26 June 2019 Final

OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT NINTH RECOMMENDATION OF THE PRIORITY SUBSTANCES TO BE INCLUDED IN ANNEX XIV OF THE REACH REGULATION AND THE ASSOCIATED ANNEX XIV ENTRIES

Adopted on 26 June 2019

OPINION

This opinion of the Member State Committee (MSC) is on the draft 9th recommendation of European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV. The opinion was adopted on 26 June 2019 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006[1].

THE DRAFT NINTH RECOMMENDATION OF ECHA

The draft 9th recommendation for priority substances to be included in Annex XIV of REACH (hereafter referred to as the "draft 9th recommendation") prepared by ECHA included 18 substances and specified the following information for priority substances:

- The identity of the substance as specified in section 2 of Annex VI
- The intrinsic property(-ies) of the substance referred to in Article 57
- Transitional arrangements
    - The sunset date
    - The application date

No review periods, uses or categories of uses exempted from the authorisation requirement or PPORD exemptions were specified in the draft 9th recommendation.

The draft 9th recommendation addressed in a public consultation is attached to this opinion (Annex II).

FOCUS OF THE OPINION OF MSC

The opinion of MSC focuses on the draft 9th recommendation and the comments received during the public consultation. Further details of the information taken into account by MSC in the preparation of its opinion and further justification for MSC views are presented in the support document (see Annex I).

[1] Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Emphasis in the support document is given to comments received and issues raised during the public consultation that are not specifically addressed in *'ECHA's general responses on issues commonly raised in public consultations on draft recommendations'* [2] document.

OPINION OF MSC ON THE NINTH DRAFT RECOMMENDATION FOR PRIORITISATION OF SUBSTANCES TO BE INCLUDED IN ANNEX XIV

PRIORITISED SUBSTANCES

MSC is of the opinion that no information has been received that would justify not including all 18 substances in the final recommendation. MSC is of the opinion that all substances listed in the draft 9th recommendation of ECHA, and as indicated in the table below, should be prioritised for inclusion into Annex XIV in accordance with Article 58(3) of REACH.

#	Substance	EC number	CAS number
1	4,4'- isopropylidenediphenol (Bisphenol A; BPA)	201-245-8	80-05-7
2	1,6,7,8,9,14,15,16,17, 17,18,18-Dodecachloropentacyclo [12.2.1.16,9.02,13.05,10] octadeca-7,15-diene ("Dechlorane Plus"™)	-	-
3	Reaction products of 1,3,4-thiadiazolidine- 2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear with ≥0.1% w/w 4-heptylphenol, branched and linear (RP-HP)	-	-
4	2-ethylhexyl 10-ethyl- 4,4-dioctyl-7-oxo-8- oxa-3,5-dithia-4-Stannatetradecanoate (DOTE)	239-622-4	15571-58-1
5	Reaction mass of 2-ethylhexyl 10-ethyl- 4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2- ethylhexyl)oxy]-2- oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4- stannatetradecanoate (Reaction mass of DOTE and MOTE)	-	-
6	4,4'- bis(dimethylamino)- 4''-(methylamino)trityl alcohol with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2) (Trityl alcohol)	209-218-2	561-41-1
7	Dioxobis(stearato) trilead	235-702-8	12578-12-0
8	Fatty acids, C16-18, lead salts	292-966-7	91031-62-8
9	Trilead dioxide phosphonate	235-252-2	12141-20-7
10	Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7
11	[Phthalato(2-)] dioxotrilead	273-688-5	69011-06-9
12	Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6
13	Lead oxide sulfate	234-853-7	12036-76-9
14	Cyclohexane-1,2-dicarboxylic anhydride [1],	201-604-9,	85-42-7,

[2] https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf/44e192e5-ac72-4458-b4f5-c016754a1d4c (version 2 March 2017)

#	Substance	EC number	CAS number
	cis-cyclohexane-1,2- dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis-HHPA [2] and trans-HHPA [3] isomer substances and all possible combinations of the cis- and trans isomers of HHPA [1]are covered by this entry] (HHPA)	236-086-3, 238-009-9	13149-00-3, 14166-21-3
15	Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis and trans-stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry] (MHHPA)	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9
16	Tetraethyllead	201-075-4	78-00-2
17	2-methoxyethanol	203-713-7	109-86-4
18	2-ethoxyethanol	203-804-1	110-80-5

TRANSITIONAL ARRANGEMENTS

MSC notes that the draft 9th recommendation of ECHA proposed to allocate the substances to one of three latest application date (LAD) slots: 18, 21 or 24 months after the date of inclusion in Annex XIV. ECHA indicated that the final LAD allocation for each substance/substance group would be done taking into account all available information including feedback from the public consultation and registration updates. Sunset dates for all substances were proposed as LAD plus 18 months.

Following the public consultation, ECHA proposed LADs for each substance/substance group which are presented in the table below.

Taking into account all available information, the MSC is of the opinion that the LAD allocation proposed by ECHA is appropriate.

Substance/Group	No. of substances in Group	Proposed LAD
Tetraethyllead	1	18 months
2-methoxy and 2-ethoxy ethanol	2	18 months
HHPA AND MHHPA	2	18 months
Trityl alcohol	1	18 months
RP-HP	1	21 months
Dechlorane plus	1	21 months
DOTE and reaction mass of DOTE and MOTE	2	21 months
Lead stabilisers[3]	7	24 months
Bisphenol A	1	24 months

[3] Dioxobis(stearato) trilead; fatty acids, C16-18, lead salts; trilead dioxide phosphonate; sulfurous acid, lead salt, dibasic; [phthalato(2-)] dioxotrilead; trilead bis(carbonate) dihydroxide and lead oxide sulfate.

