ECHA/MSC-8/2009/015 - **Adopted**

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

Adopted on 20 May 2009

OPINION

This opinion of the Member State Committee on the draft recommendation of European Chemicals Agency (ECHA) for priority substances to be included in Annex XIV was adopted on 20 May 2009 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006[1].

PROCESS FOR ADOPTION OF THE OPINION

ECHA consulted the Member State Committee on 17-18 December 2008 on the preliminary draft recommendation and justification for Annex entries for priority substances to be included in Annex XIV. The Committee provided its first comments on the general approach for priority setting and principles to be applied for specification of Annex XIV entries. ECHA published its draft recommendation on 14 January 2009 on its website for public consultation.

The Member State Committee appointed a Rapporteur, for preparing its opinion on ECHA's recommendation for Annex XIV on 17-18 December 2008, and a Working Group to support the Rapporteur.

For the preparation of its opinion the Committee has been provided with the following background documents:

- ECHA's priority setting approach and its application to all substances on the candidate list

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

- ECHA's general approach for defining Annex XIV entries and its application to all prioritised substances
- Justification document for each substance summarising the available information used for priority setting and specification of items for Annex XIV entries prepared by ECHA
- Reports of ECHA's contractors for each substance (except for anthracene and bis(tributyltin)oxide)
- Comments of the interested parties provided during the public consultation period started on 14 January 2009 and closed on 14 April 2009
- Responses to comments provided by the ECHA Secretariat.

The draft opinion provided to the Committee by the Rapporteur was finalised and adopted at the meeting of the Member State Committee (MSC) on 20 May 2009. The support document for the MSC opinion is attached to this opinion (Annex I).

THE DRAFT RECOMMENDATION OF ECHA AND FOCUS OF THE OPINION

The draft recommendation for Annex XIV of the REACH Regulation specifies for priority substances:

- The identity of the substance as specified in section 2 of Annex VI
- The intrinsic property(ies) of the substance referred to in Article 57
- Transitional arrangements
    - The sunset date
    - The application date
- Review periods for certain uses, if appropriate
- Uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any

Furthermore, from the draft recommendation it is apparent that no exemptions are recommended in accordance with Article 56(3) for uses in product and process oriented research and development.

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

OPINION ON THE DRAFT RECOMMENDATION FOR

- PRIORITISATION OF SUBSTANCES

The Member State Committee supports the draft recommendation by ECHA for priority substances to be included in Annex XIV.

- ANNEX XIV ENTRIES

Substance identities

As agreed:

5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)
EC number: 201-329-4, CAS number: 81-15-2

4,4'-Diaminodiphenylmethane (MDA)
EC number: 202-974-4 CAS number: 101-77-9

Alkanes, C10-13, chloro
(Short Chain Chlorinated Paraffins - SCCPs)
EC number: 287-476-5 CAS number: 85535-84-8

Hexabromocyclododecane (and all major diastereoisomers identified, i.e. alpha-, beta- and gamma-hexabromocyclododecane) (HBCDD)
EC number: 247-148-4 and 221-695-9, CAS number: 25637-99-4 and 3194-55-6 (diastereoisomers, respectively: 134237-50-6, 134237-51-7, 134237-52-8)

Bis(2-ethylhexyl) phthalate (DEHP)
EC number: 204-211-0 CAS number: 117-81-7

Benzyl butyl phthalate (BBP)
EC number: 201-622-7 CAS number: 85-68-7

Dibutyl phthalate (DBP)
EC number: 201-557-4 CAS number: 84-74-2

Intrinsic properties

Intrinsic properties remained as agreed.

The Member State Committee supports the draft recommendation concerning possible routes of authorisation for the prioritised substances that are based on the intrinsic properties of the substances.

Transitional arrangements

The Member State Committee supports the draft recommendation for latest application dates and sunset dates.

Review periods for certain uses

The Member State Committee agrees with ECHA's position that specified review periods are not warranted already in the specification of Annex XIV entries.

Uses or categories of uses exempted from the authorisation requirement

The Member State Committee proposes to modify the draft recommendation concerning some exemptions from authorisation.

The MSC proposes not to exempt the use of DEHP, BBP, DBP and MDA in artists´ paints.

At this point in time, the MSC is not able to define its opinion on the proposal by ECHA to exempt from the authorisation requirement the placing on the market of SCCPs in mixtures in a concentration at or lower than 1% by weight for use in metalworking and in fat liquoring of leather as an opinion on this issue for SCCP would need further legal analysis.

Exemptions for the use in product and process oriented research

The Member State Committee supports the recommendation not to exempt uses in product and process oriented research.

Support document for the opinion of MSC

adopted on 20 May 2009

on ECHA's Draft Recommendation of Substances

for Inclusion in Annex XIV

(ANNEX I to the opinion of the Member State Committee on the draft recommendation of the priority substances and Annex XIV entries)

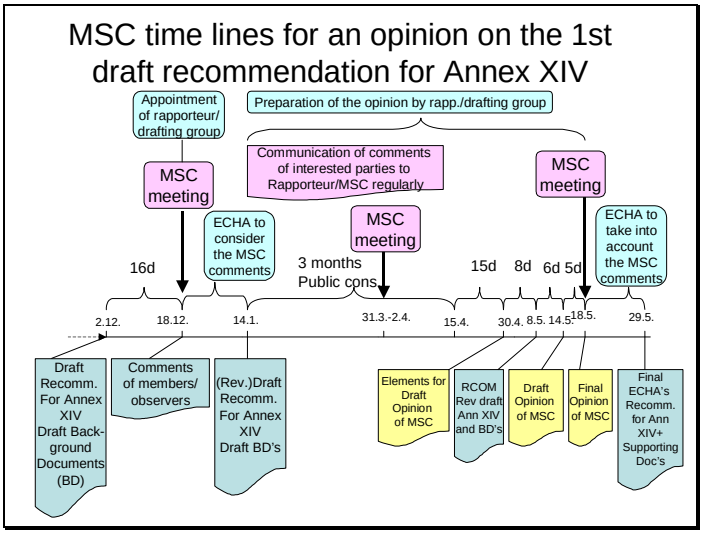
1 Content

2 Draft Recommendation of substances for inclusion in Annex XIV

2.1 Introduction

The Member State Committee (MSC) needs to provide an opinion on ECHA's draft recommendation for priority substances to be included in Annex XIV, the Annex containing substances that need authorisation. The relevant Article 58 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*".

For this first recommendation, ECHA developed the following timeline:



In the public consultation, approximately 360 comments were received on the priority substances, on the priority setting itself, and on the non-priority substances. The comments were analysed by ECHA (in their RCOM (Response to Comments (received in the public consultation)) and the Rapporteur (i.e. Rapporteur plus Working Group members) for the MSC.

2.2 MSC opinion on the draft recommendation

Many of the received comments dealt with general issues. Some of these issues may require more specific examination by the Commission and CARACAL (Meeting of the Competent Authorities for the REACH and CLP Regulations) since these concern the interpretation of Community legislation. These general issues are in principle not part of the MSC opinion, since they focus on legal aspects. But since these issues are part of the comments received and part of the discussion in the MSC, the RCOM prepared by ECHA and the MSC view is reflected here[2].

The most frequent type of comments received were requests for exemptions from authorisation. REACH Article 58(2) specifies that exemptions should be justified on the basis of specific existing community legislation. However, in almost all cases the existing legislation that was indicated was not specific enough according to the criteria defined and applied by ECHA. In addition, exemptions were requested for which no reference was made to community legislation at all. Other comments questioned

[2] For the exact formulations in the RCOM: see the relevant ECHA documents available on its website

the general exemption from authorisation for the use of CMR substances in artist's paints (DEHP, BBP, DBP and MDA).

Another important issue that became apparent while discussing these substances is that the MSC was placed in the position to decide about authorisation for the prioritised substances, when restrictions might have been a suitable instrument to control the risks. The discussions in the Committee illustrated that it is important that the choice on restrictions vs. authorisation must be considered well in advance.

As to the substance specific comments that were received, the MSC concluded that these do not lead to a change in the priority setting of the seven substances that were included in the draft recommendation.

In conclusion, the MSC opinion on the draft recommendation is as follows:

For **Musk-Xylene** no changes in the draft recommendation are proposed.

For **MDA**, the exemption from authorisation for use in artists' paints is not supported by the MSC and the MSC proposes to delete this exemption. No further changes are proposed.

For **SCCP**, the MSC is at this point in time not able to define its opinion on the proposal by ECHA to exempt from the authorisation requirement the placing on the market of SCCPs in mixtures in a concentration at or lower than 1% by weight for use in metalworking and in fat liquoring of leather. An opinion on this issue for SCCP would need further legal analysis. Anyway, the MSC does not believe that uses of substances that are explicitly permitted under specific conditions set out in Annex XVII should always be exempted from the authorisation requirement.

