Recommendation of the European Chemicals Agency of 1 July 2015 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 amended by Decision ED/69/2013[2],

Having regard to the opinion of ECHA's Member State Committee of 11 June 2015[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) Using the approach developed to support the prioritisation of substances for inclusion in Annex XIV pursuant to Article 58(3) of the REACH Regulation[4], ECHA had prioritised the following 22 substances from the Candidate List for its draft Recommendation of substances to be included in Annex XIV [5]:

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/10162/13640/opinion_draft_6th_axiv_recommendation_en.pdf

4 http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

5 http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf as published on ECHA's website on 1 September 2014

Draft recommendation		
#	**Substance name**	**EC**
1	*Anthracene oil*	*292-602-7*
2	*Pitch, coal tar, high temp.*	*266-028-2*
3	*1-bromopropane (n-propyl bromide)*	*203-445-0*
4	*Diisopentylphthalate*	*210-088-4*
5	*1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich*	*276-158-1*
6	*1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters*	*271-084-6*
7	*1,2-Benzenedicarboxylic acid, dipentylester, branched and linear*	*284-032-2*
8	*Bis(2-methoxyethyl) phthalate*	*204-212-6*
9	*Dipentyl phthalate (DPP)*	*205-017-9*
10	*N-pentyl-isopentylphthalate*	-
11	*Orange lead (lead tetroxide)*	*215-235-6*
12	*Lead monoxide (lead oxide)*	*215-267-0*
13	*Tetralead trioxide sulphate*	*235-380-9*
14	*Pentalead tetraoxide sulphate*	*235-067-7*
15	*Silicic acid, lead salt*	*234-363-3*
16	*Pyrochlore, antimony lead yellow*	*232-382-1*
17	*Acetic acid, lead salt, basic*	*257-175-3*
18	*4-Nonylphenol, branched and linear, ethoxylated* *[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]*	-
19	*Boric acid*	*233-139-2, 234-343-4*
20	*Disodium tetraborate, anhydrous*	*215-540-4*
21	*Diboron trioxide*	*215-125-8*
22	*Tetraboron disodium heptaoxide, hydrate*	*235-541-3*

(4) In accordance with Article 58(4) of the REACH Regulation, ECHA published on its website on 1 September 2014 the draft Recommendation and invited all interested parties to submit comments by 1 December 2014. ECHA has analysed and prepared responses to comments received and will make these publicly available[6].

(5) In accordance with Article 58(3), the number of substances included in Annex XIV shall take account of the Agency's capacity to handle applications in the time provided for. Having taken into account information received during the public consultation and based on the priority the substances receive by applying the prioritisation approach[4], ECHA recommends the following 15 substances for inclusion in Annex XIV.

Recommendation		
#	**Substance name**	**EC**
1	1-bromopropane (n-propyl bromide)	203-445-0
2	Diisopentylphthalate	210-088-4
3	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1
4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6
5	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2
6	Bis(2-methoxyethyl) phthalate	204-212-6
7	Dipentyl phthalate (DPP)	205-017-9
8	N-pentyl-isopentylphthalate	-
9	Anthracene oil	292-602-7
10	Pitch, coal tar, high temp.	266-028-2
11	4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]	-
12	Boric acid	233-139-2, 234-343-4
13	Disodium tetraborate, anhydrous	215-540-4
14	Diboron trioxide	215-125-8
15	Tetraboron disodium heptaoxide, hydrate	235-541-3

(6) 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) referred to in Article 58(1)(c)(ii) of the REACH Regulation by which an application should be received if the applicant wishes to continue to use the substance or place the substance on the market ("latest application date"); the date referred to in Article 58(1)(c)(i) of the REACH

[6] See responses given under: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

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.

(7) Using the approach developed to support determining the Annex XIV entries of prioritised substances[7] ECHA has determined the specific Annex XIV entries for each of the above listed substances.

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

(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 latest 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) The recommended latest application dates are based on the assumption that the substances listed in this Recommendation will be included in Annex XIV in August 2016[8]. The latest application dates have been set having regard to ECHA's capacity to handle applications in the time provided for, in accordance with Art. 58(3) of the REACH Regulation, over a period of 9 months (18, 21, 24 or 27 months from entry into force) to distribute the workload in the authorisation application and decision phase more evenly.

(11) The information available for the recommended substances, including the comments received during the public consultation, which took place from 1 September to 1 December 2014, does not provide information that would justify for the upfront 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 1 September to 1 December 2014, comments requesting exemptions of uses. Based on its assessment of these exemption requests[9], 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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7 http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

8 In case the amendment of Annex XIV will not enter into force in August 2016, the latest application dates may need to be adapted in order to fit with the application submission windows (i.e. with their end dates) as communicated on ECHA's website (http://echa.europa.eu/web/guest/applying-for-authorisation/submission-windows).

9 Refer to responses given under: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

(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 PPORD on the basis of Article 56(3) of the REACH Regulation.

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	1-bromopropane (n-propyl bromide)	203-445-0	106-94-5	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
2	Diisopentylphthalate	210-088-4	605-50-5	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
3	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 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 pursuant to REACH Art. 58 (1) (c) (ii) ****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
5	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	84777-06-0	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
6	Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
7	Dipentyl phthalate (DPP)	205-017-9	131-18-0	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
8	N-pentyl-isopentylphthalate	-	776297-69-9	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
9	Anthracene oil	292-602-7	90640-80-5	Carcinogenic (category 1B)[1)], PBT, vPvB	Date of inclusion in Annex XIV plus 21 months [3)]	Latest application date plus 18 months	None	None	None
10	Pitch, coal tar, high temp.	266-028-2	65996-93-2	Carcinogenic (category 1B), PBT, vPvB	Date of inclusion in Annex XIV plus 21 months [3)]	Latest application date plus 18 months	None	None	None
11	4-Nonylphenol, branched and linear, ethoxylated *[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and*	-	-	Equivalent level of concern having probable serious effects to the environment (Article 57 f)	Date of inclusion in Annex XIV plus 24 months [4)]	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 pursuant to REACH Art. 58 (1) (c) (ii) ****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
	well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]								
12	Boric acid	233-139-2, 234-343-4	10043-35-3, 11113-50-1	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 27 months [5)]	Latest application date plus 18 months	None	None	None
13	Disodium tetraborate, anhydrous	215-540-4	1330-43-4, 12179-04-3, 1303-96-4	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 27 months [5)]	Latest application date plus 18 months	None	None	None
14	Diboron trioxide	215-125-8	1303-86-2	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 27 months [5)]	Latest application date plus 18 months	None	None	None
15	Tetraboron disodium heptaoxide, hydrate	235-541-3	12267-73-1	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 27 months [5)]	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) Does not meet the criteria for identification as a carcinogen if it contains < 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5)
2) Assuming that the Commission amendment of Annex XIV of the REACH Regulation on the basis of this sixth Recommendation would enter into force in August 2016, the latest application date would be February 2018