MSC is also of the opinion that the sunset date for all substances should be assigned as the LAD plus 18 months.

REVIEW PERIODS FOR CERTAIN USES

In its draft 9th recommendation, ECHA did not recommend any review period.

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for inclusion of substances in Annex XIV.

USES OR CATEGORIES OF USES EXEMPTED FROM THE AUTHORISATION REQUIREMENT

In its draft 9th recommendation, ECHA did not recommend any uses or categories of uses that should be exempted from authorisation pursuant to Article 58(2) of REACH.

MSC is of the opinion that there is currently not a clearly sufficient basis for recommending exemptions in Annex XIV for the prioritised substances under Article 58(2) of REACH.

MSC notes the upcoming restriction for lead stabilisers in PVC that covers the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds. MSC is of the opinion that as the restriction on lead in PVC articles is not yet adopted, it cannot be taken into account at this stage. MSC notes that ECHA intends to invite the European Commission to consider whether conditions for an exemption under Article 58(2) of REACH could be met once this restriction is adopted, while also taking into consideration other regulations relating to lead substances. While MSC' is of the opinion that the restriction cannot be taken into account at this stage, MSC can support an invitation to the European Commission to review the possibility for an exemption under Article 58(2) at the stage of drafting of, and discussions amongst REACH Committee experts on, the Annex XIV entry for the lead stabilisers, as the final scope of the restriction will be known at that stage.

MSC also notes that ECHA intends to invite the European Commission to assess if a similar conclusion in relation to Article 58(2) exemptions which were granted in the past for DEHP, BBP and DBP for use in immediate packaging of pharmaceuticals may apply for the same uses of DOTE and reaction mass of DOTE and MOTE and supports this invitation to the European Commission. However, MSC also notes the MSC Opinion on the first amendment of existing Annex XIV entries of DEHP, BBP, DBP and DIBP as agreed on 26 June 2019. MSC is of the opinion that similar considerations by the European Commission as outlined in that opinion should also apply to DOTE and reaction mass DOTE and MOTE.

Regarding the use of tetraethyllead in aviation fuel, MSC notes that ECHA intends to invite the European Commission to make an assessment of the exemption possibilities by reference to aviation law. MSC supports this invitation to the European Commission.

EXEMPTIONS FOR THE USE IN PRODUCT AND PROCESS ORIENTED RESEARCH AND DEVELOPMENT

ECHA in its draft 9th recommendation did not recommend any exemptions from the authorisation requirements for uses in product and process oriented research and

development (PPORD), as provided for in Article 56(3) of REACH. No requests for exemptions for PPORD were received during the public consultation.

MSC is of the opinion that PPORD exemptions in Annex XIV are not required.

OTHER ISSUES

MSC is of the opinion that no additional issues were raised in the public consultation which would lead to a different opinion on the draft 9th recommendation.

Annex I: Support document for the opinion of MSC.

Annex II: ECHA's draft 9th recommendation for Annex XIV, published on 5 September 2018.

ANNEX TO THE MEMBER STATE COMMITTEE'S OPINION ON

ECHA'S DRAFT NINTH RECOMMENDATION OF PRIORITY SUBSTANCES FOR INCLUSION IN ANNEX XIV

(ADOPTED ON 26 JUNE 2019)

ANNEX I SUPPORT DOCUMENT FOR THE OPINION OF MSC

ANNEX II DRAFT RECOMMENDATION OF PRIORITY SUBSTANCES TO BE INCLUDED IN ANNEX XIV OF THE REACH REGULATION AS SUBMITTED FOR PUBLIC CONSULTATION ON 5 SEPTEMBER 2018

ANNEX I

SUPPORT DOCUMENT FOR THE OPINION OF THE MEMBER STATE COMMITTEE ON ECHA'S DRAFT NINTH RECOMMENDATION OF PRIORITY SUBSTANCES TO BE INCLUDED IN ANNEX XIV OF THE REACH REGULATION (ADOPTED ON 26 JUNE 2019)

1. INTRODUCTION

In accordance with Article 58(3) of REACH, the Member State Committee (MSC) must provide an opinion on ECHA's draft recommendation for priority substances to be included in Annex XIV of REACH (hereafter referred to as the "draft recommendation"). ECHA takes into account the opinion of the MSC, as well as comments received during the public consultation, when finalising its recommendation for priority substances to be included in Annex XIV of REACH to be sent to the European Commission for decision making.

This support document aims at providing background information on the process for adoption of the MSC opinion on the draft recommendation, the information taken into account by MSC in forming its opinion and further details on the grounds for MSC's views on the draft 9th recommendation.

The aim of this document is not to reproduce the full information justifying the prioritisation of the substances or to summarise all the comments received during the public consultation. Rather, emphasis is given to comments received and issues raised that are not addressed in '*ECHA's general responses on issues commonly raised in public consultations on draft recommendations*'[4] document.

2. PROCESS FOR ADOPTION OF THE OPINION

ECHA published its draft 9th recommendation on 5 September 2018 on its website for public consultation. The draft 9th recommendation addressed in the public consultation is included in Annex II of the MSC Opinion.

