OPINION OF THE MEMBER STATE COMMITTEE ON THE SEVENTH DRAFT RECOMMENDATION OF THE PRIORITY SUBSTANCES AND ANNEX XIV ENTRIES

Adopted on 13 September 2016

OPINION

This opinion of the Member State Committee (MSC) on the seventh draft recommendation of European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV was adopted on 13 September 2016 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006[1].

PROCESS FOR ADOPTION OF THE OPINION

ECHA consulted MSC in the autumn of 2015 on its draft 7th Recommendation of priority substances for inclusion in Annex XIV of REACH, including the results of the prioritisation of the Substances of Very High Concern (SVHC) on the Candidate List and the proposed draft REACH Annex XIV entries for the priority substances. The Committee had a discussion about the proposed draft recommendation and draft REACH Annex XIV entries of the substances suggested for inclusion in the recommendation on 27-29 October 2015. After that, ECHA published its draft recommendation on 18 November 2015 on its website for public consultation.
MSC appointed a Rapporteur for preparing its opinion on ECHA's draft recommendation for Annex XIV of REACH and, in addition, a Working Group to support the Rapporteur at its 44th meeting (27-29 October 2015).
For the preparation of its opinion the Committee has been provided with the following documents:

- ECHA's priority setting approach[2] and its application to all substances on the candidate list not already included or recommended for inclusion in Annex XIV of REACH[3]
- General approach for defining the REACH Annex XIV entries[4]
- ECHA's draft recommendation of priority substances for inclusion in the list of substances subject to authorisation (available for public consultation on 18 November 2015)[5]
- (Draft) Background documents for each substance summarising the available information used for priority setting and specification of draft REACH Annex XIV entries prepared by ECHA (published 18 November 2015 on the ECHA website in the context of the public consultation)
- Comments of the interested parties provided during the public consultation period that started on 18 November 2015 and closed on 18 February 2016
- Draft responses to comments provided by the ECHA Secretariat (by 26 May 2016 and in updated version by 1 September 2016).

The draft opinion provided to the Committee by the Rapporteur was finalised and adopted on 13 September 2016 after discussion at the 49th meeting of MSC. The support document for the MSC opinion is attached to this opinion (Annex I).

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[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
[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_CL_substances_nov_2015_en.pdf
[4] http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[5] http://echa.europa.eu/documents/10162/13640/7th_recom_draft_axiv_entries_en.pdf

THE SEVENTH DRAFT RECOMMENDATION OF ECHA AND FOCUS OF THE OPINION

MSC is requested to provide an opinion to ECHA on the draft recommendation for inclusion of SVHCs from the candidate list to the authorisation list (Annex XIV). The opinion reviews whether the substances that ECHA has prioritised meet the criteria of REACH Article 58(3) 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)[2] and the document on General approach for Preparation of draft Annex XIV entries for substances to be included in Annex XIV[4]. ECHA will take the opinion of the MSC, as well as comments received during the public consultation, into account when finalising the recommendation to be sent to the European Commission for decision making.

It is noted by MSC that some substances that attain a very high prioritisation score may not be recommended by ECHA for inclusion in Annex XIV. These substances are subject to an on-going parallel regulatory process at the time of the prioritisation process, and so are not included in that particular recommendation in order to avoid undesired interference between different regulatory actions.

Other issues not directly related to comparison of the substances against the criteria in Article 58(3) of REACH, e.g. considerations on the most appropriate risk management option, are included under the heading "Other issues" in the support document for the opinion of MSC (**Annex I** to this opinion).

The seventh draft recommendation prepared by ECHA for Annex XIV of the REACH Regulation specifies 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
- Review periods for certain uses, if appropriate
- Uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any
- Possible PPORD exemptions

In its draft recommendation addressed in the public consultation, ECHA did not recommend any uses or categories of uses that should be exempted from authorisation pursuant to Article 58(2). Moreover, in its draft recommendation ECHA 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).

ECHA's draft recommendation for Annex XIV that was addressed in the public consultation and was used while developing the opinion of MSC is attached to this opinion (**Annex II)**. The opinion of the Member State Committee focuses on this draft recommendation and the items of Annex XIV entries.

OPINION ON THE DRAFT RECOMMENDATION FOR PRIORITISATION OF SUBSTANCES

The members of the Member State Committee are of the opinion that all substances listed in the draft recommendation of ECHA, published on 18 November 2015, should be proposed for inclusion into Annex XIV. They agree that these substances should be prioritised in accordance with Art. 58(3) following application of approaches presented in the document on Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)[2] and the document on General approach for Preparation of draft Annex XIV entries for substances to be included in Annex XIV[4]. MSC notes that no information/ comments have been submitted during public consultation that

would alter the outcome of the prioritisation of all substances listed in the draft recommendation of ECHA.

The Member State Committee supports ECHA's proposal for the following priority substances to be included REACH Annex XIV:

- 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear
- Dihexyl phthalate
- Orange lead (lead tetroxide)
- Lead monoxide (lead oxide)
- Pentalead tetraoxide sulphate
- Tetralead trioxide sulphate
- Trixylyl phosphate
- Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]
- 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]
- Sodium perborate; perboric acid, sodium salt
- Sodium peroxometaborate

REACH ANNEX XIV ENTRIES

Substance identities

#	Substance	EC number	CAS Number
1	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4
2	Dihexyl phthalate	201-559-5	84-75-3
3	Orange lead (lead tetroxide)	215-235-6	1314-41-6
4	Lead monoxide (lead oxide)	215-267-0	1317-36-8
5	Pentalead tetraoxide sulphate	235-067-7	12065-90-6
6	Tetralead trioxide sulphate	235-380-9	12202-17-4
7	Trixylyl phosphate	246-677-8	25155-23-1
8	Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3
9	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]	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9

10	Sodium perborate; perboric acid, sodium salt	239-172-9; 234-390-0	-
11	Sodium peroxometaborate	231-556-4	7632-04-4

Intrinsic properties

The intrinsic properties are as outlined in the candidate list and further elaborated in the Support Document for each substance when identifying them as SVHCs.

Transitional arrangements

MSC has previously agreed that, in general, the application dates should be established as close as possible to the date of the entry into force of the updated REACH Annex XIV. Normally, the application dates should not be set more than 12 to 18 months after that date. However, if justified in individual cases, longer application periods may be acceptable. Also, the transitional arrangements for groups of substances may need to be spread over time in order to distribute the workload of the ECHA secretariat, ECHA's committees and the Commission.

Article 58(1)(c)(ii) provides that the application date should be set at least 18 months before the sunset date. MSC considers that the application dates should be set at 18 months before the sunset dates as the default choice.
Although Article 58(1)(c)(i) specifies that the sunset date(s) for uses of a substance should, where appropriate, take into account the production cycles specified for those uses, the Member State Committee is of the opinion that the currently available information does not provide sufficient basis to differentiate sunset dates by various uses of the prioritised substances.

MSC notes that in the comments received during the public consultation it was indicated that the use of two lead compounds (orange lead (lead tetroxide) and lead monoxide (lead oxide)) involve complex supply chains. The MSC also notes that the possible complexity of the supply chain was previously taken into account when establishing a latest application date of 35 months for the chromate compounds (Regulation 348/2013) and in the assessment made by MSC for the lead substances in the 6th recommendation. While industry experience and understanding has increased and there are many supports now in place from ECHA, MSC is of the opinion that the complexity of supply chains issues still needs to be taken into account.

Due to the considerations mentioned above MSC is of the opinion that the proposed latest application date for orange lead (lead tetroxide) and lead monoxide (lead oxide) could be modified as follows:

- Application date: 30 months (instead of 24) after entry into force of the Regulation. The sunset date should remain as proposed by ECHA (latest application date plus 18 months).

Furthermore, MSC is of the opinion that no information has been provided during the public consultation that would challenge the suggested latest application date and sunset date for other substances presented in the ECHA's draft recommendation.

Review periods for certain uses

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, the MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for REACH Annex XIV inclusion. The review periods should be set up in accordance with Article 60(8).

Uses or categories of uses exempted from the authorisation requirement

MSC is of the opinion that in order to benefit from an exemption under Article 58(2) for a particular use, the existing EU legislation must properly control the risk to human health and/or the environment from the use of the Substance specifically. Generally, the legislation should refer to the substance, either by naming it or referring to the group the substance belongs to. MSC emphasises that the existing EU legislation must impose minimum requirements for the control of risks for the use in question by defining the measures to be implemented by the users of the substance, covering all life cycle stages and these minimum requirements must be binding and enforceable.

