



EUROPEAN
COMMISSION

Brussels, **XXX**
[...](2019) **XXX** draft

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

of XXX

amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(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.

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amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 131 thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1907/2006 lays down requirements for the compilation of safety data sheets, used to provide information on chemical substances and mixtures in the Union.
- (2) As of 1 January 2020, Commission Regulation (EU) 2018/1881² amending Annexes I, III and VI to XII to Regulation (EC) No 1907/2006 shall apply. Regulation (EU) 2018/1881 introduces specific requirements for nanoforms of substances. As information related to those requirements is to be included in the safety data sheets, Annex II to Regulation (EC) No 1907/2006 should be modified accordingly.
- (3) The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) developed in the framework of the United Nations, sets out internationally harmonised criteria for the classification and labelling of chemicals and rules on safety data sheets. The Union confirmed its intention to incorporate the GHS criteria into Union law.
- (4) The instruments foreseen by GHS to communicate the hazards of substances and mixtures are labels and safety data sheets. The GHS provisions on safety data sheets are included in Regulation (EC) No 1907/2006. Therefore, the requirements for safety data sheets laid down in Annex II to Regulation (EC) No 1907/2006 should be adapted to the rules for safety data sheets of the sixth and seventh revision of the GHS.

¹ OJ L 396, 30.12.2006, p. 1.

² Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances (OJ L 308, 4.12.2018, p. 1).

- (5) Annex VIII to Regulation (EC) No 1272/2008 of the European Parliament and of the Council³ will allow, inter alia, the possibility that the unique formula identifier be indicated only in the safety data sheet as regards hazardous mixtures supplied for use at industrial sites. It will also require for certain mixtures which are not packaged that the unique formula identifier be indicated in the safety data sheet. As operators need to comply with the relevant obligations of Annex VIII to Regulation (EC) No 1272/2008 as of 1 January 2021, for reasons of consistency, Annex II to Regulation (EC) No 1907/2006 should reflect those changes as well.
- (6) The Commission Communication of 7 November 2018 ‘Towards a comprehensive European Union framework on endocrine disruptors’⁴ indicates that the Commission is assessing how to improve the communication through the supply chain for endocrine disruptors under Regulation (EC) No 1907/2006 in the context of the work on safety data sheets. A number of specific requirements for safety data sheets have been identified as relevant for substances and mixtures with endocrine disrupting properties and Annex II of this Regulation should therefore be modified accordingly.
- (7) Specific concentration limits, multiplying factors and acute toxicity estimates set in accordance with Regulation (EC) No 1272/2008, are relevant for the safe use of substances and mixtures, and should therefore be provided in safety data sheets, if available.
- (8) Requiring economic operators who have already compiled safety data sheets, to update them immediately in accordance with the provisions of this Regulation would impose a disproportionate burden on them. Operators should rather be allowed to continue using safety data sheets provided, in accordance with Regulation (EC) No 1907/2006, as amended by Commission Regulation (EU) 2015/830⁵, to any recipient for a certain period. This is without prejudice to the obligation to update the safety data sheets in accordance with Article 31(9) of Regulation (EC) No 1907/2006, including the cases where the unique formula identifier has to be added for the first time to safety data sheets as provided for in section 5.3 of Part A of Annex VIII to Regulation (EC) No 1272/2008.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1907/2006 is replaced by the text in the Annex to this Regulation.

³ 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 (OJ L 353, 31.12.2008, p. 1).

⁴ COM(2018)734

⁵ Commission Regulation (EU) 2015/830 of 28 May 2015 amending 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 132, 29.5.2015, p. 8).

Article 2

Safety data sheets provided to a recipient before 1 January 2020 may continue to be used and need not comply with the Annex to this Regulation until 31 December 2022.

The first paragraph shall not apply in cases when the safety data sheets need to be updated as provided for in Article 31(9) of Regulation (EC) No 1907/2006, including cases when the unique formula identifier has to be added to the safety data sheet, as provided for in section 5.3 of Part A of Annex VIII to Regulation (EC) No 1272/2008.

Article 3

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 January 2020.

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

Done at Brussels,

*For the Commission
The President*