Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 453/2010

of 20 May 2010

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on 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/EC[(1)], and in particular Article 131 thereof,

Whereas:

(1) Safety data sheets have been a well-accepted and effective method for the provision of information on substances and mixtures in the Community and have been made an integral part of the system of Regulation (EC) No 1907/2006.

(2) With a view to facilitating worldwide trade while protecting human health and the environment, harmonised criteria for classification and labelling and rules for safety data sheets have been carefully developed over a period of more than 10 years within the United Nations (UN) structure, resulting in the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as the GHS).

(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[(2)] harmonises the provisions and criteria for the classification and labelling of substances, mixtures and certain specific articles within the Community, taking into account the classification criteria and labelling rules of the GHS.

(4) Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[(3)] and Directive 1999/45/EC of the European

Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[(4)] were amended several times. Directives 67/548/EEC and 1999/45/EC will be replaced over a transitional period according to which substances must be classified, labelled and packaged according to Regulation (EC) No 1272/2008 from 1 December 2010 and mixtures from 1 June 2015, although from 1 December 2010 until 1 June 2015 classification of substances according to both Directive 67/548/EEC and Regulation (EC) No 1272/2008 is required. Both Directives will be repealed in full by Regulation (EC) No 1272/2008 with effect from 1 June 2015.

(5) Therefore Annex II to Regulation (EC) No 1907/2006 should be amended to adapt it to the criteria for classification and other relevant provisions laid down in Regulation (EC) No 1272/2008.

(6) The requirements for safety data sheets laid down in Annex II to Regulation (EC) No 1907/2006 should moreover be adapted taking into account the rules for safety data sheets of the GHS, in order to allow the threefold mechanism of classification, labelling and safety data sheets to fulfil its role through interaction of its component parts.

(7) Safety data sheets thus amended should continue to be an important element of hazard communication and provide a mechanism for transmitting appropriate safety information on substances and mixtures meeting the criteria for classification in accordance with applicable Community legislation, as well as certain substances and mixtures not meeting those criteria, taking into account information from any relevant chemical safety report, down the supply chain to the immediate downstream user.

(8) The application of the requirement to include classification and labelling according to Regulation (EC) No 1272/2008 for substances and mixtures into the safety data sheet, as amended by this Regulation, should follow the staggered application of the classification and labelling provisions for substances and mixtures in accordance with Regulation (EC) No 1272/2008. Therefore, and because the classification and hazard communication for mixtures depends on the classification and hazard communication for substances, the requirement to include classification and labelling according to Regulation (EC) No 1272/2008 for mixtures should only be applied after the requirement to include classification and labelling according to Regulation (EC) No 1272/2008 for substances.

(9) Suppliers of mixtures choosing to rely on the possibility to apply, on a voluntary basis, both the classification and the labelling in accordance with Regulation (EC) No 1272/2008 earlier than 1 June 2015 should provide in the relevant safety data sheet the classification in accordance with Regulation (EC) No 1272/2008 together with the classification in accordance with Directive 1999/45/EC.

(10) Safety data sheets for substances providing classification and labelling information in accordance with Regulation (EC) No 1272/2008 should, before 1 June 2015, be required to provide classification information in accordance with Directive 67/548/EEC as well, in order to allow suppliers of mixtures not relying on the possibility to apply both

the classification and the labelling in accordance with Regulation (EC) No 1272/2008 earlier, to classify and label those mixtures correctly.

(11) 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

Regulation (EC) No 1907/2006 is amended as follows:

1. with effect from 1 December 2010:

   (a) Annex II is replaced by Annex I to this Regulation;

   (b) in Section 3.7 of Annex VI, in the title, the words '(see Safety Data Sheet heading 16)' are replaced by '(see Section 1 of the safety data sheet)';

2. with effect from 1 June 2015, Annex II to Regulation (EC) No 1907/2006 is replaced by Annex II to this Regulation.

Article 2

1 Until 1 December 2010, suppliers of substances applying Article 61(2) of Regulation (EC) No 1272/2008 may apply Annex II to Regulation (EC) No 1907/2006, as amended by point 1 of Article 1 of this Regulation.

2 Until 1 December 2010, suppliers of mixtures may apply Annex II to Regulation (EC) No 1907/2006, as amended by point 1 of Article 1 of this Regulation.

3 Until 1 June 2015, suppliers of mixtures applying Article 61(2) of Regulation (EC) No 1272/2008 may apply Annex II to Regulation (EC) No 1907/2006, as amended by point 2 of Article 1 of this Regulation.

