

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/EC (Text with EEA relevance)

[^{XI}TITLE II

REGISTRATION OF SUBSTANCES

CHAPTER 1

General obligation to register and information requirements

[^{XI}Article 14

Chemical safety report and duty to apply and recommend risk reduction measures

1 Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a [^{F1}mixture] or in an article or a group of substances.

[^{F12} A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a mixture if the concentration of the substance in the mixture is less than:

- a the cut-off value referred to in Article 11, paragraph 3 of Regulation (EC) No 1272/2008;
- b 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to this Regulation.]

3 A chemical safety assessment of a substance shall include the following steps:

- a human health hazard assessment;
- b physicochemical hazard assessment;
- c environmental hazard assessment;
- d persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

[^{F14} If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

Status: Point in time view as at 01/01/2020. This version of this provision has been superseded.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, Article 14. (See end of Document for details)

- a hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- b hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- c hazard class 4.1;
- d hazard class 5.1,

or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:]

- a exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;
- b risk characterisation.

The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.

5 The chemical safety report need not include consideration of the risks to human health from the following end uses:

- a in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food⁽¹⁾;
- b in cosmetic products within the scope of Directive 76/768/EEC.

6 Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31.

7 Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.]

Editorial Information

- X1** Substituted by [Corrigendum 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/EC \(Official Journal of the European Union L 396 of 30 December 2006\).](#)

Textual Amendments

- F1** Substituted by [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 \(Text with EEA relevance\).](#)

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Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, Article 14. (See end of Document for details)

(1) [^{XI}OJ L 338, 13.11.2004, p. 4.]

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