The MSC requests ECHA to raise at the next CARACAL meeting the fact that a considerable amount of the emissions of SCCP are through the use of MCCP. Preparation of an Annex XV dossier for MCCP as a SVHC by the Commission/ECHA or a Member State is an important next step in the control of SCCP emissions and ECHA is requested to invite the relevant parties to take action.

For **HBCDD** no changes in the draft recommendation are proposed.

For **DEHP**, **BBP** and **DBP** the exemption from authorisation for use in artists' paints is not supported by the MSC and the MSC proposes to delete this exemption. No further changes are proposed.

A general remark that could not be addressed in the light of this recommendation (as imported articles are not within the scope of authorisation) is that some of the substances (Phthalates, SCCP, HBCDD) will be imported in articles. ECHA shall (based on Article 69(2)) consider at a later stage to complement authorisation with a restriction if relevant, in relation to exposure to substances in articles.

The MSC's opinion is that ECHA should consider the possible risks of these substances (Phthalates, SCCP, HBCDD) in articles that will be included in Annex XIV before the sunset date and initiate the restriction process in a timely manner.
It could also be decided by a Member State or the Commission to prepare an Annex XV dossier focussing on restriction of these substances in articles before the sunset date, taking into account the necessity of initiating a restriction procedure before this date.

3 MSC opinion on the prioritisation criteria

3.1 General conclusions and recommendations regarding the priority setting

For the first recommendation on substances to be included in Annex XIV, ECHA used a pragmatic approach for the priority setting of the substances on the current 'candidate list'. The approach taken is documented in the report *Prioritisation of Substances of Very High Concern*[3].

The basis for the priority setting is primarily the set of legal criteria provided in Article 58(3) of REACH, being PBT/vPvB properties, high volume, and wide dispersive use. Additional considerations to decide whether prioritisation of a substance for inclusion in Annex XIV is appropriate or not were also used:

- Would inclusion in Annex XIV be effective from a regulatory point of view? Situations may for instance occur where inclusion in Annex XIV will only require regulatory efforts but most likely will not result in benefits for human health or the environment
- Are risks already properly controlled under existing community legislation?
- Can all or most known uses of the substance be readily replaced by a substance from the same (chemical) group with a similar hazard profile that is not on the candidate list?
- Are the emissions and exposures insignificant compared to natural emissions or emissions from uses outside the scope of authorisation?

The criteria were applied in a weight of evidence approach by ECHA. The overall approach used therefore was partly a qualitative and semi-quantitative evaluation. Because the candidate list contains at present only 15 substances, it was not deemed necessary to elaborate on any of the criteria for further differentiation.

During the MSC-6 meeting this weight of evidence approach was discussed and generally accepted although some specific questions were raised regarding the outcome for some substances. During the discussions in MSC-6, some of the issues raised are outlined below:

- The issue as to whether ECHA could have prioritised more than seven substances was raised. ECHA informed the MSC that the number of substances prioritised was not limited by the Agency's capacity but was the outcome of the applied prioritisation approach.
- Some members in the MSC wanted to include (with a lower priority) other inherent properties, such as CMR properties or skin sensitising effects. While the discussion in MSC-6 was not concluded, it was agreed that for this prioritisation round, it would not affect the prioritisation.
- ECHA decided for this first recommendation not to prioritise substances that may easily be replaced by other substances with an equivalent hazard profile (grouping approach), but that are not on the candidate list. This approach was agreed on by some members, but other members argued that such substances could also have been prioritised, even though a grouping approach might be applied at a later stage.
- Some members consider the PBT or vPvB properties as particularly important and therefore wish to see this reflected in future prioritisations.

The MSC recognised the fact that ECHA needed to apply a pragmatic weight of evidence approach for this first prioritisation process due to time constraints, a limited availability of data (a situation that will change in the near future when more registration dossiers will become available) and a relatively limited number of substances on the candidate list.

[3] Prioritisation of Substances of Very High Concern (SVHC) for Inclusion in the List of Substances Subject to Authorisation: http://echa.europa.eu/doc/consultations/recommendations/gen_approach_prioritisation.pdf. See also ECHA website for update: General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for inclusion in the list of Substances Subject to Authorisation

During the public consultation, many comments were received relating to the prioritisation approach. The MSC discussed the comments and came to the following conclusions:

1. The REACH text (Art. 58(3)) states that *normally* Substances of Very High Concern should be prioritised if they meet the following criteria: PBT/vPvB or high volume or wide dispersive use. For future prioritisations, substances meeting any of these criteria should be prioritised. However, this should be balanced with a Weight of Evidence approach as employed by ECHA and possibly, extended with a transparent semi-quantitative ranking approach. One MSCA developed a semi-quantitative ranking method, which could be used as a basis for future ranking. A substance meeting any of the three criteria is therefore not automatically prioritised.

2. Some comments claimed that a minimum number of substances should be prioritised in each prioritisation round. It was concluded that a fixed or minimum number of priority substances is not feasible because the workload for ECHA and the committees may vary per specific substance and there might be valid reasons not to prioritise a substance on the candidate list. The MSC concluded that ECHA can include more substances in the public consultation than may be included in the final recommendation. Thus, a final conclusion on the capacity needed can wait until after the public consultation.

3. Some comments stated that exposure of workers was not (sufficiently) included in the criteria applied by ECHA. The opinion of the MSC is that occupational exposure was taken into account in the current priority setting. The MSC concluded further that ECHA should try and weigh the different criteria (especially those related to the wide dispersive use and exposure of workers) in a more transparent way in the future. This may be achieved by developing a ranking system.

4. With regards to phthalates, some comments raised concern that cumulative effects arising from substances with a similar mode of action are not considered and that the cumulative effects of similarly acting substances are the reason that in practice a threshold level can not always be established. The MSC concluded that this may be true, but that application of this approach had not been used in the Annex XV dossiers for these phthalates. The MSC furthermore noted that REACH is primarily based on a substance-by-substance approach but also allows for grouping of substances. Grouping was, however, not addressed in the priority setting and only marginally addressed in the context of the CSA (Chemical Safety Assessment) guidance. The MSC requests ECHA to propose discussion of this issue at the next CARACAL meeting. Additionally, consideration of the application of such a cumulative risk assessment approach, if possible and scientifically relevant, should be considered in future. This could be considered when updating the CSA guidance, when preparing an Annex XV dossier, when applying for authorisation, when deciding on granting the application for authorisation, or in substance evaluation.

5. With respect to comments proposing low priority based on the fact that the emission is *relatively* low from use of the substance addressed under this regulation compared to non-intentional and natural releases, the MSC recommends that the priority setting should be based on an analysis of the relevant (intentional) tonnage of the substance and also include other relevant release and exposure considerations[4].

6. As it was indicated, not all members agreed with the ECHA rationale not to prioritise substances when not all substances belonging to the same (functional) group are on the candidate list. It was argued by ECHA that industry could easily replace a substance included in Annex XIV by a substance with a similar or potentially worse hazard profile. On the other hand, it could be argued that not acting on acknowledged hazardous substances is also not an option. The MSC concluded that ideally all relevant substances belonging to the same group

[4] Please note: The substance could be of priority based on other exposure considerations even if the relative release of the substance regulated addressed here is small compared with other unintentional and natural releases

(cf. REACH Annex XI 1.5) should be included in the candidate list. For the future, the MSC concluded that the best option is to prioritise all relevant members of the group at once. When not all relevant substances from the same group are on the candidate list, the substances that are already on the list should be taken into account for prioritisation after a maximum of 2 years, since 'infinite' waiting is undesirable. For the arsenic substances and the chromate salts, ECHA is requested to raise the issue of preparing an overview of the relevant substances in those groups applicable for use as replacement in the next CARACAL meeting to the relevant parties. The MSC also requests ECHA to suggest to the Commission and the MSCAs to prepare Annex XV dossiers in support of nominating these substances for the candidate list.

