



EUROPEAN  
COMMISSION

Brussels, XXX  
[...] (2015) XXX draft

ANNEX 1

**ANNEX**

**to the**

**Commission Regulation**

**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 a new  
Annex on harmonised information relating to emergency health response**

## **DISCLAIMER**

### **Draft document that might be subject to further modification distributed only for discussion purposes**

The late distribution of this document is due to the timing of the Commission Inter Service Consultation that was closed on Monday 1<sup>st</sup> February 2016.

Next 4<sup>th</sup> February 2016 a presentation and initial discussion on the proposal will take place. In any case, full discussion will take place at the next Reach Committee (mid-March 2016).

Thank you for your understanding.

## **ANNEX**

### **'ANNEX VIII**

#### **HARMONISED INFORMATION RELATING TO EMERGENCY HEALTH RESPONSE**

##### **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 2.5 of this Annex, shall comply with this Annex from 1 July 2019.
- 1.2. Importers and downstream users placing on the market mixtures for professional use, within the meaning of section 2.5 of this Annex, shall comply with this Annex from 1 July 2020.
- 1.3. Importers and downstream users placing on the market mixtures for industrial use within the meaning of section 2.5 of this Annex, shall comply with this Annex from 1 July 2023.
- 1.4. Importers and downstream users having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) of Regulation (EC) No 1272/2008 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 not be required to comply with this Regulation 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 relating to the tasks laid down in Article 45(2).
- 2.2. This Annex shall apply to downstream users placing mixtures on the market, whether or not they also qualify as distributors.
- 2.3. 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 physical hazards:

- (1) Gases under pressure;
  - (2) Explosives (Unstable explosives and Divisions 1.1 to 1.6).
- 2.4. 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 submitted in accordance with section 1.3 of Part B.
  - 2.5. For the purposes of this Annex the following definitions shall apply:
    - (1) 'Mixture for industrial use' means a mixture destined for use at industrial sites;
    - (2) 'Mixture for consumer use' means a mixture destined for use by consumers;
    - (3) 'Mixture for professional use' means a mixture destined for use by professional users but not at industrial sites.

## **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 a XML format provided by the Agency.

- 3.2. Further to a reasoned request from an appointed body, submitters shall provide to the appointed bodies any additional information necessary for the appointed body to carry out its tasks.
- 3.3. The language used in the submission shall be the official language or languages of the Member State or Member States where the mixture is placed on the market, except where a Member State allows submission in another language as an alternative.
- 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 as laid down in section 4 of Part B in the case of a change in the product identifier or in the composition of a mixture, or when new toxicological information on its hazardous properties becomes available.

#### **4. Group submission**

- 4.1. A single submission may be provided for more than one mixture where all grouped mixtures have the same classification for health and physical hazards and the information in that submission covers all the composition variants of the grouped mixtures in accordance with section 1.1.1 of Part B for each of those mixtures, hereinafter 'group submission'.
- 4.2. A group submission shall only be permitted when the concentration level of a substance present in the group of mixtures belongs to the same concentration range, as provided in section 3.4 of Part B.

#### **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 to a specific mixture. The assignment of a UFI is free of charge and it shall be provided in the format set out in Part C.
- 5.2. The submitter shall print or affix the UFI on the label or packaging of a hazardous mixture supplied for consumer and/or professional use. The UFI shall be preceded by the acronym "UFI" in capital letters and it shall be clearly visible, legible and indelibly marked.
- 5.3. In the case of a limited submission referred to in section 2.4, the UFI shall be indicated only in the Safety Data Sheet.

#### **5. Formats and technical support for submission of information**

- 5.1. 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.
- 5.2. 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 17(2) and Article 18(3).

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.

***1.1.1. Group submission***

In the case of a group submission, all product identifiers for the relevant mixtures shall be provided according to the criteria listed in section 1.1.

**1.2. Details of the submitter**

The name, full address, telephone number, VAT number and e-mail 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 for rapid access to additional product information**

In the case of a limited submission as laid down in section 2.4 of Part A, a telephone number for rapid access to additional detailed product information services shall be provided. It shall consist of a telephone number accessible 24 hours per day, 7 days per week at which rapid access to detailed additional product information is available for appointed bodies during emergencies.

***2. Hazards identification and additional information***

This section sets out 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

At least the following labelling elements required in accordance with Article 17 shall be provided:

- hazard pictograms;
- signal words;
- hazard statements (including supplemental hazard information);
- precautionary statements.

