Recommendation of the European Chemicals Agency (ECHA)

of 17 December 2010

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/68/2009[2],

Having regard to the opinion of ECHA's Member State Committee of 3 December 2010[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 1 July 2010 a draft Recommendation of substances to be included in Annex XIV and invited all interested parties to submit comments by 30 September 2010. 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/chem_data/candidate_list_table_en.asp

3 http://echa.europa.eu/doc/about/organisation/msc/opinion_draft_recommendation_annex_xiv_second.pdf

4 http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec/second_subst_spec_docs_en.asp

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

- Diisobutyl phthalate (DIBP)
- Diarsenic trioxide
- Diarsenic pentaoxide
- Lead chromate
- Lead sulfochromate yellow (C.I. Pigment Yellow 34)
- Lead chromate molybdate sulfate red (C.I. Pigment Red 104)
- Tris (2-chloroethyl) phosphate (TCEP)
- 2,4 – Dinitrotoluene (2,4-DNT)

(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.

(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) Pursuant to Article 58(4) of 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006[8], as from 1 December 2010 Article 57(a), (b) and (c) of Regulation (EC) No 1907/2006 shall refer to the classification criteria laid down respectively in sections 3.6, 3.5 and 3.7 of Annex I to Regulation (EC) No 1272/2008. Therefore, references in this Recommendation to the classification criteria referred to in Article 57 of Regulation (EC) No 1907/2006 is made in accordance with that provision. However, for the sake of clarity reference is also

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5 http://echa.europa.eu/doc/consultations/recommendations/axiv_priority_setting_gen_approach_20100701.pdf

6 http://echa.europa.eu/doc/consultations/recommendations/prioritisation_results_2nd_rec_20100701.pdf

7 http://echa.europa.eu/doc/consultations/recommendations/draft_axiv_entries_gen_approach_20100701.pdf

8 OJ L 353, 31.12.2008, p.1

made to the classification criteria referred to in accordance with Directive 67/548/EEC.

(9) 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.

(10) No information on production cycles is available from the Annex XV dossiers or from the public consultation on the recommended substances that would allow proposing different application dates. The recommended latest application dates are based on the assumption that the Commission Regulation amending Annex XIV to the REACH Regulation for the first time will enter into force in January 2011 and that the substances recommended in this Recommendation will be included in Annex XIV in January 2012. The latest application dates have been set having regard to (i) the Guidance on inclusion of 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 and (iii) application dates stipulated for the substances in the draft Commission Regulation amending Annex XIV of the REACH Regulation for the first time. On that basis the application dates for the recommended substances are spread in two lots over a period of 3 months.

(11) The information available for the recommended substances including the comments received during the public consultation (1 July to 30 September 2010) does not provide information that would support definition of review periods in accordance with article 58(1)(d) for any uses of the substances.

(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 Community 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 its public consultation of 1 July to 30 September 2010 some comments requesting exemptions of certain uses. 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..

(14) Article 56(3) of the REACH Regulation requires Annex XIV to specify if it applies to product and process orientated research and development.

(15) 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.

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):

#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties	Transitional arrangements		Review periods	Exempted (categories of) uses	Exemptions for PPORD
					Latest application date pursuant to Art. 58 (1) (c) (ii)	Sunset date			
1	**Diisobutyl phthalate (DIBP)**	201-553-2	84-69-5	*Article 57(c)* Repr. 1B [#] Repr. Cat. 2; R61 [##]	01/07/2013 *	Latest application date plus 18 months	None	None	None
2	**Diarsenic trioxide**	215-481-4	1327-53-3	*Article 57(a)* Carc. 1A [#] Carc. Cat. 1; R45 [##]	01/10/2013 **	Latest application date plus 18 months	None	None	None
3	**Diarsenic pentaoxide**	215-116-9	1303-28-2	*Article 57(a)* Carc. 1A [#] Carc. Cat. 1; R45 [##]	01/10/2013 **	Latest application date plus 18 months	None	None	None
4	**Lead chromate**	231-846-0	7758-97-6	*Article 57(a) and 57(c)* Carc. 1B Repr. 1A [#] Carc. Cat. 2; R45 Repr. Cat. 1; R61 [##]	01/10/2013 **	Latest application date plus 18 months	None	None	None
5	**Lead sulfochromate yellow (C.I. Pigment Yellow 34)**	215-693-7	1344-37-2	*Article 57(a) and 57(c)* Carc. 1B Repr. 1A [#] Carc. Cat. 2; R45 Repr. Cat. 1; R61 [##]	01/10/2013 **	Latest application date plus 18 months	None	None	None
6	**Lead chromate molybdate sulfate red (C.I. Pigment Red 104)**	235-759-9	12656-85-8	*Article 57(a) and 57(c)* Carc. 1B Repr. 1A [#] Carc. Cat. 2; R45 Repr. Cat. 1; R61 [##]	01/10/2013 **	Latest application date plus 18 months	None	None	None