3.2 Conclusions on the substances that were not in the first recommendation

In line with the recommendations for the prioritisation of substances and taking into account the specific comments received, the MSC concludes for the substances that were not included in the first recommendation:

- **Anthracene** is identified as PBT substance and could be prioritised and included in the next public consultation if ranking and the weight of evidence indicates prioritisation;
- For **TBTO** no specific comments were received that would need to be addressed in the next round for priority setting. TBTO is identified as a PBT substance and could be prioritised and included in the next public consultation if ranking and the weight of evidence indicates prioritisation;
- Comments suggest that **Diarsenic trioxide** poses a high risk for workers in (SME) glass workshops. Dispersive use is therefore considered to be high in these comments. For the next priority setting this should be clarified. Diarsenic trioxide and diarsenic pentaoxide could be included in the public consultation when the other relevant substances of this group are on the candidate list. In any case this should not be later than 2011, provided that ranking and the weight of evidence confirms at least one of the relevant substances of the group to be of priority;
- Comments received for **Diarsenic pentaoxide** also recommend a grouping approach. As for diarsenic trioxide, the workers exposure should be considered more explicitly in the next prioritisation round. On review it was noted that a higher figure for the use of the substance was indicated in the comments than that which was used in the ECHA background document. Diarsenic trioxide and diarsenic pentaoxide could be included in the public consultation when the other relevant substances of this group are on the candidate list. In any case this should not be later than 2011, provided that ranking and the weight of evidence confirms at least one of the relevant substances of the group to be of priority;
- **Sodium dichromate.** The conclusion of the MSC is that the substance could be included in the public consultation when the other relevant substances of this group are on the candidate list. In any case this should not be later than 2011, provided that ranking and the weight of evidence confirms at least one of the relevant substances of the group to be of priority;
- **Lead hydrogen arsenate.** No new information was received. One comment suggested a grouping approach, but application of such an approach on this particular substance is currently considered as difficult by the MSC. At this moment there is no reason to include lead hydrogen arsenate in the next public consultation;
- The main comment on **Triethyl arsenate** was that it is used as an intermediate in the electronics industry. The MSC agrees with ECHA's RCOM that this is an intermediate use. At this moment there is no reason to include triethyl arsenate in the next public consultation;
- The relevant comment on **Cobalt dichloride** claimed a potential high volume of wide dispersive use and exposure to the substance through the use as humidity indicator but the available background information indicates that the volume is small (< 1 tpa). Therefore there is currently no reason to include Cobalt dichloride in the next public consultation.

4 Recommendations from the Rapporteur and the WG on the working method for future MSC Opinions

The Working Group discussed the working procedures that were followed for developing the MSC opinion on the recommendation for inclusion of substances in Annex XIV and came to the following recommendations:

1. It is highly recommended that the MSC be informally consulted on the prioritisation before the public consultation. The informal MSC views should be documented, commented on by ECHA and taken into account.
2. Since it is not possible that information from the public consultation can lead to additional priority substances in that consultation round, it is recommended that the (definite) agreement on the number of substances in the recommendation in line with the Agency's capacity will be concluded after the public consultation.
3. It is highly recommended that ECHA's RCOM is available before the Rapporteur and the WG starts to work on preparing the MSC opinion. It would allow including ECHA's RCOM in the draft MSC opinion (or first outline of the opinion) and it would also prevent double work.
4. It is recommended to allow the Rapporteur/WG more time for preparing the draft opinion.
5. The work in the WG was divided over the members: each WG member was assigned 2-3 substances. This division of work over the members worked well and should be continued in future preparation of MSC opinions.
6. The WG had regular teleconferences during the public consultation and two meetings (immediately before the oral presentation of the first outline and shortly after the public consultation). This seems to be sufficient.
7. The WG used a template for evaluation and analysis of the comments (and RCOM), using a categorisation for general comments that were received for several substances. This template worked quite well.
8. The comments received came in very late, which is probably unavoidable and should be taken into account when planning the work in the future.
9. The total workload for all 15 substances for the WG was approximately 75 working days[5]. When the ECHA RCOM is available before the WG starts working on the comments, this may be less in the future.
10. It seems that not every MSCA was aware that comments should have been provided through the public consultation to be officially taken up in the RCOM. When MSCA comments are only provided through the MSC member, they will be less explicitly reported. The roles of MSC members in relation to MSCAs need more discussion.
11. For the discussions in the MSC, it is valuable to have the MSCAs' positions on board, but the opinion of the MSC should be the result of the discussions between the MSC members and the comments from the MSCAs received in the public consultation.

[5] Calculated as follows:
- 3 days evaluating the comments per substance: 45 days
- 2 meetings of 1 day of the WG: 14 days
- 4 teleconferences: 7 days
- Reporting: 1 day per WG member + 3 additional days Rapporteur: 10 days

APPENDIX 1 OF THE SUPPORT DOCUMENT

MSC views on general comments received from stakeholders

Many of the comments received were general comments on the priority setting approach or e.g. on exemptions. Even those comments that were substance specific could often be answered with a general response. In this paragraph, these general comments are considered.

Intermediate uses
According to Article 3(15) of the REACH Regulation, an intermediate is defined as: "Intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance(s) (hereinafter referred to as "synthesis").

Some of the comments claim a use of a substance is considered an intermediate use. In other cases brought forward in the comments, the use of a substance does not result in formation of another substance which is manufactured/imported or placed on the market as such or in a mixture. Such a use is not regarded as intermediate use in a manufacturing process of another substance but as an end use of the substance.

The MSC agrees with ECHA's interpretation.

Exemptions
According to Article 58(2) specific uses can be exempted for authorisation. "*Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.*"

From ECHA's RCOMs it is the MSC's understanding that ECHA has used the following considerations to determine whether an exemption under Article 58(2) applies:

- There is existing Community legislation addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definitions. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed

- This existing Community legislation should properly control the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV. Generally, the use in question should also specifically refer to the substance to be included in Annex XIV either by naming the substance specifically or by referring to the group the substance belongs to e.g. by referring to the classification criteria or the Annex XIII criteria;

- The existing Community legislation imposes minimum requirements[6] for the control of risks of the use. Legislation setting only the aim of measures or not clearly specifying the actual type and

[6] Legislation imposing minimum requirements means that
- The Member States may adopt more stringent but not less stringent requirements when implementing the specific Community legislation in question.
- The piece of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the similar minimum level of control of risks throughout the EU and that this level can be regarded as proper.

effectiveness of measures required is not sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s) as relevant) are covered in the existing legislation.

The MSC agrees with this operational definition, which however does not mean that the MSC agrees with exemptions suggested by ECHA for the substances in ECHA's recommendation.

In many comments requesting an exemption, it is argued that a certain use does not give rise to a risk because there is legislation in place (e.g. the Carcinogens Directive). Since the legislation referred to in these comments (such as the OEL's[7] in the Carcinogens Directive) does not fulfil the three criteria mentioned earlier, this is not considered to be a sufficient justification for an exemption. Many other individual companies request an exemption claiming that their specific process is adequately controlled. Again, these claims do not generally meet the three criteria. Individual companies may in any case prove their case when applying for authorisation.

Other companies claim that their use should be exempted because there are no alternatives available or the economic impact of authorisation would be very high. In general, this is not an issue to be decided on in this phase of the decision making process. Considerations like these are part of the decision making process of granting an authorisation.
A third category of requests for exemptions is the defence uses. Based on the three criteria to determine if specific community legislation is in place, these exemptions cannot be considered justified. Article 2(3) states: "*Member States may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a preparation or in an article, where necessary in the interests of defence.*"
In other words: it is in the hands of the Member States to allow for these exemptions.

Analytical use
According to Article 56(3) of the REACH Regulation, the obligations of Article 56(1) and 56(2) "*shall not apply to the use of substances in scientific research and development*".
ECHA is of the opinion that, provided that the use of the substance is actually in accordance with the definition of "*scientific research and development*" under REACH, and in particular fulfils its specific conditions, the placing on the market for this specific use does not require an authorisation.

The MSC has the opinion that Article 3(23) of REACH specifies the conditions for the exemption of substances used in scientific research and development and agrees with ECHA that substances used for analytical purposes, meeting these criteria are exempted from authorisation.

Medical devices
On the requests for exemption of certain uses of substances in medical devices ECHA indicated that on the basis of the available information it is not in a position to assess fully whether the existing Community legislation on medical devices meets the conditions for exemption under Article 58(2) of the REACH Regulation. ECHA is still examining this issue further and will request the European Commission to examine this issue.
The MSC awaits the outcome of this clarification.

Immediate/Primary packaging of medicinal products
On the requests for exemption of certain uses of substances in immediate/ primary packaging of medicinal products ECHA indicated that on the basis of the available information it is not in a position to assess fully whether the existing Community legislation on medicinal products meets the conditions for exemption under Article 58(2) of the REACH Regulation. ECHA is still examining this issue further and will request the European Commission to examine this issue.
The MSC awaits the outcome of this clarification.

[7] An Occupational Exposure Limit (OEL) is the level at or below which, based on current knowledge, a given substance can be present in the air in the workplace without health effects.

Carcinogens Directive

ECHA does not consider that the Carcinogens Directive entirely fulfils Article 58(2) requirements. The MSC agrees with this viewpoint. The MSC also agrees with ECHA that the Carcinogens Directive does not cover self-employed persons although some Member States may have covered self-employed persons in their national legislation.

Artists' Paints

ECHA sees the following situations regarding exemptions on authorisation based on Annex XVII entries:

i) Annex XVII includes a restriction on a specified use of a substance and this restriction specifies condition(s) under which the restriction does not apply
ii) Annex XVII includes a generic ban on a substance and a specified use is exempted from this generic ban. Such an exemption can be subject to further conditions.