MSC was requested to provide an opinion to ECHA on the draft 9th recommendation. The opinion of MSC considers whether the substances that ECHA has prioritised meet the criteria of Article 58(3) of REACH for prioritisation of substances from the candidate list for inclusion in Annex XIV, using the agreed approach presented in the document on prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)[5] and the document on general approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[6].

MSC appointed a Rapporteur for preparing its opinion on ECHA's draft 9th recommendation and a Working Group to support the Rapporteur at its 60th meeting (12 – 14 June 2018).

For the preparation of its opinion the MSC took into account:

- ECHA's priority setting approach and its application to all substances on the candidate list not already included or recommended for inclusion in Annex XIV of REACH
- General approach for defining the REACH Annex XIV entries[7]
- ECHA's draft 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (available for public consultation on 5 September 2018)[8]
- (Draft) Background documents for each substance summarising the available information used for priority setting at the start of the public consultation and specification of draft REACH Annex XIV entries prepared by ECHA (published 5 September 2018 on the ECHA website in the context of the public consultation)

[4] https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf/44e192e5-ac72-4458-b4f5-c016754a1d4c (version 2 March 2017)
[5] http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[6] http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[7] http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[8] https://echa.europa.eu/documents/10162/13640/9th_recom_draft_axiv_entries_en.pdf/4a78f73f-5d04-4f74-ca9e-9f7fcb555404

- Comments of the interested parties provided during the public consultation period that started on 5 September 2018 and closed on 5 December 2018. In its review of the comments received, MSC also took into account 'ECHA's general responses on issues commonly raised in public consultations on draft recommendations'
- Preliminary assessment by the ECHA Secretariat of the information received during the public consultation and its potential impact on the Annex XIV entries, including
    - Updated prioritisation table (with a summary of changes)
    - Table with proposed latest applications dates (slots) after closure of the public consultation
    - Preliminary assessment of exemption requests
- Draft responses to comments as provided by the ECHA Secretariat to the Rapporteur and Working Group as supportive material during the process (3 May 2019 and in updated version 10 June 2019).

The Rapporteur, supported by the Working Group, assessed the above information, together with input from MSC, for drafting the opinion of MSC on the draft 9th recommendation.

The draft opinion provided to the MSC by the Rapporteur was finalised and adopted on 26 June 2019 after discussion at the **65th** meeting of MSC.

3. MSC VIEWS ON THE RECOMMENDATION

3.1 PRIORITISED SUBSTANCES LISTED IN THE DRAFT 9TH RECOMMENDATION

In its draft 9th recommendation, ECHA proposed 18 substances for possible inclusion in Annex XIV. The 18 substances are listed in the following table:

#	Substance	EC number	CAS number
1	4,4'- isopropylidenediphenol (Bisphenol A; BPA)	201-245-8	80-05-7
2	1,6,7,8,9,14,15,16,17, 17,18,18-Dodecachloropentacyclo [12.2.1.1$_{6,9}$.0$_{2,13}$.0$_{5,10}$] octadeca-7,15-diene ("Dechlorane Plus"™)	-	-
3	Reaction products of 1,3,4-thiadiazolidine- 2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear with ≥0.1% w/w 4-heptylphenol, branched and linear (RP-HP)	-	-

#	Substance	EC number	CAS number
4	2-ethylhexyl 10-ethyl- 4,4-dioctyl-7-oxo-8- oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	239-622-4	15571-58-1
5	Reaction mass of 2-ethylhexyl 10-ethyl- 4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2- ethylhexyl)oxy]-2- oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4- stannatetradecanoate (Reaction mass of DOTE and MOTE)	-	-
6	4,4'- bis(dimethylamino)- 4''-(methylamino)trityl alcohol with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2) (Trityl alcohol)	209-218-2	561-41-1
7	Dioxobis(stearato) trilead	235-702-8	12578-12-0
8	Fatty acids, C16-18, lead salts	292-966-7	91031-62-8
9	Trilead dioxide phosphonate	235-252-2	12141-20-7
10	Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7
11	[Phthalato(2-)] dioxotrilead	273-688-5	69011-06-9
12	Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6
13	Lead oxide sulfate	234-853-7	12036-76-9
14	Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] *[The individual cis-HHPA [2] and trans-HHPA [3] isomer substances and all possible combinations of the cis- and transisomers of HHPA [1]are covered by this entry]* (HHPA)	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3
15	Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] *[The individual isomers [2], [3] and [4] (including their cis and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]* (MHHPA)	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9
16	Tetraethyllead	201-075-4	78-00-2
17	2-methoxyethanol	203-713-7	109-86-4
18	2-ethoxyethanol	203-804-1	110-80-5

MSC is of the opinion that no information was received during the public consultation that would justify not including all 18 substances, as indicated in the table above, in the final recommendation. MSC is of the opinion that prioritisation is justified for all substances/substance groups due to the intrinsic properties, the volume used in the scope of authorisation and the wide dispersiveness of use or based on grouping considerations.

3.1.1 COMMENTS RECEIVED ON PRIORITISATION DURING PUBLIC CONSULTATION

During the public consultation, comments were received on most substances that challenged the prioritisation of the substances. MSC considered all of the comments in preparing its opinion. MSC notes that many of the comments were similar across many substances and these are addressed in section 3.1.1.1 below. In addition to the comments that were similar across many substances, some comments were received which related to individual substances only. These were noted by MSC and are addressed in section 3.1.1.2 below, where deemed relevant.

