ECHA
EUROPEAN CHEMICALS AGENCY

Recommendation of the European Chemicals Agency of 17 January 2013 for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation)

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 (the REACH Regulation), establishing a European Chemicals Agency (ECHA), 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 58 thereof,

Having regard to the Candidate List of Substances of Very High Concern for authorisation, as last amended by Decision ED/77/2011[2],

Having regard to the opinion of ECHA's Member State Committee of 13 December 2012[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 to the REACH Regulation.

(2) Pursuant to Article 58(3) of the REACH Regulation, ECHA is required to make further recommendations of priority substances at least every second year with a view to including further substances in Annex XIV.

(3) In accordance with Article 58(4) of the REACH Regulation, ECHA published on its website on 20 June 2012 a draft Recommendation of substances to be included in Annex XIV and invited all interested parties to submit comments by 19 September 2012. 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/10162/13576/opinion_draft_recommendation_annex_xiv_fourth_en.pdf

4 See link to responses to comments (RCOM) documents in overview table: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

(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 ten substances from the Candidate List of Substances of Very High Concern for inclusion in Annex XIV[6]:

#	Substance name	EC
1	Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1
2	Arsenic Acid	231-901-9
3	Bis(2-methoxyethyl) ether (Diglyme)	203-924-4
4	N,N-Dimethylacetamide (DMAC)	204-826-4
5	1,2-Dichloroethane (EDC)	203-458-1
6	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9
7	Dichromium tris(chromate)	246-356-2
8	Strontium chromate	232-142-6
9	Potassium hydroxyoctaoxodizincatedichromate	234-329-8
10	Pentazinc chromate octahydroxide	256-418-0

(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(s) 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, if appropriate; and uses or categories of uses to be exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

(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 approach ECHA has determined the specific Annex XIV entries for each of the above listed substances.

(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.

5 http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf
6 http://echa.europa.eu/documents/10162/13640/prioritisation_results_4th_rec_en.pdf
7 http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_4th_en.pdf

(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 2014[8]. 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)* ECHA's capacity to handle applications in the time provided for, in accordance with Art. 58(3) of the REACH Regulation[9].

(10) In order to consider and deal with the chromium (VI) substances in a consistent manner, it is desirable that the latest application dates of the four chromium (VI) substances in the present recommendation coincide with the latest application dates for the chromium (VI) substances referred to in ECHA's Recommendation of 20 December 2011 for the inclusion of substances in Annex XIV. Therefore, in order to determine the latest application dates for the four chromium (VI) substances in this Recommendation ECHA has (i) taken into account that the REACH Committee in its meeting of 21/22 November 2012 agreed that the latest application dates for the chromium (VI) substances referred to in ECHA's Recommendation of 20 December 2011 should be 35 months from the date of inclusion of these substances in Annex XIV, (ii) estimated that in March 2013 the chromium (VI) substances referred to in ECHA's Recommendation of 20 December 2011 will be included in Annex XIV, and (iii) estimated that in February 2014 the four chromium (VI) substances in the present Recommendation will be included in Annex XIV.

(11) The information available for the recommended substances, including the comments received during the public consultation, which took place from 20 June to 19 September 2012, does not provide information that would justify for the definition of review periods for any uses of the substances in accordance with Article 58(1)(d) of the REACH Regulation.

(12) 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 EU legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks.

(13) ECHA has received during the public consultation, which took place from 20 June to 19 September 2012, comments requesting exemptions of uses. Based on its assessment of these exemption requests[10], ECHA does not recommend any exemptions from the authorisation requirement on the basis of Article 58(1)(e) and Article 58(2) of the REACH Regulation.

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[8] In case the amendment of Annex XIV will not enter into force in February 2014, the latest application dates may need to be adapted in order to fit with the application submission windows as communicated on ECHA's website (http://echa.europa.eu/web/guest/applying-for-authorisation/submission-windows).

[9] The latest application dates (LADs) for the 10 substances are spread in three groups over a period of 6 months (LADs 18, 21 or 24 months from entry into force) to distribute the workload in the authorisation application and decision phase more evenly.

[10] See link to responses to comments (RCOM) documents in overview table: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

(14) Article 56(3) of the REACH Regulation requires Annex XIV to specify if it applies to product and process orientated research and development (PPORD). 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 for the reasons set out in Annex I to this Recommendation, the following entries are included in Annex XIV to the REACH Regulation (List of Substances subject to Authorisation)

Draft Annex XIV entries									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties#	Latest application date pursuant to REACH Art. 58 (1) (c) (ii)	Sunset date	Review periods	Exempted uses or categories of uses	Exemptions for PPORD
1	Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	25214-70-4	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	Arsenic Acid	231-901-9	7778-39-4	Art. 57 (a); Carcinogen 1A	Date of inclusion in Annex XIV plus 18 months [1)]	Latest application date plus 18 months	None	None	None
3	Bis(2-methoxyethyl) ether (Diglyme)	203-924-4	111-96-6	Art. 57 (c); Toxic for Reproduction 1B	Date of inclusion in Annex XIV plus 18 months [1)]	Latest application date plus 18 months	None	None	None
4	N,N-Dimethylacet-amide (DMAC)	204-826-4	127-19-5	Art. 57 (c); Toxic for Reproduction 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
5	1,2-Dichloroethane (EDC)	203-458-1	107-06-2	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
6	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9	101-14-4	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
7	Dichromium tris(chromate)	246-356-2	24613-89-6	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None
8	Strontium chromate	232-142-6	7789-06-2	Art. 57 (a); Carcinogen 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									
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9	Potassium hydroxyoctaoxodi-zincatedichromate	234-329-8	11103-86-9	Art. 57 (a); Carcinogen 1A	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None
10	Pentazinc chromate octahydroxide	256-418-0	49663-84-5	Art. 57 (a),; Carcinogen 1A	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 Table 3.1 of Annex VI (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 (the CLP Regulation).

1) Assumed that the Commission Regulation including the substances of this fourth Recommendation in Annex XIV would enter into force in February 2014, the latest application date would be August 2015*

2) Assumed that the Commission Regulation including the substances of this fourth Recommendation in Annex XIV would enter into force in February 2014, the latest application date would be November 2015*

3) Assumed that the Commission Regulation including the substances of this fourth Recommendation in Annex XIV would enter into force in February 2014, the latest application date would be February 2016*

Done at Helsinki, 17 January 2013

For the European Chemicals Agency,

Jukka Malm
Director of Regulatory Affairs[11]

* In case the amendment of Annex XIV will not enter into force in February 2014, the Latest Application Dates need to be adapted in order to fit with the application submission windows as communicated on ECHA's website.

11 Mandated to sign this decision pursuant to the decision by the Executive Director ED/110/2010 *Delegation of the power to sign certain science-based regulatory decisions and communications*