3) Assuming that the Commission amendment of Annex XIV of the REACH Regulation on the basis of this sixth Recommendation would enter into force in August 2016, the latest application date would be May 2018
4) Assuming that the Commission amendment of Annex XIV of the REACH Regulation on the basis of this sixth Recommendation would enter into force in August 2016, the latest application date would be August 2018
5) Assuming that the Commission amendment of Annex XIV of the REACH Regulation on the basis of this sixth Recommendation would enter into force in August 2016, the latest application date would be November 2018

Done at Helsinki, 1 July 2015

For the European Chemicals Agency,

signed

Jukka Malm[10]

Deputy Executive Director

[10] Mandated to sign this decision pursuant to the decision of the Executive Director ED/20/2015 delegating the power to sign the submissions to the European Commission of the final Agency recommendation of priority substances to be included in Annex XIV under Article 58(3) of the REACH Regulation to Jukka Malm, Deputy 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 15 substances for inclusion in Annex XIV and the determination of their draft Annex XIV entries.

1. 1-bromopropane (n-propyl bromide)
2. Diisopentylphthalate
3. 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich
4. 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters
5. 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear
6. Bis(2-methoxyethyl) phthalate
7. Dipentyl phthalate (DPP)
8. N-pentyl-isopentylphthalate
9. Anthracene oil
10. Pitch, coal tar, high temp.
11. 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO)[1]
12. Boric acid
13. Disodium tetraborate, anhydrous
14. Diboron trioxide
15. Tetraboron disodium heptaoxide, hydrate

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 Authorisation List (Annex XIV)* (10 February 2014)[2]
- *Draft results of the 6th prioritisation of the SVHCs on the Candidate List with the objective to recommend priority substances for inclusion in Annex XIV* (1 September 2014)[3]
- *Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach* (21 August 2014)[4]
- Substance-specific background documents (1 July 2015)[5]

[1] The full name of this Candidate List entry is: 4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]

[2] http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

[3] http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf

[4] http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

[5] Background documents to be found in substance details at this link: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

- Substance-specific "C*omments and references to responses*" (ComRef) documents (1 July 2015)[6]
- Substance / substance group specific "*Response documents*" (1 July 2015)[7]
- Opinion of the Member State Committee on the 6th draft recommendation of the priority substances and Annex XIV entries (Adopted on 11 June 2015)[8]

The substance specific sections 1 to 15 below provide i) a summary of the reasons for prioritising the substance including ECHA's reflection on the main issues brought up in the MSC opinion and ii) a summary of the reasons for defining the Annex XIV entries.

[6] ComRef documents to be found in substance details at this link: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

[7] Response documents to be found in substance details at this link: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

[8] http://echa.europa.eu/documents/10162/13640/opinion_draft_6th_axiv_recommendation_en.pdf

1. 1-bromopropane (n-propyl bromide)

Reasons for prioritising 1-bromopropane

1-Bromopropane is classified as toxic for reproduction, category 1B (meeting the criteria of Art. 57 (c)). The substance is used at high volumes in the scope of authorisation at industrial sites and potentially also by professional workers.

1-Bromopropane received relatively high priority among the substances on the Candidate List assessed and its priority is further increased due to grouping consideration with trichloroethylene which is already included in Annex XIV.[9] Therefore, ECHA has recommended 1-bromopropane for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name: 1-bromopropane (n-propyl bromide)
EC Number: 203-445-0
CAS Number: 106-94-5

2) Intrinsic properties of the substance

1-Bromopropane was identified as a Substance of Very High Concern (SVHC) according to Article 57(c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360Fd ("May damage fertility. Suspected of damaging the unborn child.")[10], and was therefore included in the candidate list for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on 1-bromopropane does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (10) of the Recommendation.

[9] The qualifiers used for volumes and wide-dispersiveness of uses as well as how further considerations such as grouping can be taken into account when recommending substances for inclusion in Annex XIV are described in the document *General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (*http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

[10] There is a mistake in the entry for the substance in the CLP Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.1, indicating its classification as 'Repr. 1B, H360FD". However, the correct hazard statement code is Repr. 1B, H360Fd.

In its draft Recommendation for public consultation, ECHA had proposed that the LAD for 1-bromopropane would be the date of inclusion of the substance in Annex XIV plus 18 months.

During the public consultation comments on transitional arrangements were received. One MSCA supported the shortest latest application date whereas two comments by industry requested extending the transitional arrangements e.g. based on arguments that more time is needed for preparing applications for authorisation due to fragmented industry and high number of SMEs. ECHA has assessed all these requests on the basis of the approach set out in the document *'Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014) and has not found grounds to deviate from the originally determined transitional arrangements. ECHA also reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance is information which should be included in an eventual application for authorisation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for 1-bromopropane.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 18 months

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

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA did not receive comments on setting review periods in accordance with Article 58(1)(d) for 1-bromopropane.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of 1-bromopropane.

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of 1-bromopropane on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received support from one MSCA for not proposing any exemptions but also requests from industry for exemptions of 1-bromopropane for specific uses. Some of the requests referred to existing EU legislation, while there were also requests based on other justifications such as the control measures in place or the lack of suitable alternative substances.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of 1-bromopropane. It is also noted that some of the uses for which exemptions were requested may already qualify as exempt under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for 1-bromopropane.