MSC notes that in the public consultation a large number of comments were submitted stating that certain uses should be exempted from authorisation based on the statement that the use would fulfil the definition of an intermediate use according to Article 3(15) of REACH. MSC points out that it is ultimately the responsibility of an individual company to assess whether its use fulfils this definition and therefore would be exempted from the requirement to obtain an authorisation for continued use after the sunset date. Whether a specific use of a substance does or does not fulfil the definition according to Article 3(15) does not alter the assessment of MSC whether an exemption based on Article 58(2) should be considered when the substance is proposed for inclusion in REACH Annex XIV.

After assessing the information provided during the public consultation, MSC is of the opinion that there could possibly be grounds for exemptions from authorisation for:

- uses of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate that are regulated under the RoHS and ELV legislation.

However, MSC notes that these pieces of legislation do not regulate the whole lifecycle and may therefore not offer the same level of protection for the environment or human health as could be achieved under the authorisation scheme.

Furthermore, MSC is of the opinion that no information was submitted during the public consultation that would form the basis for inclusion of a specific exemption under Article 58(2) for a use or a category of use in Annex XIV for other substances presented in the ECHA's draft recommendation.

Exemptions for the use in product and process oriented research

ECHA in its draft recommendation did not propose PPORD exemptions for any of the substances. During the public consultation, no specific comments were received with regard to possible PPORD exemptions. Thus MSC supports the recommendation not to exempt uses in product and process oriented research.

Annex I: Support document for the opinion of MSC.
Annex II: ECHA's draft recommendation for Annex XIV, published on 18 November 2015.

13 September 2016

Annex I and II to the Member State Committee's opinion on ECHA's 7th draft recommendation (adopted on 13 September 2016)

Annex I Support document for the opinion of MSC

Annex II Draft 7th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation as submitted for public consultation on 18 November 2015

Support document for the opinion of MSC (Annex I)
on ECHA's 7th draft recommendation for inclusion of priority substances in the Authorisation List (adopted on 13 September 2016)

1. Introduction

In accordance with REACH Article 58(3), MSC must provide an opinion on ECHA's draft recommendation for priority substances to be included in Annex XIV. The relevant Article 58(3) states:
"*Prior to a decision to include substances in Annex XIV, the Agency shall, taking into account the opinion of the Member State Committee, recommend priority substances to be included [...]. Priority shall normally be given to substances with: (a) PBT or vPvB properties; or (b) wide dispersive use; or (c) high volumes. [...]*"

Prioritisation determines the order in which substances are included in Annex XIV of REACH, i.e. more relevant substances are included before less relevant substances. The primary basis of the prioritisation is the Article 58(3) criteria. Further considerations on which substances are to be recommended for inclusion in Annex XIV take into account other substances already recommended or included in Annex XIV, in particular the potential interchangeability of substances in (some of) their uses. In order to avoid undesired interference between different regulatory actions other on-going regulatory risk management activities can also be considered when deciding on which substances to include in a specific recommendation However, it should be stressed, that other potential risk management options and whether they could be more appropriate than the authorisation requirement are not analysed during the prioritisation step. Prioritisation is not the appropriate process for the assessment of the risks and/or exposure of a substance as a whole or, of the risks and/or exposure exerted by a particular use at a particular site/in a particular sector or, of the availability and suitability of alternatives or, of socio-economic considerations. Thus prioritisation of substances from the Candidate list for inclusion in Annex XIV is not based on a socio-economic analysis, a risk assessment or an exposure assessment. The prioritisation step in the authorisation process comprises a general evaluation of the use pattern and exposure potential a substance may have. The inclusion in Annex XIV is per substance and not per use thus the assessment of priority is performed on a substance-specific basis. In particular with regard to criterion b) of Article 58(3) ('wide dispersive use'), it is important to remember that all uses of a substance in the scope of authorisation need to be assessed. The wide dispersiveness of uses is primarily assessed based on the types of actors which are relevant for the use of a substance (industrial (IND), professional (PROF) and consumer (CONS)) uses. However the assessment of the wide dispersiveness of the uses is limited to a general evaluation of the use pattern and exposure potential that a substance may have.

2. MSC views on comments received from stakeholders during the public consultation

During the three month public consultation on the draft recommendation a large number of comments from various stakeholders were received. Stakeholders submitted a number of general comments and also comments on specific substances or specific issues. The comments mostly addressed the prioritisation of individual substances or groups of substances, exemptions of uses or groups of uses from the authorisation provisions and transitional arrangements. Some of these issues are summarised below, together with the views of MSC.

2.1 Phthalates (1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear; Dihexyl phthalate)

Justification for prioritisation

1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear and Dihexyl phthalate were identified as Substances of Very High Concern (SVHCs) according to Article 57 (c). 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear was identified as a SVHC owing to the

adopted opinion by the Committee for Risk Assessment (RAC) which has agreed that the substance meets the criteria for classification as toxic for reproduction category 1B according to Regulation (EC) No 1272/2008 (CLP). The substance was therefore included in the Candidate List for authorisation on 16 June 2014, following ECHA's decision ED/49/2014. The substance is now 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"*). Dihexyl phthalate was identified as SVHC 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. May damage the unborn child"*). The substance was therefore included in the Candidate List for authorisation on 16 December 2013, following ECHA's decision ED/121/2013.

Both phthalates have similarities in terms of structure or physico-chemical properties with other phthalates already included in Annex XIV. There are indications on the potential for using the substances in the same types of application (e.g. sealant, plasticiser in polymers).

There are no registrations for 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear and Dihexyl phthalate under Regulation (EC) No 1907/2006 (REACH).

Based on this information, 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear and Dihexyl phthalate meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation comments were only received from 2 MSCAs and one NGO. None of the commenting MSCAs opposed the prioritisation of 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear and Dihexyl phthalate for inclusion in Annex XIV.

One MSCA supported grouping of SVHC to avoid substitution with substances with similar properties within the same use categories.

Another MSCA supported prioritisation of 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear and Dihexyl phthalate for inclusion in Annex XIV in order to ensure a consistent regulation of phthalates. It was stated that the inclusion of 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear and Dihexyl phthalate in Annex XIV will prevent substitution of other short-chained phthalates by these ones and will establish an equal level of regulation for all phthalates having reprotoxic properties.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear and Dihexyl phthalate.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for 2 phthalate substances (*1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear and Dihexyl phthalate)*:

(i) Latest application date: Date of inclusion in Annex XIV plus 18 months;

(ii) Sunset date: Latest application date plus 18 months.

There were no comments received during the public consultation requesting changes in the proposed transitional arrangements.

MSC is of the opinion that no new information was submitted during the public consultation that would challenge the suggested latest application date and sunset date.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation. No requests for review periods were received during the public consultation.

MSC notes that the review period is closely connected to the use(s) for which an authorisation would be requested and therefore it is of the opinion that upfront specified review periods are not warranted in the recommendation for inclusion of substances in Annex XIV.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation. No requests for exemption of uses or categories of uses were received during the public consultation.

Overall, MSC is of the opinion that no information was submitted during the public consultation that would form the basis for inclusion of a specific exemption under Article 58(2) for a use or a category of use in Annex XIV.

PPORD exemptions

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

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not required.

Other issues

No other issues were raised during public consultation with regard to the phthalates.

2.2 Lead substances (Orange lead (lead tetroxide); Lead monoxide (lead oxide); Pentalead tetraoxide sulphate and Tetralead trioxide sulphate)

Justification for prioritisation

Orange lead (lead tetroxide), lead monoxide (lead oxide), tetralead trioxide sulphate and pentalead tetraoxide sulphate were identified as Substances of Very High Concern 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 1A, H360D (*"May damage the unborn child"*), and were therefore included in the candidate list for authorisation on 19 December 2012, following ECHA's decision ED/169/2012. These substances were included in the draft recommendation for the previous (6th) prioritisation round, but were ultimately not included in the final recommendation sent to the Commission. ECHA has selected these substances again in the 7th draft recommendation, based on the scores assigned to the substances in the prioritisation approach.

The amount of orange lead (lead tetroxide) manufactured and/or imported into the EU is according to registration data in the range of 10, 000 – 100, 000 tonnes per annum.
This includes the uses that appear not to be in the scope of authorisation, such as use as intermediate in manufacture of certain pigments, technical ceramic materials (PZT, PTC, PLZT), frits and glass (lead crystal glass and lead special glass). The volume used in these applications was assessed by ECHA during the prioritisation process before the public consultation, as reflected in the background document for the draft 7th recommendation. This information was taken into account when allocating the volume score, although this did not ultimately change the volume score. Registered uses of orange lead (lead tetroxide) considered by ECHA to be in the scope of authorisation include uses at industrial sites (e.g. use in the production of batteries, rubber and explosives, use in adsorbents) and uses by professional workers (use in paints). In addition, there are potentially also other uses that take place at industrial sites or are carried out by professional workers. The volume in the scope of authorisation remains in the same range as reported in registration dossiers even after considering the volume for the uses appearing not to be in the scope of authorisation.

