Commission Regulation (EU) No 125/2012 of 14 February 2012 amending Annex XIV to 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 125/2012

of 14 February 2012

amending Annex XIV to 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 Articles 58 and 131 thereof,

Whereas:

(1) Regulation (EC) No 1907/2006 provides that substances meeting the criteria for classification as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) and toxic for reproduction (category 1A or 1B) in accordance with 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[(2)], substances that are persistent, bioaccumulative and toxic, substances that are very persistent and very bioaccumulative, and substances for which there is scientific evidence of probable serious effects to human health or the environment giving rise to an equivalent level of concern may be subject to authorisation.

(2) Diisobutyl phthalate (DIBP) meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(c) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006.

(3) Diarsenic trioxide meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006.

(4) Diarsenic pentaoxide meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006.

(5) Lead chromate meets the criteria for classification as carcinogenic (category 1B) and toxic for reproduction (category 1A) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) and (c) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006.

(6) Lead sulfochromate yellow (C.I. Pigment Yellow 34) meets the criteria for classification as carcinogenic (category 1B) and toxic for reproduction (category 1A) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) and (c) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006.

(7) Lead chromate molybdate sulphate red (C.I. Pigment Red 104) meets the criteria for classification as carcinogenic (category 1B) and toxic for reproduction (category 1A) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) and (c) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006.

(8) Tris (2-chloroethyl) phosphate (TCEP) meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(c) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006.

(9) 2,4-Dinitrotoluene (2,4 DNT) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006.

(10) The abovementioned substances have been prioritised for inclusion in Annex XIV to Regulation (EC) No 1907/2006 by the European Chemicals Agency in its recommendation of 17 December 2010[3] in accordance with Article 58 of that Regulation.

(11) For each substance listed in Annex XIV to Regulation (EC) No 1907/2006, where the applicant wishes to continue to use the substance or place the substance on the market, it is appropriate to set a date by which applications must be received by the European Chemicals Agency, in accordance with Article 58(1)(c)(ii) of that Regulation.

(12) For each substance listed in Annex XIV to Regulation (EC) No 1907/2006 it is appropriate to set a date from which the use and placing on the market is prohibited, in accordance with Article 58(1)(c)(i) of that Regulation.

(13) The European Chemicals Agency recommendation of 17 December 2010 has identified different latest application dates for the substances listed in the Annex to this Regulation. These dates should be set on the basis of the estimated time that would be required to prepare an application for the authorisation, taking into account the information available on the different substances and the information received during the public consultation carried out in accordance with Article 58(4) of Regulation (EC) No 1907/2006. The Agency's capacity to handle applications in the time provided for in the Regulation (EC) No 1907/2006 should also be taken into account.

(14) In accordance with Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006, the latest application date is to be set at least 18 months before the sunset date.

(15) Diisobutyl phthalate is an alternative substance to dibutyl phthalate which is already included in Annex XIV to Regulation (EC) No 1907/2006. In order to avoid potential substitution between these two substances, the latest application date for diisobutyl phthalate should be set as close as possible to the latest application date set out for dibutyl phthalate.

(16) Article 58(1)(e) in conjunction with Article 58(2) of Regulation (EC) No 1907/2006 provides for the possibility of exemptions of uses or categories of uses in cases where there is specific EU legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks. In accordance with the information currently available it is not appropriate to set exemptions based on those provisions.

(17) On the basis of the information currently available it is not appropriate to set exemptions for product and process orientated research and development.

(18) On the basis of the information currently available it is not appropriate to set review periods for certain uses.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Committee established pursuant to Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XIV 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 third 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.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 125/2012. (See end of Document for details)

Done at Brussels, 14 February 2012.

For the Commission

The President

José Manuel BARROSO