#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties	Transitional arrangements		Review periods	Exempted (categories of) uses	Exemptions for PPORD
					Latest application date pursuant to Art. 58 (1) (c) (ii)	Sunset date			
7	**Tris (2-chloroethyl) phosphate (TCEP)**	204-118-5	115-96-8	*Article 57(c)* Repr. 1B [#] Repr. Cat 2; R60 [##]	02/01/2014 **	Latest application date plus 18 months	None	None	None
8	**2,4 – Dinitrotoluene (2,4-DNT)**	204-450-0	121-14-2	*Article 57(a)* Carc. 1B [#] Carc. Cat. 2; R45 [##]	02/01/2014 **	Latest application date plus 18 months	None	None	None

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.

Classification in accordance with Annex VI, Table 3.2 *(The list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) 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.

* The sunset date for diisobutyl phthalate should be set as close as possible to the sunset dates for the phthalates included in the Commission Regulation amending Annex XIV to the REACH Regulation for the first time. The Commission is invited to take into account the principles set out in Annex I of this Recommendation in order to determine the appropriate latest application dates.

** The recommendation of the latest application dates is based on the assumption that the Commission Regulation amending Annex XIV to the REACH Regulation for the first time will enter into force in January 2011 and that the substances mentioned in the present Recommendation will be included in Annex XIV in January 2012. The Commission is invited to take into account the principles set out in Annex I of this Recommendation in order to determine the appropriate latest application dates.

Done at Helsinki, 17 December 2010

For the European Chemicals Agency,

Geert DANCET
Executive Director

ANNEX I - Reasons for the recommendation to include the prioritised substances in Annex XIV

Introduction:

The purpose of this Annex is to describe the reasons for recommending the following eight substances for inclusion in Annex XIV and the determination of their draft Annex XIV entries.

A. Diisobutyl phthalate (DIBP)
B. Diarsenic trioxide
C. Diarsenic pentaoxide
D. Lead chromate
E. Lead sulfochromate yellow (C.I. Pigment Yellow 34)
F. Lead chromate molybdate sulfate red (C.I. Pigment Red 104)
G. Tris (2-chloroethyl) phosphate (TCEP)
H. 2,4–Dinitrotoluene (2,4-DNT)

For the preparation of this Recommendation ECHA has used the following documents:

- *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation Document developed in the context of ECHA's second Recommendation* (dated 28 May 2010)[9]
- *Results of the prioritisation of the SVHCs on the Candidate List with the objective to recommend priority substances for inclusion in Annex XIV* (dated 1 July 2010)[10]
- *Preparation of draft Annex XIV entries for the second Recommendation of substances to be included in Annex XIV – General approach* (dated 1 July 2010)[11]
- Substance-specific background documents (dated 17 December 2010)[12]
- Substance-specific technical reports on manufacture, import, export, uses, releases and alternatives (available for Diarsenic trioxide, Diarsenic pentaoxide, Lead chromate and 2,4-Dinitrotoluene)[13]
- Substance-specific "*Responses to comments*" (RCOM) documents (dated 17 December 2010)[14]
- Opinion of the Member State Committee of 3 December 2010[15]