In conclusion, ECHA could not identify grounds to recommend exemptions for uses of 1-bromopropane 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)*

During the public consultation on the draft Recommendation, ECHA did not receive any requests for exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend to include in Annex XIV any exemption from authorisation for the use of 1-bromopropane for PPORD.

2.-8. Phthalates:

2. Diisopentylphthalate
3. 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich
4. 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters
5. 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear
6. Bis(2-methoxyethyl) phthalate
7. Dipentyl phthalate
8. N-pentyl-isopentylphthalate

Reasons for prioritising Diisopentylphthalate; 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters; 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Bis(2-methoxyethyl) phthalate; Dipentyl phthalate; N-pentyl-isopentylphthalate

Diisopentylphthalate; 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters; 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Bis(2-methoxyethyl) phthalate; Dipentyl phthalate and N-pentyl-isopentylphthalate are recommended for inclusion in Annex XIV based on grouping considerations with other phthalates already on Annex XIV.[11]

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substances*

Chemical name: Diisopentylphthalate
EC Number: 210-088-4
CAS Number: 605-50-5

Chemical name: 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich
EC Number: 276-158-1
CAS Number: 71888-89-6

Chemical name: 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters
EC Number: 271-084-6
CAS Number: 68515-42-4

Chemical name: 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear
EC Number: 284-032-2
CAS Number: 84777-06-0

Chemical name: Bis(2-methoxyethyl) phthalate

[11] How further considerations such as grouping can be taken into account when recommending substances for inclusion in Annex XIV is described in the document *General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List* (http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

EC Number: 204-212-6
CAS Number: 117-82-8

Chemical name: Dipentyl phthalate (DPP)
EC Number: 205-017-9
CAS Number: 131-18-0

Chemical name: N-pentyl-isopentylphthalate
EC Number: -
CAS Number: 776297-69-9

2) Intrinsic properties of the substances

The substances listed under point *1)* above were identified as Substances of Very High Concern (SVHC) according to Article 57 (c) as they are classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360FD: "May damage fertility. May damage the unborn child.", and were therefore included in the candidate list for authorisation on:

- 20 June 2011 following ECHA's decision ED/31/2011 (1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters);
- 19 December 2011 following ECHA's decision ED/77/2011 (Bis(2-methoxyethyl) phthalate);
- 19 December 2012 following ECHA's decisionED/169/2012 (Diisopentylphthalate; 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; N-pentyl-isopentylphthalate);
- 20 June 2013, following ECHA's decision ED/69/2013 (Dipentyl phthalate)

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on the substances listed under point *1)* above does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (10) of the Recommendation.

In its draft Recommendation for public consultation, ECHA had proposed that the LAD for the seven phthalates would be the date of inclusion of the substance in Annex XIV plus 18 months.

During the public consultation on the draft 6th recommendation one MSCA supported the proposed latest application dates.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 18 months

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

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA did not receive comments on setting review periods in accordance with article 58(1)(d).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of the substances listed under point *1)* above.

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of the substances listed under point *1)* above on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received support for not proposing any exemptions by one MSCA. ECHA did not receive any requests for exemptions.

ECHA therefore does not recommend exemptions of uses of the recommended phthalates 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)

During the public consultation on the draft Recommendation, ECHA did not receive any requests for exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA therefore does not recommend to include in Annex XIV any exemption from authorisation for the use of the substances listed under point *1)* above for PPORD.

9. Anthracene oil

Reasons for prioritising Anthracene oil

Anthracene oil is classified as carcinogenic Cat. 1B and is identified as PBT and vPvB (meeting the criteria of Art. 57(a), (d) and (e)). Anthracene oil is used in very high volumes in the scope of authorisation. Anthracene oil is used at industrial sites and by professional workers. Furthermore, the substance is used in articles. [12,13]

Anthracene oil received high priority among the substances in the Candidate List assessed; hence ECHA has recommended it for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name: Anthracene oil
EC Number: 292-602-7
CAS Number: 90640-80-5

2) *Intrinsic properties of the substance*

Antracene oil was identified as a Substance of Very High Concern (SVHC) according to Article 57 (a), (d) and (e) of Regulation (EC) No 1907/2006 (REACH) and was therefore included in the Candidate List for authorisation on 13 January 2010, following ECHA's decision ED/68/2009.

Anthracene oil is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Carcinogenic, Category 1B, H350 ("May cause cancer"). This classification does not apply if it can be shown that the substance contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5).

In addition, on the basis of the PBT and/or vPvB properties of its PAH-constituents, anthracene oil fulfils the PBT and the vPvB criteria according to Article 57 (d) and (e) of the REACH Regulation.

3) *Transitional arrangements*

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12 The qualifiers used for volumes and wide-dispersiveness of uses are further explained and described in the document *General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List* (http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

13 The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background, ComRef and Response documents to be found at the link http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on anthracene oil does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (10) of the Recommendation.

In its draft Recommendation for public consultation, ECHA had proposed that the LAD for anthracene oil would be the date of inclusion of the substance in Annex XIV plus 18 months.

During the public consultation one MSCA supported the proposed latest application dates for anthracene oil. Comments were received from industry indicating the need of longer transitional periods because of the complexity of the supply chain (many uses, sectors and players) and challenges in communication through the supply chain.

ECHA has assessed these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014). To acknowledge the complexity of supply chain commented, ECHA decided to assign the coal stream substances to a later slot than what was proposed in the draft recommendation. Further details on setting LAD and SSD can be found in the *'Comments and references to responses document' for anthracene oil and 'Response document' for coal stream substances*.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 21 months

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

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA did not receive comments on setting review periods in accordance with article 58(1)(d) for anthracene oil.

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

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of anthracene oil on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation one MSCA indicated that they do not support any exemptions from authorisation. ECHA did not receive requests for exemptions. It was indicated in one comment that some uses are generically exempted from the authorisation, i.e. use of anthracene oil and CTPHT as fuel (Art. 56(4)(d)) and the use of anthracene oil for the manufacture of biocidal creosote (Art. 56(4)(b)). ECHA's view is that it is the responsibility of the companies to assess whether any of their uses complies with the requirements for the generic exemptions from the authorisation requirement.

