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EUROPEAN CHEMICALS AGENCY

Recommendation of the European Chemicals Agency (ECHA) of 20 December 2011 for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) of Regulation (EC) No 1907/2006

The European Chemicals Agency,

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], (the REACH Regulation), and in particular Article 58 thereof,

Having regard to the Candidate List of Substances of Very High Concern for authorisation as last amended by ED/95/2010[2],

Having regard to the opinion of ECHA's Member State Committee of 19 December 2011[3],

Whereas:

(1) This Recommendation aims to assist the Commission in taking its decision pursuant to Article 58(1) of the REACH Regulation to include substances referred to in Article 57 in Annex XIV of the REACH Regulation.

(2) Pursuant to Article 58(3) of the REACH Regulation, ECHA is required to make at least every second year a Recommendation of priority substances to be included in Annex XIV.

(3) Pursuant to Article 58(4) of the REACH Regulation ECHA published on its website on 15 June 2011 a draft Recommendation of substances to be included in Annex XIV and invited all interested parties to submit comments by 14 September 2011. ECHA has analysed and prepared responses to comments received and will make these publicly available[4].

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1 OJ L 396, 30.12.2006, p 1

2 http://echa.europa.eu/web/guest/candidate-list-table

3 http://echa.europa.eu/documents/10162/17087/opinion_draft_recommendation_annex_xiv_third_en.pdf

4 http://echa.europa.eu/documents/10162/17232/rcom_trichloroethylene_en.rtf
http://echa.europa.eu/documents/10162/17232/rcom_cobalt_compounds_en.pdf
http://echa.europa.eu/documents/10162/17232/rcom_chromium_compounds_en.pdf

(4) ECHA has developed a paper presenting ECHA's approach for prioritising, pursuant to Article 58(3) of the REACH Regulation, substances for inclusion in Annex XIV[5]. On the basis of this approach ECHA has prioritised the following thirteen substances from the Candidate List of Substances of Very High Concern for inclusion in Annex XIV[6]:

Group	#	Substance name	EC
	1	Trichloroethylene	201-167-4
Chromium(VI) compounds	2	Chromium trioxide	215-607-8
	3	Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid, Dichromic acid Oligomers of chromic acid and dichromic acid	231-801-5 236-881-5 not yet assigned
	4	Sodium dichromate	234-190-3
	5	Potassium dichromate	231-906-6
	6	Ammonium dichromate	232-143-1
	7	Potassium chromate	232-140-5
	8	Sodium chromate	231-889-5
Cobalt(II) compounds	9	Cobalt(II) sulphate	233-334-2
	10	Cobalt dichloride	231-589-4
	11	Cobalt(II) dinitrate	233-402-1
	12	Cobalt(II) carbonate	208-169-4
	13	Cobalt(II) diacetate	200-755-8

(5) ECHA is required by Article 58(1) of the REACH Regulation to recommend for each priority substance an Annex XIV entry specifying its identity, its intrinsic properties referred to in Article 57, the date by which an application should be received where the applicant wishes to continue to use the substance or place the substance on the market according to Article 58(1)(c)(ii) of the REACH Regulation ("latest application date"), the date according to Article 58(1)(c)(i) of the REACH Regulation from which the placing of the market and use of a substance is prohibited unless an authorisation is granted ("sunset date"), the review periods for certain uses, and uses or categories of uses to be exempted from the authorisation requirement.

[5] http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf
[6] http://echa.europa.eu/documents/10162/17232/prioritisation_results_3rd_rec_en.pdf

(6) ECHA has developed a paper presenting ECHA's approach for determining the Annex XIV entries of prioritised substances[7]. On the basis of this paper ECHA has determined the specific Annex XIV entries for each substance.

(7) In order to identify the substances pursuant to Article 58(1)(a) of the REACH Regulation ECHA provides the names of the substances, their EC numbers and CAS numbers.

(8) For the transitional arrangements referred to in Article 58(1)(c) of the REACH Regulation ECHA has applied for each substance a standard time period of 18 months between the suggested application date and the sunset date because neither the available information for the recommended substances nor the comments received during public consultation provide information that would support the recommendation of longer periods.

(9) The recommended latest application dates are based on the assumption that the substances listed in this Recommendation will be included in Annex XIV in February 2013. The latest application dates have been set having regard to (i) the estimate by the stakeholder expert group that was following the development of the guidance for including substances in Annex XIV regarding the time that normally should be given for preparing authorisation applications (18 months), (ii) factors which indicate that more time than 18 months may be needed to prepare the authorisation applications, such as complexity of the supply-chain, (iii) ECHA's capacity to handle applications in the time provided for and (iv) application dates stipulated for the substances in the Commission Regulation amending Annex XIV of the REACH Regulation for the first time and in the draft Commission Regulation amending Annex XIV for the second time. On this basis the application dates for the recommended substances are spread in three lots over a period of 6 months.