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9 http://echa.europa.eu/doc/consultations/recommendations/axiv_priority_setting_gen_approach_20100701.pdf
10 http://echa.europa.eu/doc/consultations/recommendations/prioritisation_results_2nd_rec_20100701.pdf
11 http://echa.europa.eu/doc/consultations/recommendations/draft_axiv_entries_gen_approach_20100701.pdf
12 http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec/second_subst_spec_docs_en.asp
13 http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec/second_subst_spec_docs_en.asp
14 http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec/second_subst_spec_docs_en.asp
15 http://echa.europa.eu/doc/about/organisation/msc/opinion_draft_recommendation_annex_xiv_second.pdf

Transitional arrangements

With respect to the setting of the latest application dates and sunset dates for each substance, ECHA has worked on the assumption that a first set of substances will be included in Annex XIV by a Commission Regulation in January 2011 and that the substances in the present Recommendation will be included in Annex XIV in January 2012.

ECHA however recommends to the Commission to take into account the following aspects when determining the latest application dates and sunset dates addressed in this Recommendation[16]:

- Potential overlaps with the application dates set out in the 1st amendment of Annex XIV should be considered in order to take into account ECHA's capacity to handle authorisation applications in the time provided for.
- To further avoid capacity problems of ECHA, the substances included in this second Recommendation (apart from diisobutyl phthalate, see Annex IA) may be grouped in two lots with a time interval of three months between the lots.
- As there is no specific information available that would allow to come to the conclusion that shorter time intervals for preparing appropriate authorisation applications are sufficient, the standard time interval recommended in the guidance on inclusion of substances in Annex XIV should be respected in setting the latest application dates. Therefore, the time interval between entry into force of the inclusion of a substance in Annex XIV and its latest application date should normally not be shorter than 18 months.[17]

[16] On the basis of the Opinion of the Member State Committee and the comments received during public consultation, ECHA reconsidered its proposal for the transitional arrangements made in the draft Recommendation of 1 July 2010 and developed the generic principles set out in the bullet points. In practice, consideration of the anticipated entry into force of the Commission Regulation amending Annex XIV to the REACH Regulation for the first time (i.e. January 2011) and the transitional arrangements as set out in the draft Regulation, ECHA revised the dates. This was because without these revisions there would presumably have been unfeasible overlaps between the application dates of the first amendment of Annex XIV and the second one, which will implement the current (2nd) Recommendation, if this latter Commission Regulation would enter into force in January 2012.

[17] The Member State Committee is of the opinion that the application dates should be established as close as possible to the entry into force of the inclusion of substances in Annex XIV and that the interval between entry into force and latest application date should normally not be more than 12 to a maximum of 18 months. ECHA did not follow this opinion as no specific information was available that would have allowed to justify deviations from the standard time interval recommended in the guidance on inclusion of substances in Annex XIV.

Annex I.A. - Diisobutyl phthalate (DIBP)

Reasons for prioritising Diisobutyl phthalate (DIBP)

To determine whether Diisobutyl phthalate should be prioritised pursuant to Article 58(3) of the REACH regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*"(version 28/05/2010). ECHA concluded that DIBP is used in high volumes and that its use pattern is wide dispersive (confirmed by monitoring data).

Hence, ECHA has prioritised Diisobutyl phthalate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:	Diisobutyl phthalate (DIBP)
EC Numbers:	201-553-2
CAS Numbers:	84-69-5
IUPAC Name:	bis(2-methylpropyl) benzene-1,2-dicarboxylate

2) Intrinsic properties

Diisobutyl phthtalate was identified as a Substance of Very High Concern (SVHC) according to Article 57(c) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as toxic to reproduction category 2, R61 (may cause harm to the unborn child)[18], and was therefore included in the candidate list for authorisation on 13 January 2010, following ECHA's decision ED/68/2009.

3) Transitional arrangements

Article 58 (1) (c) (ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Diisobutyl phthalate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

No information on production cycles is available that would allow to propose different application dates for different uses. ECHA has determined the application dates as described in Recital (10) of the Recommendation, taking into account the considerations set out above in this Annex on transitional arrangements.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

[18] This corresponds to a classification as toxic to reproduction 1B, H 360Df (May damage the unborn child. Suspected of damaging fertility.) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances).

- In order to avoid that Diisobutyl phthalate could be used as a replacement for other phthalate substances subject to authorisation, it is recommended to set the sunset date for this substance as close as possible to the sunset dates of the phthalates included in the Commission Regulation amending Annex XIV to the REACH Regulation for the first time.