3.1.1.1 COMMON ELEMENTS FOR ALL SUBSTANCES/SUBSTANCE GROUPS

As indicated above, comments were received from industry that were similar across many substances. These addressed such issues as authorisation not being the most appropriate risk management measure to control risk, that other regulatory processes would be more appropriate and that there are already measures in place to control risks and so there is no need to prioritise the substances. For some substances, the comments indicated that a restriction or an occupational exposure limit (OEL) would be more appropriate or that an RMOA should be first prepared. For others, it was indicated that there are many other regulatory measures that already exist for the substance and that these should be taken into account when considering prioritisation. Some comments also noted such issues as industry's voluntary commitment being a more appropriate risk management tool than authorisation to manage risks while others made the point that any risks could be controlled by means of appropriate safety and risk management measures already in place.

On the above aspects, MSC notes ECHA's view expressed in its '*responses to issues commonly raised in public consultations on draft recommendations*' document and is of the opinion that such requests to not prioritise the substances for authorisation on this basis are not justified.

3.1.1.2 SUBSTANCE SPECIFIC ISSUES ON PRIORITISATION

Bisphenol A

Industry challenged the prioritisation of bisphenol A, indicating that they do not agree with it being identified as an SVHC and noted that they have challenged that decision before the European Court of Justice. As these Court proceedings are still on-going, with a conclusion not expected until the second half of 2019, it is their opinion that it is premature to proceed with the prioritisation for authorisation before the outcome of that challenge is known. MSC has considered this and is of the opinion that it is still appropriate to proceed with prioritisation of bisphenol A as the substance has been identified as an SVHC and is included on the candidate list presently. It is noted that the court case does not have a suspensive effect.

Comments were also received from industry indicating that authorisation would have no effect on environmental releases of bisphenol A and that restriction would be preferable. Additionally, a Member State commented that a tailored restriction would be better suited to achieving a decrease in environmentally relevant emissions. MSC has considered these comments and is of the opinion that it is not appropriate to assess if other risk management measures would be more appropriate at this stage of the process.

Other comments from industry indicated that in certain applications, bisphenol A is used as an intermediate and thus out of scope of authorisation. MSC notes ECHA's post public consultation assessment of these comments that based on the available information and the current state of play of the interpretation of the intermediate status following the judgement of the European Court of

Justice in Case C-650/15 P, ECHA has not taken a position as to whether the uses qualify as intermediate uses. For this reason, ECHA has applied a reasonable worst case approach and assumed the uses and related volumes are relevant for prioritisation. The MSC is in agreement with the approach taken by ECHA.

Dechlorane Plus

The identification of Dechlorane Plus as vPvB was challenged in one comment from industry. MSC considers that this is not relevant for this stage of the process as the substance has been identified as an SVHC and included on the candidate list.

DOTE and reaction mass of DOTE and MOTE

During the public consultation, comments were received from industry indicating that DOTE and reaction mass of DOTE and MOTE act as intermediates when used as stabilisers during PVC processing. MSC notes ECHA's post public consultation assessment of these comments that based on the available information and the current state of play of the interpretation of the intermediate status following the judgement of the European Court of Justice in Case C-650/15 P, ECHA has not taken a position as to whether the uses qualify as intermediate uses. For this reason ECHA has applied a reasonable worst case approach and assumed the uses and related volumes are relevant for prioritisation. The MSC is in agreement with the approach taken by ECHA.

Comments were also received indicating that, with respect to the use as heat stabiliser in the production of PVC articles, the prioritisation score for service life in articles is not justified. It was indicated that the substances act as stabilisers and are not embedded in the polymer matrix. MSC is of the opinion that the information provided does not lead to a conclusion that use in articles no longer exists and it cannot be excluded that a portion of the substances remain unreacted in the matrix.

In the submitted comments, industry also raised concerns with regard to possible double counting of the same volumes for both substances. MSC has considered the comments submitted and also ECHA's assessment of the comments and is of a similar view as expressed by ECHA on this issue.

MSC notes that following the public consultation, ECHA adjusted the volume and wide dispersive use (WDU) score of DOTE, based on additional information provided during the public consultation on tonnage for uses generally exempted from authorisation. This adjustment resulted in a decrease in the prioritisation score from 19 to 15. The prioritisation score for reaction mass of DOTE and MOTE remained unchanged at 20.

MSC agrees with the revised score for DOTE and notes that it does not affect the overall prioritisation of DOTE and reaction mass of DOTE and MOTE. It is noted that prioritisation of DOTE is still justified based on grouping with reaction mass of DOTE and MOTE.

Lead Stabilisers

The term 'lead stabilisers' covers the following 7 substances: dioxobis(stearato) trilead; fatty acids, C16-18, lead salts; trilead dioxide phosphonate; sulfurous acid, lead salt, dibasic; [phthalato(2-)] dioxotrilead; trilead bis(carbonate) dihydroxide and lead oxide sulfate.

MSC notes that two lead stabilisers, fatty acids, C16-18, lead salts and trilead dioxide phosphonate, are of priority based on scores equal to or above 18 (the numerical threshold for prioritisation used by ECHA in the draft 9th recommendation) and the grouping argument. The remaining five substances, dioxobis(stearato)trilead; sulfurous acid, lead salt, dibasic; [phthalato(2-)]dioxotrilead;

trilead bis(carbonate)dihydroxide and lead oxide sulfate, are of priority based on grouping related to the potential use as stabilisers in PVC.

