EUROPEAN
COMMISSION

Brussels, XXX
D046374/01
[…](2015) XXX draft

COMMISSION 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 by adding an Annex on harmonised information relating to emergency health response

(Text with EEA relevance)

COMMISSION 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 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/EEFC 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.

[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) 03.03.2015

(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 percent 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 is added:

'*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 July 2019.

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