According to registration data the amount of lead monoxide manufactured and/or imported into the EU is well above 100,000 tonnes per annum. Some uses appeared to ECHA as potentially not to be in the scope of authorisation, such as use in manufacturing of PVC stabilisers, certain inorganic pigments, explosives and technical ceramics, and use as laboratory reagent and in chemical analysis. Also the volume used in glass (lead crystal glass and lead special glass) and frits appeared to be out of scope of authorisation. This was taken into account when allocating the volume score, although this did not ultimately change the volume score. Registered uses of lead monoxide which appear to be in the scope of authorisation include uses at industrial sites (e.g. batteries, rubber, adsorbents). In addition, there might potentially also be other uses that take place at industrial sites or are carried out by professional workers. Considering the volume for the uses appearing not to be in the scope of authorisation, such as potential intermediate uses in the manufacture of PVC stabilisers, certain pigments, explosives, technical ceramics, glass and frits as well as some uses as laboratory reagent and in chemical analysis, the volume in the scope of authorisation is estimated to be in the range of 100, 000 - > 1, 000, 000 tonnes per annum.

According to registration data the amounts of tetralead trioxide sulphate and pentalead tetraoxide sulphate manufactured and/or imported in the EU is over 1, 000, 000 and 100, 000 tonnes per annum respectively. According to ECHA, part of the registered tonnage is claimed as being used as an intermediate (in lead-based battery production). However, based on available information it appears to ECHA that the use described is not likely to be an intermediate use. It should be noted that in the context of the 6th recommendation, there were comments on the volume used in stabilisers (industry had a voluntary commitment to phase out the use in the EU by the end of 2015). It was concluded that the volume range did not change even if the use in stabilisers is not taken into account.

Based on this information, orange lead (lead tetroxide), lead monoxide (lead oxide), tetralead trioxide sulphate, pentalead tetroxide sulphate meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, a large number of comments were received, of which several comments were also submitted during the previous (6th prioritisation round) public consultation. The comments submitted in the previous and current public consultation were taken into account by MSC in compiling its opinion on the 7th draft recommendation.

One Member State commented on all the substances, challenging the effectiveness and proportionality of the prioritisation of the lead substances and the possible high workload for ECHA, due to a foreseen high number of applications for authorisation. In the commenting round for the 7th recommendation, this Member State added a comment challenging the prioritisation of all four substances in the light of the envisaged restriction for lead stabilisers in PVC.

Another Member State supported the grouping approach for the lead substances. A similar comment by a stakeholder was received for all lead substances, supporting inclusion of these substances in Annex XIV.

Besides these general comments, in the public consultation for the draft 6th recommendation, a large number of substance specific comments were received that challenged the prioritisation of the lead substances.

With regard to orange lead (lead tetroxide), several sector organisations are of the opinion that it should not be prioritised. In the public consultation for the draft 6th recommendation a large international sector organisation for batteries, on behalf of the lead REACH consortium, supported by many companies and industry associations, commented on the justification for prioritisation. The use of lead tetroxide in lead based battery production should in their view not be subject to authorisation for two reasons:

- They are used as intermediates in the manufacture of lead based batteries, and/or
- The use of lead tetroxide in the manufacture of lead based batteries would in any case meet the conditions for an exemption under Article 58(2) of REACH.

Furthermore, it was stated that the score assigned to orange lead (lead tetroxide) should be adjusted to account for the volume in these uses.

A sector organisation for the use of lead in the manufacture of glass (various types) also claims that lead oxides are intermediates in the manufacture of lead-containing glass and crystal and therefore should not be subject to authorisation.

A similar case is made for the use of lead tetroxide in the production of frits and ceramics and for piezo-electric ceramic components consisting of almost 100% lead zirconium titanium oxide (PZT). Lead tetroxide is claimed to be an intermediate in the production of PZT and frits.

The European trade association for the tire and rubber industry claimed that lead oxides cannot be easily replaced in many rubber applications. A similar, less documented case was made by a national association active in the same field. According to other stakeholders, this also applies to the use of lead tetroxide in the production of explosives and pigments, such as pyrochlore, antimony lead yellow which is mainly used in the production of ceramic glazing, and for corrosion protection and lubrication for which uses it is claimed that no alternative exists for lead tetroxide.

With regard to lead monoxide essentially the same comments (mostly from the same stakeholders) were submitted as for orange lead (lead tetroxide). In addition to the above mentioned comments for orange lead (lead tetroxide), a Member State's regional EPA commented that the use of lead monoxide in battery production is not likely to contribute to high releases to the water environment. Furthermore, the specific use of glass frits in the production of semiconductors is claimed to be not in the scope of authorisation because it is an intermediate use and/or it is already covered by EU legislation that would justify an exemption based on Article 58 (2). Finally, comments were received on the use of lead monoxide for specific catalyst uses, it was submitted that the substance could not be replaced here. Also the use in the analysis of precious metals was reported not to be replaceable.

For the third and fourth substance, tetralead trioxide sulphate and pentalead tetraoxide sulphate, fewer comments were submitted, although those that were submitted overlapped with the comments for lead monoxide and lead tetroxide, e.g. the comment with regard to the use in lead-based battery production was also submitted. The same stakeholders also commented on the scoring of these two substances. They stated that both tetralead trioxide sulphate and pentalead tetraoxide sulphate should receive a score of 21 instead of 23, based on a lower potential for wide dispersive use (score 5 instead of 7) because only trace amounts are expected to be released from articles. Another submitter stated that due to the phase-out of lead based stabilisers, the score for pentalead tetraoxide sulphate should be lowered to 21.

An assessment of most of the information received during the public consultation was performed already by MSC when it composed its opinion on the draft 6th recommendation. It should also be noted that ECHA took these comments already into account while preparing its draft 7th recommendation. For reasons of transparency, sections of MSC's opinion on the ECHA's draft 6th recommendation are repeated here to show how all comments were taken into account.

With regard to the priority setting and the scores assigned to the substances orange lead (lead tetroxide) and lead monoxide, MSC reconsidered the scores based on the information provided in the public consultation and in the registration dossiers. With regard to orange lead (lead tetroxide), MSC, in finalising its opinion on the draft 6th recommendation, did not agree with the comment proposing to lower the wide dispersive use (WDU) score from 12 to 5. More information on this can be found in the response document that was prepared in response to the comments submitted in the public consultation for the 6th prioritisation round[6].

Concerning lead monoxide, the information received in the public consultation and in the updated registration dossiers led to an update of the WDU score by ECHA, as it appeared that professional use of the substance as a laboratory reagent may possibly fulfil the description of an industrial use and is of a less wide-spread nature. Also taking into account recent updates of the registration dossiers, based on which it was concluded that some professional and consumer uses reported are

[6] https://echa.europa.eu/documents/10162/8a3dd6bf-78e1-4097-935c-43021ebe5f1e

unlikely to occur, the WDU score was now proposed to be 7 (original proposal for the 6th recommendation: 7-10). This led to a new priority score of 23 (originally 23-26).

The assessment of information received in the public consultation and in the updated registration dossiers concerning the priority scores proposed by the ECHA for pentalead tetraoxide sulphate and tetralead trioxide sulphate did not lead to changes in the scores that were initially proposed (23 for both substances).

ECHA also provided MSC with an assessment of the workload and the capacity the Agency has in handling requests for authorisation. In summary the conclusion of the Agency is that the anticipated workload does not exceed its capacity.

With regard to orange lead (lead tetroxide), lead monoxide, tetralead trioxide sulphate and pentalead tetraoxide sulphate MSC noted that information has been submitted that challenges the prioritisation score of these substances. These comments were taken into account and led to an adjustment of the scores for lead monoxide (23) in the 6th recommendation. This adjusted score was also used in the prioritisation of substances for the 7th recommendation. MSC agrees with the way these comments and the updated registration information were taken into account and with the calculated new scores.

MSC notes that a debate on the restriction proposal for lead stabilisers in PVC (as well as for lead containing ammunition) is ongoing, but that a proposal has not been submitted yet. Therefore MSC cannot assess whether this would impact the scoring/prioritisation or a possible exemption of this use and concludes that at this point in time this information does not challenge the conclusion on the prioritisation, latest application dates and/or sunset dates for these substances.