ECHA therefore does not recommend exemptions for uses of anthracene oil 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)*

During the public consultation on the draft Recommendation, ECHA did not receive any requests for exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation for anthracene oil.

ECHA therefore does not recommend to include in Annex XIV any exemption from authorisation for the use of anthracene oil for PPORD.

10. Pitch, coal tar, high temp. (CTPHT)

Reasons for prioritising Pitch, coal tar, high temp. (CTPHT)

Pitch, coal tar, high temp. (CTPHT) is classified as carcinogenic Cat. 1B and it is identified as PBT and vPvB (meeting the criteria 57 a, d and e). The amount of CTPHT used in the scope of authorisation is very high. CTPHT is used at industrial sites and by professional workers. Furthermore, the substance is used in articles. [14,15]

CTPHT received high priority among the substances in the Candidate List assessed; hence ECHA has recommended it for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name: Pitch, coal tar, high temp.
EC Number: 266-028-2
CAS Number: 65996-93-2

2) *Intrinsic properties of the substance*

Pitch, coal tar, high temp. (CTPHT) was identified as a Substance of Very High Concern (SVHC) according to Article 57 (a), (d) and (e) of Regulation (EC) No 1907/2006 (REACH) and was therefore included in the Candidate List for authorisation on 13 January 2010, following ECHA's decision ED/68/2009.

CTPHT is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Carcinogenic, Category 1B, H350 ("May cause cancer").

In addition, on the basis of the PBT and vPvB properties of some of its PAH-constituents, CTPHT fulfils the PBT and the vPvB criteria according to Article 57 (d) and (e) of the REACH Regulation.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on CTPHT does not

[14] The qualifiers used for volumes and wide-dispersiveness of uses are further explained and described in the document *General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List* (http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

[15] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background, ComRef and Response documents to be found at the link http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (10) of the Recommendation.

In its draft Recommendation for public consultation, ECHA had proposed that the LAD for CTPHT would be the date of inclusion of the substance in Annex XIV plus 18 months.

During the public consultation one MSCA supported the proposed latest application dates. Comments were received from industry indicating the need of longer transitional periods based on arguments that more time is needed for developing and implementing alternatives or for organising and preparing applications for authorisation (due to e.g. complexity of supply chain, complexity of the SEA). One company from aluminium industry, aluminium industry association, and consortium of CaC_2 -manufacturers proposed a latest application date of 24 months.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014). ECHA reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards is information which should be included in an eventual application for authorisation. However, to acknowledge the complexity of supply chain commented, ECHA decided to assign the coal stream substances to a later slot than what was proposed in the draft recommendation. Further details can be found in the *'Comments and references to responses –document' for CTPHT and 'Response document' for coal stream substances*.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 21 months

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

4) <u>Review periods for certain uses</u>

During the public consultation on the draft Recommendation, ECHA did not receive comments on setting review periods in accordance with article 58(1)(d) for CTPHT.

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

5) <u>Exempted (categories of) uses</u>

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of CTPHT on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received support for not proposing any exemptions by one MSCA but also a number of requests for exemptions of CTPHT for specific uses. Several requests referred to existing EU legislation but other justifications such as the control measures in place or the lack of suitable alternative substances were also provided. One broader exemption from the authorisation requirement was requested for the supply of past model service parts of vehicles (based on the potentially long service life of these vehicles and the need to ensure that their safety is not compromised).

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of CTPHT. It is also noted that some of the uses for which exemptions were requested may already qualify as exempt under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the *'Comments and references to responses document' for CTPHT and 'Response document' for coal stream substances*.

In conclusion, ECHA could not identify grounds to recommend exemptions for uses of CTPHT 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)*

During the public consultation on the draft Recommendation, ECHA did not receive any requests for exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation for CTPHT.

ECHA therefore does not recommend to include in Annex XIV any exemption from authorisation for the use of CTPHT for PPORD.

11. 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO)

Reasons for prioritising 4-nonylphenol, branched and linear, ethoxylated

4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO) are identified as substances with endocrine disrupting properties, because through their degradation, they are substances for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH. The amount of 4-NPnEO used in the scope of authorisation is very high. The substances are used at industrial sites, by professional workers and by consumers. Furthermore, the substances are used in articles. [16,17]

4-NPnEO received high priority among the substances in the Candidate List assessed; hence ECHA has recommended it for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name: 4-Nonylphenol, branched and linear, ethoxylated [*substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof*]
EC Number: -
CAS Number: -

2) *Intrinsic properties of the substance*

The substances covered by the entry '4-Nonylphenol, branched and linear, ethoxylated' were identified as substances of very high concern (SVHC) according to Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because, through their degradation, they are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH. Therefore, 4-Nonylphenol, branched and linear, ethoxylated were included in the Candidate List for authorisation on 20 June 2013, following ECHA's decision ED/69/2013.

[16] The qualifiers used for volumes and wide-dispersiveness of uses are further explained and described in the document *General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (*http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

[17] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background, ComRef and Response documents to be found at the link http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on 4-NPnEO does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (10) of the Recommendation.

In its draft Recommendation for public consultation, ECHA had proposed that the LAD for 4-NPnEO would be the date of inclusion of the substance in Annex XIV plus 24 months.

During the public consultation comments on transitional arrangements were received. One comment by a Member State proposed the shortest possible LAD. Two comments by industry (automotive, pharmaceutical / life sciences) requested extension of the transitional arrangements based on arguments that more time is needed for revalidation processes and implementing alternatives (if the use was not exempted). More specifically, a LAD of 48 months after inclusion in Annex XIV was requested in one of these comments. ECHA has assessed all these requests on the basis of the approach set out in the document *'Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014) and has not found grounds to deviate from the originally determined transitional arrangements. ECHA also reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards etc. is information which should be included in an eventual application for authorisation. Further details can be found in the *'Comments and references to responses –document" and "Response document"* for 4-NPnEO.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 24 months

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

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA received a comment requesting a review period, in accordance with Article 58(1)(d), of 12 years for a use of 4-NPnEO in pharmaceutical industry / life sciences due to the difficulty to develop technical alternatives and potential socio-economic impact on the complex supply chain The information available, including the information provided in the comment, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the *'Comments and references to responses document" and "Response document"* for 4-NPnEO.