In this first recommendation the proposed exemption from the authorisation requirement on SCCPs is based on case i) and the proposed exemptions on DEHP, DBP, BBP and MDA are based on case ii).

In ECHA's view the authorisation process should not put into question such assessments made by the Community legislator in the restrictions process. ECHA concludes that recital 80 of the REACH Regulation states that "*The proper interaction between the provisions on authorisation and restriction should be ensured in order to preserve the efficient functioning of the internal market and the protection of human health, safety and the environment."* ECHA reasons that if exemptions, derogations or conditions included in the entries of Annex XVII are of concern and further measures may be needed to address these concerns, a revision of these entries should have been initiated.

The MSC has the opinion that the exemptions given in Annex XVII should not be automatically mirrored in the exemptions for authorisation. Especially in the cases (ii) where it is unknown whether a specific substance is used in a specific product, the authorisation instrument seems an adequate instrument to control risks. When there are no provisions in REACH according to Articles 2(5)a, 56(4) (c) and (d) and 56(5)(a), the MSC holds the opinion to not automatically exempt substances in other products such as artists' paints.

Grouping and Cumulative effects

These issues were generally included in comments. However, they may also have an immediate impact on prioritisation and therefore are addressed in that part of the opinion.

Appendix 2 OF THE SUPPORT DOCUMENT

MSC Views on Specific Comments Received from Stakeholders

1. Prioritised Substances

1.1 Musk Xylene - 5-tert-butyl-2,4,6-trinitro-m-xylene

Priority setting

The comments of seven MSCAs and one EFTA state show agreement with the ECHA recommendation that musk xylene is prioritised for inclusion into Annex XIV. Not opposing the prioritisation of musk xylene, one MSCA argues that the relatively low volumes (estimated at 25 tonnes per year) indicate that there may be little benefit from authorisation. This MSCA also raises a general issue on the relationship between results from the Existing Substances Regulation (ESR) and the need for authorisation.
Several environmental and worker protection NGOs support ECHA's proposed prioritisation and, in addition, relevant industry associations (EFFA - European Flavour and Fragrance and Association, IFRA - International Fragrance Association and A.I.S.E.) do not oppose the prioritisation of musk xylene for inclusion in Annex XIV.

The MSC is of the opinion that wide dispersive use of musk xylene was adequately demonstrated in the ESR risk assessment report on musk xylene and in the background report compiled by ECHA to support the prioritisation process.[8] No new information has been brought forward in the stakeholder consultation to challenge the criterion of wide dispersive use.

Route for authorisation

ECHA concludes that requests for authorisation for musk xylene should be based on the "socio–economic analysis (SEA)" route (REACH Art. 60(4)), due to the fact that the "adequate control route" (REACH Art. 60(2)) is not applicable for granting an authorisation for a vPvB substance. No comments on this issue have been submitted in the stakeholder consultation.

The MSC agrees with ECHA's proposal to apply the 'SEA route' (REACH Art. 60(4)) for granting an authorisation of musk xylene.

Transitional arrangements: Application date/Sunset date

The transitional arrangements for musk xylene are proposed to be as follows:

(i) Latest application date: 24 months after the entry into force of the Decision to include the substance in Annex XIV.
(ii) Sunset date: 42 months after the entry into force of the decision to include the substance in Annex XIV.

Environmental NGOs have argued for earlier application and sunset dates due to the limited complexity (number of levels) in the supply chain for musk xylene. The MSC is of the opinion that the transitional arrangements proposed by ECHA are appropriate and recommends using the dates as suggested.

[8] ECHA (2009). Justification for the draft recommendation of inclusion in annex xiv, 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) EC number: 201-329-4. CAS number: 81-15-2. ECHA, 14 January 2009. See also the relevant updated document available on ECHA's website: Justification for the prioritisation and Annex XIV recommendation for Musk Xylene.

Proposed review period for certain uses
No review period is suggested by ECHA and no comments on this issue were received in the stakeholder consultation.
The MSC agrees that review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories) of uses
A comment was received that musk xylene should be exempted from the use as an analytical standard for test and measurement instruments. This is a general issue that is addressed for all of the substances. The MSC would like to refer to the general comments of ECHA on this issue.

Information on the need to exempt PPORD from the authorisation requirement, including the maximum tonnage
No exemptions for PPORD are suggested by ECHA and no comments were received in the stakeholder consultation. The MSC agrees that exemptions for PPORD are not warranted in the recommendation for Annex XIV inclusion.

Other issues
None

1.2 MDA - 4,4' – Diaminodiphenylmethane

Priority Setting
Eight MSCAs expressed agreement with ECHA's recommendation that MDA is prioritised for inclusion into Annex XIV, along with a trade union and International NGOs. There were no objections to the prioritisation.
One comment submitted indicated that MDA does not have any uses other than intermediate and claimed that its use as a hardener in epoxy resins and in adhesives is an intermediate use. The MSC would like to refer to ECHA's opinion on this and agrees with ECHA's position that this use does not meet the requirements of 'intermediate use' and so this use will be subject to the requirements of authorisation.
Additionally, some comments indicated that exposure to MDA is controlled in the workplace through the requirements of both the Chemicals Agents Directive and the Carcinogens Directive and so the additional regulatory benefits of the authorisation process were questioned. Again, the MSC refers to, and agrees with, ECHA's response on this general issue, as it was made for a number of prioritised substances.
A comment was submitted (for all substances, including MDA) suggesting that occupational disease due to exposure to a substance should be considered as an additional prioritisation criterion. If such a situation would arise for a substance, it is considered to be due to significant worker exposure. This criterion can be considered in the next round of prioritisation.

Route for authorisation
ECHA concludes that requests for authorisation for MDA should be based on the socio–economic analysis (SEA) route, due to the fact that, according to available information on genotoxicity of the substance, it is not possible to determine a threshold in accordance with Section 6.4 of Annex I. No comments on this issue have been submitted in the stakeholder consultation.
The MSC agrees with ECHA's proposal to use the 'SEA route' for authorisation of MDA.

Transitional arrangements: Application date/Sunset date
The transitional arrangements for MDA are proposed to be as follows:

(i) Latest application date: 24 months after the entry into force of the Decision to include the substance in Annex XIV.

(ii) Sunset Date: 42 months after the entry into force of the Decision to include the substance in Annex XIV.

Four MSCAs agreed with these transitional arrangements. International NGOs argued that they were too long and should be shortened to 18 months. The MSC concludes that the transitional arrangements proposed by ECHA are appropriate and recommends using the dates as suggested.

Proposed review period for certain uses
No review period is suggested by ECHA.

Two comments were received in relation to review periods, one suggesting an annual review period and the other suggesting a review period every 4 years. However, no argumentation was provided with these comments, and so the MSC agrees with ECHA's proposal for no review period.

Proposed exempted (categories) of uses
ECHA proposes an exemption for MDA for "Placing on the market in preparation (*mixture*) for supply to the general public for the use as artists' paints which are covered by Directive 1999/45/EC". There were two objections to this proposed exemption, from an NGO and the other from an MSCA. The objection was mostly based on the fact that it is not considered appropriate to automatically take over this general exemption from the previous legislation (Directive 76/769/EC) where this derogation has been established for all CMRs. In addition, the point was made that it is not known whether MDA is actually used in artist's paints or not. The MSC proposes not to exempt the use of the genotoxic carcinogen MDA in artists´ paint since no justification for this exemption can be found in the REACH Regulation or any other Community legislation.

A comment was received that MDA should be exempted from the use as an analytical standard for test and measurement instruments. This is a general issue that is addressed for all of the substances. The MSC would like to refer to the general comments of ECHA on this issue.

Some comments were also received from companies requesting exemptions for the use of MDA e.g. for use as a hardener and in the process for encapsulating radioactive ion-exchange resins. Overall, these uses are considered to be routine uses of MDA for which an application for authorisation must be submitted, and so they do not qualify for an exemption.
An exemption was also requested for the use of "technical grade MDA". On review, this substance appears to be a different one than the substance prioritized, as it has a different CAS number and EC number and so will not be subject to authorisation; therefore, there is no need for an exemption. The MSC notes that an Annex XV dossier identifying "technical grade MDA" as an SVHC substance would be warranted as soon as possible.

Information on the need to exempt PPORD from the authorisation requirement, including the maximum tonnage
No exemptions for PPORD are suggested by ECHA and no comments were received in the stakeholder consultation.

The MSC agrees that exemptions for PPORD are not warranted in the recommendation for Annex XIV inclusion.