Therefore, based on the information provided, MSC is of the opinion that for orange lead (lead tetroxide), lead monoxide, tetralead trioxide sulphate and pentalead tetraoxide sulphate, no information has been provided that would alter the outcome of the prioritisation and therefore this information does ultimately not challenge the prioritisation of these substances by ECHA.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed to set a similar latest application date (LAD) and sunset date for all lead substances. The following transitional arrangements are proposed:

(i) Application date: 24 months after entry into force of the Regulation;

(ii) Sunset date: Latest application date plus 18 months.

In the public consultations various comments were submitted. During the consultation on the 6th draft recommendation for orange lead (lead tetroxide) and lead monoxide (lead oxide) one stakeholder, an industrial association, stated that the LAD should be extended to 36 months rather than the proposed 21 months due to the complexity of the supply chain and the large number of companies, many being SME's, in it. Several other commenting parties referred to the case of the chromates and MSC's opinion on the lead substances in the 6th recommendation, where, due to the complexity of the supply chain, finally the LAD of 35 months was suggested.

On the other hand, also during the public consultation for the draft 6th recommendation, a Member State submitted comments stating that the shortest possible LAD should be used for these substances.

In addition to these comments, for lead monoxide (lead oxide) another stakeholder proposed to set the LAD at 48 months after inclusion in Annex XIV.

One stakeholder commented on the sunset date, stating that this should be set at least 18 months after the LAD, and at least three years after inclusion of the substance in Annex XIV. A Member State referred to the restriction proposal for the use of lead stabilisers in PVC, stating that this process should be finalised before a decision on inclusion of the lead substances in Annex XIV could be taken.

Finally, a third stakeholder, an industrial trade association, stated that for lead monoxide (lead oxide) the sunset date should be at least seven years after the inclusion of the substance in Annex XIV.

With regard to tetralead trioxide sulphate and pentalead tetraoxide sulphate, during the public consultation for the draft 6th recommendation one comment was received, from a Member State, on the proposed LAD and sunset date, supporting the shortest possible LAD. Several other comments were received mentioning the fact that these substances could be found in recycled PVC for several years after the 2015 phase-out. Both, an extended LAD or an exemption were suggested to deal with this issue.

Furthermore, a company producing commercial airlines noted the use of tetralead trioxide sulphate in its products, but did not comment on the LAD or sunset date.

MSC notes that in the comments received during the public consultation it was indicated that the use of two lead compounds (orange lead (lead tetroxide) and lead monoxide (lead oxide)) involve complex supply chains. The MSC also notes that the possible complexity of the supply chain was previously taken into account when establishing a latest application date of 35 months for the chromate compounds (Regulation 348/2013) and in the assessment made by MSC for the lead substances in the 6th recommendation.

While industry experience and understanding has increased and there are many supports now in place from ECHA, MSC is still of the opinion that this cannot completely overcome the complex supply chain issues.

Due to the considerations mentioned above MSC is of the opinion that the proposed latest application date for orange lead (lead tetroxide) and lead monoxide (lead oxide) could be modified as follows:

- *Application date: 30 months (instead of 24) after entry into force of the Regulation.*

The sunset date should remain as proposed by ECHA (latest application date plus 18 months).

The issue raised in the public consultation with regard to the presence of these stabilisers in recycled PVC is noted by MSC. Although MSC acknowledges the fact that recycling of materials containing Annex XIV substances has its challenges, it has no information to assess what the influence of this voluntary phase-out would be on the amount of lead stabilisers in recycled PVC and when a complete phase-out, also from recycled PVC, could be achieved. Furthermore, these substances are also used in other applications outside the scope of the phase-out or the envisaged restrictions. Therefore MSC does not have information at hand to conclude that for this reason the LAD or sunset dates should be adjusted.

In conclusion, MSC is of the opinion that no information has been provided during the public consultation that would challenge the suggested latest application date and sunset date for tetralead trioxide sulphate and pentalead tetraoxide sulphate.

Proposed review period for certain uses

No review periods were suggested by ECHA.

With regard to orange lead (lead tetroxide) and lead monoxide (lead oxide), some comments were submitted during the previous (6th prioritisation round) public consultation regarding possible review period. Several stakeholders had claimed that it was not possible to comment on what an appropriate review period could be, since no viable alternatives were identified. On the other hand, an association representing the airline industry stated that for its use of these substances a review period of eight to ten years would be appropriate.

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.

Proposed exempted (categories of) uses

In its draft recommendation ECHA did not propose any exemptions for the lead substances.

During the public consultation a large number of comments from companies, associations and organizations were received that proposed the exemption of uses or categories of uses. In some cases they could also be interpreted as comments on the justification for prioritisation of the substance, hence there might be duplication with the paragraph of this annex dealing with that topic.

As a general observation, a Member State submitted comments stating that no uses should be exempted from the authorisation requirement.

Also a more general comment was submitted several times on the interpretation of the ruling of the General Court of the EU in case T-360/13 (VECCO v Commission), in particular on whether other legislation should contain a similar driver for substitution as the authorisation procedure has before that legislation could be accepted as a basis for an exemption from the authorisation requirement. These commenters challenged the interpretation given by MSC in previous recommendation rounds that such an incentive for substitution was a prerequisite for an exemption.

In the context of the draft 6th recommendation, several companies and industry associations proposed to exempt the use of orange lead (lead tetroxide) in the manufacture of lead zirconium titanium oxide based (PZT) dielectric ceramic materials, both as this should be seen as intermediate use in the meaning of Article 3(15) and secondly because it could be considered for an exemption under Article 58(2). Furthermore, existing Community-wide legislation, such as the Chemical Agents Directive would be sufficient to adequately control the risks from the lead compounds used in lead based battery manufacturing. Several companies, industry associations and consortiums proposed exemptions for the applications of orange lead (lead tetroxide) in several industrial processes where the substance would be used as an intermediate for the manufacture of: automotive and industrial lead acid batteries, lead crystal glass and lead special glass and technical ceramics, inorganic pigments, frits for ceramics, rubber products. Also some non-intermediate uses were proposed to be exempted such as the industrial production of explosives.

With regard to the proposed exemption of the use in the production of rubber, it was submitted that there is a lack of substitutes and that existing Community-wide legislation would already sufficiently address the risk of the use of the substance throughout its lifecycle. Additionally, comments reflected that the orange lead (lead tetroxide) is strictly bound into the matrix, so there is no danger for human exposure and the environment caused by the foreseen use of rubber products containing lead oxides. Additional to the claim that the use of the orange lead (lead tetroxide) for the production of lead based batteries could be seen as an intermediate use in the meaning of Article 3(15), it was also submitted that this use would in any case meet the conditions for an exemption under Article 58(2).

An association of vehicle manufacturers proposed an exemption of lead and lead compounds for all categories of uses covered by Annex II of the End of Life Vehicles (ELV) Directive, 2000/53/EC. Article 58(1)(e) in conjunction with Article 58(2) would in their view provide for the possibility to grant such an exemption. A number of associations and companies proposed to exempt the intermediate use of orange lead (lead tetroxide) in the production of lead special glass and lead crystal glass, stating that this use could already be seen as falling outside of the scope of authorisation.

An exemption for the use in production of food contact materials based on Article 56(5) was also proposed, noting that this application already had an exemption under RoHS and should be considered for an exemption under REACH as well. In this context it was also claimed that the orange lead (lead tetroxide) is already heavily regulated in the EU and current legislation adequately protect human health and the environment. Also the lack of alternatives was mentioned as a reason for proposing this exemption.

Also an exemption was proposed for the use of the orange lead (lead tetroxide) in the production of the pigment pyrochlore, antimony lead yellow (which is also an SVHC). Several stakeholders

proposed to exempt the use in mixtures incorporated in detonators for civil (industrial) use manufactured under the provisions of Community wide legislation such as Directives 2010/75/EU, 2012/4/EU and 2014/28/EU; and exempt the use in the manufacture of explosives and pyrotechnic components for civilian and military applications. Furthermore, companies and associations proposed to exempt the use in frits. They commented that this use would already be adequately covered by Community wide legislation, such as the RoHS Directive, the ELV Directive and the Industrial Emissions Directive.

