V),

— signal word,

— hazard statement codes (Annex III, including supplemental hazard information),

— precautionary statement codes.

2.3. *Toxicological information*

The submission shall include the information on the toxicological effects of the mixture or its components that is required in Section 11 of the Safety Data Sheet of the mixture, in accordance with Annex II to Regulation (EC) No 1907/2006.

2.4. *Additional information*

The following additional information shall be provided:

— the type(s) and size(s) of the packaging used to place the mixture on the market for consumer or professional use,

— the colour(s) and the physical state(s) of the mixture, as supplied,

— the pH, where applicable,

— product categorisation (see Section 3.4 of Part A),

— use (consumer, professional, industrial, or a combination of any of the three).

3. **Information on mixture components**

3.1. *General requirements*

The chemical identity and the concentrations of the components contained in the mixture shall be indicated in the submission in accordance with Sections 3.2, 3.3 and 3.4.

Components which are not present in a mixture shall not be notified.

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

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

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 components is rapidly available on request in emergencies in accordance with Section 1.3.

3.2. *Mixture components*

3.2.1. Substances

The product identifier for the substances identified according to Section 3.3 shall be provided in accordance with Article 18(2). However, an INCI name, a colour index name or another international chemical name may be used, provided the chemical name is well-known and unambiguously defines the substance identity. The chemical name of substances for which an alternative chemical name has been allowed in accordance with Article 24 shall be provided as well.

3.2.2. Mixture in mixture

When a mixture is used in the composition of a second mixture placed on the market, the first mixture is referred to as a mixture in mixture (hereinafter MIM).

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, information in accordance with Section 3 on known mixture components shall be provided and the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI, when available. In absence of a UFI, the Safety Data Sheet of the MIM shall be provided, as well as the name, email address and telephone number of the MIM supplier.

3.2.3. Generic product identifiers

By derogation from Sections 3.2.1 and 3.2.2, the generic product identifiers "perfumes", "fragrances" or "colouring agents" may be used for mixture components used exclusively to add perfume, fragrance 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 fragrances; and

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

3.3. *Mixture components subject to submission requirements*

The following mixture components (substances and MIM) 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 %.

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 (substances and MIM), identified in accordance with Section 3.3.

3.4.1. Hazardous components of major concern for emergency health response and preventative measures

When mixture components are classified in accordance with this Regulation for at least one of the hazard categories listed below, their concentration in a mixture shall be expressed as exact percentages, in descending order by mass or volume:

— acute toxicity, Category 1, 2 or 3,

— specific target organ toxicity — Single exposure, Category 1 or 2,

— specific target organ toxicity — Repeated exposure, Category 1 or 2,

— skin corrosion, Category 1, 1A, 1B or 1C,

— serious eye damage, Category 1.

As an alternative to providing concentrations as exact percentages, a range of percentages may be submitted in accordance with Table 1.

Table 1

Concentration ranges applicable to hazardous components of major concern for emergency health response (substances or MIM)

Concentration range of the hazardous component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 - < 100	5 % units
≥ 10 - < 25	3 % units
≥ 1 - < 10	1 % units
≥ 0,1 - < 1	0,3 % units
> 0 - < 0,1	0,1 % units

3.4.2. Other hazardous components and components not classified as hazardous

The concentration of the hazardous components in a mixture 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 derogation from the first subparagraph, for perfume or fragrance 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 the total concentration does not exceed 5 %.

Table 2

Concentration ranges applicable to other hazardous components and components not classified as hazardous (substances or MIM)

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

3.5. *Classification of mixture components (substances and MIM)*

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. Alternatively, in the case of a MIM, only its classification for health and physical hazards may be provided.

4. **Submission update**

4.1. Where one of the following changes applies to a mixture in an individual or group submission, submitters shall provide a submission update before placing that mixture, as changed, on the market:

— when the mixture product identifier (including the UFI) has changed,

— when the mixture classification for health or physical hazards has changed,

— when relevant new toxicological information that is required in Section 11 of the Safety Data Sheet becomes available on the hazardous properties of the mixture or its components,

— if a change in the composition of the mixture fulfils one of the following conditions:

(a) addition, substitution, or deletion of one or more components in the mixture that shall be indicated in accordance with Section 3.3;

(b) change in the concentration of a component in the mixture beyond the concentration range provided in the original submission;

(c) the exact concentration of a component was provided in accordance with Sections 3.4.1 or 3.4.2, and a change occurs to that concentration beyond the limits identified in Table 3.

Table 3

Variations of the concentration of components requiring a submission update

Exact concentration of the component contained in the mixture (%)	Variations (±) of the initial component concentration requiring a submission update
> 25 - ≤ 100	5 %
> 10 - ≤ 25	10 %
> 2,5 - ≤ 10	20 %
≤ 2,5	30 %

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

4.2. Content of the submission update

The submission update shall comprise a revised version of the previous submission containing the new information available as described in Section 4.1.

PART C

SUBMISSION FORMAT

1.1. **Submission format**

The submission of information to appointed bodies in accordance with Article 45 shall be in a format to be provided by the Agency. The submission format shall address the following elements:

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

Product identifier

— Complete trade name 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

— Name

— Full address

— Telephone number

— Email address

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

— Name

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

— Email address

1.3. **Classification of the mixture, label elements and toxicology**

Classification of the mixture and label elements

— Hazard class and category

— Hazard pictogram codes (Annex V)

— Signal word

— Hazard statement codes, including supplemental hazard information codes (Annex III)

— Precautionary statement codes (Annex IV)

Toxicological information

— Description of the toxicity of the mixture or its components (as required in Section 11 of the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006)

Additional information on the mixture

— Colour

— pH (where applicable)

— Physical state

— Packaging (type and size)

— Intended use (product categorisation code)

— Uses (consumer, professional, industrial)

1.4. **Product identifiers of the mixture components**

Product identifiers of the mixture components (substances and mixtures in mixtures where applicable)

— Chemical/trade name of the components

— CAS number (where applicable)

— EC number (where applicable)

— UFI (where applicable)

Concentration and concentration ranges of the mixture components

— Exact concentration or concentration range

Classification of mixture components (substances and MIM)

— Hazard classification (where applicable)

— Additional identifiers (where applicable and relevant for health response)

List according to Part B, Section 3.1, fourth paragraph (where applicable)'