During the public consultation, comments were received from industry which were relevant for the scoring of some of the lead stabilisers and some registration dossiers were updated. Tonnages were updated in some of the registration dossiers and the registration status was also changed in relation to some of the substances. In addition, comments were received in relation to the upcoming restriction for lead stabilisers in PVC that covers the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds. MSC noted these comments from industry and also noted that, following the public consultation, ECHA revised the scores accordingly for these lead stabilisers.

Comments were also received from industry questioning the grouping of lead oxide sulfate with other lead substances used as stabilisers. In those comments, it was indicated that lead oxide sulfate is not used as a stabiliser in PVC and recent dossier updates reflected this. MSC notes that as indicated by ECHA, while the use as a stabiliser is no longer reported in registration dossiers of lead oxide sulfate, such a use of lead oxide sulfate was reported in earlier dossiers. Also, no information has been provided to allow a conclusion that the use of lead oxide sulfate as a stabiliser is not technically feasible. MSC is in agreement with ECHA's assessment on this and therefore supports the grouping of lead oxide sulfate with other lead substances used as stabilisers.

MSC notes that, based on the updated tonnage in registrations and updated registration status, ECHA adjusted the volume score for 5 of the lead stabilisers. For 3 of those (dioxobis(stearato) trilead; fatty acids C16-18, lead salts and trilead dioxide phosphonate), the volume score was reduced and for the other 2 (sulfurous acid, lead salt, dibasic and [phthalato(2-)] dioxotrilead), the volume score was removed as there are no active registrations for these 2 substances. The WDU score for those 2 latter substances was also removed by ECHA following the public consultation, again due to the fact there are no active registrations for these substances.

With respect to the use as a lead stabiliser, MSC and ECHA note the upcoming restriction. In its post public consultation assessment, ECHA considered that the scope of the restriction and the next steps towards finalisation were sufficiently clear to consider those uses covered by the upcoming restriction as not relevant for priority setting. The priority of all lead stabilisers has been revised on this basis and MSC notes that ECHA lowered the WDU for dioxobis(stearato) trilead and fatty acids C16-18, lead salts from 7 to 5 (2 extra points for service life were no longer considered relevant as the sole use in articles reported for those substance was the use covered by the restriction). Contrary to ECHA, MSC considers that the WDU scores should not be lowered for dioxobis(stearato) trilead and fatty acids, C16-18, lead salts. MSC is of the opinion that the impact of the proposed restriction should not be taken into account at this stage, considering that the restriction process is not yet finalised. In conclusion, MSC is of the opinion that in addition to industrial uses, the WDU score should reflect article service life for PVC articles (5 for industrial uses + 2 for article service life).

MSC notes that the scores for the remaining 2 lead stabilisers (trilead bis(carbonate) dihydroxide and lead oxide sulfate) remain unchanged following the public consultation.

Notwithstanding the opinion noted above, MSC notes that the changes in scores for the lead stabilisers do not affect the overall prioritisation of these substances and agrees that all 7 lead stabilisers should be prioritised for inclusion in Annex XIV. On that, MSC is of the opinion that lead stabilisers with lower (i.e. below the threshold to prioritise based on the individual score), or no, scores, should be prioritised for inclusion in Annex XIV based on grouping considerations.

HHPA and MHHPA

MSC notes comments received from industry claiming certain uses, including those in the production of high voltage rotating devices and switch gears, as intermediate use. Based on those claims, the volume of HHPA and MHHPA within the scope of authorisation was challenged. MSC notes ECHA's post public consultation assessment of these comments that based on the available information and the current state of play of the interpretation of the intermediate status following the judgement of the European Court of Justice in Case C-650/15 P, ECHA has not taken a position as to whether the uses qualify as intermediate uses. For this reason ECHA has applied a reasonable worst case approach and assumed the uses and related volumes are relevant for prioritisation. The MSC is in agreement with the approach taken by ECHA.

The prioritisation of HHPA and MHHPA was also challenged as regards the assessment of equivalent level of concern (ELoC) and the comment submitter suggested that an assessment as to whether this is still relevant should be carried out. MSC is of the opinion that it is appropriate to proceed with prioritisation of HHPA and MHHPA as the substances have been identified as SVHCs and are included on the candidate list presently. MSC notes that it is not possible to re-open the ELoC assessment at the prioritisation stage of the process.

Tetraethyllead

Comments were received during the public consultation which indicate that there is professional use of tetraethyllead (TEL) in aviation fuel falling in the scope of authorisation (i.e. TEL content in aviation fuel could exceed the specific concentration limit of 0.1 %). MSC notes that according to recently updated registration dossiers, aviation fuel (containing a fuel additive comprising 61.5 % TEL) contains less than 0.1 % TEL. MSC also notes that the use of TEL itself or of the fuel additive by professionals or consumers is explicitly advised against.

MSC is of the opinion that as professional uses of aviation fuel containing greater than 0.1 % TEL are not reported in the registration dossiers and as uses of TEL and of the fuel additive by professionals or consumers are advised against, this professional use does not need to be taken into account in the prioritisation of TEL.

2-methoxyethanol and 2-ethoxyethanol

MSC notes comments were received from industry during the public consultation stating that it is not appropriate to group 2-methoxyethanol and 2-ethoxyethanol as the main use of 2-methoxyethanol in the scope of authorisation cannot be replaced by 2-ethoxyethanol because of the different physico-chemical properties of the substances. MSC notes that based on the information received during the public consultation, similar uses of 2-ethoxyethanol and 2-methoxyethanol exist and that based on the available information it is not possible to conclude that substitution between these substances for some uses would not be possible. MSC is of the opinion that grouping is justified.