Other issues
Suggestion by an MSCA that perhaps restrictions may be a more appropriate control mechanism than authorisation

1.3 SCCPs - Alkanes, C10-13, chloro

Priority setting

Eight MSCAs expressed agreement with ECHA's recommendation that SCCPs are prioritised for inclusion into Annex XIV, along with a trade union and international NGOs. There were no objections to the prioritisation.
A comment was submitted for all substances, including SCCPs, suggesting that occupational disease due to exposure to a substance should be considered as an additional prioritisation criterion. If such a situation would arise for a substance, it is considered to be due to significant worker exposure. This criterion could be considered in the next round of prioritisation.

Route for authorisation

ECHA concludes that requests for authorisation for SCCPs should be based on the "socio–economic analysis (SEA)" route (REACH Art. 60(4)), due to the fact that the "adequate control route" (REACH Art. 60(2)) is not applicable for granting of authorisation for a PBT and vPvB substance. No comments on this issue have been submitted in the stakeholder consultation.

The MSC agrees with ECHA's proposal to apply the 'SEA route' (REACH Art. 60(4)) for granting of authorisation of SCCPs.

Transitional arrangements

The transitional arrangements for SCCPs are proposed to be as follows:
(i) Latest application date: 27 months after the entry into force of the Decision to include the substance in Annex XIV.
(ii) Sunset Date: 45 months after the entry into force of the Decision to include the substance in Annex XIV.

There were comments from NGOs with the proposal to shorten both the application date and the sunset date due to long lasting agreements with industry. Industry commenters argue that the complexity of the supply chain and limited availability of substitutes justify longer periods in the transitional arrangements.

Industry's arguments for longer application and sunset dates were already taken into account by ECHA in setting the dates. The MSC concludes that the transitional arrangements proposed by ECHA are appropriate and recommends using the dates as suggested.

Proposed review period for certain uses

No review period is suggested by ECHA and no comments were received in the stakeholder consultation.
The MSC agrees that review periods are not warranted in the recommendation for Annex XIV inclusion.

Exempted categories of uses

The use of SCCP is restricted under the Directive 76/769/EEC. Starting from the 1st June 2009, SCCP will be restricted due to entry 42 of Annex XVII of the REACH Regulation.
ECHA recommends the use of SCCP in metalworking and in fat liquoring of leather to be exempted from authorisation, based on the Annex XVII entry for SCCPs, which includes a restriction on these specified uses of SCCPs. Under this restriction the application of SCCP in mixtures for these uses is permitted in concentrations lower than 1%.

There were comments from one MSCA and several NGOs proposing not to exempt such uses of SCCP with the arguments that uses up to 1% can theoretically still lead to significant SCCP releases and that

the arguments relevant in deciding under the limitation directive are not necessarily relevant in deciding whether these uses should be exempted from the authorisation.

The MSC is at this point in time not able to define its opinion on the proposal by ECHA to exempt from the authorisation requirement the placing on the market of SCCPs in mixtures in a concentration at or lower than 1% by weight for use in metalworking and in fat liquoring of leather. An opinion on this issue for SCCP would need further legal analysis. Anyway, the MSC does not believe that uses of substances that are explicitly permitted under specific conditions set out in Annex XVII should always be exempted from the authorisation requirement.

For SCCP, the MSC requests ECHA to raise at the next CARACAL meeting the fact that a considerable amount of the emissions of SCCP are through the use of MCCP. Preparation of an Annex XV dossier for MCCP by the Commission/ECHA or a Member State is an important next step in the control of SCCP emissions and ECHA is requested to invite the relevant parties to take action.

A comment was also received from an industry organisation requesting exemptions due to a lack of suitable alternatives for the use of SCCPs in rubber products, plastic products, coatings and paints, polymer preparations and construction and building materials. Overall, the lack of alternatives is not a valid reason according to REACH art. 58(2) and so they do not qualify for an exemption.

A comment was received that SCCPs should be exempted from the use as an analytical standard for test and measurement instruments. This is a general issue that is addressed for all of the substances. The MSC would like to refer to the general comments of ECHA on this issue.

Information on the need to exempt PPORD from the authorisation requirement, including the maximum tonnage

No exemptions for PPORD are suggested by ECHA and no comments were received in the stakeholder consultation. The MSC agrees that exemptions for PPORD are not warranted in the recommendation for Annex XIV inclusion.

Other issues

One company argues that SCCPs in imported articles should be restricted.

One MSCA mentioned that MCCPs are used as a replacement for SCCPs and that MCCPs are also potential PBT substances. In addition, a considerable amount of the emissions of SCCP is through the use of MCCPs. According to the MSC, preparation of an Annex XV dossier by the Commission/ECHA or a Member State would be an important next step in the control of SCCP emissions. SCCPs are identified as a Substance of Very High Concern (PBT and vPvB) according to REACH Article 57 (d) and (e) and is submitted as a persistent organic pollutant (POP) under the Stockholm Convention.

1.4 HBCDD - Hexabromocyclododecane

Priority setting

The comments of seven MSCAs, several NGOs and one EFTA state show agreement with the ECHA recommendation that HBCDD is prioritised for inclusion into Annex XIV.

One MSCA and several companies are of the opinion that HBCDD should not be treated as a priority substance for inclusion in Annex XIV, thereby contesting that some of the criteria for priority setting are met.

Industry considers HBCDD not to be persistent, less toxic than suggested and therefore not a PBT substance. It is argued that the steep rising occurrence of HBCDD is connected to HBCDD being used as the substitute for the banned PDBEs in textiles and high emissions from one outdated UK production plant from the year. These emissions ceased in 2003.

The MSC is of the opinion that no new information on the PBT properties of HBCDD has been brought forward since HBCDD was placed on the candidate list (including the arguments put forward by SCHER[9]). Therefore, the MSC agreement of October 2008 that HBCDD is a PBT substance is still valid.
Industry and one MSCA bring forward arguments and information that the release of HBCDD from Expanded Polystyrene (EPS) and Extruded Polystyrene (XPS) insulation material is limited and does not constitute wide dispersive uses. Main arguments that were brought forward in the public consultation to substantiate limited releases from EPS and XPS are:

- The content of HBCDD in insulation material is low
- Dust and waste created during the manufacture of EPS en XPS insulation is typically recycled back into the product
- Once installed within a building, the bulk of EPS and XPS insulation is contained within the structure and not released to the environment
- At the end of the life cycle, the product is most likely going to be recycled due to changing waste regulation.

One MSC member submitted counter arguments, focussing on the life cycle of HBCDD. The main arguments were as follows:

- A large amount (>10000 tons/year) of HBCDD is yearly built into buildings/constructions, giving a potential for substantial future emissions when these buildings are repaired or demolished
- A continued use of HBCDD in EPS/XPS insulation will add very large volumes of insulation material for recycling within a few decades, thereby adding to the potential for large releases of HBCDD from waste even if a recycling system with a reasonable efficiency in taking care of old EPS/XPS-insulation would be in operation.
- A recycling system would be required to collect more than 99.9% of the used EPS/XPS to prevent the environmental concentrations from increasing.

The MSC is of the opinion that wide dispersive use for HBCDD was adequately demonstrated in the background report compiled by ECHA[10] to support the prioritisation process.

Route for authorisation

ECHA concludes that requests for authorisation for HBCDD should be based on the socio–economic analysis (SEA) route, because the adequate control route is not allowed for an authorisation request for a PBT/vPvB substance. No comments have been submitted on this specific issue in the stakeholder consultation.

The MSC agrees with ECHA's proposal to apply the 'SEA route' for granting of authorisation of HBCDD.

Transitional arrangements: Application date/Sunset date

The transitional arrangements for HBCDD are proposed to be as follows:
(i) Latest application date: 27 months after the entry into force of the Decision to include the substance in Annex XIV
(ii) Sunset date: 45 months after the entry into force of the Decision to include the substance in Annex XIV

[9] SCHER = Scientific Committee on Health and Environmental Risks
[10] ECHA (2009). Justification for the draft recommendation of inclusion in annex XIV. Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified EC number: 247-148-4 and 221-695-9, CAS number: 25637-99-4 and 3194-55-6 Names of the major diastereoisomers identified: alpha-hexabromocyclododecane CAS No 134237-50-6, beta-hexabromocyclododecane CAS No 134237-51-7, gamma-hexabromocyclododecane CAS No 134237-52-8. ECHA, 14 January 2009. See also the relevant updated document available on ECHA's website: Justification for the prioritisation and Annex XIV recommendation for HBCDD.

Several NGO parties argue for earlier application and sunset dates, and industry parties argue for later application and sunset dates, while some MSCAs agree with the timelines set by ECHA. The MSC is of the opinion that no convincing justifications were put forward to prefer one to the other and recommends using the dates as suggested by ECHA.

Proposed review period for certain uses

No review period is suggested by ECHA and no comments were received.

Proposed exempted (categories) of uses

No exemptions are recommended by ECHA in this authorisation procedure.