- *Application date*:
  1 July 2013.
  In case ECHA's working assumption that a first set of substances will be included in Annex XIV by a Commission Regulation in January 2011 and that the substances in the present Recommendation will be included in Annex XIV in January 2012 proves not to be correct: As close as possible to the latest application dates of the phthalates included in the Commission Regulation amending Annex XIV to the REACH Regulation for the first time, taking into account the considerations set out in Annex I above on transitional arrangements.

- *Sunset date*:
  18 months after the application date.

4) Review periods for certain uses

The information available for Diisobutyl phthalate, including the comments received during public consultation (1 July to 30 September 2010), does not provide information that would support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of Diisobutyl phthalate.

5) Exempted (categories of) uses

ECHA did not receive requests for exemptions on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation and it does not see grounds to recommend exemptions of uses of Diisobutyl phthalate on the basis of these Articles.

6) Application of authorisation to product and process oriented research and development (PPORD)

The information available on Diisobutyl phthalate does not provide information that would support introducing in Annex XIV any exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. Exemptions for PPORD with Diisobutyl phthalate were not requested during public consultation on the draft Recommendation.

Therefore, ECHA does not recommend exempting the use of Diisobutyl phthalate for PPORD from authorisation.

Annex I.B. - Diarsenic trioxide (As_2O_3)

Reasons for prioritising Diarsenic trioxide

To determine whether Diarsenic trioxide should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*" (version 28/05/2010). ECHA concluded that Diarsenic trioxide is supplied to uses in the scope of authorisation in relatively high amounts. As regards occupational exposure there appear to exist problems with exposure control in parts of the glass industry, in particular in manufactories for small scale manufacture of artisan glass. The data available suggest that workers could be exposed and that the use of As_2O_3 in the manufacture of artisan glass is wide-dispersive.

Hence, ECHA has prioritised Diarsenic trioxide for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:	Diarsenic trioxide
EC Number:	215-481-4
CAS Number:	1327-53-3
IUPAC Name:	Dioxodiarsoxane

2) Intrinsic properties of the substance

Diarsenic trioxide was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as a carcinogen, category 1[19], R45 (may cause cancer) and was therefore included in the candidate list for authorisation on 28 October 2008, following ECHA's decision ED/67/2008.

3) Transitional arrangements

Article 58 (1) (c) (ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Diarsenic trioxide does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

No information on production cycles is available that would allow to propose different application dates for different uses. ECHA has determined the application dates as described in Recital (10) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

[19] This corresponds to a classification as carcinogen 1A, H350 (may cause cancer) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances)

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Application date*:
  1 October 2013.
  In case ECHA's working assumption that a first set of substances will be included in Annex XIV by a Commission Regulation in January 2011 and that the substances in the present Recommendation will be included in Annex XIV in January 2012 proves not to be correct, the Commission is invited to take into account the principles set out in Annex I above on transitional arrangements to determine the appropriate latest application date.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

The information available for Diarsenic trioxide, including the comments received during public consultation (1 July to 30 September 2010), does not provide information that would support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of Diarsenic trioxide.

5) *Exempted (categories of) uses*

During the public consultation on the draft Recommendation, ECHA received some requests for use-specific exemptions of Diarsenic trioxide. These requests seemed however to refer to uses of the substance as analytical agent or standard under conditions covered by the exemption of scientific research and development from authorisation pursuant to Article 56(3) of the REACH Regulation.

ECHA did not receive requests for exemptions on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation and it does not see grounds to recommend exemptions of uses of Diarsenic trioxide on the basis of these Articles.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

The information available on Diarsenic trioxide does not provide information that would support introducing in Annex XIV any exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. Exemptions for PPORD with Diarsenic trioxide were not requested during public consultation on the draft Recommendation.

Therefore, ECHA does not recommend exempting the use of Diarsenic trioxide for PPORD from authorisation.