3.2. TRANSITIONAL ARRANGEMENTS: LATEST APPLICATION DATE AND SUNSET DATE

In its draft 9th recommendation, ECHA proposed to set the latest application date (LAD) to one of three slots: 18, 21 or 24 months after the date of inclusion in Annex XIV. ECHA indicated the final allocation of the substances into those slots would be made after the public consultation, taking all new information available into account. Sunset date for all substances was proposed as the LAD plus 18 months.

MSC notes ECHA's general principles to setting LADs:

- Substances with no registration requirement or those which are not registered should be assigned a longer LAD
- Substances with complex supply chains and high number of uses should be assigned a longer LAD
- Substances considered as a group should preferably be included together in same LAD slot
- Assignment of substances to slots should support balanced workload for the ECHA Committees/ European Commission.

Following the public consultation, ECHA analysed information available on the complexity of the supply chain for each prioritised substance/substance group and used that information to derive a 'complexity of supply chain score'. Using that score, ECHA then proposed LADs for each substance/substance group which are presented in the table below. Substances/substance groups with the lowest scores were assigned to the 18 month slot, while substances/substance groups with the highest scores were assigned to the 24 month slot.

During the public consultation, comments in relation to transitional arrangements were received on a number of substances. MSC reviewed these comments and is of the opinion that no information was provided that would result in a different LAD than that proposed by ECHA following their analysis post the public consultation. Therefore, MSC is of the opinion that LADs presented in the table below are appropriate.

Substance/Group	No. of substances in Group	Proposed LAD
Tetraethyllead	1	18 months
2-methoxy and 2-ethoxy ethanol	2	18 months
HHPA AND MHHPA	2	18 months
Trityl alcohol	1	18 months
RP-HP	1	21 months
Dechlorane plus	1	21 months
DOTE and Reaction mass of DOTE and MOTE	2	21 months
Lead stabilisers[9]	7	24 months
Bisphenol A	1	24 months

MSC is of the opinion that the sunset date for all substances should be set as the LAD date plus 18 months.

3.3. REVIEW PERIODS FOR CERTAIN USES

No review period was suggested by ECHA in its draft 9th recommendation.

MSC notes comments received from industry on Dechlorane Plus requesting that review periods are extended and on 2-methoxyethanol requesting a 12 year review period for use in the pharmaceutical industry.

[9] Dioxobis(stearato) trilead; fatty acids, C16-18, lead salts; trilead dioxide phosphonate; sulfurous acid, lead salt, dibasic; [phthalato(2-)] dioxotrilead; trilead bis(carbonate) dihydroxide and lead oxide sulfate.

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, MSC is of the opinion that upfront specified review periods are not warranted in the recommendation.

3.4 USES OR CATEGORIES OF USES EXEMPTED FROM THE AUTHORISATION REQUIREMENT

ECHA did not propose any specific exemption of uses or categories of uses in its draft 9th recommendation.

Requests for exemption of uses or categories of uses were received on most of the substances during the public consultation. The requests were motivated by the fact that the uses of the substances appear to fall under the generic exemptions from the authorisation requirement, by the existence of specific EU legislation addressing the uses (requests under Article 58(2) of REACH) or by other elements (requests that were not substantiated by reference to specific EU legislation). These requests, and MSC's consideration on them, are detailed below.

3.4.1 EXEMPTION REQUESTS FOR USES THAT APPEAR TO FALL UNDER THE GENERIC EXEMPTIONS FROM THE AUTHORISATION REQUIREMENT

There were similar exemption requests for many of the substances regarding uses that appear to fall under the generic exemptions from authorisation, such as use in the production of a medical device (Articles 60(2) and 62(6) of REACH), use in a mixture below the thresholds specified in Article 56(6) of REACH, used as an intermediate (Article 2(8)(b) of REACH), use in research and development (Articles 3(23) and 56(3) of REACH) or use in applications for food contact (Article 56(5)(b) of REACH). MSC is of the view that industry has to examine whether the specific uses of a substance can be regarded as uses where the generic exemptions from authorisation can be applied. MSC notes that for such uses that fall under the generic exemptions from the authorisation requirement, there is no need to propose any additional specific exemptions.

Comments were received from industry on the use of DOTE and reaction mass of DOTE and MOTE in immediate packaging of pharmaceuticals. The comments appeared to be a request for an exemption for uses that fall under the generic exemptions from the authorisation requirement in that they indicated that aspects of the safety of the immediate packaging of medicines are covered by Directive 2001/83/EC and Regulation (EC) 726/2004. Thus, industry's view is that the use falls outside the scope of authorisation pursuant to Article 2(5)(a) of REACH. MSC has assessed these comments and has a similar view to ECHA on this in that Article 2(5)(a) of REACH exempts the use of a substance in medicinal products but not the use in the packaging of such products. Therefore, rather than a generic exemption applying under Article 2(5)(a), an exemption for such a use could only apply under Article 58(2). This is further addressed in section 3.4.2.1 below.