## 2.3. Toxicological information

The submission shall include the information on the toxicological effects of the mixture or its components contained 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 and the physical state of the mixture, as supplied;
- the pH of the mixture (where applicable the pH shall be indicated for an aqueous solution of the mixture; in that case the concentration shall be expressed in % w/w);
- product categorisation (see section 3.4 of Part A);
- use (consumer, professional, industrial).

## 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.

#### 3.1.1. Requirements for mixtures for industrial use

In the case of a limited submission as laid down in section 2.4 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: product identifier

### 3.2. Substances

The product identifier for the substances identified according to section 3.3 shall be provided in accordance with Article 17(2) and Article 18(2).

By derogation from the first paragraph, the generic product identifiers ‘perfumes’, ‘fragrances’ or ‘colouring agents’ may be used for mixture components where applicable, where the following conditions are met:

- the mixture components are not classified for health hazards of major concern as defined in Section 3.4.1.;
- to the extent that the concentration of mixture components identified with a given generic product identifier does not exceed 10 % of the mixture in total.

The chemical name of substances for which an alternative chemical name has been allowed in accordance with Article 24 shall be provided as well.

#### 3.2.1. 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 composition of substances contained in a MIM shall be provided in accordance with the criteria of this Section, unless the submitter does not have access to information on its full composition. 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), together with its concentration and UFI, when available; the name, e-mail address and telephone number of the MIM supplier shall also be provided.

### 3.3. Mixture components subject to submission requirements

The following mixture components (substances and MIM) shall be indicated:

- a) Mixture components classified as hazardous on the basis of their health or physical effects which:
  - i. are present in concentrations equal or higher than 0.1%;
  - ii. are identified, even if in concentrations lower than 0.1%;
- b) 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 following information 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

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 percentage, 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
$\geq 25 - < 100$	5 % units
$\geq 10 - < 25$	3 % units
$\geq 1 - < 10$	1 % units
$\geq 0.1 - < 1$	0.3 % units
$>0 - < 0.1$	0.1 % units

3.4.2. *Other hazardous components and non-hazardous components*

The concentration of the hazardous components in a mixture not included in section 3.4.1. and of the identified non-hazardous components present at 1 % or above 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.

*Table 2*

**Concentration ranges applicable to other hazardous components and non-hazardous components (substances or mixtures in mixture MIM)**

Concentration range of the component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
---	---

$\geq 25 - < 100$	20 % units
$\geq 10 - < 25$	10 % units
$\geq 1 - < 10$	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 of the compilation of Safety Data Sheet. Alternatively, in the case of a MIM, only its classification may be provided.

## 4. Submission update

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

- when the mixture product identifier (including the UFI) or the mixture classification for health and physical hazards has been changed;
- when new toxicological information contained 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 substances in 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) when the exact concentration of a component was provided, in accordance with section 3.4.1., and a change occurs to that concentration beyond the limits identified with Table 3.

*Table 3*

### Variations of the concentration of components requiring a submission update

Initial concentration range of the component contained in the mixture (%)	Variations ( $\pm$ ) of the initial substance concentration requiring a submission update
$> 25 - \leq 100$	5 %
$> 10 - \leq 25$	10 %
$> 2.5 - \leq 10$	20 %
$\leq 2.5$	30 %

#### 4.2. Content of the submission update

The submission update shall consist in 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. If required in accordance with this Annex it shall include the following data:

#### 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 (UFI)
- Others identifiers (registration number, authorisation number, company product codes)

##### *Contact details of the submitter*

- Name
- Address (street, city, postal code, country)
- Telephone number
- E-mail
- VAT number

*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)

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

##### *Classification of the mixture and label elements*

- Hazard class and category
- Hazard pictograms code (Annex V)
- Signal word
- Hazard statement code (Annex III including supplemental hazard information)

- Precautionary statement code (Annex IV)

#### *Toxicological information*

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

#### *Additional Information on the mixture*

- Colour
- pH
- Physical state
- Packaging (type and size)
- Intended use (Product categorisation Code)
- Uses identification (indicate all uses: consumer, professional or industrial)

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

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

- Chemical name of the components
- CAS number (where applicable)
- EC number (where applicable)
- UFI (where applicable)
- Exact concentration or maximum/minimum concentration
- Hazard classification (where applicable)
- Additional identifiers (where applicable and relevant for health response)'