Annex I.C. - Diarsenic pentaoxide (As_2O_5)

Reasons for prioritising Diarsenic pentaoxide

To determine whether Diarsenic pentaoxide should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*" (version 28/05/2010). ECHA concluded that Diarsenic pentaoxide may potentially be supplied to uses in the scope of authorisation in amounts < 10 t/yr and that it may be used in the glass industry, where it can replace Diarsenic trioxide. However, according to information received from industry during public consultation on the Recommendation, there seems to be no current manufacture or import of the substance in the EU. This presumption is supported by the fact that ECHA did not receive registration dossiers for the substance. Nonetheless, this substance has the same SVHC properties as Diarsenic trioxide and can be used to replace the latter substance in at least some of its applications.

Hence, ECHA has prioritised Diarsenic pentaoxide (as a group together with Diarsenic trioxide) for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:	Diarsenic pentaoxide
EC Number:	215-116-9
CAS Number:	1303-28-2
IUPAC Name:	1,3-dioxodiarsoxane 1,3-dioxide

2) Intrinsic properties of the substance

Diarsenic pentaoxide was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as a carcinogen, category 1[20], R45 (may cause cancer) and was therefore included in the candidate list for authorisation on 28 October 2008, following ECHA's decision ED/67/2008.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Diarsenic pentaoxide does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

[20] This corresponds to a classification as carcinogen 1A, H350 (may cause cancer) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances)

No information on production cycles is available that would allow to propose different application dates for different uses. ECHA has determined the application dates as described in Recital (10) of the Recommendation, taking into account the considerations set out above in this Annex on transitional arrangements.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Application date*:
  1 October 2013.
  In case ECHA's working assumption that a first set of substances will be included in Annex XIV by a Commission Regulation in January 2011 and that the substances in the present Recommendation will be included in Annex XIV in January 2012 proves not to be correct, the Commission is invited to take into account the principles set out in Annex I above on transitional arrangements to determine the appropriate latest application date.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

The information available for Diarsenic pentaoxide, including the comments received during public consultation (1 July to 30 September 2010), does not provide information that would support determination of review periods in accordance with article 58 (1) (d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of Diarsenic pentaoxide.

5) *Exempted (categories of) uses*

ECHA did not receive requests for exemptions on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation and it does not see grounds to recommend exemptions of uses of Diarsenic pentaoxide on the basis of these Articles.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

The information available on Diarsenic pentaoxide does not provide information that would support introducing in Annex XIV any exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. Exemptions for PPORD with Diarsenic pentaoxide were not requested during public consultation on the draft Recommendation.

Therefore, ECHA does not recommend exempting the use of Diarsenic pentaoxide for PPORD from authorisation.

Annex I.D. – Lead chromate

Reasons for prioritising Lead chromate

To determine whether Lead chromate should be prioritised pursuant to Article 58(3) of the REACH regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*"(version 28/05/2010). ECHA concluded that Lead chromate is supplied to uses in the scope of authorisation in relatively high volumes. Exposure of professionals may occur in applications including, for example, painting, restoration and pyrotechnics. Furthermore, releases to the environment may occur especially after the end of the service life of articles (coated articles, plastics). The uses of the substance are widespread to wide dispersive.

Hence, ECHA has prioritised Lead chromate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:	Lead chromate
EC Numbers:	231-846-0
CAS Numbers:	7758-97-6[21]
IUPAC Name:	Lead (2+) chromate

2) Intrinsic properties

Lead chromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (c) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as a carcinogen category 2, R45 (may cause cancer), and as toxic to reproduction category 1, R61 (may cause harm to the unborn child)[22], and was therefore included in the candidate list for authorisation on 13 January 2010, following ECHA's decision ED/68/2009.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Lead chromate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

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[21] (Deleted CAS numbers: 8049-64-7, 181768-98-9)

[22] This corresponds to a classification as carcinogen 1B, H350 (may cause cancer) and as toxic to reproduction 1A, H 360D (may damage the unborn child) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances).

No information on production cycles is available that would allow to propose different application dates for different uses. ECHA has determined the application dates as described in Recital (10) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Application date*:
  1 October 2013.
  In case ECHA's working assumption that a first set of substances will be included in Annex XIV by a Commission Regulation in January 2011 and that the substances in the present Recommendation will be included in Annex XIV in January 2012 proves not to be correct, the Commission is invited to take into account the principles set out in Annex I above on transitional arrangements to determine the appropriate latest application date.