(10) The information available for the recommended substances, including the comments received during the public consultation (15 June to 14 September 2011), does not provide information that would support the definition of review periods in accordance with article 58(1)(d) for any uses of the substances.

(11) Article 58(1)(e) in conjunction with Article 58(2) of Regulation (EC) 1907/2006 provides for the possibility of exemptions of uses or categories of uses in cases where there is specific Community legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks.

(12) ECHA has received during the public consultation of 15 June to 14 September 2011 numerous comments requesting exemptions of many uses. Based on its assessment of these exemption requests[8], ECHA does not recommend any exemptions from the authorisation requirement on the basis of Article 58(1)(e) in conjunction with Article 58(2) of the REACH Regulation.

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7 http://echa.europa.eu/documents/10162/17232/draft_axiv_entries_gen_approach_en.pdf

8 See response to comments (RCOM) documents
http://echa.europa.eu/documents/10162/17232/rcom_trichloroethylene_en.rtf
http://echa.europa.eu/documents/10162/17232/rcom_cobalt_compounds_en.pdf
http://echa.europa.eu/documents/10162/17232/rcom_chromium_compounds_en.pdf

(13) Article 56(3) of the REACH Regulation requires Annex XIV to specify if it applies to product and process orientated research and development. The information available for the recommended substances, including the comments received during public consultation, does not provide grounds to recommend exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

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HEREBY RECOMMENDS, that on the basis of the reasons set out in the Annex to this Recommendation, the following entries are included in Annex XIV of the REACH Regulation (the list of substances subject to authorisation):

Draft Annex XIV entries									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties[#]	Latest application date	Sunset date	Review periods	Exempted (categories of) uses	Exemptions for PPORD
1	**Trichloroethylene**	201-167-4	79-01-6	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 18 months [1)]	Latest application date plus 18 months	None	None	None
2	**Chromium trioxide**	215-607-8	1333-82-0	Art. 57 (a) & (b); Carcinogen 1A, Mutagen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
3	**Acids generated from chromium trioxide and their oligomers** Group containing: Chromic acid Dichromic acid Oligomers of chromic acid and dichromic acid	 231-801-5 236-881-5 not yet assigned	 7738-94-5 13530-68-2 not yet assigned	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
4	**Sodium dichromate**	234-190-3	7789-12-0 10588-01-9	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
5	**Potassium dichromate**	231-906-6	7778-50-9	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None

Draft Annex XIV entries									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties#	Latest application date	Sunset date	Review periods	Exempted (categories of) uses	Exemptions for PPORD
6	**Ammonium dichromate**	232-143-1	7789-09-5	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
7	**Potassium chromate**	232-140-5	7789-00-6	Art. 57 (a) & (b); Carcinogen 1B, Mutagen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
8	**Sodium chromate**	231-889-5	7775-11-3	Art. 57 (a), (b) & (c); Carcinogen 1B, Mutagen 1B, Toxic for Reproduction 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
9	**Cobalt(II) sulphate**	233-334-2	10124-43-3	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None
10	**Cobalt dichloride**	231-589-4	7646-79-9	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None
11	**Cobalt(II) dinitrate**	233-402-1	10141-05-6	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None
12	**Cobalt(II) carbonate**	208-169-4	513-79-1	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None

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Draft Annex XIV entries									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties#	Latest application date	Sunset date	Review periods	Exempted (categories of) uses	Exemptions for PPORD
13	**Cobalt(II) diacetate**	200-755-8	71-48-7	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None

Reference is made to the identified SVHC properties in accordance with Article 57 of the REACH Regulation and to the corresponding classification in accordance with Annex VI, Table 3.1 (*List of harmonised classification and labelling of hazardous substances) of* 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.

1) Assuming the Commission Regulation including the substances of this third Recommendation in Annex XIV would enter into force in February 2013, the latest application date would be August 2014

2) Assuming the Commission Regulation including the substances of this third Recommendation in Annex XIV would enter into force in February 2013, the latest application date would be November 2014

3) Assuming the Commission Regulation including the substances of this third Recommendation in Annex XIV would enter into force in February 2013, the latest application date would be February 2015

Done at Helsinki, 20 December 2011

For the European Chemicals Agency,

Jukka Malm
Director of Regulatory Affairs