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

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of 4-NPnEO on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received support for not proposing any exemptions but also some requests for exemptions of 4-NPnEO for specific uses. There were two exemption requests by industry for upstream processes of exempted uses, and one for legacy spare parts. There was also one request for exemption based on arguments that the particular use is critical for the company's business and the risks in this industrial use are adequately controlled.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of 4-NPnEO. It is also noted that some of the uses for which exemptions were requested may already qualify as exempt under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for 4-NPnEO.

In conclusion, ECHA could not identify grounds to recommend exemptions for uses of 4-NPnEO 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)*

During the public consultation on the draft Recommendation, ECHA did not receive any requests for exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend to include in Annex XIV any exemption from authorisation for the use of 4-NPnEO for PPORD.

12. Boric acid

Reasons for prioritising boric acid

Boric acid is classified as toxic for reproduction, cat. 1B (meeting the criteria of Art. 57 (c) of the REACH Regulation). The amount of the substance used in the scope of authorisation is very high. The substance is used at industrial sites and by professional workers. Furthermore, the substance is used in articles.[18,19]

Boric acid received high priority among the substances on the Candidate List assessed; hence ECHA has recommended it for inclusion in Annex XIV.

Notes to MSC views

The majority of the MSC agreed to the prioritisation of the boron compounds, however, six MSC members provided a minority position against the inclusion of boron compounds in the 6th recommendation. They argue that the important use of boric acid in nuclear power plants is covered by EU legislation and that therefore the environmental and health risks are managed efficiently. They further argue that the essential use of boron as micronutrient in fertilisers cannot be replaced.

While ECHA acknowledges these concerns, ECHA's assessment of the cited regulation relating to nuclear installations led to the conclusion that it does not seem to justify an exemption under Art. 58(2). Similarly, there appears to be no specific EU legislation meriting an Art. 58(2) exemption of boron compounds when used as fertilisers. It is worth noting that even in case the uses in nuclear power plants and fertilisers were not taken into account, the priority of the boron compounds would remain very high due to the other uses within the scope of authorisation. The establishment of a streamlined authorisation process for specific cases, including biologically essential elements, as currently considered by the Commission, MSCAs and ECHA is foreseen to mitigate the concerns raised in the minority opinion. Based on information provided by the nuclear power industry the preparation of an adequate authorisation application for the use in the nuclear power plants seems straight forward.

The minority position further refers to the Commission's REFIT[20] programme and to considerations by the Commission to take into account socio-economic elements for future amendments of Annex XIV. Finally, the minority position calls the Commission to clarify the conditions for Art. 58(2) exemptions. ECHA notes these statements referring to policy aspects which ECHA is not in position to take into account in the current recommendation step of the authorisation process.

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18 The qualifiers used for volumes and wide-dispersiveness of uses are further explained and described in the document *General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (*http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

19 The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background, ComRef and Response documents to be found at the link http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

20 REFIT is the European Commission's Regulatory Fitness and Performance programme. Please refer to http://ec.europa.eu/smart-regulation/refit/index_en.htm

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name: Boric acid
EC Number: 233-139-2, 234-343-4
CAS Number: 10043-35-3, 11113-50-1

2) *Intrinsic properties of the substance*

Boric acid was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360-FD (May damage fertility. May damage the unborn child) and was therefore included in the candidate list for authorisation on 18 June 2010, following ECHA's decision ED/30/2010.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on boric acid does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 month time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (10) of the Recommendation.

In its draft Recommendation for public consultation, ECHA had proposed that the LAD for boric acid would be the date of inclusion of the substance in Annex XIV plus 24 months.

During the public consultation many comments requesting longer transition periods for boric acid were received. The comments referred to long term investments, complexity of the supply chain, high level of regulation and the need to search for alternatives. The periods requested for the LADs ranged from 3-4 up to 60 years. One MSCA indicated preference to place the borates in the shortest LAD slot.

The MSC opinion proposes the consideration of LAD of 35 months for the boron compounds. This proposal is based on comments made during the public consultation which state that supply chains for these substances are complex. The opinion further notes that such LADs were previously established for the chromate compounds that were included at the third amendment of Annex XIV.

ECHA has assessed the requests made in the comments on the basis of the approach set out in the document *'Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014) and also carefully assessed MSC opinion. ECHA fully agrees that complexity of the supply chain seems to be one of the main factors affecting the time needed to prepare an application for authorisation. At the same time a systematic approach to define and assess the factors determining the complexity of a supply chain is lacking. Better insight may be available

after the applications for chromates have been submitted. Following this, ECHA will work together with industry and MSCAs to develop means for assessing supply chain complexity and how this may influence setting LADs.

Furthermore, ECHA agrees that the boron compounds have a high number and a high diversity of uses as well as many functions. In recognition of the concerns raised and the absence of a systematic assessment methodology, ECHA prolongs the proposed LAD for boron compounds to 27 months.

ECHA reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards is information which should be included in an eventual application for authorisation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for boric acid.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 27 months

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

4) Review periods for certain uses

Comments received requested longer review periods based on long development cycles, high costs of substitution, no alternative available within the normal review period, specific legislative measures for possible alternatives under the relevant area or low remaining risk and high socioeconomic benefits. Requested periods ranged from 7-12 up to 40 years, some asking for an unlimited period.

The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with Article 58(1)(d) for any use of the substance. Further details can be found in the *'Comments and references to responses document" and "Response document"* for boric acid.

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

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of boric acid on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

One MSCA stated that they do not support any exemptions while another MSCA expressed their opinion that the use of borates in fertilisers and in nuclear power plants should be exempted.