For lead monoxide (lead oxide) similar proposals for exemption were received as for orange lead (lead tetroxide). They addressed the use in dielectric ceramic materials, automotive and industrial lead acid batteries, lead based stabilizers, crystal, glass and special glasses and technical ceramics, frits manufacture for ceramics, crystal and special glass, explosives and pyrotechnic components (propellants), catalysts, analytical techniques for precious metal production, the uses falling under Annex II of the ELV Directive and uses for the production of food contact materials and for the production of pyrochlore, antimony lead yellow. In addition to these proposals, several companies commented on the lack of availability of an alternative substance with the same performance level. Some companies reflected that no equal alternative and very small use (less than 5 kg/year) should be considered as a reason for an exemption for the use in electroplating and surface treatment. Additionally it was submitted that the electroplating of lead is a process that is already very well controlled by EU and national regulations. The requests for exemptions were submitted for such non-intermediate uses as the use in the production of rubber or the use as an industrial adsorbent. In their requests for exemptions for the use in the production of rubber companies stated that an exemption should be proposed taking into account Article 58 (2), as in their opinion existing Community-wide legislation already covered the risks related to the use of the substances in rubber products and this is further supported by additional legislation. Additionally they stated that Community-wide legislation already addresses the use categories that should be exempted and provides for binding and enforceable minimum requirements for the control of risks from industrial use.

One company proposed an exemption for the use in the removal of arsenic and sulfur compounds from hydrocarbon streams (e.g. cracked gases). Companies commented that the use of the substance for the manufacture of catalysts ("Lindlar catalysts") should be exempted, as the catalyst itself is fully recycled during the manufacturing process. One company proposed to exempt the substance's use in the manufacture of rocket motors, as this would ensure maintaining an adequate defence capacity. Another company proposed an exemption for the use as an intermediate/processing aid for the analysis of precious metal content of secondary and complex materials.

For tetralead trioxide sulphate and pentalead tetraoxide sulphate similar comments were submitted: several companies and organisations claimed that the use in recycled PVC containing these substances as a stabiliser should be exempted because the substances cannot be removed from recycled plastic and are characterized with low migration from the plastic and very low bio-availability. They also reminded of the voluntary phase-out of lead based stabilizers by the industry in 2015. Stakeholders also proposed to extend the scope of an exemption to all recycling material or a similar arrangement that would make recycling not subject to authorisation.

Several companies, individual as well as in industry associations and consortiums proposed an exemption for the industrial use of tetralead trioxide sulphate and pentalead tetraoxide sulphate in the manufacture of lead based batteries, either directly via Article 3, paragraph 15, because of the substances being used as an intermediate in the manufacture of lead based batteries, and/ or because of the use of the substances for the manufacture of lead based batteries would meet the conditions for an exemption under Article 58(2).

Additionally, an association of vehicle manufacturers proposed an exemption of lead and lead compounds for all categories of uses covered by Annex II of the End of Life Vehicles (ELV) Directive, 2000/53/EC. Article 58(1)(e) in conjunction with Article 58(2) would in their view provide for the possibility to grant such an exemption. Several industry associations proposed to exclude the use in the manufacture of PZT based dielectric ceramic materials from authorisation. They submitted that existing Community-wide legislation like the Chemical Agents Directive is sufficient to adequately

control the risks from the lead compounds used in lead based battery manufacturing. One company proposed an exemption for the use of tetralead trioxide sulphate in the manufacture of microporous plastic separators (to prevent any short-circuits between electrodes inside industrial lead-based battery), based on Article 58(2), as use and exposure is well controlled by other EU legislation. This stakeholder submitted an extensive list of Community-wide legislation that should be considered in that context.

These comments were already taken into account by ECHA when it compiled the draft 7th recommendation. MSC acknowledged already, when composing its opinion on the draft 6th recommendation, that the use and disposal of lead and lead compounds is heavily regulated in the EU. For example, in relation to workers health, inorganic lead and its compounds is the only group of substances under Directive 98/24/EC to have a binding OEL and lead and its ionic compounds are the only substances for which a binding biological limit value and health surveillance measures are set out. In addition, risks to man via the environment from uses of lead compounds are addressed by legislation dealing with ambient air, water, drinking water, waste and food (though there is uncertainty related to soil coverage).

However, MSC notes that for the Water Framework Directive (WFD) it is foreseen that the REACH authorisation and restriction processes may be initiated by the Commission to achieve the objectives of that legislation. Therefore, in order not to limit the Commission's possibility to take such action, MSC considers that it may not be appropriate to allow an exemption from the authorisation requirement on the basis of the WFD. If the REACH risk management processes are necessary to achieve the objectives of other legislation (e.g. that relating to drinking water, ambient air), then the same considerations may apply as for the WFD.

Given the wealth of EU legislation governing lead and its compounds the uses with perhaps the strongest case for Art. 58(2) exemption are those for which a legislative regime is already in place that sets minimum requirements to control the risk arising from that specific substance and use, in line with the ruling of the General Court of the EU in case T-360/13 (VECCO v Commission). In the view of MSC, pushes for substitution, in particular in a similar manner to the authorisation requirement, as mentioned in e.g. recitals 12, 70, 72-74 and Article 55 of the REACH regulation, may support that the EU legislation in question properly controls the risks arising from the use of the substance. Although REACH allows for exemptions from the authorisation requirement, these exemptions may, in the view of MSC, not lead to a lowering of the protection of human health and the environment.

MSC notes that applying these criteria to the substances and uses at hand, those uses of lead compounds which are exempted under the RoHS and ELV legislation (e.g. ~75 % of lead batteries) could possibly meet these criteria. These exemptions and their review could possibly be regarded as similar to the time limited review period set out in authorisation, although the role and duties of industry differ.

In relation to certain uses of lead compounds in applications other than those covered or exempted by RoHS and/or ELV, current EU legislation, when considered holistically, may provide a basis for granting exemptions under Article 58(2) of REACH. This is due to the overall protection afforded by EU legislation to human health in the workplace and to man via the environment. These may include uses of lead compounds which are not covered or exempted by RoHS and/or ELV, such as remaining uses in batteries, frits, PZT manufacture, lead crystal glass, lead special glass and glass frits and pyrochlore antimony lead yellow manufacture. However, MSC considers that the case for Article 58(2) exemption of these uses is weaker, as there appears not to be a legislative regime in place to push for substitution in a similar manner to the authorisation requirement.

In relation to other uses of lead compounds MSC does not consider that current legislation provides a sufficient basis for exempting them from authorisation. These uses include use of lead compounds in rubber and electroplating, and as PVC stabiliser (in the absence of a restriction), due to potential non-negligible exposure during article service life for which EU legislation does not appear to impose minimum requirements for controlling risks to human health.

After assessing the information provided during the public consultation, MSC is of the opinion that there could possibly be grounds for exemptions from authorisation for:

- *uses of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate that are regulated under the RoHS and ELV legislation.*

However, MSC notes that these pieces of legislation do not regulate the whole lifecycle and may therefore not offer the same level of protection for the environment or human health as could be achieved under the authorisation scheme.

For other uses of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate MSC is of the opinion that no information was submitted during the public consultation that would form the basis for inclusion of a specific exemption under Article 58(2) in Annex XIV for other uses or categories of uses for the lead substances.

MSC notes that during the public consultation (both on the 6th and 7th draft recommendation) a large number of comments were submitted stating that some uses should be exempted from authorisation based on the statement that the use would fulfil the definition of an intermediate use according to Article 3(15) of REACH. MSC notes that it is ultimately the responsibility of an individual company to assess whether its use fulfils this definition and therefore would be exempted from the requirement to obtain an authorisation for continued use after the expiration of the sunset date.

Whether a specific use of a substance does or does not fulfil the definition according to Article 3(15) does not alter the assessment of MSC whether an exemption based on Article 58(2) should be considered when the substance is proposed for inclusion in Annex XIV.

PPORD exemptions

ECHA in its draft recommendation did not propose PPORD exemptions for any of the lead substances.

In the public consultation, no specific comments were received that explicitly mentioned possible PPORD exemptions. One comment, on the use of lead monoxide in precious metal analysis, could be considered as such.

MSC is of the opinion that the use of lead monoxide in precious metal analysis does not fall under the scope of a possible PPORD exemption, as it is an existing analytical method falling under the scope of Article 3(23) of the REACH regulation. Such use is exempted under controlled conditions when the volume does not exceed 1 tonne per year, as specified in Article 56(3).

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not required.

Other issues

A number of issues, mostly from a socio-economic point of view, were raised during the public consultation. In a number of comments complex supply chains and lack of alternatives were mentioned as well. Comments challenging whether authorisation is the most appropriate risk management measure were also received. In some comments the regulatory effectiveness of inclusion of lead substances in Annex XIV was questioned. It was stressed that a high workload for authorities/companies related to these substances at the authorisation application/evaluation stage is expected. It was also mentioned that ECHA should not proceed with the 6th recommendation of substances into Annex XIV, while the decision on the 5th recommendation is still not taken.