3.4.2 EXEMPTION REQUESTS SUBSTANTIATED BY REFERENCE TO SPECIFIC EU LEGISLATION

3.4.2.1 BISPHENOL A, DECHLORANE PLUS, 2-METHOXYETHANOL, 2-ETHOXYETHANOL, DOTE REACTION MASS OF DOTE AND MOTE AND TETRAETHYLLEAD

There were requests for exemptions for some specific uses of bisphenol A, Dechlorane Plus, 2-methoxyethanol, 2-ethoxyethanol, DOTE, reaction mass of DOTE and MOTE and tetraethyllead under Article 58(2) of REACH which were substantiated by reference to specific EU legislation or standards. Legislation or standards referred to in these requests across the different substances included:

- Chemical Agents Directive (98/24/EC)
- Indicative occupational exposure limits (in Directive 2009/161)
- Industrial Emissions Directive (2010/75/EC)
- Medicinal Products Directive (2001/83/EC)
- Ordinance on the Manufacture of Medicinal Products and Active Pharmaceutical Ingredients, ICH12 Q7
- REACH restrictions in consumer products (entry 30, Annex XVII)
- Food law permitting use in food contact material with defined migration limit (Regulation 1935/2004/EC)
- International Fuel Specifications (ASTM D910, UK Def. Stan 91-90)
- Regulation establishing the European Aviation Safety Agency (EU 2018/1139)
- Airworthiness certificates of aircraft based on EU 216/2008
- Prior Informed consent (PIC) Regulation (EU 649/2012)
- Various EU standards including those for the automotive sector
- National restrictions.

MSC notes that according to Article 58(2) of REACH, it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that on the basis of the existing community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substances, the risk is properly controlled'*.

In considering the requests above, MSC acknowledged the existence of EU legislation or standards applying to the uses of the different substances. However, MSC noted that with these exemption requests, no additional information on specific Community legislation imposing minimum requirements was provided to indicate that exemptions under Article 58(2) would be met. MSC also took into account '*ECHA's general responses on issues commonly raised in public consultations on draft recommendations'* and ECHA's previous responses to Article 58(2) exemption requests. MSC is of the opinion that exemptions under Article 58(2) are not warranted for bisphenol A, Dechlorane Plus, 2-methoxyethanol or 2-ethoxyethanol.

With respect to **DOTE and reaction mass of DOTE and MOTE**, as indicated in section 3.4.1 above, an exemption request was received for the use of DOTE and reaction mass of DOTE and MOTE in immediate packaging of pharmaceuticals. In line with the ECHA view on this, MSC notes that Article 58(2) exemptions have been granted by the European Commission in the past for DEHP, BBP and DBP for a similar use. In the current Authorisation list entries for those substances, the European Commission included the following exemption under Article 58(2): Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC. In the Regulation including DEHP, BBP and DBP in Annex XIV the European Commission indicated that " legislation of the Union provides for a framework to properly control risks of such immediate packaging materials by imposing requirements on the quality, stability, and safety of the immediate packaging materials". MSC notes that ECHA intends to invite the European Commission to assess if a similar conclusion may apply for the uses of DOTE and reaction mass of DOTE and MOTE and MSC supports this invitation. However, MSC also notes the MSC opinion on the first amendment of existing Annex XIV entries of DEHP, BBP, DBP and DIBP, as agreed on 26 June 2019. MSC is of the opinion that similar considerations by the European Commission as outlined in that opinion should also apply to DOTE and reaction mass DOTE and MOTE.

Additionally, regarding **tetraethyllead**, while MSC is of the opinion that there appears to be no grounds for an exemption under Article 58(2), it is noted that following its assessment of requests for exemptions for the use of tetraethyllead in aviation fuel by reference to aviation law, ECHA

intends to invite the European Commission to make an assessment of the exemption possibilities. MSC supports this invitation.

3.4.2.2 LEAD STABILISERS

MSC notes that specific requests were received from industry during the public consultation on lead stabilisers in relation to (i) the recycling of PVC containing lead and (ii) uses restricted to industrial processing (such as formulation for export only). These requests noted existing legislation, the upcoming restriction on lead in PVC, the binding OEL for inorganic lead and its compounds and the binding biological limit value set for lead and its ionic compounds under Directive 98/24/EC. The comments noted that all of these would cover any risk related to worker exposure.

As regards the binding OEL, MSC notes that minimum requirements relating to the protection of workers may be imposed by the legislation and so the risk for workers health arising from the use of these lead substances may be controlled. This may mean that for the workplace (and the target population, workers) the requirements in relation to the proper control of risk defined under Article 58(2) may be met. However, MSC notes that the cited legislation does not cover subsequent life cycle stages. MSC also notes that ECHA indicated that it has not assessed the adequacy of these limit values, the factors on which these limit factors were adopted or whether they meet the conditions of Article 58(2) of REACH. MSC has also not done this assessment but notes that such an assessment will be done in the near future, as the European Commission (DG Empl) has requested that ECHA prepares a scientific report which shall include, where appropriate, proposals for OEL(s), biological limit value(s), health surveillance measures and/or appropriate notations.

With respect to the request for exemptions for uses restricted to industrial processing, MSC is of a similar view to ECHA in that the request is not specific enough to allow a correct assessment as to which life cycle stages are relevant for the use and if there is existing legislation in place to fully control the risk for each of those life cycle stages and thus justify an exemption under Article 58(2).

With respect to recycling of PVC containing lead, MSC notes the upcoming restriction on lead in PVC articles. As indicated in section 3.1.1.2 above, the scope of this upcoming restriction is the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds. MSC notes however that the restriction has not yet been adopted.