Requests for exemptions of the borates were received from industry and representative groups. Apart from uses claimed as falling under generic exemptions, exemptions were requested for a wide range of uses. Exemptions for specific uses were requested for the use of the borate substances in fertilisers, where they function as essential micro-nutrient. There were also many requests for exemptions for the use of borates in nuclear power plants. Several requests referred to existing EU legislation, while there were also requests based on other justifications such as the control measures in place or the lack of suitable alternative substances.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of boric acid. It is also noted that some of the uses for which exemptions were requested may already qualify as exempt under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for boric acid.

In conclusion, ECHA could not identify grounds to recommend exemptions for uses of boric acid 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)*

During the public consultation on the draft Recommendation, ECHA did not receive any requests for exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend to include in Annex XIV any exemption from authorisation for the use of boric acid for PPORD.

13. Disodium tetraborate, anhydrous

Reasons for prioritising disodium tetraborate, anhydrous

Disodium tetraborate, anhydrous is classified as toxic for reproduction, cat. 1B (meeting the criteria 57 c of the REACH Regulation). The amount of the substance used in the scope of authorisation is very high. The substance is used at industrial sites and by professional workers. Furthermore, the substance is used in articles.[21,22]

Disodium tetraborate, anhydrous received high priority among the substances on the Candidate List assessed; hence ECHA has recommended it for inclusion in Annex XIV.

Notes to MSC views

The majority of the MSC agreed to the prioritisation of the boron compounds, however, six MSC members provided a minority position against the inclusion of boron compounds in the 6th recommendation. They argue that the important use of boric acid in nuclear power plants is covered by EU legislation and that therefore the environmental and health risks are managed efficiently. They further argue that the essential use of boron as micronutrient in fertilisers cannot be replaced.

While ECHA acknowledges these concerns, ECHA's assessment of the cited regulation relating to nuclear installations led to the conclusion that it does not seem to justify an exemption under Art. 58(2). Similarly, there appears to be no specific EU legislation meriting an Art. 58(2) exemption of boron compounds when used as fertilisers. It is worth noting that even in case the uses in nuclear power plants and fertilisers were not taken into account, the priority of the boron compounds would remain very high due to the other uses within the scope of authorisation. The establishment of a streamlined authorisation process for specific cases, including biologically essential elements, as currently considered by the Commission, MSCAs and ECHA is foreseen to mitigate the concerns raised in the minority opinion. Based on information provided by the nuclear power industry the preparation of an adequate authorisation application for the use in the nuclear power plants seems straight forward.

The minority position further refers to the Commission's REFIT[23] programme and to considerations by the Commission to take into account socio-economic elements for future amendments of Annex XIV. Finally, the minority position calls the Commission to clarify the conditions for Art. 58(2) exemptions. ECHA notes these statements referring to policy aspects which ECHA is not in position to take into account in the current recommendation step of the authorisation process.

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21 The qualifiers used for volumes and wide-dispersiveness of uses are further explained and described in the document *General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List* (http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

22 The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background, ComRef and Response documents to be found at the link http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

23 REFIT is the European Commission's Regulatory Fitness and Performance programme. Please refer to http://ec.europa.eu/smart-regulation/refit/index_en.htm

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name: Disodium tetraborate, anhydrous
EC Number: 215-540-4
CAS Number: 1330-43-4, 12179-04-3, 1303-96-4

The description covers also disodium tetraborate hydrates covered by the EINECS entry of anhydrous form.

2) *Intrinsic properties of the substance*

Disodium tetraborate, anhydrous was identified as a substance of very high concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360-FD (May damage fertility. May damage the unborn child) and was therefore included in the candidate list for authorisation on 18 June 2010, following ECHA's decision ED/30/2010.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on disodium tetraborate, anhydrous does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 month time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (10) of the Recommendation.

In its draft Recommendation for public consultation, ECHA had proposed that the LAD for disodium tetraborate, anhydrous would be the date of inclusion of the substance in Annex XIV plus 24 months.

During the public consultation comments requesting longer transition periods for disodium tetraborate, anhydrous were received. The comments referred to long term investments, complexity of the supply chain and the need to search for alternatives. The periods requested for the LADs ranged up to 60 years. One MSCA indicated preference to place the borates in the shortest LAD slot.

The MSC opinion proposes the consideration of LAD of 35 months for the boron compounds. This proposal is based on comments made during the public consultation which state that supply chains for these substances are complex. The opinion further notes that such LADs were previously established for the chromate compounds that were included at the third amendment of Annex XIV.

ECHA has assessed the requests made in the comments on the basis of the approach set out in the document *'Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014) and also carefully assessed MSC opinion. ECHA fully agrees that complexity of the supply chain seems to be one of the main factors affecting the time needed to prepare an application for authorisation. At the same time a systematic approach to define and assess the factors determining the complexity of a supply chain is lacking. Better insight may be available after the applications for chromates have been submitted. Following this, ECHA will work together with industry and MSCAs to develop means for assessing supply chain complexity and how this may influence setting LADs.

Furthermore, ECHA agrees that the boron compounds have a high number and a high diversity of uses as well as many functions. In recognition of the concerns raised and the absence of a systematic assessment methodology, ECHA prolongs the proposed LAD for boron compounds to 27 months.

ECHA reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards is information which should be included in an eventual application for authorisation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for disodium tetraborate, anhydrous.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 27 months

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

4) Review periods for certain uses

Comments received requested longer review periods based on e.g. no alternative available within the normal review period, specific legislative measures for possible alternatives under the relevant area or low remaining risk and high socioeconomic benefits. Requested periods ranged from 10 up to 40 years, some asking for an unlimited period.

The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the *'Comments and references to responses document" and "Response document"* for disodium tetraborate, anhydrous.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of disodium tetraborate, anhydrous.

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of disodium tetraborate, anhydrous on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

One MSCA stated that they do not support any exemptions while another MSCA expressed their opinion that the use of borates in fertilisers and in nuclear power plants should be exempted.