MSC took note of these comments, but considers that partly they are not in the scope of either the draft recommendation or MSC's opinion on it (socio-economic arguments, regulatory effectiveness) and partly have been addressed in other sections of this Annex (workload). As the Commission has announced that it will prepare a proposal on the inclusion of substances in Annex XIV that were prioritised in the 5th and 6th round, the comment on this is no longer valid. Therefore MSC concludes that these other issues do not lead to a different opinion on the draft recommendation.

2.3 Trixylyl phosphate

Justification for prioritisation

Trixylyl phosphate (TXP) 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 of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360F (*"May damage fertility"*). Trixylyl phosphate was therefore included in the Candidate List for authorisation on 16 December 2013, following ECHA's decision ED/121/2013.

According to registration information the amount of TXP manufactured and/or imported into the EU is above 100 tonnes per annum and, from information in the registrations, it is estimated that the volume used in the scope of authorisation is in the range of 100-1,000 tonnes per annum.

Registered uses in the scope of authorisation include uses at industrial sites (formulation and use in lubricants, lubricant additives, greases, hydraulic fluids and metal working fluids, formulation and use in polymer mixtures and compounds in plastics production) and uses by professional workers (use in lubricants, lubricant additives, greases, hydraulic fluids and metal working fluids. Furthermore, the substance is used in articles (plastic articles). It could be noted that the substance is mainly used for its lubricant, flame retardant and/or plasticiser properties. Additionally, as stated in the draft background document, TXP and tris(2-chloroethyl) phosphate (TCEP, EC 204-118-5) both belong to the chemical group of organophosphate esters and are reported to have similar uses. Therefore, in some uses it may be possible to use TXP as substitute for TCEP. TCEP has already been included in Annex XIV, therefore grouping considerations apply.

Based on this information, trixylyl phosphate meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation comments were received from one Member State authority and two companies.

The Member State authority supported the prioritisation of TXP for inclusion in Annex XIV, particularly as it may be used as a substitute for TCEP.

Neither company provided any information to challenge the prioritisation score or the conclusion that TXP meets the criteria for prioritisation. One company only confirmed that TXP was used by the aerospace industry as a lubricant and corrosion inhibitor. The other claimed that the substance is strategic for energy production.

MSC *is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of trixylyl phosphate.*

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for trixylyl phosphate:

(i) Latest application date: Date of inclusion in Annex XIV plus 21 months;

(ii) Sunset date: Latest application date plus 18 months.

Comments on the transitional arrangements were received from the company based in the energy sector. They proposed that a Sunset date of 2028 would focus the efforts of industry on substitution rather than applying for authorisation.

MSC agrees with ECHA's responses in the RCOM and that the efforts already made by the company to find alternatives for TXP will form an important part of any application for authorisation. If there are uncertainties over some potential substitutes then obtaining an authorisation and justifying why extra time is needed to transfer may be more efficient.

MSC is of the opinion that no information has been provided during the public consultation that would challenge the suggested latest application date and sunset date for trixylyl phosphate.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation. No requests for review periods were received during the public consultation.

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.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation. No requests for exemption of uses or categories of uses were received during the public consultation.

Overall, MSC is of the opinion that no information was submitted during the public consultation that would form the basis for inclusion of a specific exemption under Article 58(2) for a use or a category of use in Annex XIV.

PPORD exemptions

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

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not required.

Other issues

The commenting company claiming that the substance is strategic for energy production also provided information on the work done to date to find alternatives. As a general point they felt the short time from classification (July 2012) to candidate list (December 2013) to prioritisation had given them little time to seek and implement alternatives. Initial research had shown that changing to other phosphate ester type fluids may be possible but that due to the need to schedule fluid replacement during planned power plant maintenance outages, they estimated the implementation of suitable alternatives could be 10 years with a cost of around €10 million. Additionally, one possible substitute contains the substance triphenyl phosphate which is on the CoRAP due to suspected endocrine disruption concerns. This creates uncertainty as to whether this potential replacement would be safer. They indicated it would be useful to have some early indication of the outcome of assessments of potentially hazardous substances.

MSC took note of this comment and shares ECHA's view that information on the availability of alternatives as well as on relevant research and development efforts are taken into account in the application and authorisation decision making phase. MSC notes that while for some uses in the short term there may not to be suitable alternatives, the authorisation title of REACH gives a long term incentive to find them and deploy them when these alternatives are technically and economically feasible while enabling continued use where that is justified. Therefore MSC concludes that these other issues do not lead to a different opinion on the draft recommendation.

2.4 Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry] (HHPA) and 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)

Justification for prioritisation

Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry] (HHPA) and 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) were identified as SVHC according to Article 57 f) as there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57. HHPA and MHHPA are MHHPA are classified in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as a respiratory sensitiser, (amongst other endpoints). Substances were included in the candidate list for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

Based on registration information HHPA is manufactured and/or imported into the EU in the range of 10, 000-100, 000 tonnes per annum. According to the registration information, the amount of MHHPA manufactured and/or imported in the EU is in the range of 1, 000 -10, 000 tonnes per annum. Some uses of both substances appear not to be in the scope of authorisation, such as use as intermediate including use as a monomer in the manufacture of thermoplastics. ECHA has estimated the volumes in the scope of authorisation in the EU to be in the range of 1, 000- 10, 000 tonnes per annum for both substances.

According to the registration information assessed by ECHA during the prioritisation process before public consultation, registered uses of HHPA and MHHPA in the scope of authorisation include uses at industrial sites as hardener for epoxy resins, process regulator for polymer processes and formulation.
As the registered uses of HHPA and MHHPA are nearly identical and the substances are structurally very similar (differing only by one methyl group) the substances could potentially substitute each other in some of their uses.

Based on this information, HHPA and MHHPA meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation one member state and one environmental NGO supported the prioritisation of HHPA and MHHPA for inclusion in Annex XIV.

Many comments were received from industry associations and individual companies. Most of these comments were submitted for both substances in parallel, some were just submitted for one of the anhydrides but cover arguments for both substances. The main arguments brought forward for both substances concern:

- SVHC identification. The industry claimed that the evidence for respiratory sensitisation is based on old information gained from limited data without details and that the level of

concern is not equivalent to CMR and PBT/*v*P*v*B substances as respiratory sensitising substances do not have the same health impacts.

- Overestimation of risk. Industry argued that the actual level of concern which the substances present do not justify their inclusion in Annex XIV as the data in the Annex XV dossiers do not reflect the real situation as worker exposure has been dramatically reduced in the last years.
- Legal uncertainty. It was noted in some comments that the identification of HHPA and MHHPA is being challenged before the Court of Justice of the European Union and therefore it is premature to suggest their inclusion into Annex XIV.
- Prioritisation scores for volumes and wide dispersive use are too high. Industry claims that majority of uses (also the use as process regulator for polymerisation processes) is monomer use in the manufacture of polymers which –as intermediate use- is not in the scope of authorisation. It was also noted that neither of the substances is used in consumer or professional applications. It was also claimed that the grouping of the substances cannot be a supporting argument for prioritisation as –according to ECHA´s judgement- both substances qualify for prioritisation based on their high scores.

In their comments industry informed that a task force of manufacturers, importers and downstream users of the substances was built up and it is planned to consult industry in order to gather more data on exposure and risks. As a second step, based on collected data, it is planned to provide detailed instructions on the safe use of HHPA and MHHPA to the suppliers of HHPA and MHHPA for potential inclusion of this information in the registration dossiers.

In some comments doubt about the existence of professional and consumer uses for HHPA was expressed.

Some comments on the priority setting were submitted specifically for MHHPA. In their comments industry claimed that MHHPA is just used in industrial applications where RMM are in place and risk for workers is minimised. It was also mentioned that many other respiratory sensitising substances have not been included into the candidate list and there is no reason to treat MMMPA differently to these substances as the available RMMS for respiratory sensitisers are available for MHHPA as well.

With respect to challenging the identification of the anhydrides as SVHC the MSC agrees with ECHA that the inclusion of the substances in the candidate list is based on their harmonized classification as respiratory sensitisers and the equivalent level of concern arguments in the Annex XV dossiers. This has been agreed by the MSC and cannot be changed based on the comments submitted during the public consultation.

MSC also agrees with ECHA that actions taken before the European Court of Justice cannot have suspensive effect on the prioritisation step.

With respect to the arguments questioning the scores for volumes and wide dispersive use of the substances, MSC follows ECHA´s argumentation that it is difficult to conclude on the intermediate status for all uses and the volume per use based on the information in the registration dossiers. MSC follows ECHA´s conclusion that the available information is not sufficient to lower the volume scores. Concerning ECHA´s conclusion on the WDU score for HPPA the MSC agrees with ECHA´s consideration that –based on the comments and registration updates- the WDU score for HHPA could be lowered from 7 to 5 and the overall score could be lowered from 20 to 18.

Regarding the arguments on grouping of the substances MSC agrees with ECHA´s considerations that grouping can generally be applied for substances for which the available information gives indication that the substances could potentially replace each other. MSC notes that HHPA and MHHPA are structurally very similar (differing only by one methyl group) and the registered uses of the substances are nearly identical.

During the MSC discussions ECHA raised the question whether the anhydrides should be taken from the 7th recommendation as the score for HPPA slightly decreased based on comments received in the public consultation and other substances with similar priorities were not included in ECHA´s draft

7th recommendation. Also an industry task force suggested postponing the prioritisation of the anhydrides as they have the same scores as substances which were not prioritised yet, evidence of recent adverse health effects is absent and investigation on exposure and health effects of the substances is going on at the moment.

Regarding the suggestion to postpone the prioritisation of the anhydrides, MSC notes that the score had slightly decreased based on comments received in the public consultation but did not see a compelling argument to postpone or remove the anhydrides from the 7th draft recommendation. It could be pointed out that the scores for both anhydrides are quite high and it is reasonable to believe that the substances would anyway qualify for prioritisation in ECHA´s 8th recommendation. MSC notes that only one substance with a slightly higher score than the anhydrides (19 vs. 18) was not recommended for Annex XIV in the draft 7th recommendation. MSC also notes that the difference in scores is very small and as there always is some uncertainty about the assigned scores it is very reasonable to recommend the anhydrites for inclusion into Annex XIV in this round. Therefore MSC is of the opinion that the anhydrides should stay in the 7th recommendation.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of HHPA and MHHPA.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for HHPA and MHHPA:

(i) Application date: 18 months after entry into force of the Regulation;
(ii) Sunset date: Latest application date plus 18 months.

During the public consultation some comments on transitional arrangements were received all requesting for longer transitional periods. Arguments for the need of longer transitional periods were the absence of alternative materials, the need of research on alternative materials and testing of their functionality as well as the complexity of the supply chains of the substances. Comments were also received on the high number of applications estimated for both anhydrides. These applications could include key heavy and strategic industrial sectors for Europe.

MSC notes that the availability of an alternative is not a precondition for applying for Authorisation and, thus, should not have a bearing on the deadline for application and the sunset date. If there are uncertainties over some potential alternatives then obtaining an authorisation and justifying why extra time is needed to transfer may be more efficient.

MSC is of the opinion that no information has been provided during the public consultation that would challenge the suggested latest application date and sunset date.

Proposed review period for certain uses

No review periods were suggested by ECHA. No requests for review periods were received during the public consultation.

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.

Proposed exempted (categories of) uses

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

One industry association asked for an exemption for the use in scientific research and development according to article 56(3) of REACH. Another one asked for exemption from registration for MHHPA as the substance should be available for scientific research and industrial development.

Different companies commented in this chapter that they use automatic or closed processes and worker exposure is low or not existent but these comments do not directly ask for exemptions of uses.

MSC agrees with ECHA's responses in the RCOM and that industry have to examine themselves whether the specific uses of the substance can be regarded as uses for scientific research and development in accordance with Article 3(23) and 56(3) of REACH.

Overall, MSC is of the opinion that no information was submitted during the public consultation that would form the basis for inclusion of a specific exemption under Article 58(2) for a use or a category of use in Annex XIV.

PPORD exemptions

ECHA did not propose any exemptions for PPORDs. No requests for exemptions for PPORD were received during the public consultation.

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not required.

Other issues

Comments on the socio-economic impacts of inclusion of HHPA and MHHPA into Annex XIV –foreseen for consideration by the Commission- were also submitted for both substances.

Regarding the comments on potential socio-economic impacts of inclusion of HHPA and MHHPA into Annex XIV MSC agrees with ECHA´s view that the prioritisation approach explicitly states that the socio-economic considerations are not considered within the prioritisation and are taken into account in the application for authorisation phase.

The argument was brought forward that authorisation is not the best risk management measure for HHPA and MHHPA. As an alternative to Authorisation it was suggested to add HHPA and MHHPA to Annex XVII. It was noted that these substances should be treated similarly to the respiratory sensitizers - diisocyanates - for which a restriction dossier is being prepared at the moment.

MSC took note of comments provided and is of the opinion that these other issues do not lead to a different opinion on the draft recommendation.

2.5 Perborate substances (Sodium perborate; perboric acid, sodium salt; Sodium peroxometaborate)

Justification for prioritisation

Sodium perborate; perboric acid, sodium salt and sodium peroxometaborate were identified as Substances of Very High Concern (SVHCs) according to Article 57 (c) due to their classification in Annex VI of Regulation (EC) No. 1272/2008 as toxic for reproduction, Category 1B, (H360Df: *"May damage the unborn child. Suspected of damaging fertility"*), and were therefore included in the Candidate List for authorisation on 16 June 2014, following ECHA's decision ED/49/2014.

According to registration information (from 2010) the amount of sodium perborate; perboric acid, sodium salt manufactured and/or imported into the EU is in the range of 10, 000 - 100, 000 tonnes per annum. Based on information from industry received during the preparation of the Annex XV report (2014) and as documented therein, the volume has decreased over the past years and was estimated to be less than 40, 000 tonnes per annum in 2013.

Some uses appear to be outside the scope of authorisation, such as use as laboratory chemical in scientific research and development (SRD), use in detergents and bleaching products below the specific concentration limit (SCL) as well as use in cosmetic products.

Based on information from registration and from industry submitted during the SVHC public consultation, almost the complete volume used in the EU corresponds to uses appearing to fall in the scope of authorisation. Therefore, it is estimated that the volume in the scope of authorisation is greater than 10, 000 tonnes per annum.

Registered uses of sodium perborate; perboric acid, sodium salt in the scope of authorisation include uses at industrial sites (formulation of mixtures) and uses by professional workers (use in detergents and bleaching products above the SCL). A high number of diverse professional users are expected to be involved in the use of washing and cleaning products. As of 1 June 2013 consumer uses of the substance in detergents above the specific concentration limit are not allowed anymore.

For sodium peroxometaborate there were no registrations under the REACH Regulation as of 1 June 2015. During the public consultation to identify sodium peroxometaborate as SVHC comments were received indicating the use of the substance as laboratory chemical in scientific research and development (SRD), however this use appears to be outside the scope of authorisation. Based on structural similarities it appears that sodium peroxometaborate could potentially replace sodium perborate and be used in similar applications. Therefore, although currently not registered, sodium peroxometaborate is proposed to be prioritised for inclusion in Annex XIV on the basis of grouping considerations.

Based on this information, sodium perborate; perboric acid, sodium salt and sodium peroxometaborate meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

In the public consultation one Member State Competent Authority (MSCA) and one NGO supported the prioritisation of sodium perborate and sodium peroxometaborate for inclusion in Annex XIV. The MSCA in general supported the grouping of substances of very high concern to avoid substitution with substances having similar properties.

Comments were received from an industry association primarily challenging the intersubstitutability of the perborates and the boron substances already recommended. The industry association challenged the additional consideration for inclusion based on structural similarities with and potential to replace other boron compounds already recommended by ECHA. They claimed that the chemistry of these perborates confirms that they are different classes of compounds than the boron compounds already recommended, and that it would appear that there are very few such applications where they can be intersubstituted.

A set of comments were received from several companies in an industry consortium for sodium perborate opposing inclusion in the Authorisation list.

One comment challenged the basis for harmonised classification as toxic for reproduction, category 1B, which was claimed to be based on read-across of the classification of boric acid/borates instead of using data for sodium perborate tetrahydrate. The harmonised classification of boric acid was also disputed and reference was made to a request from a MS for re-classification of boric acid.

In relation to the grouping with other boron compounds it was also argued that ECHA should not proceed with recommending the perborates until the procedure for prioritising borates in the 6th recommendation is concluded.

Some comments noted that the use as bleaching agent in detergents and cleaning products is already regulated by a restriction in Annex XVII of REACH and therefore authorisation is not relevant. It was also claimed that the use in cosmetics and pharmaceutical products is not relevant.

The volume score used for the priority calculation was disputed, claiming that the volume figure applied for use in scope of authorisation (>10, 000 tonnes per annum) is outdated according to existing statistical data for 2014 and 2015, since the use in the EU area is in constant decrease.

It was noted in another comment that in the chemical safety report in the registration for sodium perborate considering all viewpoints of production and use of sodium perborate the following conclusion was made in the risk characterisation: "Under the specified conditions all uses can be regarded as safe and the RCR is below 1".

MSC agrees with ECHA's responses provided in the RCOM with respect to the issues raised during the public consultation in relation to priority setting as outlined above.

In particular, MSC is in agreement with ECHA on issues such as the challenge to the harmonised classification of sodium perborate where ECHA responded that as the cited harmonised classification is applicable law at the present, it will not be questioned or discussed in the context of this recommendation. ECHA notes that in relation to the proposal from a MSCA to change the existing classification for boric acid, the Risk Assessment Committee in 2014 agreed to maintain the current classification of Repr 1B which the Commission included in the ATP to the CLP.

With respect to the comment regarding the grouping with other boron substances, MSC agrees with ECHA in recognising that the borates and the perborates currently under consideration might have only limited interchangeability. In the RCOM ECHA, however, notes that the perborate substances have high priority even without any considerations of grouping with the borates. MSC also notes that according to the information provided during the public consultation the interchangeability between borates and perborates seems to be applicable in the use for detergents and the vast majority of the volume of perborates are used in detergents.

Regarding the request to await the conclusion of the procedure for prioritising borates for Annex XIV MSC agrees with ECHA's response that according to Art. 59 (3), ECHA has an obligation to recommend to the Commission priority substances to be included in Annex XIV. The decision to include substances in Annex XIV is taken by the Commission and it is for the Commission to decide when and how it proceeds with ECHA's recommendations.

Regarding the comment that use as bleaching agent in detergents and cleaning products is already regulated in Annex XVII, again MSC agrees with ECHA's response that uses by professionals above the SCL are not covered by the restriction, however, such uses do fall within the scope of authorisation. MSC would like to point out that according to the registration information, the substance is used by professionals above the SCL.

Regarding non-relevance of use in cosmetics and pharmaceuticals MSC supports ECHA's response in the RCOM suggesting examination whether the mentioned uses can be regarded as exempted from authorisation as set out in REACH. MSC notes that it is ultimately the responsibility of an individual company to assess whether its use can benefit from these exemptions.

With respect to the comments disputing the volume score in relation to outdated volumes used for prioritisation, MSC agrees with ECHA's points in their response that: the registration data are the main source of information for the prioritisation assessment; the priority assessment of sodium perborate is based on the most recent registration data (2010); registration information submitted to ECHA has to be kept up to date; and that it is the responsibility and the duty of registrants to update their registration information when needed without undue delay, e.g. in case of a change in the tonnage band. MSC notes that the registration data from 2010 indicate a production volume in the tonnage band from 10, 000-100, 000 tonnes per annum, and that the lower end of this range was used in the priority assessment. MSC is of the opinion that based on the currently available information the overall volume score used for the priority calculation should remain the same.

With regard to the comment made that according to the registered CSR all uses can be regarded as safe, the MSC notes and agrees with section A.5.4 of "ECHA's general responses on issues commonly raised in public consultations on draft recommendations" indicating that such aspects are not considered in ECHA's prioritisation because an assessment of the level of control is not appropriate during the recommendation phase since it would shift the burden of proof back to authorities. MSC notes that prioritisation is a task of comparing the substances on the Candidate List based on certain agreed criteria. It does not intend to assess the risks arising from the uses of substances, but to provide a very basic and general assessment of indicators such as the use pattern and tonnages in the EU. Should authorisation be requested the applicant will make an assessment which will be assessed by the Risk Assessment Committee (RAC) for appropriateness and effectiveness of risk management measures. Further conditions could also be specified in the authorisation decision. This provides an additional level of scrutiny of the appropriateness of the control measures compared to the registration and downstream user obligations.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of sodium perborate; perboric acid, sodium salt and sodium peroxometaborate.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for sodium perborate; perboric acid, sodium salt and sodium peroxometaborate:

(i) Application date: 21 months after entry into force of the Regulation;

(ii) Sunset date: Latest application date plus 18 months.

There were no comments received during the public consultation requesting changes in the proposed transitional arrangements.

MSC notes that no new information has been provided during the public consultation that challenge the latest application date and sunset date.

Proposed review period for certain uses

No review periods were suggested by ECHA. No requests for review periods were received during the public consultation.

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.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation. No requests for exemption of uses or categories of uses were received during the public consultation.

Overall, MSC is of the opinion that no information was submitted during the public consultation that would form the basis for inclusion of a specific exemption under Article 58(2) for a use or a category of use in Annex XIV.

PPORD exemptions

ECHA did not propose any exemptions for PPORDs. No requests for exemptions for PPORD were received during the public consultation.

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not required.

Other issues (not relevant to ECHA's recommendation)

One NGO commented that socio-economic implications and availability of alternatives should not play a role in the inclusion of substances in Annex XIV but only be taken into account when companies apply for authorisation and for specific uses.

A comment was received indicating that inclusion in the Authorisation list and later authorisation/ prohibition of use could lead to drastic rise of raw material prices for detergent industry and consequently also higher prices for end users. Economic effects were also indicated from closing down the production of sodium perborates in the EU and consecutive effects for employees and company owners.

Regarding the comments on potential socio-economic implications of inclusion of perborates in the authorisation list, MSC agrees with ECHA's view that the prioritisation approach explicitly states that the socio-economic considerations are not considered within the prioritisation but that these are taken into account in the application for authorisation phase.

MSC took note of comments provided and is of the opinion that these other issues do not lead to a different opinion on the draft recommendation.

Annex II of MSC Opinion

Draft recommendation submitted for public consultation, 18 November 2015

Draft 7th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation

(List of Substances Subject to Authorisation)

The selection of substances in the draft recommendation is based on the priority assessment of the substances included in the Candidate List. The prioritisation results can be found at http://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_nov_2015_en.pdf. The draft Annex XIV entries are determined on the basis of the general approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV (http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf).
The number of substances selected reflects the anticipated capacity of ECHA and the Commission to handle application for authorisation in the time provided for and also considers workability and practicality for applicants preparing their applications for 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	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [1)]	Latest application date plus 18 months	None	None	None
2	Dihexyl phthalate	201-559-5	84-75-3	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [1)]	Latest application date plus 18 months	None	None	None
3	Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3	Equivalent level of concern having probable serious effects to human health (Article 57 f)	Date of inclusion in Annex XIV plus 18 months [1)]	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] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]								
4	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]	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9	Equivalent level of concern having probable serious effects to human health (Article 57 f)	Date of inclusion in Annex XIV plus 18 months [1)]	Latest application date plus 18 months	None	None	None
5	Trixylyl phosphate	246-677-8	25155-23-1	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 21 months[2)]	Latest application date plus 18 months	None	None	None

Draft Annex XIV entries									
#	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii)****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
6	Sodium perborate; perboric acid, sodium salt	239-172-9; 234-390-0	-	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
7	Sodium peroxometaborate	231-556-4	7632-04-4	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
8	Orange lead (lead tetroxide)	215-235-6	1314-41-6	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 24 months[3)]	Latest application date plus 18 months	None	None	None
9	Lead monoxide (lead oxide)	215-267-0	1317-36-8	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 24 months[3)]	Latest application date plus 18 months	None	None	None
10	Pentalead tetraoxide sulphate	235-067-7	12065-90-6	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 24 months[3)]	Latest application date plus 18 months	None	None	None
11	Tetralead trioxide sulphate	235-380-9	12202-17-4	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 24 months[3)]	Latest application date plus 18 months	None	None	None

* Reference is made to the identified SVHC properties in accordance with Article 57 of the REACH Regulation and to the corresponding classification in accordance with 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.

** The determination of LADs is based on the "General approach for the preparation of draft Annex XIV entries".

Substances potentially fulfilling the definition of a group according to Section 1.5 of Annex XI of REACH (provision allowing submission of multi-substances applications for authorisation) are placed in the same slot. The proposed assignment of the substances aims at supporting an even workload for all parties during the opinion forming and decision making on the authorisation applications. The assignment to the different slots reflects ECHA's current assumptions taking into account the information available about the complexity of the substances' supply chains in a particular recommendation round and how they compare with each other.

1) Assuming that the Commission amendment of Annex XIV of the REACH Regulation on the basis of this seventh Recommendation would enter into force in November 2017, the latest application date would be May 2019

2) Assuming that the Commission amendment of Annex XIV of the REACH Regulation on the basis of this seventh Recommendation would enter into force in November 2017, the latest application date would be August 2019

3) Assuming that the Commission amendment of Annex XIV of the REACH Regulation on the basis of this seventh Recommendation would enter into force in November 2017, the latest application date would be November 2019