- *Sunset date*:
  18 months after the application date.

4) Review periods for certain uses

The information available for Lead chromate, including the comments received during public consultation (1 July to 30 September 2010), does not provide information that would support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of Lead chromate.

5) Exempted (categories of) uses

ECHA did not receive requests for exemptions on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation and it does not see grounds to recommend exemptions of uses of Lead chromate on the basis of these Articles.

6) Application of authorisation to product and process oriented research and development (PPORD)

The information available on Lead chromate does not provide information that would support introducing in Annex XIV any exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. Exemptions for PPORD with Lead chromate were not requested during public consultation on the draft Recommendation.

Therefore, ECHA does not recommend exempting the use of Lead chromate for PPORD from authorisation.

Annex I.E. - Lead sulfochromate yellow (C.I. Pigment Yellow 34)

Reasons for prioritising Lead sulfochromate yellow

To determine whether Lead sulfochromate yellow should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*" (version 28/05/2010). ECHA concluded that Lead sulfochromate yellow is supplied to uses in the scope of authorisation in high volumes. The substance may be released (presumably in relatively low amounts) at very many sites from articles during service life or (in potentially higher but unknown and uncontrolled amounts) after the end of the service life in the waste state or during recycling. There is potentially worker exposure, e.g. during repair/refurbishing of coated surfaces. At least widespread and in some applications wide dispersive use can be concluded.

Hence, ECHA has prioritised Lead sulfochromate yellow for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:	Lead sulfochromate yellow (C.I. Pigment Yellow 34)
EC Number:	215-693-7
CAS Number:	1344-37-2

2) Intrinsic properties of the substance

Lead sulfochromate yellow was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and 57(c) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as a carcinogen category 2, R45 (may cause cancer), and as toxic to reproduction category 1, R61 (may cause harm to the unborn child)[23], and was therefore included in the candidate list for authorisation on 13 January 2010, following ECHA's decision ED/68/2009.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Lead sulfochromate yellow does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

[23] This corresponds to a classification as carcinogen 1B, H350 (may cause cancer) and as toxic to reproduction 1A, H 360D (may damage the unborn child) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances).

No information on production cycles is available that would allow to propose different application dates for different uses. ECHA has determined the application dates as described in Recital (10) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Application date*:
  1 October 2013.
  In case ECHA's working assumption that a first set of substances will be included in Annex XIV by a Commission Regulation in January 2011 and that the substances in the present Recommendation will be included in Annex XIV in January 2012 proves not to be correct, the Commission is invited to take into account the principles set out in Annex I above on transitional arrangements to determine the appropriate latest application date.

- *Sunset date*:
  18 months after the application date.

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA received one request for a review period in accordance with article 58(1)(d) for several uses of Lead sulfochromate yellow. The information available, including the information provided in this request, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of Lead sulfochromate yellow.

5) Exempted (categories of) uses

ECHA received by one company requests for exemption of specific uses on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation. ECHA assessed that the risks arising from the relevant life-cycle stages of the uses in question are at most *partly* covered by the relevant pieces of Community legislation, and as a result existing Community legislation could not justify exemption of any (categories of) uses of Lead sulfochromate yellow in accordance with Article 58(2).

On the same basis (Art. 58(2)), ECHA received one request for exemption of the fully silica-encapsulated grades (i.e. forms) of Lead sulfochromate yellow. The information provided was evaluated as neither sufficient to conclude that the risk is indeed modified (decreased) by silica encapsulation of the pigment, nor to which extent this would be the case. Consequently, the information available was regarded as providing no sufficient basis for exempting the silica encapsulated grades of Lead sulfochromate yellow from authorisation.

In conclusion, ECHA does not see grounds to recommend exemptions of uses of Lead sulfochromate yellow on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

ECHA received one request for exemption from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. The information submitted in that case suggested that it may not be appropriate to recommend an exemption for PPORD for this use as there is not enough certainty whether this use actually fulfils the criteria for PPORD. On the other hand, under certain conditions the described use could fulfil the definition of scientific research and development (SRD) in Article 3(23), in which case the use would be exempted from authorisation as set out in Article 56(3).

