

Brussels, **XXX**
[...](2020) **XXX** draft

COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

amending Article 25 of Regulation (EC) 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards bespoke paints

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

According to Article 45(1) of Regulation (EC) No 1272/2008, Member States' appointed bodies shall be responsible for receiving information from importers and downstream users on the hazardous chemical mixtures they place on the market. Commission Regulation (EU) 2017/542 amended Regulation (EC) 1272/2008 by adding an Annex harmonising the information to be provided relating to emergency health response (“Annex VIII”)¹.

Annex VIII was adopted in March 2017. After adoption, Member States and industry stakeholders called for amendments of Annex VIII before its compliance date, for reasons of serious workability concerns². The Commission commissioned a study to assess the legitimacy of the claims and the impact on duty holders and concluded that an amendment of Annex VIII was indeed necessary. The amendment would constitute a second amendment to the Regulation, after the adoption of Regulation (EU) 2020/11, which deferred the compliance date for mixtures for consumer use and aimed at a more streamlined interpretation of the rules, improving internal coherence and mitigating some unintended consequences that had only become apparent since the adoption of Regulation (EU) 2017/542.

The Commission is now proposing to add paragraph (8) to Article 25 as well as amend Annex VIII of Regulation (EC) 1272/2008 as they contain the solutions to solve those workability issues.

In line with the empowerments given under Regulation (EC) 1272/2008, amended through Regulation (EU) 2019/1243, and in particular Article 53c thereof, the Commission shall adopt a separate delegated act in respect of each power delegated to it. Since powers delegated for the amendment of Article 25 and Annex VIII are different, the Commission is proposing two separate delegated acts.

This proposed act contains the addition of paragraph (8) to Article 25 providing for a solution for bespoke paints. The act constitutes only part of the solution, namely the consequence for the labelling obligations in Article 25 of Regulation (EC) 1272/2008 of the non-necessity to create a UFI for bespoke paints. The non-necessity to create a UFI for bespoke paints, being the other part of the solution, is stipulated in [Commission Delegated Regulation (EU) YYYY/XXX *[OP: please insert reference to Commission Delegated Regulation ...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]*].

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Pursuant to Article 53a(4) of Regulation (EC) No 1272/2008 experts designated by each Member State were consulted in the relevant expert group CARACAL [Competent Authorities

¹ OJ L 78, 23.3.2017, p. 1–12.

² For example the effects on compliance possibility of mixtures with a highly variable composition due to the natural origin of their components; the difficulty of knowing the exact composition of products in cases involving complex supply chains; and the impact of multiple suppliers of mixture components with the same technical properties and hazards.

for REACH and CLP (E02385)] according to the rules of the Interinstitutional Agreement on Better Law-Making of 13 April 2016³.

Furthermore, the initiative was published for feedback during the period [insert] under the title [insert] (link). The public feedback received can be summarised as follows.

[insert part on public feedback mechanism after ISC]

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal act amends Regulation (EC) 1272/2008. The legal basis of this delegated act is Article 53(1) of Regulation (EC) 1272/2008.

³ OJ L 123, 12.5.2016, p. 1.

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of **XXX**

amending Article 25 of Regulation (EC) 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards bespoke paints

(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 1907/2006⁴, and in particular Article 53(1) thereof,

Whereas:

- (1) Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) 2017/542⁵ to add certain requirements for the submission of information relating to emergency health response and for the inclusion of a ‘unique formula identifier’ (UFI) in the supplemental information provided on the label of a hazardous mixture. 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) The paints sector has raised a specific concern regarding the workability of the emergency health response requirements in the case of paints formulated in limited amounts on a tailor made basis for an individual consumer or professional user at the point of sale. In order to satisfy customer demand for very specific paint shades, formulators can be asked to formulate and supply paints with an almost unlimited number of different compositions. Compliance with the emergency health response requirements would therefore require formulators either to submit information and create UFIs in advance for an extremely large number of paints of all possible colour combinations, many of which may never be supplied in reality, or else to postpone each supply at the point of sale until the information had been submitted and the UFI had been created. Either approach would place a disproportionate burden on the bespoke paints industry.
- (3) In order to avoid disproportionate administrative burden, in particular for small and medium sized enterprises, for bespoke paints, the requirements are to be amended by Commission Delegated Regulation (EU) YYYY/XXX [OP: please insert reference to Commission Delegated Regulation ... amending Regulation (EC) No 1272/2008 of the

⁴ OJ L 353, 31.12.2008, p.1.

⁵ 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 (OJ L 78, 23.3.2017, p. 1).

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] to provide for the possibility to exempt bespoke paints from the notification obligations in Annex VIII to Regulation (EC) No 1272/2008 and from the obligation in that Annex 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 are to remain subject to all the requirements of Annex VIII.

- (4) In the light of that, it is appropriate to amend Article 25 of Regulation (EC) No 1272/2008 in order to lay down a rule for bespoke paints for which no information is notified and no corresponding UFI created requiring the UFIs of all the mixtures contained in the bespoke paint to be indicated on the label of the bespoke paint. In addition, if the concentration of a mixture with a UFI contained in the bespoke paint exceeds 5%, the concentration should be included in the supplemental information indicated on the label of the bespoke paint, since mixtures in bespoke paints of such concentration are more likely to be relevant for emergency health responses.
- (5) Regulation (EC) No 1272/2008 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 25 of Regulation (EC) No 1272/2008, the following paragraph is added:

‘8. In the case of a bespoke paint for which no submission in accordance with Annex VIII has been made and no corresponding unique formula identifier has been created, the unique formula identifiers of all the mixtures contained in the bespoke paint which themselves are subject to notification under Article 45 shall be included in the supplemental information on the label of the bespoke paint, located together and listed in descending order of the mixtures’ concentration in the bespoke paint, in accordance with the provisions of section 5 of Part A of Annex VIII.

In a case falling within the first subparagraph, where the concentration of a mixture with a unique formula identifier in the bespoke paint exceeds 5 %, the concentration of that mixture shall also be included in the supplemental information on the label of the bespoke paint next to its unique formula identifier, in accordance with section 3.4. of Part B of Annex VIII.

For the purposes of this paragraph, ‘bespoke paint’ means a paint that is formulated in limited amounts on a tailor made basis for an individual consumer or professional user at the point of sale by tinting or colour mixing.’

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*.

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

Done at Brussels,

*For the Commission
The President
Ursula von der Leyen*