Requests for exemptions of the borates were received from industry and representative groups. Apart from uses claimed as falling under generic exemptions, exemptions were requested for a wide range of uses. Exemptions for specific uses were requested for the use of the borate substances in fertilisers, where they function as essential micro-nutrient. There were also many requests for exemptions for the use of borates in nuclear power plants. Several requests referred to existing EU legislation, while there were also requests based on other justifications such as the control measures in place or the lack of suitable alternative substances.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of disodium tetraborate, anhydrous. It is also noted that some of the uses for which exemptions were requested may already qualify as exempt under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for disodium tetraborate, anhydrous.

In conclusion, ECHA could not identify grounds to recommend exemptions for uses of disodium tetraborate, anhydrous 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)*

During the public consultation on the draft Recommendation, ECHA did not receive any requests for exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend to include in Annex XIV any exemption from authorisation for the use of disodium tetraborate, anhydrous for PPORD.

14. Diboron trioxide

Reasons for prioritising diboron trioxide

Diboron trioxide is classified as toxic for reproduction, cat. 1B (meeting the criteria of Art. 57 (c) of the REACH Regulation). The amount of the substance used in the scope of authorisation is high. The substance is used at industrial sites and by professional workers. Furthermore, the substance is used in articles.[24][25]

Diboron trioxide received relatively high priority among the substances on the Candidate List assessed and its priority is further increased due to grouping consideration with boric acid and disodium tetraborate, anhydrous. Therefore, ECHA has recommended diboron trioxide for inclusion in Annex XIV.

Notes to MSC views

The majority of the MSC agreed to the prioritisation of the boron compounds, however, six MSC members provided a minority position against the inclusion of boron compounds in the 6th recommendation. They argue that the important use of boric acid in nuclear power plants is covered by EU legislation and that therefore the environmental and health risks are managed efficiently. They further argue that the essential use of boron as micronutrient in fertilisers cannot be replaced.

While ECHA acknowledges these concerns, ECHA's assessment of the cited regulation relating to nuclear installations led to the conclusion that it does not seem to justify an exemption under Art. 58(2). Similarly, there appears to be no specific EU legislation meriting an Art. 58(2) exemption of boron compounds when used as fertilisers. It is worth noting that even in case the uses in nuclear power plants and fertilisers were not taken into account, the priority of the boron compounds would remain very high due to the other uses within the scope of authorisation. The establishment of a streamlined authorisation process for specific cases, including biologically essential elements, as currently considered by the Commission, MSCAs and ECHA is foreseen to mitigate the concerns raised in the minority opinion. Based on information provided by the nuclear power industry the preparation of an adequate authorisation application for the use in the nuclear power plants seems straight forward.

The minority position further refers to the Commission's REFIT[26] programme and to considerations by the Commission to take into account socio-economic elements for future amendments of Annex XIV. Finally, the minority position calls the Commission to

[24] The qualifiers used for volumes and wide-dispersiveness of uses as well as how further considerations such as grouping can be taken into account when recommending substances for inclusion in Annex XIV are described in the document *General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List* (http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

[25] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background, ComRef and Response documents to be found at the link http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

[26] REFIT is the European Commission's Regulatory Fitness and Performance programme. Please refer to http://ec.europa.eu/smart-regulation/refit/index_en.htm

clarify the conditions for Art. 58(2) exemptions. ECHA notes these statements referring to policy aspects which ECHA is not in position to take into account in the current recommendation step of the authorisation process.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name: Diboron trioxide
EC Number: 215-125-8
CAS Number: 1303-86-2

2) *Intrinsic properties of the substance*

Diboron trioxide was identified as a substance of very high concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360-FD (May damage fertility. May damage the unborn child) and was therefore included in the candidate list for authorisation on 18 June 2012, following ECHA's decision ED/87/2012.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on diboron trioxide does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 month time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (10) of the Recommendation.

In its draft Recommendation for public consultation, ECHA had proposed that the LAD for diboron trioxide would be the date of inclusion of the substance in Annex XIV plus 24 months.

During the public consultation comments requesting longer transition periods for diboron trioxide were received. The comments referred to the time needed to develop alternatives. The periods requested for the LADs ranged from 4 up to 20 years. One MSCA indicated preference to place the borates in the shortest LAD slot.

The MSC opinion proposes the consideration of LAD of 35 months for the boron compounds. This proposal is based on comments made during the public consultation which state that supply chains for these substances are complex. The opinion further notes that such LADs were previously established for the chromate compounds that were included at the third amendment of Annex XIV.

ECHA has assessed the requests made in the comments on the basis of the approach set out in the document *'Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014) and also carefully

assessed MSC opinion. ECHA fully agrees that complexity of the supply chain seems to be one of the main factors affecting the time needed to prepare an application for authorisation. At the same time a systematic approach to define and assess the factors determining the complexity of a supply chain is lacking. Better insight may be available after the applications for chromates have been submitted. Following this, ECHA will work together with industry and MSCAs to develop means for assessing supply chain complexity and how this may influence setting LADs.

Furthermore, ECHA agrees that the boron compounds have a high number and a high diversity of uses as well as many functions. In recognition of the concerns raised and the absence of a systematic assessment methodology, ECHA prolongs the proposed LAD for boron compounds to 27 months.

ECHA reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards is information which should be included in an eventual application for authorisation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for diboron trioxide.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 27 months

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

4) Review periods for certain uses

Comments received requested longer review periods based on arguments like time is needed to develop alternatives. Requested periods were e.g. 7 years.

The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the *'Comments and references to responses document" and "Response document"* for diboron trioxide.

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

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of diboron trioxide on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

One MSCA stated that they do not support any exemptions while another MSCA expressed their opinion that the use of borates in fertilisers and in nuclear power plants should be exempted.

Requests for exemptions of the borates were received from industry and representative groups. Apart from uses claimed as falling under generic exemptions, exemptions were requested for a wide range of uses. Exemptions for specific uses were requested for the use of the borate substances in fertilisers, where they function as essential micro-nutrient. There were also many requests for exemptions for the use of borates in nuclear power plants. Several requests referred to existing EU legislation, while there were also requests based on other justifications such as the control measures in place or the lack of suitable alternative substances.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of diboron trioxide. It is also noted that some of the uses for which exemptions were requested may already qualify as exempt under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for diboron trioxide.