Therefore, ECHA does not recommend exempting the use of Lead sulfochromate yellow for PPORD from authorisation.

Annex I.F. - Lead chromate molybdate sulfate red (C.I. Pigment Red 104)

Reasons for prioritising Lead chromate molybdate sulfate red

To determine whether Lead chromate molybdate sulfate red should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*" (version 28/05/2010). ECHA concluded that Lead chromate molybdate sulfate red is supplied to uses in the scope of authorisation in high volumes. The substance may be released (presumably in relatively low amounts) at very many sites from articles during service life or (in potentially higher but unknown and uncontrolled amounts) after the end of the service life in the waste state or during recycling. There is potentially worker exposure, e.g. during repair/refurbishing of coated surfaces. At least widespread and in some applications wide dispersive use can be concluded.

Hence, ECHA has prioritised Lead chromate molybdate sulfate red for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:	Lead chromate molybdate sulfate red (C.I. Pigment Red 104)
EC Number:	235-759-9
CAS Number:	12656-85-8

2) Intrinsic properties of the substance

Lead chromate molybdate sulfate red was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and 57(c) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as a carcinogen category 2, R45 (may cause cancer), and as toxic to reproduction category 1, R61 (may cause harm to the unborn child)[24] , and was therefore included in the candidate list for authorisation on 13 January 2010, following ECHA's decision ED/68/2009.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Lead chromate molybdate sulfate red does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

[24] This corresponds to a classification as carcinogen 1B, H350 (may cause cancer) and as toxic to reproduction 1A, H 360D (may damage the unborn child) in Annex VI, part 3, Table 3.1 of Regulation.

No information on production cycles is available that would allow to propose different application dates for different uses. ECHA has determined the application dates as described in Recital (10) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Application date*:
  1 October 2013.
  In case ECHA's working assumption that a first set of substances will be included in Annex XIV by a Commission Regulation in January 2011 and that the substances in the present Recommendation will be included in Annex XIV in January 2012 proves not to be correct, the Commission is invited to take into account the principles set out in Annex I above on transitional arrangements to determine the appropriate latest application date.

- *Sunset date*:
  18 months after the application date.

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA received one request for a review period in accordance with article 58(1)(d) for several uses of Lead chromate molybdate sulfate red. The information available including the information provided in this request was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of Lead chromate molybdate sulfate red.

5) Exempted (categories of) uses

ECHA received by one company requests for exemption of specific uses on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation. ECHA assessed that the risks arising from the relevant life-cycle stages of the uses in question are at most *partly* covered by the relevant pieces of Community legislation, and, as a result, existing Community legislation cannot justify exemption of any (categories of) uses of Lead chromate molybdate sulfate red in accordance with Article 58(2).

On the same basis (Art. 58(2)), ECHA received one request for exemption of the fully silica-encapsulated grades (i.e. forms) of Lead chromate molybdate sulfate red. The information provided was evaluated as neither sufficient to conclude that the risk is indeed modified (decreased) by silica encapsulation of the pigment, nor to which extent this would be the case. Consequently, the information available was regarded as providing no sufficient basis for exempting the silica encapsulated grades of Lead chromate molybdate sulfate red from authorisation.

In conclusion, ECHA does not see grounds to recommend exemptions of uses of Lead chromate molybdate sulfate red on the basis of Article 58(1)(e) in combination with Article 58 (2) of the REACH Regulation.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

ECHA received one request for exemption from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. The information submitted in that case suggested that it may not be appropriate to recommend an exemption for PPORD for this use as there is not enough certainty whether this use actually fulfils the criteria for PPORD. On the other hand, under certain conditions the described use could fulfil the definition of scientific research and development (SRD) in Article 3(23), in which case the use would be exempted from authorisation as set out in Article 56(3).

Therefore, ECHA does not recommend exempting the use of Lead chromate molybdate sulfate red for PPORD from authorisation.

Annex I.G. - Tris (2-chloroethyl) phosphate (TCEP)

Reasons for prioritising Tris (2-chloroethyl) phosphate (TCEP)

To determine whether TCEP should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*" (version 28/05/2010). ECHA concluded that TCEP is used in high volumes and that there are releases to workers, consumers and the environment from widespread use of articles. Wide dispersive use is confirmed by monitoring results of dust and water samples.

