Commission Regulation (EU) No 109/2012 of 9 February 2012 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 Annex XVII (CMR substances) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 109/2012

of 9 February 2012

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 Annex XVII (CMR substances)

(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 68(2) thereof,

Whereas:

(1) Annex XVII to Regulation (EC) No 1907/2006, in its entries 28 to 30, prohibits the sale to the general public of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1A or 1B or of mixtures containing them in concentration above specified concentration limits. The substances concerned are listed in Appendices 1 to 6 to Annex XVII.

(2) 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)] was amended on 5 September 2009 by Commission Regulation (EC) No 790/2009[(3)] in order to include a number of newly classified CMR substances. Appendices 1 to 6 to Annex XVII to Regulation (EC) No 1907/2006 should be amended in order to align them to the entries concerning CMR substances in Regulation (EC) No 790/2009.

(3) Under Article 68 (2) of Regulation (EC) No 1907/2006, restrictions may be proposed on the consumer use of CMR substances categories 1A and 1B on their own, in a mixture or in an article.

(4) A number of boron compounds were found to be toxic for reproduction and were classified as toxic for reproduction, hazard class and category Repr. 1B, hazard

statement H360FD under the Regulation (EC) No 790/2009. A market survey conducted for the Commission[4] on the uses of borates in mixtures sold to the general public reported that sodium perborate, tetra and monohydrate, are used in a concentration exceeding their specific concentration limit specified in Regulation (EC) No 790/2009 in household detergents and cleaners.

(5) On 29 April 2010, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) gave an opinion on the use of boron compounds in photographic applications[5]. In its opinion, the RAC noted that there were 'more possible sources that contribute to the total exposure to boron of consumers', and that these 'additional sources have to be considered in the risk assessment of boron compounds'. Multiple sources of exposure to boron of consumers were not considered in previous risk assessments, in contrast with current concerns with multiple sources of exposure in general.

(6) Sodium perborate, tetra and monohydrate, are mainly used as bleaching agents in laundry detergents and machine dishwashing products. The Rapporteur Member State, responsible for conducting the risk evaluation on sodium perborate under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances[6], submitted a dossier in accordance with Annex XV of Regulation (EC) No 1907/2006 to the European Chemicals Agency pursuant to Article 136 of that Regulation. That risk assessment, published in 2007, concluded that the use of sodium perborate in laundry detergents and household cleaners, considered in isolation as a single source of exposure to boron, did not pose an unacceptable risk to the general public. Nevertheless, because the sources of exposure of the general public to boron are multiple, as expressed in the 2010 opinion of the RAC, and due to its reproductive toxicity it is desirable to reduce the exposure of the general public to boron. Moreover, because the consumer population exposed to boron from household detergents and cleaners is considerable, and because alternatives to perborates are available in these applications, it is appropriate to restrict the use of perborates in household detergents and cleaners. However, in order to allow certain manufacturers to adapt and replace, where necessary, boron compounds with alternatives in these applications, a time-limited derogation should be granted.

(7) 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 XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply on 1 June 2012.

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

Done at Brussels, 9 February 2012.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 109/2012. (See end of Document for details)*

ANNEX

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

(1) In the table setting out the designation of the substances, groups of substances and mixtures and the conditions of restriction, in Column 2 of entries 28, 29 and 30, in paragraph 2, the following point (e) is added:

(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.

(2) In the Appendices 1 to 6, in the foreword, a note B is inserted between note A and note C, as follows:
Note B:

Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations.

(3) In Appendix 1 the table is amended as follows:

(a) The following entries are inserted in accordance with the order of the entries set out in Appendix 1 of Annex XVII of Regulation (EC) No 1907/2006:

Nickel dihydroxide; [1]	028-008-00-X	235-008-5 [1]	12054-48-7 [1]	
Nickel hydroxide; [2]		234-348-1 [2]	11113-74-9 [2]	
Nickel sulfate	028-009-00-5	232-104-9	7786-81-4	
Nickel carbonate;	028-010-00-0			
Basic nickel carbonate;				
Carbonic acid, nickel (2+) salt; [1]		222-068-2 [1]	3333-67-3 [1]	
Carbonic acid, nickel salt; [2]		240-408-8 [2]	16337-84-1 [2]	
[μ-[carbonato(2-)-O:O′]] dihydroxy trinickel; [3]		265-748-4 [3]	65405-96-1 [3]	

[carbonato(2-)] tetrahydroxytrinickel; [4]		235-715-9 [4]	12607-70-4 [4]	
Nickel dichloride	028-011-00-6	231-743-0	7718-54-9	
Nickel dinitrate; [1]	028-012-00-1	236-068-5 [1]	13138-45-9 [1]	
Nitric acid, nickel salt; [2]		238-076-4 [2]	14216-75-2 [2]	
Nickel matte	028-013-00-7	273-749-6	69012-50-6	
Slimes and sludges, copper electrolytic refining, decopperised, nickel sulphate	028-014-00-2	295-859-3	92129-57-2	
Slimes and sludges, copper electrolyte refining, decopperised	028-015-00-8	305-433-1	94551-87-8	
Nickel diperchlorate; Perchloric acid, nickel (II) salt	028-016-00-3	237-124-1	13637-71-3	
Nickel dipotassium bis(sulfate); [1]	028-017-00-9	237-563-9 [1]	13842-46-1 [1]	
Diammonium nickel bis(sulfate); [2]		239-793-2 [2]	15699-18-0 [2]	
Nickel bis(sulfamidate); Nickel sulfamate	028-018-00-4	237-396-1	13770-89-3	
Nickel bis(tetrafluoroborate)	028-019-00-X	238-753-4	14708-14-6	