In conclusion, ECHA could not identify grounds to recommend exemptions for uses of diboron trioxide 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)*

During the public consultation on the draft Recommendation, ECHA did not receive any requests for exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend to include in Annex XIV any exemption from authorisation for the use of diboron trioxide for PPORD.

15. Tetraboron disodium heptaoxide, hydrate

Reasons for prioritising tetraboron disodium heptaoxide, hydrate

Tetraboron disodium heptaoxide, hydrate is recommended for inclusion in Annex XIV based on grouping considerations with boric acid and disodium tetraborate, anhydrous.[27]

Notes to MSC views

The majority of the MSC agreed to the prioritisation of the boron compounds, however, six MSC members provided a minority position against the inclusion of boron compounds in the 6th recommendation. They argue that the important use of boric acid in nuclear power plants is covered by EU legislation and that therefore the environmental and health risks are managed efficiently. They further argue that the essential use of boron as micronutrient in fertilisers cannot be replaced.

While ECHA acknowledges these concerns, ECHA's assessment of the cited regulation relating to nuclear installations led to the conclusion that it does not seem to justify an exemption under Art. 58(2). Similarly, there appears to be no specific EU legislation meriting an Art. 58(2) exemption of boron compounds when used as fertilisers. It is worth noting that even in case the uses in nuclear power plants and fertilisers were not taken into account, the priority of the boron compounds would remain very high due to the other uses within the scope of authorisation. The establishment of a streamlined authorisation process for specific cases, including biologically essential elements, as currently considered by the Commission, MSCAs and ECHA is foreseen to mitigate the concerns raised in the minority opinion. Based on information provided by the nuclear power industry the preparation of an adequate authorisation application for the use in the nuclear power plants seems straight forward.

The minority position further refers to the Commission's REFIT[28] programme and to considerations by the Commission to take into account socio-economic elements for future amendments of Annex XIV. Finally, the minority position calls the Commission to clarify the conditions for Art. 58(2) exemptions. ECHA notes these statements referring to policy aspects which ECHA is not in position to take into account in the current recommendation step of the authorisation process.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name: Tetraboron disodium heptaoxide, hydrate
EC Number: 235-541-3

[27] How further considerations such as grouping can be taken into account when recommending substances for inclusion in Annex XIV is described in the document *General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List* (http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

[28] REFIT is the European Commission's Regulatory Fitness and Performance programme. Please refer to http://ec.europa.eu/smart-regulation/refit/index_en.htm

CAS Number: 12267-73-1

2) *Intrinsic properties of the substance*

Tetraboron disodium heptaoxide, hydrate was identified as a substance of very high concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360-FD (May damage fertility. May damage the unborn child) and was therefore included in the candidate list for authorisation on 18 June 2010, following ECHA's decision ED/30/2010.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on tetraboron disodium heptaoxide, hydrate does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 month time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (10) of the Recommendation.

In its draft Recommendation for public consultation, ECHA had proposed that the LAD for tetraboron disodium heptaoxide, hydrate would be the date of inclusion of the substance in Annex XIV plus 24 months.

During the public consultation comments requesting longer transition periods for tetraboron disodium heptaoxide, hydrate were received. The comments referred to complexity of the supply chain and the need to search for alternatives. The periods requested for the LADs ranged from several years to requests for maximum length. One MSCA indicated preference to place the borates in the shortest LAD slot.

The MSC opinion proposes the consideration of LAD of 35 months for the boron compounds. This proposal is based on comments made during the public consultation which state that supply chains for these substances are complex. The opinion further notes that such LADs were previously established for the chromate compounds that were included at the third amendment of Annex XIV.

ECHA has assessed the requests made in the comments on the basis of the approach set out in the document *'Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014) and also carefully assessed MSC opinion. ECHA fully agrees that complexity of the supply chain seems to be one of the main factors affecting the time needed to prepare an application for authorisation. At the same time a systematic approach to define and assess the factors determining the complexity of a supply chain is lacking. Better insight may be available after the applications for chromates have been submitted. Following this, ECHA will work together with industry and MSCAs to develop means for assessing supply chain complexity and how this may influence setting LADs.

Furthermore, ECHA agrees that the boron compounds have a high number and a high diversity of uses as well as many functions. In recognition of the concerns raised and the absence of a systematic assessment methodology, ECHA prolongs the proposed LAD for boron compounds to 27 months.

ECHA reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards is information which should be included in an eventual application for authorisation. Further details can be found in the *'Comments and references to responses document" and "Response document"* for tetraboron disodium heptaoxide, hydrate.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 27 months

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

4) Review periods for certain uses

Comments received requested longer review periods based on arguments like that there is no alternative available and that specific legislative requirements exist. Requested periods were e.g. 12 years; some asking for an unlimited period.

The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the *'Comments and references to responses document" and "Response document"* for tetraboron disodium heptaoxide, hydrate.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of tetraboron disodium heptaoxide, hydrate.

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of tetraboron disodium heptaoxide, hydrate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

One MSCA stated that they do not support any exemptions.

Requests for exemptions of the borates were received from industry and representative groups. Apart from uses claimed as falling under generic exemptions, exemptions were requested for a wide range of uses. Exemptions for specific uses were requested for the use of the borate substances in fertilisers, where they function as essential micro-

nutrient. There were also many requests for exemptions for the use of borates in nuclear power plants. Several requests referred to existing EU legislation, while there were also requests based on other justifications such as the control measures in place or the lack of suitable alternative substances.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2014). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of tetraboron disodium heptaoxide, hydrate. It is also noted that some of the uses for which exemptions were requested may already qualify as exempt under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the *'Comments and references to responses – document" and "Response document"* for tetraboron disodium heptaoxide, hydrate.

In conclusion, ECHA could not identify grounds to recommend exemptions for uses of tetraboron disodium heptaoxide, hydrate 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)*

During the public consultation on the draft Recommendation, ECHA did not receive any requests for exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend to include in Annex XIV any exemption from authorisation for the use of tetraboron disodium heptaoxide, hydrate for PPORD.