Comments from individual companies and Member States were received on exemptions for HBCDD. Requests were received for exemptions for use of HBCDD in the insulating foams EPS and XPS.

Many arguments were brought forward by industry to justify the exemptions, such as:

- Emissions during the life cycle of the building material are low due to specific risk management measures;
- Socio-economic and technical reasons prevent substitution of EPS/XPS in building insulation materials
- HBCDD can be replaced by other non-regulated substances but these do not have a better environmental performance than HBCDD. Therefore stringent measures on HBCDD would lead to a substantial risk only of negative environmental impact of non-regulated alternatives. The alternatives need a thorough assessment
- The high contribution of EPS and XPS as insulation materials to the realisation of EU climate change targets
-

Industry and a Member State propose restrictions as an alternative option to authorisation, and covering only the use of HBCDD in textiles. As pointed out by several parties, the ESR risk assessment for HBCDD shows the use of HBCDD in textiles is responsible for the majority of emissions.

The MSC considers these issues as examples of the information, which normally would be part of an authorisation request for a PBT/vPvB substance. The MSC is of the opinion that under the current provisions of REACH Article 58(2) exemptions should be based on specific existing community legislation. For HBCDD, such specific legislation does not exist and therefore, no exemptions are possible for the use of HBCDD in EPS and XPS.

Other issues

In authorisation requests, it seems that special attention should be paid to the issue of packaging residues as this can be seen as a major emission source based on the survey of HBCDD Potential Emissions in Europe 2008.

HBCDD will be imported in articles, and these imported articles are not within the scope of authorisation. ECHA shall (based on Article 69(2)) consider at a later stage (as soon as possible after the sunset date) to complement authorisation with a restriction if relevant in relation to the estimated current and future exposure from articles.

1.5 DEHP - Bis(2-ethylhexyl)phthalate

Priority setting

Five MSCAs and one EFTA state agree with ECHA's recommendation that DEHP is prioritised for inclusion into Annex XIV, along with a trade union and international NGOs. Several non-European

trade organisations or companies submitted comments that argue that DEHP is sufficiently regulated already and authorisation would pose an additional economic burden on the respective industries.

Occupational exposure
Some comments point to the fact that, in general, worker exposure seems not to be dealt with sufficiently in the prioritisation process. However, worker exposure was taken into account by ECHA although the transparency in that regard could be improved. A commenter indicated that occupational disease due to exposure to the substance should be considered as an additional prioritisation criterion. This criterion can be considered in the next round of prioritisation.

Route for authorisation

ECHA concludes that requests for authorisation for DEHP can be based on the adequate control route (Article 60(2)) or on the socio-economic evaluation (SEA) route (Article 60(4)).

Some comments disagree with the proposed "adequate control route" for authorisation. The comments suggest that effects of BBP, DBP and DEHP are similar and additive. The no-effects levels provided for each individual substance is, according to these comments, not protective for the combined phthalate exposure and there is no possibility to derive a DNEL. Comments state that phthalates are identified by the scientific community as endocrine disrupters for which it is not possible to determine a threshold.

Some comments request to conduct a cumulative risk assessment[11] for phthalates and to consider them as a group of substances. There is limited experience with cumulative risk assessments so far. REACH is primarily based on a substance-by-substance approach but also allows for grouping of substances. The recent discussions on other Annex XV substances show that this aspect should increasingly be considered. For each of the three phthalates separate Annex XV dossiers were submitted based on risk assessment reports made under the former Existing Substance Regulation where the cumulative risk assessment approach had not been used. It was suggested by a group of NGOs and two MSCAs that authorisation requests for the three phthalates under consideration should also include a cumulative risk concept.

The MSC observes that a grouping approach for the three phthalates was not applied for the current prioritisation. However, it should be investigated how cumulative effects can be taken into account in future guidance development for the CSA, Annex XV dossiers, in priority setting for Annex XIV and in the granting of authorisations.

One comment submitted by a group of NGOs requests to allow only the socio-economic analysis route because the different phthalates act additively and science has shown that the endocrine disrupting phthalates under discussion (DBP, DEHP and BBP) can together cause anti-androgenic effects even when each substance is individually present below its effect level. The MSC considers the additive effects of phthalates not a reason to principally disregard the possibility to consider the adequate control route. The MSC concludes that it agrees with ECHA's proposal in so far that the SEA route for authorisation of DEHP may be used and concludes that the appropriateness of the adequate control route may be considered in the application for authorisation.

Transitional arrangements

The transitional arrangements for DEHP are proposed to be as follows:

(i) Latest application date: 30 months after the entry into force of the Decision to include the substance in Annex XIV
(ii) Sunset date: 48 months after the entry into force of the Decision to include the substance in Annex XIV

[11] Cumulative risk assessment in this case covers the combined effects of phthalates (based on additivity of the anti-endrogenic effect). It also means that combined exposure to the relevant phthalates should be considered.

A few parties argue for earlier application and sunset dates, and other argue for later application and sunset dates. The MSC is of the opinion that no convincing arguments were put forward to prefer one to the other and recommends using the dates as suggested by ECHA.

Proposed review period for certain uses
No review period is suggested by ECHA and no comments were received in the stakeholder consultation.

The MSC agrees that review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories) of uses
The following exemption is proposed for DEHP by ECHA: To exempt from the authorisation requirement the placing on the market of DEHP in mixture for the supply to general public for the use as artists' paints when these are covered by Directive 1999/45/EC.

Some comments question the proposed exemption for the use in artists' paints. The Member State Committee recommends not to exempt the use of DEHP in artists' paint as no specific minimum requirements exist to achieve proper control of risk related to the use of DEHP in artists' paint.

A comment from a MSCA expresses concerns about the general exemption for use of DEHP in medicinal products according to REACH Article 2(5a).

Exemptions for DEHP were requested by industry for a wide range of applications:

- Specific analytical uses such as analytical standards
- Primary packaging of medicinal products and the packaging of active substances
- Medical devices including *in vitro* diagnostic medical devices
- Coatings for fabric applications

The MSC is of the opinion that some of the information provided is very valuable but may not warrant exemptions from the authorisation procedure. As noted previously, ECHA is seeking clarification in relation to the exemption for primary packaging of medicinal products and for medical devices. Some uses may be covered by the general exemptions in REACH and the authorisation title (e.g. Articles 2(3), 2(5a), 56(3)). For those, that are not covered by the general exemptions, the provided information and the specific Community legislation available seem to not be sufficient to justify a separate exemption according to Article 58(2). The MSC proposes not to exempt the use of the DEHP in artists´ paint.

Information on the need to exempt PPORD from the authorisation requirement, including the maximum tonnage
No exemptions for PPORD are suggested by ECHA and no comments were received in the stakeholder consultation. The MSC agrees that exemptions for PPORD are not warranted in the recommendation for Annex XIV inclusion.

Other issues (identity, intrinsic properties)
None

1.6 Benzyl Butyl Phthalate

Priority setting
The majority of the comments agree with the ECHA recommendation that Benzyl Butyl Phthalate (BBP) is prioritised for the recommendation for inclusion into Annex XIV.

Occupational exposure
Some comments point to the fact that, in general, worker exposure seems not to be dealt with sufficiently in the prioritisation process. However, worker exposure was taken into account by ECHA although the transparency in that regard could be improved. A commenter indicated that occupational disease due to exposure to the substance should be considered as an additional prioritisation criterion. This criterion can be considered in the next round of prioritisation.

Route for authorisation

ECHA concludes that requests for authorisation for BBP can be based on the adequate control route (Article 60(2)) or on the socio-economic evaluation (SEA) route (Article 60(4)).

Some comments disagree with the proposed "adequate control route" for authorisation. The comments suggest that effects of BBP, DBP and DEHP are similar and additive. The no-effects levels provided for each individual substance is, according to these comments, not protective for the combined phthalate exposure and there is no possibility to derive a DNEL. Comments state that the scientific community identifies phthalates as endocrine disrupters for which it is not possible to determine a threshold.

Some comments request to conduct a cumulative risk assessment for phthalates and to consider them as a group of substances. There is limited experience with cumulative risk assessments so far. REACH is primarily based on a substance-by-substance approach but also allows for grouping of substances. The recent discussions on other Annex XV substances show that this aspect should increasingly be considered. For each of the three phthalates separate Annex XV dossiers were submitted based on risk assessment reports made under the former Existing Substance Regulation where the cumulative risk assessment approach had not been used. It was suggested by a group of NGOs and two MSCAs that authorisation requests for the three phthalates under consideration should also include a cumulative risk concept.

The MSC observes that a grouping approach for the three phthalates was not applied for the current prioritisation. However, it should be investigated how cumulative effects can be taken into account in future guidance development for the CSA, for Annex XV dossiers, in priority setting for Annex XIV and in the granting of authorisations.

