# Commission Regulation (EU) No 348/2013 of 17 April 2013 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 348/2013

## of 17 April 2013

## 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 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) Trichloroethylene 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.

(3) Chromium trioxide meets the criteria for classification as carcinogenic (category 1A) and mutagenic (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) and (b) of that Regulation.

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Regulation (EU) No 348/2013. (See end of Document for details)*

(4) Acids generated from chromium trioxide and their oligomers meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meet the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) of that Regulation.

(5) Sodium dichromate meets the criteria for classification as carcinogenic (category 1B), mutagenic (category 1B) and 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(a), (b) and (c) of that Regulation.

(6) Potassium dichromate meets the criteria for classification as carcinogenic (category 1B), mutagenic (category 1B) and 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(a), (b) and (c) of that Regulation.

(7) Ammonium dichromate meets the criteria for classification as carcinogenic (category 1B), mutagenic (category 1B) and 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(a), (b) and (c) of that Regulation.

(8) Potassium chromate meets the criteria for classification as carcinogenic (category 1B) and mutagenic (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) and (b) of that Regulation.

(9) Sodium chromate meets the criteria for classification as carcinogenic (category 1B), mutagenic (category 1B) and 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(a), (b) and (c) of that Regulation.

(10) Those substances have been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006. They have furthermore been prioritised for inclusion in Annex XIV to Regulation (EC) No 1907/2006 by the European Chemicals Agency (hereinafter 'the Agency') in its recommendation of 20 December 2011[(3)] in accordance with Article 58 of that Regulation. It is therefore appropriate to include the substances in that Annex.

(11) The cobalt compounds cobalt(II) sulphate, cobalt dichloride, cobalt(II) dinitrate, cobalt(II) carbonate and cobalt(II) diacetate meet the criteria for classification as carcinogenic (category 1B) and toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meet the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) and (c) of that Regulation. They have been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006.

(12) Those cobalt compounds have also been prioritised for inclusion in Annex XIV to Regulation (EC) No 1907/2006 by the recommendation of the Agency of 20 December 2011 in accordance with Article 58 of that Regulation. However the Commission considers that at least one of the uses of those substances (i.e. surface treatment) poses a risk to human health that is not adequately controlled and needs to be addressed. Therefore, in accordance with Article 69(1) of Regulation (EC) No 1907/2006, the Commission should ask the Agency to prepare a dossier in accordance with the requirements of Annex XV to that Regulation. It is therefore appropriate to postpone the decision on the inclusion of any of these substances in Annex XIV until after the process laid down in Articles 69 to 73 of that Regulation is concluded.

(13) The Agency's recommendation of 20 December 2011 has identified the latest application dates referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006 for each of the substances listed in the Annex to this Regulation. Those dates have been identified 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 has also been taken into account.

(14) Concerning the seven chromium compounds, the Agency proposed the latest application date to be set at 21 months after entry into force of this Regulation. However, based on a discussion with Member States, a broader appreciation of the significance of the specific structure of the relevant markets and the related supply chains leads to the conclusion that the latest application date should be set at 35 months after entry into force of this Regulation.

(15) For each of the substances listed in the Annex to this Regulation the sunset date referred to in Article 58(1)(c)(i) of Regulation (EC) No 1907/2006 should be 18 months after the latest application date referred to in Article 58(1)(c)(ii) of that Regulation.

(16) It is appropriate to specify the dates referred to in points (i) and (ii) of Article 58(1)(c) of Regulation (EC) No 1907/2006 in Annex XIV to that Regulation.

(17) 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 Union 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.

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

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

(20) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Regulation (EU) No 348/2013. (See end of Document for details)*

(21) 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 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 that of 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, 17 April 2013.

*For the Commission*

*The President*

José Manuel BARROSO