Commission Delegated Regulation (EU) 2020/1677 of 31 August 2020 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures in order to improve the workability of information requirements related to emergency health response (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2020/1677

of 31 August 2020

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures in order to improve the workability of information requirements related 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) 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 requirements were amended by Commission Delegated Regulation (EU) 2020/11[(3)]. Importers and downstream users are required to start complying with the requirements in stages, according to a series of compliance dates depending on the use for which a mixture is placed on the market

(2) Concerns have been raised by various industry sectors regarding the workability of the emergency health response information requirements in certain cases, notably with regard to the difficulty of knowing the exact composition of mixtures in cases where raw materials with a highly variable or unknown composition are used in the manufacture of the mixture, in cases where toxicologically very similar components supplied by multiple, different suppliers are used together in the same production line, or in cases involving complex supply chains. Concerns have also been raised, in the case of bespoke mixtures, about the impossibility of knowing in advance which exact bespoke mixtures are to be placed on the market.

(3) It is necessary to address the situation where different but toxicologically very similar components are used in a mixture, and where it is unknown which component is

present in a particular mixture placed on the market at a given time. To ensure that the emergency health response requirements can be complied with properly in practice, importers and downstream users should be allowed to group toxicologically similar components of a mixture together in an interchangeable component group and provide information on the total concentration of those components present in the mixture, without having to specify their separate concentrations. In order to allow poison centres to formulate a suitable emergency health response, components should only be grouped in an interchangeable component group if their classification for health and physical effects is identical and if the hazards identification and the additional hazard information are identical for all possible combinations of the resulting final mixture incorporating those components. For components classified for certain hazard classes, it should also be necessary for them to have the same technical function and the same toxicological properties in order to be grouped.

(4) In order to address particular difficulties encountered by the gypsum, ready-mixed concrete and cement sectors and to allow them to comply with the emergency health response requirements without reducing the level of safety, it should be possible for emergency health response information relating to certain standardised mixtures within those three sectors to be submitted by reference to a standard composition. However, in order to allow poison centres to formulate a suitable emergency health response, this option should only be available in cases where the mixture classification does not change according to the mixture's composition within the concentration ranges specified in the standard formula, and where the information on composition is at least as detailed as the information contained in the mixture's safety data sheet, drawn up in accordance with Article 31 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ('safety data sheet')[4]. In the event that the information contained in the safety data sheet is more detailed than the information on the composition in the standard formula, importers and downstream users should be required to notify the information in the safety data sheet instead.

(5) In order to address particular difficulties anticipated for certain fuels, and taking into account the facts that fuels placed on the market normally conform to a technical standard and that poison centres have communicated a low number of poisoning incidents with fuels, it should be possible, until a more suitable solution is found, to submit emergency health response information by reference to the information contained in the safety data sheet, as well as any other known information on the products' chemical composition.

(6) In order to satisfy customer demand for very specific paint shades, formulators are sometimes asked to formulate and supply paints on a bespoke basis at the point of sale. These bespoke paints could have an almost unlimited number of different compositions. Therefore, without any mitigating measures, compliance with the emergency health response requirements in Annex VIII to Regulation (EC) No 1272/2008 would require formulators of bespoke paints either to submit information and create unique formula identifiers (UFIs) in advance for an extremely large number of paints of all possible colour combinations, many of which might never be supplied in reality, or to postpone each supply until the information had been submitted and the UFI had been created.

Either approach would place a disproportionate burden on the bespoke paints industry, in particular small and medium-sized enterprises, without improving the level of safety significantly.

(7) Poison centres have not communicated a significant number of accidents related to paints. In light of the apparently lower risks compared to other mixtures, it is justified to allow a more flexible approach, as this would not be reducing the current level of safety.

(8) It is therefore appropriate to provide for the possibility to exempt bespoke paints from the notification obligations in Annex VIII and from the requirement to create a UFI. However, in that case, in order to allow poison centres to formulate a suitable emergency health response, the individual mixtures contained in bespoke paints should remain subject to all the requirements of that Annex. Alongside this Regulation, Commission Delegated Regulation (EU) 2020/1676[(5)] amends Article 25 of Regulation (EC) No 1272/2008 to add a new rule, in the case of bespoke paints for which no submission in accordance with Annex VIII has been made and no corresponding UFI has been created, requiring the UFIs of all the individual mixtures contained in the bespoke paint to be indicated on the label of the bespoke paint, together with the specific concentration of each such mixture with a UFI that is present in a concentration exceeding 5 %.

(9) Given the number of changes to Annex VIII to Regulation (EC) No 1272/2008, it is appropriate to replace the whole Annex for the sake of legal clarity.

(10) Considering that the compliance date for mixtures for consumer and professional use of 1 January 2021 laid down in Annex VIII to Regulation (EC) No 1272/2008 is approaching, and that this Regulation enables all sectors to comply with that Annex, this Regulation should enter into force as early as possible.

(11) Regulation (EC) No 1272/2008 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex VIII to Regulation (EC) No 1272/2008 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day after its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 31 August 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/1677. (See end of Document for details)*

***Changes to legislation:** There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/1677. (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 2021.

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 or mixtures with an end use not subject to notification 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, SCOPE AND DEFINITIONS

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).

2.2a. In the case of bespoke paints, submitters may, without prejudice to Article 25(8), opt not to submit information and not to create a Unique Formula Identifier in accordance with this Annex.