ECHA concludes that requests for authorisation for BBP can be based on the adequate control route (Article 60(2)) or on the socio-economic evaluation (SEA) route (Article 60(4)).
One comment submitted by a group of NGOs requests to allow only the socio-economic route because the different phthalates act additively and science has shown that the endocrine disrupting phthalates under discussion (DBP, DEHP and BBP) can together cause anti-androgenic effects even when each substance is individually present below its effect level. The MSC considers the additive effects of phthalates not a reason to principally disregard the possibility to consider the adequate control route. The MSC concludes that it agrees with the ECHA proposal in so far that the SEA route for authorisation of DEHP may be used and concludes that the appropriateness of the adequate control route may be considered in the application for authorisation.

Transitional arrangements

In its recommendation, ECHA proposes the following transitional arrangements for BBP:

(i) Latest application date: 30 months after the entry into force of the Decision to include the substance in Annex XIV
(ii) Sunset date: 48 months after the entry into force of the Decision to include the substance in Annex XIV

Some parties argue for earlier application and sunset dates, and others argue for later application and sunset dates. The MSC is of the opinion that no convincing arguments were put forward to prefer one to the other and recommends using the dates as suggested by ECHA.

Proposed review period for certain uses

No review period is suggested by ECHA and no comments on this were received.

Proposed exempted (categories) of uses

In its recommendation, ECHA proposes to exempt from the authorisation requirement the placing of the market of BBP in mixture for the supply to general public for the use of artists' paints when these are covered by Directive 1999/45/EC.
Several comments disagree with the proposal to exempt artists' paints from the authorisation requirement, as no data have been provided indicating that BBP is presently used or could technically be used in artists´ paints, potentially making the proposed exemption unnecessary.

The MSC recommends not exempting the use of BBP in artists' paint as no specific minimum requirements exist to achieve proper control of risk related to the use of BBP in artists' paint.
Several parties proposed to exempt the use of BBP in the immediate packaging of medicinal products and in the immediate packaging of active substances as the risks to human health arising from medicinal products are covered by Directive 2001/83/EC and Regulation (EC) No 726/2004.

Information on the need to exempt PPORD from the authorisation requirement, including the maximum tonnage

No exemptions for PPORD are suggested by ECHA and no comments were received in the stakeholder consultation. The MSC agrees that exemptions for PPORD are not warranted in the recommendation for Annex XIV inclusion

Other issues (identity, intrinsic properties)

None

1.7 DBP - Dibutyl phthalate

Priority setting

The majority of the comments, among them eight from MSCAs show agreement with the ECHA recommendation that DBP is prioritised for inclusion into Annex XIV. A few priority setting issues were raised on which the MSC holds the opinion that they could be considered in the general priority setting methodology.

Occupational disease
A commenter indicated that occupational disease due to exposure to the substance should be considered as an additional prioritisation criterion. If such a situation would arise for a substance, it is considered to be due to significant worker exposure. However, worker exposure was taken into account by ECHA although the transparency in that regard could be improved.

Route for authorisation

ECHA concludes that requests for authorisation for DBP can be based on the adequate control route (Article 60(2)) or on the socio-economic evaluation (SEA) route (Article 60(4)).

Some comments disagree with the proposed "adequate control route" for authorisation. The comments suggest that effects of BBP, DBP and DEHP are similar and additive. The no-effects levels provided for each individual substance are, according to these comments, not protective for the combined phthalate exposure and there is no possibility to derive a DNEL. Comments state that the scientific community identifies phthalates as endocrine disrupters for which it is not possible to determine a threshold.

Some comments request to conduct a cumulative risk assessment for phthalates and to consider them as a group of substances. There is limited experience with cumulative risk assessments so far. REACH is primarily based on a substance by substance approach but also allows for grouping of substances. The recent discussions on other Annex XV substances show that this aspect should increasingly be considered. For each of the three phthalates separate Annex XV dossiers were submitted based on risk assessment reports made under the former Existing Substance Regulation where the cumulative risk assessment approach had not been used. It was suggested by a group of NGOs and two MSCAs that authorisation requests for the three phthalates under consideration should also include a cumulative risk concept.

Therefore, the MSC observes that a grouping approach for the three phthalates was not applied for the current prioritisation but that it should be investigated how cumulative effects can be taken into account in future guidance development for the CSA, for Annex XV dossiers, in priority setting for Annex XIV and in the granting of authorisations.

One comment submitted by a group of NGOs requests to allow only the socio-economic analysis route because the different phthalates act additively and science has shown that the endocrine disrupting phthalates under discussion (DBP, DEHP and BBP) can together cause anti-androgenic effects even when each substance is individually present below its effect level. The MSC considers the additive effects of phthalates not a reason to principally disregard the possibility to consider the adequate control route. The MSC concludes that it agrees with ECHA's proposal in so far that the SEA route for authorisation of DEHP may be used and concludes that the appropriateness of the adequate control route may be considered in the application for authorisation.

Transitional arrangements: Application date/Sunset date

The transitional arrangements for DBP are proposed to be as follows:

(i) Latest application date: 30 months after the entry into force of the Decision to include the substance in Annex XIV
(ii) Sunset date: 48 months after the entry into force of the Decision to include the substance in Annex XIV

A few parties argue for earlier application and sunset dates, and other argue for later application and sunset dates. The MSC is of the opinion that no convincing arguments were put forward to prefer one to the other and recommends using the dates as suggested by ECHA.

Proposed review period for certain uses

No review period is suggested by ECHA and only very limited comments on this were received.

Proposed exempted (categories) of uses

The following exemption is proposed for DBP by ECHA:
To exempt from the authorisation requirement the placing on the market of DBP in mixture for the supply to general public for the use as artists' paints when these are covered by Directive 1999/45/EC.

Some comments question the proposed exemption for the use in artists' paints. The Member State Committee recommends not exempting the use of DBP in artists' paint as no specific minimum requirements exist to achieve proper control of risk related to the use of DBP in artists' paint.

A comment from a MSCA expresses concerns about the use of DBP in medicinal products and in material coming into direct contact with foodstuff. Although valuable, the comment does not affect the current prioritisation.
Several comments from companies were received requesting exemptions for:

- Analytical use
- Use in medicinal products (incl. primary packaging of medicinal products)
- Uses for interests of defense

- Use as catalyst in the production of polypropylene
- Use as absorption oil in the purification of maleic anhydride

The MSC is of the opinion that some of the information provided is very valuable for industry when submitting an authorisation request but may not warrant exemptions from the authorisation procedure. Some uses may be covered by the general exemptions in REACH and the authorisation title (e.g. Articles 2(3), 2(5a), 56(3)). For those that are not covered by the general exemptions, the provided information and the specific Community legislation available seem to be not sufficient to justify a separate exemption according to Article 58(2).

Information on the need to exempt PPORD from the authorisation requirement, including the maximum tonnage

No exemptions for PPORD are suggested by ECHA and no comments were received in the stakeholder consultation. The MSC agrees that exemptions for PPORD are not warranted in the recommendation for Annex XIV inclusion

Other issues

Alternatives

Some comments concern possible alternatives (availability, feasibility, mentioning of alternatives with similar hazardous properties). Although valuable additional information, they do not affect the current prioritisation of DBP.

2. Substances not prioritised in the first recommendation

2.1 Triethylarsenate

Priority setting

ECHA proposes not to prioritise triethyl arsenate for inclusion in Annex XIV. The majority of the comments agree with the ECHA recommendation including the comments submitted by four out of five MSCAs.

Grouping of arsenic compounds

One MSCA and also a public authority in the same MS argue that arsenic compounds should be dealt with using a grouping approach. They propose that triethyl arsenate and other arsenic compounds should be considered for prioritisation and Annex XIV inclusion.

Occupational disease as an additional prioritisation criterion

A worker protection organisation indicated that occupational disease due to exposure to the substance should be considered as an additional prioritisation criterion. If such a situation would arise for a substance, it is considered to be due to significant worker exposure. This criterion can be considered in the next round of prioritisation.

Other issues

The ECHA conclusion that the use of triethyl arsenate in electronic (semi-conductor) applications should be regarded as an intermediate use is questioned by an Austrian public authority (occupational disease insurance). This agency and an UK individual also propose that a cumulative risk assessment approach should be applied to arsenic compounds.

Conclusions

At this moment the MSC recommends not to include triethyl arsenate for the next public consultation based on the current information in the background reports. This should be reconsidered when new information has become available that affects the weighting of the prioritisation criteria as done by ECHA[12].

2.2 Anthracene

Priority setting

Several MSCAs supported the ECHA view that anthracene should not be prioritised, while some MSCAs advocated prioritisation of this substance. A number of NGOs and MSCAs proposed prioritisation of this substance with the following arguments:

- PBT properties of anthracene,
- Wide dispersive use, as opposed to the conclusion in ECHA documents,
- Authorisation of anthracene would discourage new uses of this substance.