Hence, ECHA has prioritised TCEP for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:	Tris (2-chloroethyl) phosphate
EC Number:	204-118-5
CAS Number:	115-96-8
IUPAC Name:	Tris (2-chloroethyl) phosphate

2) Intrinsic properties of the substance

Tris (2-chloroethyl) phosphate was identified as a Substance of Very High Concern (SVHC) according to Article 57(c) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as toxic to reproduction category 2, R60 (may impair fertility) [25], and was therefore included in the candidate list for authorisation on 13 January 2010, following ECHA's decision ED/68/2009.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on TCEP does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

No information on production cycles is available that would allow to propose different application dates for different uses. ECHA has determined the application dates as described in Recital (10) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

[25] This corresponds to a classification as toxic to reproduction 1B, H 360F (may damage fertility) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances).

- *Application date*:
  1 January 2014.
  In case ECHA's working assumption that a first set of substances will be included in Annex XIV by a Commission Regulation in January 2011 and that the substances in the present Recommendation will be included in Annex XIV in January 2012 proves not to be correct, the Commission is invited to take into account the principles set out in Annex I above on transitional arrangements to determine the appropriate latest application date.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

The information available for TCEP, including the comments received during public consultation (1 July to 30 September 2010), does not provide information that would support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of TCEP.

5) *Exempted (categories of) uses*

ECHA did not receive requests for exemptions on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation and it does not see grounds to recommend exemptions of uses of TCEP on the basis of these Articles.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

The information available on TCEP does not provide information that would support introducing in Annex XIV any exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. Exemptions for PPORD with TCEP were not requested during public consultation on the draft Recommendation.

Therefore, ECHA does not recommend exempting the use of TCEP for PPORD from authorisation.

Annex I.H. - 2,4–Dinitrotoluene (2,4-DNT)

Reasons for prioritising 2,4-Dinitrotoluene

To determine whether 2,4-Dinitrotoluene should be prioritised pursuant to Article 58(3) of the REACH regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*"(version 28/05/2010). ECHA concluded that 2,4-Dinitrotoluene is supplied to uses in the scope of authorisation in relatively high volumes. The substance is used in explosives and ammunition, which are considered as wide dispersive uses.

Hence, ECHA has prioritised 2,4-Dinitrotoluene for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:	2,4-Dinitrotoluene
EC Numbers:	204-450-0
CAS Number:	121-14-2
IUPAC Name:	1-methyl-2,4-dinitrobenzene

2) Intrinsic properties

2,4-Dinitrotoluene was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as a carcinogen category 2[26], R45 (May cause cancer) and was therefore included in the candidate list for authorisation on 13 January 2010, following ECHA's decision ED/68/2009.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on 2,4-Dinitrotoluene does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

No information on production cycles is available that would allow to propose different application dates for different uses. ECHA has determined the application dates as described in Recital (10) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

[26] This corresponds to a classification as carcinogen 1B, H350 (may cause cancer) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances)

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Application date*:
  1 January 2014.
  In case ECHA's working assumption that a first set of substances will be included in Annex XIV by a Commission Regulation in January 2011 and that the substances in the present Recommendation will be included in Annex XIV in January 2012 proves not to be correct, the Commission is invited to take into account the principles set out in Annex I above on transitional arrangements to determine the appropriate latest application date.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

The information available for 2,4-Dinitrotoluene, including the comments received during public consultation (1 July to 30 September 2010), does not provide information that would support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of 2,4-Dinitrotoluene.

5) *Exempted (categories of) uses*

ECHA did not receive requests for exemptions on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation and it does not see grounds to recommend exemptions of uses of 2,4-Dinitrotoluene on the basis of these Articles.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

The information available on 2,4-Dinitrotoluene does not provide information that would support introducing in Annex XIV any exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56 (3) of the REACH Regulation. Exemptions for PPORD with 2,4-Dinitrotoluene were not requested during public consultation on the draft Recommendation.

Therefore, ECHA does not recommend exempting the use of 2,4-Dinitrotoluene for PPORD from authorisation.