Overall, MSC is of the opinion that there is not currently a sufficient basis for recommending exemptions in Annex XIV for the lead stabilisers under Article 58(2) of REACH. MSC is of the opinion that as the restriction on lead in PVC articles is not yet adopted, it cannot be taken into account at this stage. MSC notes that ECHA intends to invite the European Commission to consider whether conditions for an exemption under Article 58(2) of REACH could be met once this restriction is adopted, while also taking into consideration other regulations relating to lead substances. While MSC is of the opinion that the restriction cannot be taken into account at this stage, MSC can support an invitation to the European Commission to review the possibility for an exemption under Article 58(2) at the stage of drafting of, and discussions amongst REACH Committee experts on, the Annex XIV entry for the lead stabilisers, as the final scope of the restriction will be known at that stage.

3.4.3 EXEMPTION REQUESTS NOT SUBSTANTIATED BY REFERENCE TO SPECIFIC EU LEGISLATION

There were exemption requests for bisphenol A, HHPA and MHHPA, trityl alcohol, 2-methoxyethanol and 2-ethoxyethanol, tetraethyllead and lead stabilisers which were not substantiated by reference to specific EU legislation. Across the different substances, these requests were based on issues such as documented safe use, no reported health issues, no direct exposure, limited professional uses,

critical uses in certain sectors such as aerospace and defence, uses as a processing aid in the synthesis of active pharmaceutical ingredients or use mandated by international fuel specifications. Many of the comments also pointed out the fact that currently no alternatives exist, or it would take a very long time to find alternatives. For some substances, it was noted that the alternatives themselves would have to fulfil safety requirements, such as in the case of tetraethyllead in aviation fuels. It was also noted with respect to tetraethyllead that it is the only currently approved octane additive. In addition, requests were specifically received from industry groups for the addition of a 'repair as produced' clause to be included for bisphenol A in Annex XIV which would allow for legacy spare parts to be exempted.

MSC considered all of these requests and is of the opinion that, while noting the points already made above on lead stabilisers, such exemptions are not warranted. MSC particularly referred to the information provided in ECHA's document on '*General responses on issues commonly raised in public consultations on draft recommendations'* in forming its opinion in that regard.

3.5 EXEMPTIONS FOR THE USE IN PRODUCT AND PROCESS ORIENTED RESEARCH AND DEVELOPMENT

No exemptions for PPORD were proposed by ECHA. No requests for exemptions for PPORD were received during the public consultation.

MSC is of the opinion that PPORD exemptions in Annex XIV are not required.

3.6 OTHER ISSUES

For many of the prioritised substances, comments were raised during the public consultation expressing concern that inclusion of the substances in Annex XIV would lead to socio-economic impacts in general, including a loss of competitiveness for certain European industries and negative effects on manufacturing processes in Europe.

Comments were also received on most substances indicating that currently, no alternatives exist.

MSC took note of these comments and is of the view that while these are valid issues, they do not affect the prioritisation of the substances for authorisation. MSC notes that these issues have been addressed previously in ECHA's '*General responses on issues commonly raised in public consultations on draft recommendations'* and refers to the responses accordingly.

Therefore MSC concludes that these other issues do not affect the prioritisation of the substances in the draft 9th recommendation.

ANNEX II

DRAFT NINTH RECOMMENDATION SUBMITTED FOR PUBLIC CONSULTATION

Draft 9th Recommendation of Priority Substances to be included in Annex XIV of 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	4,4'-isopropylidenediphenol (Bisphenol A; BPA)	201-245-8	80-05-7	Toxic for reproduction (Article 57c), Endocrine disrupting properties (Article 57f – environment), Endocrine disrupting properties (Article 57f – human health)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
2	1,6,7,8,9,14,15,16,17,17,18,18-Dodeca chloropentacyclo [12.2.1.1^{6,9}.0^{2,13}.0^{5,10}] octadeca-7,15-diene ("Dechlorane Plus"™)	-	-	vPvB (Article 57e)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	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**
3	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear with ≥0.1% w/w 4-heptylphenol, branched and linear	-	-	Endocrine disrupting properties (Article 57f – environment)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
4	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	239-622-4	15571-58-1	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	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	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	-	-	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
6	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2)	209-218-2	561-41-1	Carcinogenic (Article 57a)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
7	Dioxobis(stearato) trilead	235-702-8	12578-12-0	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	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**
8	Fatty acids, C16-18, lead salts	292-966-7	91031-62-8	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
9	Trilead dioxide phosphonate	235-252-2	12141-20-7	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
10	Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
11	[Phthalato(2-)] dioxotrilead	273-688-5	69011-06-9	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
12	Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
13	Lead oxide sulfate	234-853-7	12036-76-9	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	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**
14	Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] *[The individual cis-HHPA [2] and trans-HHPA [3] isomer substances and all possible combinations of the cis- and trans-isomers of HHPA [1] are covered by this entry]* (HHPA)	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3	Respiratory sensitising properties (Article 57f – human health)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	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**
15	Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] *[The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]* (MHHPA)	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9	Respiratory sensitising properties (Article 57f – human health)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
16	Tetraethyllead	201-075-4	78-00-2	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
17	2-methoxyethanol	203-713-7	109-86-4	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	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**
18	2-ethoxyethanol	203-804-1	110-80-5	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	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.

** ECHA proposes to set the LADs within the range of 18, 21 or 24 months after the date of inclusion in Annex XIV. The specific LAD allocation will be done when finalising the recommendation. For this, ECHA will use all available relevant information including that received in the public consultation. ECHA's recommendation for specific LAD slots will be based on the *General approach for the preparation of draft Annex XIV entries for substances to be included in Annex XIV*[10] and as further specified in the *practical implementation document*[11]. Substances considered as a group will be allocated to the same slot.

[10] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[11] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf