11 June 2015

Annex II and III to the Member State Committee's opinion on ECHA's 6th draft recommendation (adopted on 11 June 2015)

Annex II Support document for the opinion of MSC

Annex III Draft 6th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation as submitted for public consultation on 1 September 2014

Support document for the opinion of MSC (Annex II)
on ECHA's 6th draft recommendation for inclusion of priority substances in the Authorisation List (adopted on 11 June 2015)

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, 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 more than 500 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 Lead substances (Orange lead (lead tetroxide); Lead monoxide (lead oxide); Tetralead trioxide sulphate; Pentalead tetraoxide sulphate; Silicic acid, lead salt; Pyrochlore, antimony lead yellow; Acetic acid, lead salt, basic)

Justification for prioritisation

Orange lead (lead tetroxide), lead monoxide (lead oxide), tetralead trioxide sulphate, pentalead tetroxide sulphate; silicic acid, lead salt; pyrochlore, antimony lead yellow and acetic acid, lead salt, basic 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.

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 t/y. Some uses appear not to be in the scope of authorisation, such as use as intermediate in manufacture of certain pigments and PTC / piezoelectric ceramics. The volume used in glass and frits was assessed by ECHA during prioritisation process before public consultation and was taken into account when allocating the volume score, although this does not ultimately change the volume score. Registered uses of orange lead (lead tetroxide) 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 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 certain pigments, technical ceramics, glass and frits and some uses as laboratory reagent, the volume in the scope of authorisation is estimated to be in the range of 10 000 – 100 000 t/y.

The amount of lead monoxide manufactured and/or imported into the EU is according to registration data above 100 000 t/y. Some uses appeared to ECHA as not to be in the scope of authorisation, such as use in manufacturing of PVC stabilisers, certain pigments, explosives and technical ceramics, and use as laboratory reagent and in chemical analysis. The volume used in glass and frits was assessed by ECHA during prioritisation process before public consultation and was taken into account when allocating the volume score, although this does 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 t/y.

The amount of tetralead trioxide sulphate manufactured and/or imported in the EU is according to registration data in the range of 1 000 000 – 10 000 000 t/y. After assessing the comments received during public consultation ECHA concluded that all tonnage appears to be in the scope of authorisation. It should be noted that the volume range is not changed even if the use in stabilisers (industry has a voluntary commitment to phase out the use in the EU by the end of 2015) is not taken into account.

The amount of pentalead tetroxide sulphate manufactured and/or imported into the EU is according to registration data in the range of 10 000 – 100 000 t/y. After assessing the comments received during public consultation ECHA concluded that all tonnage appears to be in the scope of authorisation. It should be noted that the volume range is not changed even if the use in stabilisers (industry has a voluntary commitment to phase out the use in the EU by the end of 2015) is not taken into account.

Silicic acid, lead salt was prioritised for inclusion in the draft 6th recommendation together with lead monoxide and lead tetroxide, as it appeared that they are used in similar applications (glass). However, before the start of the prioritisation process it had not been assessed whether the function of these substances in these applications is the same and whether and/or under which conditions substitution could happen in practice. The amount of silicic acid, lead salt manufactured and/or imported into the EU is according to registration data in the range of 100 - 1 000 t/y. There is up front no available information indicating that the use of the substance in glass production would be intermediate use. Therefore, all tonnage appears to be in the scope of authorisation.

Pyrochlore, antimony lead yellow was prioritised for inclusion in the draft 6th recommendation together with lead monoxide and lead tetroxide. This is as it appears that they are used in similar applications (pigments). However, before the start of the prioritisation process it had not been assessed whether the function of these substances in these applications is the same and whether and/or under which conditions substitution could happen in practice. The amount of pyrochlore, antimony lead yellow manufactured and/or imported into the EU is according to registration data in the range of 10 - 100 t/y. All tonnage appears to be in the scope of authorisation.

Acetic acid, lead salt, basic was prioritised for inclusion in the draft 6th recommendation by ECHA together with lead monoxide and lead tetroxide, as it appeared that they are used in similar applications (paints). However, before the start of the prioritisation process it had not been assessed whether the function of these substances in these applications is the same and whether and/or under which conditions substitution could happen in practice. The amount of acetic acid, lead salt, basic manufactured and/or imported in the EU according to registration data is > 1 t/y. Some uses appear not to be in the scope of authorisation, such as use as intermediate in the manufacture of chemicals and use as laboratory chemical in scientific research and development (SRD). The use in formulation of laboratory chemicals with the intention to supply them for SRD purposes might potentially also fall outside the scope of authorisation. Taking into account the volume corresponding to those uses, based on information from registrations, the volume in the scope of authorisation is estimated to be in the range of 1 - 10 t/y.

ECHA proposed to include silicic acid, lead salt, pyrochlore, antimony lead yellow and acetic acid, lead salt, basic in the recommendation as these substances were considered to have uses that are similar to those of lead monoxide and lead tetroxide.

Priority setting

In the public consultation, various comments were received. 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. 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, 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. 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) REACH.

Furthermore, it was submitted that the score assigned to orange lead (lead tetroxide) should be 24 instead of 25.

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 therefore should not be subject to authorization.

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 tyre 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 tetroxide 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 submitted that both tetralead trioxide sulphate and pentalead tetroxide 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.

Also for pyrochlore, antimony lead yellow few comments were submitted. Two stakeholders commented on the scoring of the substance under the priority setting approach. In the opinion of these submitters, the substance should not have been included in the group of lead substances, as its use is not interchangeable with these other substances. Because other substances have a higher score, the submitters state that antimony lead yellow should not be prioritised for inclusion in Annex XIV in this round.

With regard to acetic acid, lead salt, basic three stakeholders submitted comments on the lack of possible alternatives, questioning whether authorisation would be the most efficient regulatory option. One stakeholder challenged the grouping of this substance with the other lead substances, as acetic lead salt basic can technically and economically not be replaced by these substances. Therefore, it stated that this substance should not be part of the group of lead substances recommended for inclusion in Annex XIV.

Finally, for silicic acid, lead salt two comments were received in addition to the general comments mentioned at the start of this section. A member state's regional EPA questioned whether placing the substance on Annex XIV would lead to a lowering of lead concentrations in water. One comment was received on behalf of 33 lighting companies, questioning the effectiveness of placing these substances on Annex XIV.

Assessment of information received during the public consultation was performed by MSC. 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 does 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. In conclusion, MSC remains of the opinion that the priority score of orange lead (lead tetroxide) should be 28.

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 appears 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 is concluded that some professional and consumer uses reported are unlikely to occur, the WDU score was now proposed to be 7 (original proposal: 7-10). This leads 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 tetroxide sulphate and tetralead trioxide sulphate did not lead to changes in the scores that were initially proposed (23 for both substances).

With regard to pyrochlore, antimony lead yellow, based on the information received in the public consultation and in the updated registration dossiers on function and physico-chemical properties, MSC now considers that intersubstitution of pyrochlore, antimony lead yellow with orange lead (lead tetroxide) may not be possible. However, it is noted that MSC does not have clear information that it would be impossible to replace lead tetroxide with pyrochlore antimony lead yellow in some of its uses, especially in the use as pigment in paints.

For acetic acid, lead salt basic, which was also prioritised as a group with orange lead (lead tetroxide), the information received during public consultation led to reconsideration of this grouping. Based on the information, it seems that the function of acetic acid, lead salt basic is different from that of orange lead. In addition there are differences in the water solubility of these substances. Therefore, MSC considers that acetic acid, lead salt basic may not be used as a replacement of orange lead in paints and that therefore there appears to be no reason to group these substances.

Silicic acid, lead salt was also included in the draft 6th recommendation based on grouping with lead monoxide and lead tetroxide, due to fact that they are all used in glass production. However, based on the information provided in the public consultation, MSC considers that the use in glass production may fulfil the intermediate definition under REACH and may fall outside the scope of authorisation. Therefore, there may be no reason to group silicic acid lead salt with lead monoxide and orange lead. Moreover, there are currently no active registrations for silicic acid lead salt. Therefore, the volume and WDU score of the substance have now been set to zero by ECHA. The new priority score assigned by ECHA to silicic acid, lead salt is: 1 (old score: 15).

With regard to orange lead (lead tetroxide), lead monoxide, tetralead trioxide sulphate, pentalead tetroxide sulphate, and silicic acid, lead salt 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) and silicic acid, lead salt (1). MSC agrees with the way these comments and the updated registration information were taken into account and with the calculated new scores.

Therefore, based on the information provided, MSC is of the opinion that for orange lead (lead tetroxide), lead monoxide, tetralead trioxide sulphate and pentalead tetroxide 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.

MSC furthermore considered the information submitted with regard to silicic acid, lead salt, pyrochlore, antimony lead yellow and acetic acid, lead salt, basic. Based on information submitted via the public consultation MSC is of the opinion that there appear not to be reasons to group the three low-scoring lead substances (pyrochlore, antimony lead yellow (prioritisation score 17); acetic acid, lead salt, basic (prioritisation score 11); silicic acid, lead salt (adjusted prioritisation score 1)) with lead monoxide and orange lead. Since these substances were prioritised based on the potential grouping with orange lead (lead tetroxide) and/or lead monoxide, MSC has assessed whether these substances could also be prioritised based on their own assigned scores.

Silicic acid, lead salt was initially assigned a score of 15. Based on the information received during the public consultation and taking the updated registration information into account, ECHA adjusted the score for silicic acid, lead salt to 1. MSC is of the opinion that this would not be a score that would, in the current prioritisation round, qualify for inclusion in the recommendation. Thus, MSC advises ECHA to reconsider the prioritisation of silicic acid, lead salt, for inclusion in Annex XIV in this round.

Pyrochlore, antimony lead yellow was assigned a score of 17. MSC is of the opinion that this would not be a score that would, in the current prioritisation round, qualify for inclusion in the recommendation. Thus, MSC advises ECHA to reconsider the prioritisation of pyrochlore, antimony lead yellow for inclusion in Annex XIV in this round.

Acetic acid, lead salt, basic received a score of 11. MSC is of the opinion that this would not be a score that would, in the current prioritisation round, qualify for inclusion in the recommendation. Thus, MSC advises ECHA to reconsider the prioritisation of acetic acid, lead salt, basic, for inclusion in Annex XIV in this round.

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: 21 months after entry into force of the Regulation
(ii) Sunset date: Latest application date plus 18 months

In the public consultation various comments were submitted. 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. On the other hand, 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.
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, pentalead tetroxide sulphate, pyrochlore antimony lead yellow, acetic acid, lead salt, basic and silicic acid, lead salt, only one comment was received on the proposed LAD and sunset date, from the same Member State mentioned above, supporting the shortest possible LAD.

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), lead monoxide (lead oxide)) involves complex supply chains. 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 chromate compounds (Regulation 348/2013). Thus MSC is of the opinion that a similar latest application date could also be appropriate for the substances mentioned above.

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: 35 months 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 tetralead trioxide sulphate; pentalead tetroxide sulphate; pyrochlore antimony lead yellow; acetic acid, lead salt, basic and silicic acid, lead salt, in the case that all these substances would still be prioritised for inclusion in Annex XIV.

Proposed review period for certain uses

With regard to orange lead (lead tetroxide) and lead monoxide (lead oxide), some comments were received 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 Annex XIV inclusion.

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 subject.

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

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; crystal and special glasses and technical ceramics; frits manufacture 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 humans and the environment caused by 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 glass, stating that this use could already be seen as falling outside of the scope of authorization.

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 protected 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 prioritized for inclusion in Annex XIV in this round). 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 and glass, explosives and pyrotechnic components, 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 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 of 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 tetroxide 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. One stakeholder proposed to extend the scope of an exemption to all recycling material. Several companies, individual as well as in industry associations and consortiums, and supported by other stakeholders, proposed an exemption for the industrial use of tetralead trioxide sulphate and pentalead tetroxide 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 secondly because 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.

For pyrochlore, antimony lead yellow, only the general comment from the Member State was received that stated that no exemptions should be proposed.

Three comments were received regarding exemptions for acetic acid, lead salt, basic. One stakeholder mentioned the use of the substance as an analytical reagent, a use which in its view would already be exempted following Article 56(3). However, additional exemptions were proposed upstream of this use, like packaging/refilling of the pure substance into small packages. Two stakeholders commented on the use of the substance in a pharmaceutical context. They proposed to extend the exemptions that apply to the final medicinal product also to the

production process leading to a medicinal product within the scope of the medicinal products directive.

One stakeholder organisation proposed to exempt the use of silicic acid, lead salt in the production of specialty glass, furthermore the same stakeholder reflected that under REACH glass is classified as a UVCB substance and is exempted from the registration requirement under REACH under certain conditions laid down in Annex V, paragraph 11.

Assessment of the information received in the public consultation was performed by MSC.
With regard to the information submitted in the public consultation that certain uses of the lead substances would fulfil the definition of 'intermediate use' according to Article 3(15), MSC considers that, after a substance has been included in Annex XIV, it is ultimately the responsibility of a company to assess whether their use is indeed an intermediate use in the meaning of Article 3(15) of REACH and therefore not subject to the obligation to obtain an authorisation for continued use after the expiration of the sunset date.

As a general comment, it is clear 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, it is noted 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 adequately controls the risk arising from that use and which also pushes for substitution in a similar manner to the authorisation requirement. These comprise those uses of lead compounds which are exempted under the RoHS and ELV legislation (e.g. ~75 % of lead batteries). These exemptions and their review could 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) 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, glass and glass frits; and pyrochlore antimony lead yellow manufacture. However, ECHA considers that the case for Article 58(2) exemption of these uses (where they are not covered by RoHS/ELV) 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 (where the use is not exempted by RoHS/ELV), and as PVC stabiliser, 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. Other uses of lead compounds where ECHA does not consider current EU legislation sufficient are uses of lead compounds in dry film lubricant products, in propellants in rocket motors and in explosives and detonators due to potential non-negligible exposure at the waste life cycle stage 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 may 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.*

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) in Annex XIV for other uses or categories of uses for the lead substances.

MSC notes that in the public consultation 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 comments were received with regard to possible PPORD exemptions.

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.

2.2 Boron substances (Boric acid; Disodium tetraborate, anhydrous; Diboron trioxide; Tetraboron disodium heptaoxide, hydrate)

Justification for prioritisation

Boric acid, disodium tetraborate, anhydrous, diboron trioxide and tetraboron disodium heptaoxide, hydrate 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, H360-FD ("May damage fertility" and "May damage the unborn child"). Boric acid, disodium tetraborate, anhydrous and tetraboron disodium heptaoxide, hydrate were included in the Candidate List for authorisation on 18th June 2010 following ECHA's decision ED/30/2010. Diboron trioxide was included in the Candidate List for authorisation on 18th June 2012 following ECHA's decision ED/87/2012.

From registration data, the aggregated volume manufactured and/or imported in the EU of boric acid is 10 000 to 100 000 tonnes per annum, disodium tetraborate, anhydrous is 100 000 to 1 000 000 tonnes per annum and diboron trioxide is 1 000 to 10 000 tonnes per annum. Tetraboron disodium heptaoxide, hydrate is not registered. Some of the uses that are outside the scope of authorisation include use as an intermediate in the manufacture of other substances (including glass and ceramic frits), uses of mixtures below the specific concentration limit and use in scientific research and development. The tonnage estimated to be within the scope of authorisation is greater than 10 000 tonnes per annum for boric acid and disodium tetraborate, anhydrous and between 100 and 1 000 tonnes per annum for diboron trioxide. Although tetraboron disodium heptaoxide, hydrate is not registered, it has structural similarities with boric acid, disodium tetraborate anhydrous and diboron trioxide and so has the potential to be used in the same types of applications as the other 3 borates. Grouping was therefore considered for priority setting.

According to registration information (and data received during public consultation), borates are used in industrial sites and include uses in formulation, in mixtures, incorporation into articles and as a processing aid. These uses are across a wide number of sectors including the aerospace, automotive, nuclear energy, surface engineering, catalysts manufacturing, electroplating, metallurgy, semi-conductor, medical device and glass manufacturing industries. Borates also have a number of professional uses including use as an essential micronutrient in fertilisers, refractories, cellulose insulation and construction materials, soldering mixtures, adhesives, abrasives, paints and coatings, detergents/cleaners, diagnostic kits and machinery and transport equipment. Article service life is relevant for several uses e.g. cellulose insulation, construction materials, refractories, coatings, metallic equipment, etc. It appears that diboron trioxide could potentially replace boric acid and disodium tetraborate anhydrous in some of their uses, as these substances have structural similarities and almost identical patterns of registered uses. Overall, the number, range and types of uses indicate that borates are used at a large number of sites and there is potential for widespread dispersive use.

Based on this information, the 4 boron substances boric acid, disodium tetraborate, anhydrous, diboron trioxide and tetraboron disodium heptaoxide, hydrate meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, one Member State Competent Authority (MSCA) expressed its opinion that prioritisation of boric acid, diboron trioxide and disodium tetraborate, anhydrous does not represent regulatory effectiveness and is not proportionate. The Ministry of Agriculture from another Member State expressed its concern over the effect of subjecting boric acid to authorisation on the agricultural sector and its use as an essential micronutrient in particular. One MSCA expressed its support for the proposal to prioritise all four substances, while the Workers Compensation Board from another Member State also expressed its support for the prioritisation of boric acid, disodium tetraborate, anhydrous and diboron trioxide.

Comments on the prioritisation were received from a large number of industrial and professional users, individuals and a range of trade organisations. Some of the uses covered and sectors represented across the comments included the manufacture of catalysts, production of glass and frits, electroplating, metal finishing in the automotive and aerospace industries, control of nuclear fission in nuclear power plants, use as a buffer in metal plating and in the production of gallium arsenide for the semi-conductor industry, brazing, welding, soldering and refractories, manufacture of lithium batteries, production of etched and anode foil electrolytic capacitors, as a component in cleaners, protective paints, lubricants, stabilisers, adhesives and glass wool, as an essential element in fertilisers and culture media for biological fermentation, *in vitro* diagnostic kits, medical devices, and radiation protection in the healthcare industry. Some comments were received highlighting that the prioritisation of borates affects the same sector(s) that are also impacted by other restrictions/authorisations like for example Ni, Pb, Cd, Cr(VI) and PAH.

Some comments challenged the harmonised classification of borates as toxic to reproduction, category 1B, indicating that proposals were based on relatively old studies which do not show strong statistical value, that animal dosage was at extreme exposure levels which do not correlate with demonstrated low human exposure even in high boron environments (US, Turkey and China studies) and that available epidemiological studies do not confirm the classification. In addition it was stated that disodium tetraborate, anhydrous is an approved food ingredient, E285 and can therefore not be considered an SVHC.

It was also claimed that the grouping approach may be somewhat ineffective, where several other boron compounds are not included in the prioritisation. Some comments indicated that in March 2014 RAC recommended the classification & labelling of disodium octaborate and disodium octaborate tetrahydrate as Repr 1B H360FD. These substances are not yet considered as SVHCs. In the event that the 4 boron substances subject to this current recommendation are recommended for prioritisation, it is considered appropriate by some to suggest that all borate substances classified as Repr 1B H360FD be grouped. They believe that these substances could replace diboron trioxide, boric acid and disodium tetraborates in a number of end uses. They propose that this situation should be clarified before considering prioritisation of other borates for inclusion in Annex XIV.

A number of companies challenged the prioritisation by claiming it is based on tonnage data (from 2005-2008) that may now be irrelevant following the market's adaptation to the introduction of the harmonised classification and specific concentration limit in 2009. It was also claimed in a number of comments that many uses are outside the scope of authorisation e.g.

uses as an intermediate, uses covered by existing legislation such as biocides and medicinal products, food contact materials and also R&D uses. In particular, there were many comments indicating that the use of borates in the manufacture of catalysts is an intermediate one (it is already accepted and taken into account in the prioritisation that use in the manufacture of glass and frits is an intermediate one).

The prioritisation score was also challenged with respect to the score used for volume, as one comment indicated that the essential use of borates as a micronutrient should not come within the scope of authorisation and so the volume score would be reduced, thus reducing the overall prioritisation score accordingly.

Certain companies and industries (i.e. the electroplating industry, aerospace and defence industry) are currently facing a major challenge with respect to REACH authorisation due to the substitution of hexavalent chromium compounds (e.g. chromium trioxide) in a significant number of applications. It will be very difficult for them to substitute, at the same time, other substances involved in the same systems. They noted that it is necessary to take into account that the prioritisation of one substance has a strong impact on the overall process. This consists of currently used processes, as well as the development of new process using substances with lower risks. This is particularly important given the background of the discussion on the development of chromium (III) electrolytes to replace chromium (VI) trioxide since these electrolytes require boric acid.

Comments were received which indicated that national and EU legislation is in place to minimise the exposure of workers, consumers and the environment, with specific emphasis on the existing REACH restriction (also indicating that the outcome of the restriction should first be evaluated), adherence to risk management measures and adherence to indicative occupational exposure limits. Several companies indicated their long-term usage of these substances without encountering health problems. All of these comments expressed the opinion that the risks are adequately controlled under existing legislation and so authorisation is not proportionate.

Several industries indicated that there was a lack of suitable alternatives for borates, and highlighted that existing technologies have been adapted to include borates following the prioritisation of other substances to Annex XIV, such as Chromium (VI) and Cadmium. No other suitable alternative is foreseeable for a range of industries, including metal plating and electroplating, medical, jewellery, nuclear safety and fertilisers. There were several comments, mostly from the semi-conductor industry, indicating the importance of borates as a buffer in nickel and other metal plating processes and stressing its use in a highly automated 'clean room' environment. Moreover, these substances appear to be essential in the production of gallium arsenide used by this industry. Similarly, the importance of borates for electroplating was highlighted by several companies, including automotive and aerospace industries. Comments also indicated that borates are used in soldering in the jewellery and silversmith sector as a substitute for the use of cadmium. It was pointed out in a number of comments that borates are among the 20 critical substances for the European economy (Report on critical raw materials for the EU, Report of the Ad hoc Working Group on defining critical raw materials, May 2014). Substitution of such substances is moreover considered as very difficult (3rd most difficult substance to substitute among the 20 strategic substances and non-substitutable for uses in the nuclear energy sector) according to the same report. It was pointed out in some comments that as a consequence, there appears to be a gap between regulation of this substance under REACH and the market reality and needs.

Many comments were also received in relation to the use of borates in the formulation of boron-containing fertilisers, all indicating that it is irreplaceable as an essential micronutrient for crop nutrition. Similarly, boron was noted as an essential trace element in culture media for growth and proliferation of cells in the fermentation process in laboratory and biotechnology operations.

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 notes ECHA's responses and is in agreement with ECHA on issues such as the challenge to the harmonised classification of borates where ECHA responded to indicate that such a challenge to the inherent properties of a substance is not relevant for this part of the process and on the issue of authorisation not being the most appropriate risk management option for these substances, agreeing with ECHA's response that at this stage of the process of recommending substances from the Candidate List for inclusion in Annex XIV, ECHA is not in a position to assess the suitability of other risk management options and so this comment is not relevant for prioritisation. On the comment regarding the effectiveness of the grouping approach, again MSC agrees with ECHA's response that grouping substances of a similar nature and function for inclusion in Annex XIV does not require that all similar substances are firstly included on the Candidate List before it would be meaningful to consider further risk management activities (e.g. inclusion in Annex XIV) for the individual substances or the entire group. MSC agrees that grouping for regulatory action should not lead to a situation in which a group of substances cannot be recommended because further substances appear to belong to that group and have not yet been identified as SVHCs. Regarding the adequacy of existing EU legislation to control the risks from these substances, the MSC is agreement with the various responses from ECHA on this issue. In particular, MSC notes and agrees 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. If a substance is included in Annex XIV it is then the obligation of the applicant for authorisation to demonstrate that the risks arising from the applied for uses are properly controlled or that there are no suitable alternatives available and the socio economic benefits of the use outweigh its risks. Regarding the comments made on the lack of suitable alternatives for many uses, including critical ones, MSC is of the same opinion as ECHA as given in their response on this in 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. 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.

With respect to the comments in relation to outdated volumes used in the prioritisation, MSC notes ECHA's point in their response in that the data used for the priority assessment is the most up to date that is available, being what was reported by the lead registrant in 2014 and referring to the year 2012. Contrary to what was provided in the comments, MSC notes that while data from 2005-2008 was cited in the Annex XV report, it was not used in the priority assessment. MSC is also in agreement with ECHA's response with respect to comments challenging the overall volume score and volumes outside the scope of authorisation and, like ECHA in their response, is of the opinion that the overall volume score should remain the same.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of boric acid, disodium tetraborate anhydrous, diboron trioxide and tetraboron disodium heptaoxide hydrate.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for boric acid, disodium tetraborate anhydrous, diboron trioxide and tetraboron disodium heptaoxide hydrate

(i) Application date: 24 months after entry into force of the Regulation
(ii) Sunset date: Latest application date plus 18 months

During the public consultation, there were many comments from industry requesting longer periods of transition for the 4 substances. Several companies from the electric power industry indicated that the implementation time is short compared to the time needed for design, build and operation cycles and that uses of borates in nuclear power plants are relying on long term investments (~ 60 years) that are not proportional with the transitory periods proposed. Article 58(1)(c)(i) is quoted in the context that transitory periods "*should take into account, where appropriate, the production cycle specified for that use*".

Comments from the aerospace industry considered the inclusion of boron compounds in the authorisation list as not proportional. The period requested for the latest sunset date ranged from 36 months to 10 years considering the lack of alternatives, the long life cycle and development costs. One company claimed that efforts on the substitution of chromates will make it more difficult for the substitution of other substances involved in the same corrosion protection systems at the same time.

One association from the catalyst industry indicated its support to the proposal of including borates in the latest LAD slots, with a description of the complexity of the supply chain provided as justification.

An automotive association expressed its concerns due to the role of borates, and more specifically boric acid, in the development and use of Cr(III) technology instead of Cr(VI), whose sunset date is scheduled in 2017. One automotive company indicated that a period of 3-4 years would be needed to find an alternative.

In addition it was argued that the same industries are burdened by the authorisation requirements for the chromates.

Lack of knowledge of the authorisation process by the SME in the lubricant industry and fertilizers sector have been argued to motivate the need of latest application and sunset dates for boric acid.

The pharmaceutical sector suggested the maximum possible transitional period to allow for alternatives for boric acid to be found since it is used as essential ingredient. Due to the complexity of the supply chain, high regulation and the need to search for alternatives, 48 months has been proposed by one company. Longer transitional periods were also requested by an *in vitro* diagnostic kits manufacturer association based also on the complexity of borates supply chains. A previous decision with chromates was also referenced, underlining the analogy in the complexity of the supply chain. One diagnostic kits company stressed that the transitional arrangements for boric acid would need several years or decades to replace the present situation. The same reason has been expressed by one company from the vision care industry to justify the latest LAD slot (24 months).

Latest application dates ranging from 48 months to 20 years were proposed for diboron trioxide by companies and associations in the semiconductor industry, taking into account the lack of substitutes for boron containing glass frits in the specific application of microelectromechanical systems manufacturing and no alternative to diboron trioxide in the manufacture of gallium arsenide.

Other companies and industrial sectors included comments regarding the unavailability of alternatives of borates for their specific uses without providing any specific proposals regarding transitional periods.

One MSCA indicated preference to place borates in the shortest LAD slot.

In their response to comments, ECHA expressed their opinion again that, in general, a standard period of 18 months for the preparation of an application for authorisation is still valid. Allowing then for grouping of substances and taking committee workloads into account, LADs of between 18-24 months have generally been recommended, with substances for which preparing an application may require more time generally being allocated to the 'later' LADs. In the case of borates, ECHA's recommendation is that the LAD would be 24 months after entry into force of the Regulation.

MSC notes that in the comments received during the public consultation it was indicated that the use of the four boron compounds (boric acid; disodium tetraborate, anhydrous; diboron trioxide; tetraboron disodium heptaoxide, hydrate) involves 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 chromate compounds (Regulation 348/2013). Thus MSC is of the opinion that a similar latest application date could also be appropriate for the substances mentioned above.

Due to the considerations mentioned above MSC is of the opinion that the proposed latest application date for Boric acid; Disodium tetraborate, anhydrous; Diboron trioxide; Tetraboron disodium heptaoxide, hydrate could be modified as follows:

- *Application date: 35 months after entry into force of the Regulation.*

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

Proposed review period for certain uses

No review periods were suggested by ECHA.

Comments received from the diagnostic products industry and the semiconductor industry requested longer review periods (7-12 years) based on the fulfilment of many of the criteria established on the ECHA paper *"Setting the Review Period when RAC and SEAC give Opinions on an Application for Authorisation"* (SEAC/20/2013/03) such as long development cycles, high costs of substitution, no alternative available within the normal review period, specific legislate measures for possible alternatives under the relevant area or low remaining risk and high socioeconomic benefits.

One comment from the nuclear industry pointed out that investment in this sector cannot be granted with limited duration authorisations, even if renewable.

Furthermore, one manufacturer of medical products using nuclear technology requested a review period of 40 years based on the lack of alternatives for boric acid. In their opinion, the scientific and technical requirements to develop, validate and qualify a change in the technology to provide radiation protection for this cyclotron application should be taken into consideration.

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 Annex XIV inclusion.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation. One MSCA stated that they do not support any exemptions while another MSCA expressed their opinion that the use of borates in fertilizers and in nuclear power plants should be exempted.

Requests for exemptions were received from industry and representative groups and overlapped across all 4 substances. Many of the comments indicated that some uses were already exempt (or requested specific exemptions for these uses) including uses as an intermediate (e.g. production of glass and frits), use in mixtures below the specific concentration limit (SCL) of 5.5% w/w, use in scientific research and development (SR&D), medical products or medical devices.

There were exemptions requested for a wide range of uses including (but not limited to) that in brazing, soft soldering, use in surface treatment, production of wires, electroplating, manufacture of covered electrodes, welding, refractory castables, production of semi-conductors, use in formulation of photographic chemicals and in the formulation of solutions for use in coating inkjet printing media or digital film for medical diagnostic, formulation of ready-made adhesives, production of gallium arsenide for the semi-conductor industry, in lithium-ion batteries, and as a process chemical. An exemption was requested for the specific use of disodium tetraborate, anhydrous as a slag stabiliser. Slags are produced during the stainless steel production process. In a number of cases involving use in formulation, it was indicated that while a final mixture may contain a boron substance at below the SCL, the formulation of that mixture would involve the pure boron substance and so be subject to authorisation.

The basis for the exemption requests above varied, but most of the comments indicated that workplace exposures were controlled by the use of appropriate risk management measures and controlled under existing chemical legislation (e.g. Directive 98/24/EC on the Protection of Workers from the risks related to Chemical Agents, Council Directive 92/85/EEC (Pregnant Workers Directive) and Council Directive 94/33/EC on the protection of young people at work). Some comments also requested an exemption under Article 58(2) due to adequate control under Directive 2010/75/EU on Industrial emissions (IED), or the WEE Directive 2002/96/EC, or the SEVESO Directive 96/82/EC (repealed by Directive 2012/18/EU with effect from 1 June 2015). MSC notes that it would appear that borates are not within the scope of the SEVESO Directive. Exemption requests were also received with respect to the use of borates in medicinal products, in accordance with Directives 726/2004, 2001/83/EC and 2001/82/EC. Many comments also indicated that that there is a lack of environmental releases or consumer exposures, and/or that they are critical uses, with no alternatives available.

MSC agrees with ECHA's response to comments received regarding uses being controlled under existing chemical legislation. As outlined in ECHA's response to these comments, MSC is also of the opinion that in order to avail of 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. MSC is in agreement with ECHA in that generally, the legislation should refer to the substance, either by naming it or referring to the group the substance belongs to. MSC also agrees with ECHA's response 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.

In line with the responses provided by ECHA and summarised above, MSC considers that the above mentioned Directives do not impose minimum requirements for controlling risks to human health. Therefore, MSC agrees with ECHA's response that these Directives appear not to be a sufficient basis for exempting uses of the borate substances from authorisation in accordance with Article 58(2) of REACH.

An exemption was specifically requested for the use of borates in the manufacture of boron containing hydro-treating catalysts. Specifically for boric acid, it was indicated in the comments received that the manufacturing process is a continuous one and that during the calcination step, boric acid is fully transformed into diboron trioxide. Hence, it is claimed that the use of boric acid in the manufacture of these catalysts is an intermediate one and so should be exempt.

An exemption was also requested for the use of boric acid and disodium tetraborate in the formulation of buffering solutions for the production of contact lenses. The function of the substance contained in a buffer solution is to provide a medium allowing the lenses to be maintained in a sterile environment prior to use and this packaging environment is critical to the correct and safe functioning of the device and is required under the Medical Devices Directive. The basis of this exemption request is that the provisions of the exemptions of Article 60(2) should also include the incorporation of a substance during the manufacturing process where the final product falls within the scope of the Medical Devices Directive. *MSC takes note of the exemption allowed for under Article 60(2) for medical devices and elaborated on in recital 18 of Commission Regulation 143/2011 amending Annex XIV for the first time. MSC also notes that this exemption is also applicable when the substance is used in uses upstream preceding the end-use, in accordance with Q&A number 1029 published on the ECHA website. The information provided in that Q&A may be taken into consideration by this industry sector when deciding if their use meets the requirement of the exemption.*

Exemptions for specific uses in the aerospace and defence areas were also requested. It was indicated in comments received from these sectors that borates are irreplaceable in corrosion protection systems and the aerospace industry is already (and will still be in the coming years) putting a huge amount of effort into the substitution of chromates and it will be vastly more difficult to substitute, at the same time, other substances involved in the same systems. Boric acid is used in many metal finishing solutions at low concentrations. Boric acid is also a critical chemical ingredient to many non-electroplating processes used within the aerospace industry.

Many comments were received requesting an exemption for the use of the borate substances in fertilisers, where they function as an essential micro-nutrient. Boron is seen as an essential micro-nutrient for normal plant growth and is one of seven essential micronutrients for plants according to the EU fertilisers Regulation (2003/2003/EC). There are no alternatives to Boron in order to secure both high yields and quality of agricultural products. It was claimed in comments received that omitting this nutrient from the fertilisers' formulas would have very negative consequences over different aspects such as on crops' health, economically both to farmers and consumers, environmental pollution (as higher quantity of agrochemicals will be used) and on

nutritional security as it has been demonstrated that borates decompose quickly, having a very low risk of getting into the food chain. Requests were also received for an exemption for use in the fermentation process where borates are used as a trace element, and also in the production of dehydrated culture media. In these industries, studies have shown that the borate substances cannot be substituted with other substances due to the biological essentiality of boron.

While MSC recognises the essential use of borates in fertilisers, it is in agreement with ECHA's response on this issue whereby ECHA responded to indicate that there is not a sufficient basis for this exemption. However, it should be noted that the Commission is in the process of establishing a streamlined/simplified authorisation process for a number of scenarios and uses, including the scenario where an Annex XIV substance is used as a source of a biologically essential element. Not withstanding this, MSC is of the opinion that the Commission, at a future stage of the authorisation process, could give consideration to how to address the use of borates in fertilisers.

There were many requests for exemptions for the use of borates in nuclear power plants. In these comments, it was indicated that the natural boron isotope is essential for safety reasons. Boric acid provides the B10 isotope which captures neutrons, thus allowing the nuclear plants to control/terminate nuclear reactions. To date, no other chemical has demonstrated the same characteristics as boric acid such that it could safely substitute boric acid for these applications. It was also indicated in the comments that the nuclear power industry is one of the most regulated industries in the world. In particular, use of substances in power plants is controlled by EU Directive 2013/59/EURATOM, in addition to relevant national legislation in EU Member States. It was therefore proposed in some comments that the requirements of Article 58(2) are fulfilled for this use.

MSC recognises this essential and critical use of borates. However, MSC also agrees with ECHA's response to the comments and the request for an exemption under Article 58(2). In the response to the comments, ECHA states that Council Directives 2009/71/Euratom and 2013/59/Euratom impose minimum requirements for the control of risks from the use of radioactive substances to human health. ECHA's response indicates that as it seems that the Directives do not impose minimum requirements for the control of risks to human health and/or the environment for the use of non-radioactive substances in nuclear power plants, it would appear that these Directives are not a sufficient basis for granting an exemption under Article 58(2) of REACH. MSC is in agreement with ECHA's response on this and so is also of the opinion that there is not a sufficient basis for granting the exemption under Article 58(2). However, MSC is of the opinion that the Commission, at a future stage of the authorisation process, could give consideration to how to address the use of borates in nuclear power plants.

It was indicated in some comments received that boric acid and disodium tetraborate serve an important role in radiation protection by enabling production of Positron Emission Tomography (PET) radio isotopes. Boron is used for its efficiency in neutron shielding, capture and attenuation, and providing radiation protection for workers and environment. There are currently no known technically viable alternatives to the use of these substances for the neutron capture in the shielding required for radiation protection in the application of a cyclotron. There was a request for an exemption for this use in order to avoid a serious disruption to the global healthcare diagnostics development and availability and compromise radiation protection measures.

Some pharmaceutical companies expressed their concern that due to REACH authorisation requirements, their suppliers may discontinue the manufacture of boric acid, despite the fact that due to current exemptions, the pharmaceutical industry can continue to use boric acid in their manufacturing processes as well as in their laboratories for scientific research & development.

They requested that the list of exempt uses be broadened to ensure that the supply of the substance will not be restricted across the EU. *In relation to this, MSC notes in accordance with Q&As numbers 1027, 1029, and 1030 published on ECHA website, that uses of substances in upstream steps preceding the exempted end-use in medicinal products, medical devices and in scientific research and development, respectively, are also covered by the exemption (but limited to the volumes ending up in the exempted end-use for medicinal products and for upstream SR&D uses, those uses must be under strictly controlled conditions and in a volume less than 1 tonne per annum)*.

There was a request for an unlimited exemption from the automotive industry in order to allow them to be able to continue to supply past model service parts**.** Reasons for the exemption included the fact that there are legal type approval requirements and a minimum 10 year warranty obligation must be fulfilled, stockpiling of past model service parts has only limited possibility, and substitution of substances can cause changes in function, geometry, thermal durability and may have an unexpected impact on other related parts. The automotive industry association proposed adding to REACH Annex XIV a 'repair-as-produced' clause for each substance listed such as: "Substances for past model service parts that are manufactured after the sunset date, which are used for vehicles that ceased production before the sunset date shall be exempted from the provisions of Article 56, REACH".

While MSC agrees with ECHA's response to this comment in that there is not a sufficient basis for this exemption, it should be noted that, as indicated already above, the Commission is in the process of establishing a streamlined/simplified authorisation process for a number of scenarios, including the production of legacy spare parts. It is the intention of the Commission to adopt an implementing act for the simplification of the authorisation process for this use.

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 PPORD exemptions 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)

A number of issues, mostly from a socio-economic point of view, were raised during the public consultation. While these points are not considered at this stage of the process, they are nonetheless briefly outlined in this section, for information.

Some companies indicated the socio-economic importance of borates, the economic risks incurred by their elimination and mentioned that if borates are put in Annex XIV, these highly specialised companies will be shut down within the next few years. It was indicated that several big chemical industry companies will move out of the EU and thousands of employees will lose their jobs.

Despite the fact that the REACH Regulation does not apply if a substance is used in food, feed-products and Active Pharma Ingredients (API's) within the scope of a number of regulations, it was argued that the burden to get authorisation for the use of borates and the uncertainty of supply of this essential trace element would have impacts on these sectors such as relocation of production outside the EU:

A significant number of companies and trade organisations indicated that they believed authorisation is not the most effective risk management option (RMO) for borates, and requested that an RMO analysis be carried out before proceeding further. As an alternative to authorisation some companies suggested to add boric acid to Annex XVII. In addition, it was indicated in some comments that since the Commission has stalled proceeding with the 5th recommendation, the logic of progressing the 6th recommendation at this stage could be questioned.

2.3 Coal stream substances (Anthracene oil; Pitch, coal tar, high temperature)

Justification for prioritisation

Anthracene oil and Coal tar pitch, high temperature (CTPHT) were identified as SVHC according to Article 57 a), d) and e) as these are classified in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as Carcinogenic, Category 1B, H350 ("May cause cancer"). This classification does not apply for Anthracene oil if it can be shown that substance contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5). In addition, on the basis of the PBT and vPvB properties of some of PAH-constituents, Anthracene oil and CTPHT fulfil the PBT and the vPvB criteria according to Article 57 d and e of the REACH Regulation. Substances were included in the candidate list for authorisation on 13 January 2010 following ECHA`s decision ED/68/2009.

Based on registration information, CTPHT is manufactured and imported into the EU in the range of 1 000 000 – 10 000 000 tonnes per annum. According to registration information the amount of anthracene oil is above 100 000 tonnes per annum. Some uses of both substances appear not to be in the scope of authorisation, such as uses as intermediate. ECHA has estimated the volumes in the scope of authorisation in EU to be greater than 10 000 tonnes per annum for both substances.

According to registration information assessed by ECHA during prioritisation process before public consultation, registered uses of CTPHT in the scope of authorisation include uses at industrial sites as binding agent in the manufacture of electrodes/anodes in metal industry and in refractories. In addition, registered uses in the scope of authorisation include uses by industrial and professional workers as binding agent in clay pigeons and as anti-corrosion agent in coatings, paints and adhesives. Furthermore, the substance is used in articles (e.g. clay pigeons, metal articles, articles related to the use in paints and adhesives) in volumes greater than 10 tonnes per annum.

Registered uses of anthracene oil in the scope of authorisation that were assessed by ECHA during prioritisation process before public consultation include uses at industrial sites in the carbon and graphite industry (e.g. production of electrodes), in the metallurgic smelting, in the aluminium and electro steel industry, for refractories, coatings, paints, waterproofing materials and sealants. The substance is used as absorbent for industrial gas cleaning (scrubber) and as industrial solvent. Registered uses in the scope of authorisation by professional workers include uses in coatings, paints, waterproofing materials and sealants. Furthermore, the substance is

used in articles (such as component in tar paints for special application (e.g. underwater corrosion protection) and component of waterproof membranes for roofing and other sealing purposes) in volumes > 10 t/y.

According to registration information, anthracene oil is used in same applications in a similar manner as CTPHT and substances could potentially replace each other in some of their uses.

Based on this information, Anthracene oil and Coal tar pitch, high temperature (CTPHT) meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, one MSCA supported the prioritisation of CTPHT and anthracene oil in Annex XIV. One MSCA agreed that CTPHT appears to meet the prioritisation criteria but expressed concern as to whether authorisation is the most appropriate risk management measure. One insurance company expressed support for the prioritisation of anthracene oil.

Comments on the prioritisation were received from industry associations and individual companies. In addition, comments on CTPHT were received from local and regional authorities from one Member State.

Comments on anthracene oil covered such uses: use in manufacture of carbon black and other substances, production of refractory products, use in solvents, use in corrosion protection. Comments on CTPHT covered such uses: manufacture of carbon black and other substances, production of electrodes used to melt ore/metal in metal industry (e.g. production of aluminium, ferrochromium and steel), production of electrodes used in calcium carbide production, use in refractory products (e.g. furnace wall mass materials such as bricks, pastes and linings), use in clay pigeon, use in repair of airport runways, and in corrosion protection. In addition, comments were received on CTPHT from EU automotive industry concerning use of aluminium in vehicle manufacturing.

Comment was received from one industry association (Cefic`s Coal Chemicals Sector Group) claiming that the production volume of CTPHT in the EU is much lower (830 000 tonnes per annum) than reported in the ECHA`s draft background document. According to their view the total volumes in the registrations are misleading because of multiple reporting of volumes for the same use by different actors (suppliers and downstream users). In addition, industry association claims that the majority of the uses of CTPHT and anthracene oil are intermediate uses and should be excluded from the authorisation. In their view, the volumes in the scope of authorisation are 17 000 and 6 000 tonnes per annum for CTPHT and anthracene oil respectively. ECHA has estimated the volumes in the scope of authorisation in EU to be greater than 10 000 tonnes per annum for both substances.

According to industry association approximately 76 % of the total volume of anthracene oil is used as an intermediate to manufacture of another substance i.e. carbon black and pitch coke. Thus the only non-intermediate uses of anthracene in the scope of authorisation are uses as an industrial solvent and use in corrosion protection.

According to industry association use of CTPHT in the manufacture of other substances (e.g carbon black), pastes (collar, ramming and tap hole paste), electrodes and refractory product are

intermediate uses. Only non-intermediate uses of CTPHT in the scope of authorisation are uses in clay pigeon, repair of airport runways and corrosion protection.

According to industry association in several uses either first or second downstream user of CTPHT and anthracene oil transforms substance into another substance. It is estimated that approximately 89 % of the total volume of CTPHT in the EU is used as an intermediate for the synthesis of pitch coke. For instance in production of specific type of electrodes CTPHT is acting as a binder and mixed with solids, shaped and carbonised (pyrolysed) to form pitch coke and there is no CTPHT present in baked electrodes (e.g. anodes used in aluminium industry). Pitch coke conducts electricity and is important for the electrolysis process in metal smelters.

One industry association representing calcium carbide manufacturers expressed concerns about the appropriateness of the score for volume and wide dispersive use for CTPHT. According to their view the score for wide dispersiveness of uses should be lower because 87 % of CTPHT is used industrially (i.e. as binding agent in electrodes) and fraction from total use by professionals and in articles is small. It was proposed to select an intermediate score 7 instead of 10 for the combined industrial and professional use which would lead to a total prioritisation score of 37.

One company questioned the harmonised classification of CTPHT as genotoxic at the concentrations levels used in their stainless steel production. They referred to health surveys made for workers in stainless steel production indicating no genotoxic effects in nasal cells attributable to occupational chromium exposure. The company also referred to surveys done of health effects of exposure to compounds used in their ferrochromium production and stainless steel production. According to their view surveys do not indicate detectable adverse respiratory changes or increased risk of cancer to individuals working in the steel mills and the ferrochromium plant.

With regards to the volumes in the scope of authorisation, MSC notes ECHA`s point in the RCOM that there are discrepancies between the information provided in the public consultation and registrations. It was indicated in the public consultation that the volume of anthracene oil in the scope of authorisation is lower than 10 000 tonnes per annum (6 000 tonnes per annum) and the only uses in the scope of authorisation are uses as an industrial solvent and in corrosion protection. MSC notes ECHA`s response in the RCOM that based on information reported by the lead registrant in a recent registration dossier (last update in April 2014) the volume of anthracene oil in these uses as being in the scope of authorisation is above 10 000 tonnes per annum. MSC agrees with ECHA`s view that having the correct volumes and uses reported in the registrations is the responsibility of the registrants. Based on provided information ECHA`s current assumption is that the difference between the two estimations is due to the use in refractories (in or out of the scope of authorisation). Based on available information ECHA considers the use in refractories as non-intermediate use. Therefore the volume score remains 15. Even if it was justified to change the volume score from 15 to 12-15, the substance would remain of high priority for inclusion on Annex XIV. Therefore, MSC agrees in line with ECHA`s response that this information is not sufficient to justify challenging the high priority of anthracene oil for inclusion on Annex XIV.

With regards to the intermediate uses, MSC supports ECHA's view in the RCOM that the assessment of the relevant volumes eligible for eventual authorisation is done only for prioritisation purposes and it is not taking a formal position whether certain uses are regarded as intermediates in accordance with definition of intermediate according to Article 3(15) of REACH. In the end, it is the responsibility of individual companies to assess whether their uses of the

substance are in the scope of authorisation and there is a need to submit applications for authorisation.

The MSC agrees with ECHA`s response in the RCOM that based on new information provided during the public consultation some uses of CTPHT and anthracene oil in the production of electrodes may fulfil the definition of intermediate according to Article 3(15) of REACH. However, based on the available information the substances will have high priority for inclusion on Annex XIV even if some uses in the production of electrodes are considered to be outside of the scope of authorisation.

With regards to the score for wide dispersive use assigned by ECHA for CTPHT, MSC confirms that it is line with ECHA`s prioritisation approach, which has been endorsed by the MSC.

With regards to the comments challenging the intrinsic properties and indicating a low level of risk associated to a particular use, MSC agrees with ECHA`s responses in the RCOM that these comments are not relevant in the prioritisation phase. The identification of substances as SVHC based on their intrinsic properties has already taken place and has been agreed by the MSC. The information on the low levels of risk associated with a particular use should be provided as part of an application for authorisation and will be taken into account by the RAC and SEAC when forming their opinions and by the Commission when taking the final decision.

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

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for CTPHT and antrachene oil

(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 one MSCA supported the proposed latest application dates for CTPHT and anthracene oil. Comments were received from industry indicating the need of longer transitional periods because of the complexity of the supply chain (many uses, sectors and players) and challenges in communication through the supply chain. It was anticipated that preparation of authorisation applications will need more time than proposed. One company from aluminium industry, aluminium industry association, and consortium of CaC_2 -manufacturers proposed a latest application date of 24 months.

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 Annex XIV inclusion.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation. During the public consultation one MSCA indicated that they do not support any exemptions from authorisation. Several companies and a number of regional and local authorities and industry associations, asked for removal of CTPHT from the final proposal or, alternatively, requested to exempt its use in the metal and electrode production due to lack of proper alternatives, low occupational and environmental exposures, existing national OELs for workers protection and EU environmental protection standards (*Chemicals Agent Directive 98/24/EC (CAD), Carcinogens or mutagens at work Directive 2004/37/EC (CMD), Directive 2010/75/EU (IED), Council Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, Water Framework Directive 2000/60/EC (WFD) (and its daughter Directives 2006/118/EC, 2008/105/EC and 2013/39/EU), Council Directive 98/83/EC on the quality of water intended for human consumption, Waste Framework Directive (2008/98/EC), CLP Regulation and REACH Regulation*).

MSC agrees with ECHA's response to comments received regarding uses being controlled under existing chemical legislation. MSC is also of the opinion that in order to avail of 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 also agrees with ECHA's point 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 considers that the above mentioned Directives do not impose minimum requirements for controlling risks to human health. Therefore, these Directives appear not to be a sufficient basis for exempting uses of the coal stream substances from authorisation in accordance with Article 58(2) of REACH.

One industry association requested to set general exemption in Annex XIV for the supply of past model service parts of vehicles based on the potentially long service life of these vehicles and the need to ensure that their safety is not compromised and the legal type approval requirements are fulfilled.

While the MSC is of the opinion that there is not a sufficient basis for this exemption, it should be noted, that the Commission is in the process of establishing a streamlined/simplified authorisation process for a number of scenarios, including the production of legacy spare parts. It is the intention of the Commission to adopt an implementing act for the simplification of the authorisation process for this use.

It was also indicated in one comment that some uses are generally exempted from the authorisation, i.e. use of anthracene oil and CTPHT as fuel (Art 56(4)(d)) or use of anthracene oil for the manufacture of biocidal creosote (Art. 56(4)(b)).

MSC agrees with ECHA's view that it is the responsibility of the companies to assess whether any of their uses complies with the requirements relevant for each of the exempted uses. The

exemption in accordance with Article 56(4)(b) appears not to apply to anthracene oil in biocidal products since the substance is not approved as an active substance under the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) and based on the description of use appears to be incorporated into the final product.

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 PPORD exemptions were received during the public consultation.

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

Other issues

During the public consultation, comments were received challenging whether authorisation is the most appropriate risk management measure. One industry association proposed to use restriction as an alternative measure to maintain use as binder in electrodes. It was also proposed to establish a community wide occupational exposure limit value (OEL) for CTPHT as an alternative measure. It was pointed out in several comments that national and EU legislation (e.g. occupational worker protection legislation) is already in place to minimise the exposure of workers and the environment. Several industry associations, companies and one MSCA indicated that, at present, there are no alternatives or replacement possibilities for CTPHT in different uses. It was also pointed out that CTPHT is essential to industry to ensure a safe work environment in processes with high temperature. In several comments it was indicated that authorisation (= ban) will have negative socioeconomic impacts in Member States and in the EU. These arguments were used to justify the removal of the substance from the final proposal or exempt use (i.e. in metal and electrode production) from authorisation.

2.4 4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]

Justification for prioritisation

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

According to registration information, the amount of 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO) manufactured and/or imported into the EU is in the range of 1 000 – 10 000 tonnes per annum. However, some of the commercially available ethoxylates of 4-nonylphenol are expected to fulfil the REACH definition of polymers and therefore are exempted from registration. Based on indications about the fraction of 4-Nonylphenol used to manufacture its ethoxylates (in registrations of 4-Nonylphenol) and the estimated average contribution to the molecular weight of its ethoxylates, a further volume of ethoxylates manufactured in the EU is roughly estimated to be in the range of 10 000 – 50 000 tonnes per annum. Finally, import of 4-NPnEO cannot be excluded. All tonnage appears to be in the scope of authorisation, apart from (minor) uses in Scientific Research and Development (RCOM, 2013). Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 10 000 – 50 000 tonnes per annum.

Based on registration information (for 4-NP and for 4-NPnEOs) and information from the Annex XV report (2013) uses of 4-NPnEO in the scope of authorisation include uses at industrial sites (e.g., formulation and use as floating agent in mining applications; formulation and use of paints; emulsion polymerisation; and potentially as reducing agent in surface treatment), and professional and consumer uses of products such as paints containing NPnEO. Furthermore, the substances are used in articles (e.g. containing paints).

Based on this information, the 4-NPnEO meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

Eight comments on priority setting were received during the public consultation. Two Member State authorities supported the prioritisation of 4-NPnEO, while four industry organisations did not support the prioritisation.

The difficulties in correctly identifying 4-NPnEO due to the lack of specific CAS numbers were raised by one Member State authority and one industry organisation in the public consultation, in particular the industry organisation argues that it is not in a position to identify whether any of their products contains 4-NnPEO due to this deficit. It is suggested that ECHA provides additional guidance to duty-holders to clarify the chemical identity of the substance.

Two industry organisations argued that as the degradation product, NP, has a weak estrogenic activity which occurs at concentration levels similar to those affecting growth and survival (i.e. long-term toxicity) in aquatic species and as a threshold can be determined for endocrine-related effects, the prioritisation score assigned for the inherent properties is overstated.

According to some industry respondents, the tonnage of 4-NPnEO used within the EU is less than 20 000 tonnes per annum and is projected to decline due to existing and proposed restrictions. Furthermore, respondents suggest that although 4-NPnEO is used in paints by both professional and consumer users, such uses are only minimally dispersive as emissions to the environment mainly arise from clean-up activities, while the majority of the volume remains in cured paint. Moreover, the remaining uses in the EU are primarily industrial uses, which should be controlled by occupational exposure limits and emission control. Therefore, the wide dispersiveness score assigned is overstating the dispersiveness of the uses.

Additionally, industry respondents suggest that as some uses of 4-NPnEO are already restricted in the EU, it is doubtful whether the requirement for authorisation will bring additional value in protecting the environment.

Finally, some of the industry organisations are referring to results of environmental monitoring in surface waters conducted under the Water Framework Directive (WFD) under which 4-NPnEO are priority hazardous substances. The monitoring results show that the majority of EU waters contain the degradation product, NP, in concentrations lower than the Environmental Quality Standard established under the WFD and it is suggested that the remaining environmental exposure is due to washing of imported textiles containing the substance, which will be addressed by the restriction proposal currently addressed by the ECHA committees. Based on the above considerations, industry respondents argue that the priority scores should be reduced and that 4-NPEO should not be prioritised for inclusion in Annex XIV.

MSC notes that although the availability of a CAS Registry Number is a helpful instrument for identification of a substance, not all substances have been assigned such a number. Furthermore, substance identification aspects were considered and decided on when 4-NPEO was included in the Candidate List. In any case, it is the obligation of users of chemicals to be aware of the substance identity. Thus, MSC concurs with ECHA's response to the comments on the substance ID issue.

With regards to the priority score assigned by ECHA due to the inherent hazard properties, the MSC confirms that it is in line with the approach described in the ECHA prioritisation document, which has been endorsed by MSC. MSC also notes the confirmation of the tonnage of 4-NPnEO used within the scope of authorisation and that it is confirmed that 4-NPnEO is used in paints used by both professionals and consumers thus confirming the tonnage and wide dispersiveness scores assigned by ECHA.

MSC notes that the responses to comments provided by ECHA are in line with the above views of MSC.

Based on the above considerations, MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of 4-NPEO.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for 4-NPEO:

(i) Latest application date: Date of inclusion in Annex XIV plus 24 months
(ii) Sunset date: Latest application date plus 18 months

Comments on transitional arrangements were received from one Member State authority and five companies and industry organisations.

The Member State authority was in favour of a latest application date being set as soon as possible. One company suggested that due to the complexity of the supply chain and difficulties in identifying technically viable alternatives to 4-NnPEO, the deadline for application should be postponed until 48 months after the date of inclusion in Annex XIV.

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. Moreover, the Commission has postponed proposing more substances for Annex XIV, so it may be assumed that the deadlines and sunset dates will in any case be postponed relative to ECHA's recommendation of the latest application date being set for 24 months after inclusion in Annex XIV. Considering that industry now being aware of ECHA's recommendation will have plenty of time to prepare for applying for authorisation, there is no need to propose any changes to the deadline and sunset date.

Therefore, 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 period was suggested by ECHA in its draft recommendation.

One respondent proposed that the use as an emulsifier used in manufacture of active pharmaceutical ingredients should be exempted from authorisation or, if this is not possible, a review period of at least 12 years should be introduced for this specific use.

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 Annex XIV inclusion.

Proposed exempted (categories of) uses

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

Stakeholders from the car industry raised the issue of legacy spare parts, as production of such spare parts is necessary in order to continue supplying past models with service parts, and requested an unlimited exemption. Another stakeholder from the healthcare industry requested an exemption for the use as an emulsifier used in manufacture of active pharmaceutical ingredients, as there are no technically viable alternatives available. Finally, a stakeholder suggested that necessary upstream processes like packaging/refilling and formulation of analytical reagents intended for scientific research and development should be exempted from authorisation.

MSC notes that the lack of a technically viable alternative is not a reason for exempting a certain use from authorisation. MSC is aware of the ongoing discussion among the REACH Competent Authorities, the Commission and stakeholders on legacy spare parts. The Commission is in the process of establishing a streamlined/simplified authorisation process for a number of scenarios, including the production of legacy spare parts.

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

Other issues

No other issues were raised during public consultation.

2.5 1-Bromopropane (n-propyl bromide)

Justification for prioritisation

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

The amount of 1-bromopropane (n-propyl bromide) manufactured and/or imported into the EU is according to registration data above 1 000 tonnes per annum. The registered use as an intermediate in manufacture of chemicals appears not to be in the scope of authorisation. Furthermore, according to information from the industry (RCOM, 2012), the substance may also be used in some laboratory analyses but this use seems to fall outside the scope of authorisation due to the generic exemption on scientific development and research. Taking into account the volume corresponding to these uses – up to 69 % of the total EU volume based on information from the industry (RCOM, 2012) - the volume in the scope of authorisation is estimated to be in the range of 1 000 - <10 000 tonnes per annum.

Registered uses of 1-bromopropane (n-propyl bromide) in the scope of authorisation include uses at industrial sites (formulation and use as a solvent in mixtures for vapour degreasing and surface cleaning) and by professional workers (use as a solvent in mixtures for vapour degreasing and surface cleaning). Based on information from the industry received during the SVHC public consultation (RCOM, 2012), 1-bromopropane may be used to substitute trichloroethylene (already on Annex XIV) in vapour degreasing.

Based on this information, the 1-Bromopropane meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

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

The Member State authority supported the prioritisation of bromopropane for inclusion in Annex XIV.

In the comments received during the public consultation, the volume of bromopropane used within scope of authorisation estimated by ECHA (within the range 1 000 – 10 000 tonnes per

annum) was questioned by several stakeholders. The industry claims that the most of the tonnage is used as intermediate under strictly controlled conditions. One company suggested that the information in the REACH registration dossier is erroneous or incomplete and that only a tonnage of 300 – 500 tonnes per annum is used within the scope of authorisation.

Divergent information on the use of bromopropane was submitted by industry, with some claiming that the substance is only used for degreasing in closed systems, while others inform that it is widely used for degreasing of metals as replacement for chlorinated solvents. Furthermore, some stakeholders suggest that the use of bromopropane is limited to industrial use, while others claim that the bromopropane industry is highly fragmented and comprises many SMEs with limited resources and know-how.

All stakeholders confirm that bromopropane is not used by consumers.

In its response to the comments received, ECHA notes that information on the volume used within the scope of authorisation is different when extracted from the registration dossiers than that submitted in the public consultation. ECHA considers that the information submitted in the public consultation is not sufficient to disregard the registration information on the volumes. Having the correct volumes reported in the registrations is responsibility of the registrants. Therefore the volume score is maintained as 12. Regarding the wide-dispersiveness of uses (WDU), ECHA considers that the main use of bromopropane takes place at industrial sites. There are indications in the registrations that professional use of the substance may also occur but it is difficult to conclude it from the available information with high certainty. It is acknowledged that the differentiation between IND and PROF actors is not always straightforward but rather results of a weight of evidence assessment. Considering the uncertainties in the registration information and the comments submitted in this public consultation claiming that the substance is only used at industrial sites, ECHA suggests assigning a WDU score of 7 instead of 10. The new priority score assigned to bromopropane is: 20 (old score was 23).

MSC considers that the main information source to be used for the priority setting is the REACH registration dossiers and that it is up to the registrants to ensure that the information is correct and adequate also for this purpose. If additional information should be considered, such information has to be well documented. The information provided by the stakeholders seems to indicate that a larger fraction of the tonnage than identified by ECHA is used as intermediate, i.e. outside the scope of authorisation. However, this is not reflected in the registration dossiers despite recent updates and MSC considers that the tonnage used within the scope of authorisation is greater than 1000 tonnes per annum, which is not challenging ECHA's original priority score.

Therefore, MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of bromopropane for inclusion in Annex XIV.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for 4-NPEO:

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

Comments on transitional arrangements were received from one Member State authority and three companies and one individual.

The Member State authority was in favour of a latest application date being set as soon as possible. One respondent proposed to postpone the application date until 2019 and the sunset date until 2024 in order to allow the identification of a proper substitute, while another respondent proposed to postpone the application date until 24 months after inclusion in Annex XIV.

MSC notes that the availability of a substitute is not a precondition for applying for authorisation and, thus, should not have a bearing on the deadline for application and the sunset date. Moreover, the Commission has postponed proposing more substances for Annex XIV, so it may be assumed that the deadlines and sunset dates will in any case be postponed relative to ECHA's recommendation of the latest application date being set for 18 months after inclusion in Annex XIV. Considering that industry now being aware of ECHA's recommendation will have plenty of time to prepare for applying for authorisation, there is no need to propose any changes to the deadline and sunset date.

Therefore, 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 period was suggested by ECHA in its draft recommendation.
No comments were received.
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 Annex XIV inclusion.

Proposed exempted (categories of) uses

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

One stakeholder suggested that due to the extremely low DNEL set for bromopropane, the only way to control risks is to prescribe in the Exposure Scenario that the use is restricted to sealed and closed systems only. Therefore, the respondent considers it disproportionate and unjustified to include the substance in Annex XIV. Another stakeholder suggests that as industrial vapour degreasing is already properly controlled by EU legislation on workers protection, this use should be exempted from authorisation.

MSC notes that complying with the operational conditions and risk management measures specified in Exposure Scenarios is mandatory for all substances and, therefore, the availability of an Exposure Scenario for a specific use is not an argument for exempting this use from the authorisation.

MSC is also of the opinion that in order to avail of 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 also agrees with ECHA's point 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.

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 comments were received.

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

Other issues

No other issues were raised during public consultation.

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

Justification for prioritisation

1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP); 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Bis(2-methoxyethyl) phthalate (DMEP); Diisopentylphthalate (DIPP); Dipentyl phthalate (DPP); N-Pentyl-isopentyl phthalate 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, H360-FD ("May damage fertility" and "May damage the unborn child"). 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) were included in the Candidate List for authorisation on 20 June 2011 following ECHA's decision ED/31/2011. 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Diisopentylphthalate (DIPP) were included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012. Dipentyl phthalate (DPP); N-Pentyl-isopentyl phthalate 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich were included in the Candidate List for authorisation on 20 June 2013, following ECHA's decision ED/69/2013. Bis(2-methoxyethyl) phthalate (DMEP) was included in the Candidate List for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

All these 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. plasticisers in plastic material, use in paints, lacquers, varnishes, adhesives, printer inks, film coatings).

There are no registrations for 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP); 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Bis(2-methoxyethyl) phthalate (DMEP); Dipentyl phthalate (DPP); N-Pentyl-isopentyl phthalate under Regulation (EC) No 1907/2006 (REACH).

According to registration data Diisopentylphthalate is used in the scope of authorisation at industrial sites (use in the production of propellants and explosives and to coat them to regulate the rate of burn). Use of DIPP by consumers to coat the propellant and regulate the rate of burn is also reported but is expected to be limited to applications where the concentration is below the concentration limit specified in the generic restriction on the use of CMRs by the general public. Therefore, the use appears to be outside the scope of authorisation. The use reported as consumer use might however also apply to professionals (Annex XV report, 2012). The tonnage for that use is expected to be very low. Furthermore, according to the Annex XV report propellants containing DIPP are used in articles (ammunition).

DIPP has been registered for its specific use in the production of propellants and their coating to regulate the rate of burn. Propellants containing DIPP may be further used by producers of ammunition or used directly by professional users to manually reload empty cartridges. The reloading of cartridges may be done at many different sites (Annex XV report, 2012). The propellants are used for the production of ammunition which is mostly for military uses; however a part is also used for civil applications.

It can be assumed that the supply chain of DIPP within EU consists of a low number of industrial users and potentially a high number of professional users (mixtures and articles) and consumers (articles).

Based on this information, these substances 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP); 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Bis(2-methoxyethyl) phthalate (DMEP); Diisopentylphthalate (DIPP); Dipentyl phthalate (DPP); N-Pentyl-isopentyl phthalate meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, none of the MSCAs opposed the prioritisation 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP); 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Bis(2-methoxyethyl) phthalate (DMEP); Diisopentylphthalate (DIPP); Dipentyl phthalate (DPP); N-Pentyl-isopentyl phthalate for inclusion in Annex XIV.

One MSCA supported prioritisation of these 7 substances for inclusion in Annex XIV on the basis of grouping considerations (grouping with phthalates already on Annex XIV).

Another MSCA recommended to include 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP); 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Bis(2-methoxyethyl) phthalate (DMEP); Dipentyl phthalate (DPP); N-Pentyl-isopentyl phthalate in Annex XIV because it is possible that these substances could be registered (only Diisopentylphthalate (DIPP) is registered at this time) at a later date, e.g. as a substitute for phthalates which are already included in Annex XIV.

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, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP); 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Bis(2-methoxyethyl) phthalate (DMEP); Diisopentylphthalate (DIPP); Dipentyl phthalate (DPP); N-Pentyl-isopentyl phthalate.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for 7 phthalate substances (*Diisopentylphthalate; 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters; 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; Bis(2-methoxyethyl) phthalate; N-pentyl-isopentylphthalate; Dipentyl phthalate)*:

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

One Member State was in favour of the shortest LAD slot.

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 review period was suggested during 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 Annex XIV inclusion.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation.
During public consultation one Member State supported ECHA's recommendation not to allow any exemption.

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.
There were no requests for PPORD exemption submitted 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.

Submitted for public consultation

Draft 6th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation
(List of Substances Subject to Authorisation)

Draft Annex XIV entries									
#	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii)****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
1	Anthracene oil	292-602-7	90640-80-5	Carcinogenic (category 1B)[1)], PBT, vPvB	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
2	Pitch, coal tar, high temp.	266-028-2	65996-93-2	Carcinogenic (category 1B), PBT, vPvB	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
3	1-bromopropane (n-propyl bromide)	203-445-0	106-94-5	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
4	Diisopentylphthalate	210-088-4	605-50-5	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
5	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
6	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear	271-084-6	68515-42-4	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None

Draft Annex XIV entries									
#	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii)****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
	alkyl esters								
7	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	84777-06-0	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
8	Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
9	Dipentyl phthalate (DPP)	205-017-9	131-18-0	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
10	N-pentyl-isopentylphthalate	-	776297-69-9	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months [2)]	Latest application date plus 18 months	None	None	None
11	Orange lead (lead tetroxide)	215-235-6	1314-41-6	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 21 months [3)]	Latest application date plus 18 months	None	None	None
12	Lead monoxide (lead oxide)	215-267-0	1317-36-8	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 21 months [3)]	Latest application date plus 18 months	None	None	None
13	Tetralead trioxide sulphate	235-380-9	12202-17-4	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 21 months [3)]	Latest application date plus 18 months	None	None	None
14	Pentalead tetraoxide sulphate	235-067-7	12065-90-6	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 21 months [3)]	Latest application date plus 18 months	None	None	None
15	Silicic acid, lead salt	234-363-3	11120-22-2	Toxic for	Date of inclusion in	Latest	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**
				Reproduction (category 1A)	Annex XIV plus 21 months [3)]	application date plus 18 months			
16	Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 21 months [3)]	Latest application date plus 18 months	None	None	None
17	Acetic acid, lead salt, basic	257-175-3	51404-69-4	Toxic for Reproduction (category 1A)	Date of inclusion in Annex XIV plus 21 months [3)]	Latest application date plus 18 months	None	None	None
18	4-Nonylphenol, branched and linear, ethoxylated *[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]*	-	-	Equivalent level of concern having probable serious effects to the environment (Article 57 f)	Date of inclusion in Annex XIV plus 24 months [4)]	Latest application date plus 18 months	None	None	None
19	Boric acid	233-139-2, 234-343-4	10043-35-3, 11113-50-1	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 24 months [4)]	Latest application date plus 18 months	None	None	None

Draft Annex XIV entries									
#	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii)****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
20	Disodium tetraborate, anhydrous	215-540-4	1330-43-4, 12179-04-3, 1303-96-4	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 24 months [4)]	Latest application date plus 18 months	None	None	None
21	Diboron trioxide	215-125-8	1303-86-2	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 24 months [4)]	Latest application date plus 18 months	None	None	None
22	Tetraboron disodium heptaoxide, hydrate	235-541-3	12267-73-1	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 24 months [4)]	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 was based on the following considerations (see also "General approach for the preparation of draft Annex XIV entries"):

- *LAD slots*: set in 3 months intervals which are set to coincide with the (last days of) the submission windows established by ECHA for applications for authorisation; see footnotes 2 to 4.
- *Substances to be placed in same slots*: Phthalate-, Lead-, Boron-, and Coal-stream-substances, as these substances may fulfil the definition of a group in section 1.5 of Annex XI of REACH (provision allowing submitting common applications for authorisation).
- *Allocation per slot:* The allocation of substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. The differences between the total time for preparing the application (i.e. 18, 21 and 24 months) can be regarded minor. However, substances for which the preparation of the application may require longer time are allocated to the later LAD slots (2nd and 3rd), i.e. 4-Nonylphenol, branched and linear, ethoxylated (due to the apparent lack of registration requirements for the members of this group entry fulfilling the polymer definition in REACH) and Lead-substances and Boron-substances (due to the potentially high number of uses and overall complexity of supply chain).

1) Does not meet the criteria for identification as a carcinogen if it contains < 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5)

2) Assuming that the Commission amendment of Annex XIV of the REACH Regulation on the basis of this sixth Recommendation would enter into force in summer 2016, the latest application date would be February 2018

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

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