4 Until 1 June 2015, suppliers of mixtures applying paragraph 3 shall provide in subsection 3.2 of the relevant safety data sheets the classification of the substances indicated in that subsection in accordance with Directive 67/548/EEC, including indication of danger, symbol letter(s) and R phrases, in addition to the classification including hazard statements in accordance with Regulation (EC) No 1272/2008.

5 Until 1 June 2015, suppliers of mixtures applying paragraph 3 shall provide in subsection 2.1 of the relevant safety data sheets the classification of the mixture in accordance with Directive 1999/45/EC in addition to the classification including hazard statements in accordance with Regulation (EC) No 1272/2008.

Until 1 June 2015, suppliers of mixtures meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008 shall, when applying paragraph 3, indicate the substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC in subsection 3.2 of the relevant safety data sheets if those substances are present in concentrations equal to or greater than the lowest of the values listed in point 3.2.1(a) of Annex II to this Regulation in addition to the substances mentioned in point 3.2.1 of that Annex.

Until 1 June 2015, suppliers of mixtures not meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008 shall, when applying paragraph 3, indicate the substances presenting a health or environmental hazard within the meaning

of Directive 67/548/EEC in subsection 3.2 of the relevant safety data sheets if those substances are present in an individual concentration equal to or greater than 1 % by weight in non-gaseous mixtures and 0,2 % by volume in gaseous mixtures in addition to the substances mentioned in point 3.2.2 of Annex II to this Regulation.

6 Without prejudice to Article 31(9) of Regulation (EC) No 1907/2006, for substances which are placed on the market before 1 December 2010 and which are not required to be relabelled and repackaged in accordance with Article 61(4) of Regulation (EC) No 1272/2008, the safety data sheet need not be replaced with a safety data sheet complying with Annex I to this Regulation before 1 December 2012.

Without prejudice to Article 31(9) of Regulation (EC) No 1907/2006, for mixtures which are placed on the market before 1 June 2015 and which are not required to be relabelled and repackaged in accordance with Article 61(4) of Regulation (EC) No 1272/2008, the safety data sheet need not be replaced with a safety data sheet complying with Annex II to this Regulation before 1 June 2017.

7 Without prejudice to Article 31(9) of Regulation (EC) No 1907/2006, safety data sheets for mixtures provided to any recipient at least once before 1 December 2010 may continue to be used and need not comply with Annex I to this Regulation until 30 November 2012.

Article 3

This Regulation shall enter into force on the 20th day following 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.

Done at Brussels, 20 May 2010.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 453/2010. (See end of Document for details)*

ANNEX I

ANNEX II

REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS

PART A

0.1. Introduction

0.1.1. This Annex sets out the requirements that the supplier shall fulfil for the compilation of a safety data sheet that is provided for a substance or a mixture in accordance with Article 31.

0.1.2. The information provided in the safety data sheet shall be consistent with the information in the chemical safety report, where one is required. Where a chemical safety report has been completed, the relevant exposure scenario(s) shall be placed in an annex to the safety data sheet.

0.2. General requirements for compiling a safety data sheet

0.2.1. The safety data sheet shall enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment. The writer of the safety data sheet shall take into account that a safety data sheet must inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or the mixture.

0.2.2. The information provided by safety data sheets shall also meet the requirements set out in Council Directive 98/24/EC. In particular, the safety data sheet shall enable employers to determine whether any hazardous chemical agents are present in the workplace, and to assess any risk to the health and safety of workers arising from their use.

0.2.3. The information in the safety data sheet shall be written in a clear and concise manner. The safety data sheet shall be prepared by a competent person who shall take into account the specific needs and knowledge of the user audience, as far as they are known. Suppliers of substances and mixtures shall ensure that such competent persons have received appropriate training, including refresher training.

0.2.4. The language used in the safety data sheet shall be simple, clear and precise, avoiding jargon, acronyms and abbreviations. Statements such as “may be dangerous”, “no health effects”, “safe under most conditions of use” or “harmless” or any other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with the classification of that substance or mixture shall not be used.

0.2.5. The date of compilation of the safety data sheet shall be given on the first page. When a safety data sheet has been revised and the new, revised version is provided to recipients, the changes shall be brought to the attention of the recipient in Section 16 of the safety data sheet, unless they have been indicated elsewhere. In that case, the date of compilation identified as “Revision: (date)” as well as a version number, revision number, supersedes date or other indication of what version is replaced shall appear on the first page.

0.3. Safety data sheet format