COMMISSION DELEGATED REGULATION (EU) 2021/643

of 3 February 2021

amending, for the purposes of its adaptation to technical and scientific progress, Part 1 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

(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 53(1) thereof,

Whereas:

(1) Member States and stakeholders have requested that a number of the notes set out in subsection 1.1.3 of Part 1 of Annex VI to Regulation (EC) No 1272/2008 be amended.

(2) The Commission accepts that the wording of those notes needs to be improved. Some of the notes related to substances are inaccurate and bring in some uncertainty as to the correct interpretation of legal obligations. In particular, some of those notes could be interpreted as not requiring the substances with respect of which those notes apply to be classified at all under certain conditions, whereas, in fact, they should not be covered by the harmonised classification and labelling but should still be subject to classification in accordance with Title II of Regulation (EC) No 1272/2008 (self-classification).

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

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1272/2008

Part 1 of Annex VI to Regulation (EC) No 1272/2008 is amended as set out in the Annex to this Regulation.

Article 2

Entry into force

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 all Member States.

([1]) OJ L 353, 31.12.2008, p. 1.

Done at Brussels, 3 February 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Part 1 of Annex VI to Regulation (EC) No 1272/2008 is amended as follows:

(1) in point 1.1.3.1, notes J to R are replaced by the following:

'Note J:

The harmonised classification as a carcinogen or mutagen applies unless it can be shown that the substance contains less than 0,1 % w/w benzene (Einecs No 200-753-7), in which case a classification in accordance with Title II of this Regulation shall be performed also for those hazard classes.

Note K:

The harmonised classification as a carcinogen or mutagen applies unless it can be shown that the substance contains less than 0,1 % w/w 1,3- butadiene (Einecs No 203-450-8), in which case a classification in accordance with Title II of this Regulation shall be performed also for those hazard classes. Where the substance is not classified as a carcinogen or mutagen, at least the precautionary statements (P102-)P210-P403 shall apply.

Note L:

The harmonised classification as a carcinogen applies unless it can be shown that the substance contains less than 3 % of dimethyl sulphoxide extract as measured by IP 346 ("Determination of polycyclic aromatics in unused lubricating base oils and asphaltene free petroleum fractions – Dimethyl sulphoxide extraction refractive index method" Institute of Petroleum, London), in which case a classification in accordance with Title II of this Regulation shall be performed also for that hazard class.

Note M:

The harmonised classification as a carcinogen applies unless it can be shown that the substance contains less than 0,005 % w/w benzo[a]-pyrene (Einecs No 200-028-5), in which case a classification in accordance with Title II of this Regulation shall be performed also for that hazard class.

Note N:

The harmonised classification as a carcinogen applies unless the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen, in which case a classification in accordance with Title II of this Regulation shall be performed also for that hazard class.

Note P:

The harmonised classification as a carcinogen or mutagen applies unless it can be shown that the substance contains less than 0,1 % w/w benzene (Einecs No 200-753-7), in which case a classification in accordance with Title II of this Regulation shall be performed also for those hazard classes. Where the substance is not classified as a carcinogen or mutagen, at least the precautionary statements (P102-)P260-P262-P301 + P310-P331 shall apply.

Note Q:

The harmonised classification as a carcinogen applies unless one of the following conditions is fulfilled:

— a short term biopersistence test by inhalation has shown that fibres longer than 20 μm have a weighted half-life less than 10 days; or

— a short term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 μm have a weighted half-life less than 40

days; or

— an appropriate intra-peritoneal test has provided no evidence of excess carcinogenicity; or

— no relevant pathogenicity or neoplastic changes are noted in a suitable long term inhalation test

Note R:

The harmonised classification as a carcinogen applies except in the case of fibres with a Length Weighted Geometric Mean Diameter (LWGMD) minus two geometric standard errors greater than 6 μm, as measured in accordance with Test method A.22 in the Annex to Commission Regulation (EC) No 440/2008 (*).

(*) Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).';

(2) in point 1.1.3.2, Notes 8 and 9 are replaced by the following:

'Note 8:

The classification as a carcinogen shall apply unless it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 0,1 %.

Note 9:

The classification as a mutagen shall apply unless it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 1 %.'