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COVER NOTE

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council
of the European Union

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Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 31.8.2020
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

Delegations will find attached document C(2020) 5759 final.

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Brussels, 31.8.2020
C(2020) 5759 final

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

of 31.8.2020

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)

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 [C(2020)5759].

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 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 12 May 2020 to 9 June 2020 under the title “Introducing labelling requirements for bespoke paints relevant for

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.

³ OJ L 123, 12.5.2016, p. 1.

poison centers” (<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12315-Amending-Regulation-EC-No-1272-2008-as-regards-supplemental-labelling-information-for-emergency-health-response>). The public feedback received can be summarised as follows.

The Commission received 46 comments from individuals and organisations, mostly associated with the chemicals industry and mainly located in Europe.

More specifically, the vast majority of comments was submitted by industrial stakeholders (92% of the comments came from either companies, or business organisations/associations) whilst comments submitted by other entities made up 8% in total (4% - EU citizen, 2% - NGO, 2% - other).

Overall, commentators very much welcomed this proposed act stating that much progress was made in providing a workable solution for bespoke paints.

The vast majority of the comments concerned a request to postpone the first compliance date of 1 January 2021 stipulated in Commission Delegated Regulation (EU) YYYY/XXX [C(2020)5759]. The reasons provided were the large numbers of mixtures claimed to have to be notified, the delay of the adoption of this act compared with the original timeline due to COVID-19 and the ensuing impossibility to adopt this act before the non-transmission period of the European Parliament and the Council during a certain period in summer⁴, the concern that the necessary IT tools developed by ECHA to which industry needs to adapt their systems may not be ready in time and the concern that the IT systems of the Member States may suffer from potential security breaches if not ready in time.

The Commission does not intend to postpone the compliance date of 1 January 2021 for the following reasons: The European Chemicals Agency (“Agency”) developed and published the submission format as per Part C of Annex VIII already in April 2019. Further, the Agency developed and established a searchable database which is operational since November 2019.

Concerning the readiness of the Member States’ IT systems, the preparation for their access to the searchable database is going according to plan for all Member States that have opted to use the searchable database of the Agency. Member States only get access to the searchable database if they fulfil all security requirements, so the concerns regarding security breaches are unfounded

Regarding the delay caused by COVID-19 and the ensuing impossibility to adopt this act before the non-transmission period of the co-legislators in a certain period in summer, the Commission estimates that it amounted to approximately two and a half months. In the view of the Commission, this however does not warrant a postponement of the compliance date.

The feedback pointed out that a significant number of mixtures need to be notified as of 1 January 2021. It should be taken into account that Annex VIII merely harmonises the submission format and that the submission obligations under Article 45 are already applicable since Regulation (EC) 1272/2008 entered into force. A transitional period until 1 January 2025 for already notified mixtures under the existing national systems is foreseen under Regulation (EU) 2017/542, so mixtures already placed on the market can benefit from it.

Concerning the introduction of Article 25(8), it was commented that no concentration threshold for the mentioning of the UFIs on the bespoke paint’s packaging of the hazardous mixtures contained in it is set and a 10% threshold was proposed. The expert group consulted and quoted above discussed the same matter and reached the conclusion that a much lower

⁴ OJ L 123, 12.5.2016, p. 1.

threshold is needed to provide adequate emergency health response. A concentration threshold of 0.1% is now introduced, which is consistent with the threshold for the identification of hazardous components in a notification.

Regarding the second subparagraph of Article 25(8) providing for the obligation to include the concentration of a mixture with a unique formula identifier on the label of the bespoke paint where it exceeds 5%, industrial stakeholders proposed to increase the threshold to 10% to properly protect confidential business information. The expert group consulted and quoted above discussed the same issue and concluded that the set limit should be kept in order to provide adequate emergency health response, taking into account in particular that most paints are formulated with a concentration of less than 5% per colouring component. The Commission is of the view that since the draft text already allows to indicate a certain concentration range instead of a specific concentration, the possibility to reverse engineer the chemical composition of the mixture is significantly reduced and that the arguments provided were not substantiated sufficiently to justify an additional reduction in the level of safety.

Further suggestions concerned the broadening of the definition of “bespoke paint” to “bespoke colour mixtures” under the third subparagraph of Article 25(8) and subparagraph (5) Section 2.4., Part A of Annex VIII in order to allow all bespoke colour mixtures to benefit from the derogation. In the Commission’s view, a differentiation needs to be made between mixtures having the purpose to add colour and mixtures that are coloured. Coloured mixtures cannot fall under the definition of “paint”. No market or incident data of other bespoke colour mixtures was provided, thus an extension of the definition without any supporting data would be unjustified.

Further comments suggest deleting the reference to “limited amounts” in the definition of “bespoke paint”. The Commission believes that this specification is necessary in order to clearly define the bespoke paint concept, as without it an unlimited quantity of bespoke paints could be placed on the market which would result in a different risk scenario. At the same time, any specific limit set would have been arbitrary and unjustified considering that the definition should suit different case scenarios.

Moreover, it was proposed to include “bespoke industrial paints and inks” in the definition of bespoke paint under the third subparagraph of Article 25(8) and subparagraph (5) Section 2.4., Part A of Annex VIII given that mixing tinters or colours at the point of sale also exists for the industrial segment. Given the lack of evidence on the need for a derogation for such paints and the late timing of the request, the Commission does not find it justified to expand the derogation. The matters related to bespoke paints were also discussed with the expert group consulted and quoted above and the majority of experts preferred to not extend the simplification in any way.

Comments were raised to provide more flexibility for placing the unique formula identifier(s) (UFI(s)) on other parts of the packaging (such as on top, on the lid) instead of in the section for supplemental information on the label or the packaging located with the other label elements by virtue of Article 29(4a) and Section 5.3. Part A of Annex VIII. The Commission is of the view that the current provisions allow for enough flexibility relating to the location of the UFI.

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.

Commission Delegated Regulation (EU) .../... of 31.8.2020 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 1907/2006⁵, and in particular Article 53(1) thereof,

Whereas:

- (1) Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) 2017/542⁶ 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 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, C(2020)5759*] to provide for the

⁵ OJ L 353, 31.12.2008, p.1.

⁶ 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).

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) 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.
- (6) 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 in a concentration exceeding 0.1% 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 day after 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, 31.8.2020

For the Commission
The President
Ursula VON DER LEYEN