Conclusions

Anthracene, which is identified as a PBT substance according to REACH Article 57 (d), could be prioritised and included in the next public consultation if ranking and the weight of evidence indicates prioritisation.

[12] Prioritisation of Substances of Very High Concern (SVHC) for Inclusion in the List of Substances Subject to Authorisation: http://echa.europa.eu/doc/consultations/recommendations/gen_approach_prioritisation.pdf. See also ECHA website for update: General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for inclusion in the list of Substances Subject to Authorisation

2.3 Cobalt Dichloride

Priority setting

The majority of the comments agree with the ECHA recommendation that cobalt dichloride is not prioritised for the recommendation for inclusion into Annex XIV. Several issues were raised that could be considered in the next round of prioritisation.

Worker exposure and wide dispersive uses

There is additional information provided that worker exposure in electroplating industry is not negligible and could be considered to be wide dispersive (SMEs). In the current prioritisation, worker exposure is considered already but the additional information can be used in the next round of prioritisation.

Non-quantitative information has been provided that cobalt dichloride is used as humidity indicator but according to the background document, this tonnage is very low (< 1 tpa).

Occupational disease as an additional prioritisation criterion

A commenter indicated that occupational disease due to exposure to the substance should be considered as an additional prioritisation criterion. If such a situation would arise for a substance, it is considered to be due to significant worker exposure. This criterion can be considered in the next round of prioritisation.

Exemptions

A comment was received that electroplating should be considered as an intermediate use that is exempted from authorisation (if the substance is prioritised), due to the fact that during electroplating, the metal ion is deposited onto the metal surface as the zero-valent metal. The MSC does not regard this as intermediate use in the meaning of REACH Article 3(15) but as an end use.

This is a general issue that is addressed by several commenters for different chemicals. The MSC would like to refer to the general comments of ECHA on this issue.

Conclusions

At this moment the MSC recommends not to include cobalt dichloride for the next public consultation based on the current information in the background reports[13].

[13] Prioritisation of Substances of Very High Concern (SVHC) for Inclusion in the List of Substances Subject to Authorisation: http://echa.europa.eu/doc/consultations/recommendations/gen_approach_prioritisation.pdf. See also ECHA website for update: General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for inclusion in the list of Substances Subject to Authorisation.

2.4 Diarsenic trioxide

Priority setting

Two MSCAs supported ECHA's view not to prioritise the substance, stating that the widespread use and the potential exposure are not very high, while two others urged for fast prioritisation based on its toxic properties and relatively high volumes used. One MSCA proposed later prioritisation together with other arsenic compounds with the use of a grouping approach.

A number of NGOs urged for prioritisation, some of them proposing the grouping approach, together with other arsenic compounds. The following arguments for fast prioritisation were given by some MSCAs and/or NGOs:

- Carcinogenicity (category 1) of the substance,
- Considerable workers exposure, especially in SMEs not applying IPCC directive,
- Diffuse uses
- Occupational cancer linked to arsenic exposure,
- Precautionary principle,
- More probable development of substitutes after the substance is placed on Annex XIV.

Exemptions

A comment was received that diarsenic trioxide should be exempted from the use as an analytical standard for test and measurement instruments. While this comment is not directly applicable to diarsenic trioxide at present, as it is currently not prioritised, it is a general issue that is addressed for all of the substances. The MSC would like to refer to, and support, the general comments of ECHA on this issue.

Conclusions

At this moment the MSC agrees with ECHA not to prioritise diarsenic trioxide. However, due to the grouping issue raised, it is recommended that ECHA raises this issue at an upcoming CARACAL meeting and encourages the preparation of an Annex XV dossier for the relevant arsenate oxides. The MSC also considers that while this is the best approach to ensure regulatory effectiveness, it recognises that an indefinite wait for the preparation of the Annex XV dossier is not appropriate. It is therefore of the opinion that if the grouping Annex XIV dossier is not prepared within 2 years, that diarsenic trioxide is prioritised for inclusion in Annex XIV at that stage, if the ranking/weight of evidence confirms the priority of at least one of the arsenic oxides.

2.5 Diarsenic pentaoxide

Priority setting

ECHA proposes not to prioritise diarsenic pentaoxide for inclusion in Annex XIV.

Four MSCAs agreed with ECHA's proposal at present. One MSCA suggested that it should be prioritised. Overall however, the majority of the comments received on the prioritisation of diarsenic pentaoxide raised the issue of grouping relevant members of a particular group together for prioritisation. While one substance from a group could theoretically be prioritised, the regulatory effectiveness of doing this could be questioned and so it is considered by the MSC that the most

effective option is to group and prioritise relevant arsenic oxides, including diarsenic pentaoxide, together.

Worker exposure and wide dispersive uses

No extra information was submitted during the commenting period. There is some discrepancy between the information on tonnages submitted in the Annex XV dossier prepared by France and what is contained in ECHA's prioritisation document. Additionally, there is some uncertainty around the use of diarsenic pentaoxide in glass and glass products and it is recommended that further information/clarification is sought to deal with this uncertainty.

Occupational disease as an additional prioritisation criterion

A comment was submitted (for all substances, including diarsenic pentaoxide) suggesting that occupational disease due to exposure to a substance should be considered as an additional prioritisation criterion. If such a situation would arise for a substance, it is considered to be due to significant worker exposure. This criterion can be considered in the next round of prioritisation.

Exemptions

A comment was received that diarsenic pentaoxide should be exempted from the use as an analytical standard for test and measurement instruments. While this comment is not directly applicable to diarsenic pentaoxide at present, as it is currently not prioritised, it is a general issue that is addressed for all of the substances. The MSC would like to refer to, and support, the general comments of ECHA on this issue.

Conclusions

At this moment the MSC agrees with ECHA not to prioritise diarsenic pentaoxide. However, due to the grouping issue raised, it is recommended that ECHA raises this issue at an upcoming CARACAL meeting and encourages the preparation of an Annex XV dossier for the relevant arsenate oxides. The MSC also considers that while this is the best approach to ensure regulatory effectiveness, it recognises that an indefinite wait for the preparation of the Annex XV dossier is not appropriate. It is therefore of the opinion that if the grouping Annex XIV dossier is not prepared within 2 years, that diarsenic pentaoxide is prioritised for inclusion in Annex XIV at that stage, if the ranking/weight of evidence confirms the priority of at least one of the arsenic oxides.

2.6 Sodium Dichromate

Priority setting

ECHA proposes not to prioritise sodium dichromate for inclusion in Annex XIV.

Three MSCAs agreed with ECHA's proposal at present. Two MSCAs and a group of international NGO suggested that it should be prioritised. The majority of the comments received on the prioritisation of sodium dichromate raised the issue of grouping relevant members of a particular group together for prioritisation. While one substance from a group could theoretically be prioritised, the regulatory effectiveness of doing this could be questioned and so it is considered by the MSC that the most effective option is to group and prioritise relevant chromium VI compounds, including sodium dichromate, together.

Occupational disease as an additional prioritisation criterion.

A comment was submitted (for all substances, including sodium dichromate) suggesting that occupational disease due to exposure to a substance should be considered as an additional prioritisation criterion. If such a situation would arise for a substance, it is considered to be due to significant worker exposure. This criterion can be considered in the next round of prioritisation.

Exemptions

A comment was received that sodium dichromate should be exempted from the use as an analytical standard for test and measurement instruments. While this comment is not directly applicable to sodium dichromate at present, as it is currently not prioritised, it is a general issue that is addressed for all of the substances. The MSC would like to refer to, and support, the general comments of ECHA on this issue.

Conclusions

At this moment the MSC agrees with ECHA not to prioritise sodium dichromate. However, due to the grouping issue raised, it is recommended that ECHA raises this issue at an upcoming CARACAL meeting and encourages the preparation of an Annex XV dossier for the relevant chromium VI compounds. The MSC also considers that while this is the best approach to ensure regulatory effectiveness, it recognises that an indefinite wait for the preparation of the grouping Annex XV dossier is not appropriate. It is therefore of the opinion that if the dossier is not prepared within 2 years, that sodium dichromate is prioritised for inclusion in Annex XIV at that stage, if the ranking/weight of evidence confirms the priority of at least one of the chromium VI compounds.

2.7 TBTO

Priority setting

Several comments agree with the ECHA recommendation that Bis(tributyltin) oxide (TBTO) is not prioritised for the recommendation for inclusion into Annex XIV, as no non-intermediate use of TBTO are known in Europe. Other comments favour a prioritisation of TBTO due to its PBT properties.

Conclusions

At this moment the MSC recommends not to include TBTO in the recommendation based on the current information in the background reports and based on the prioritisation approach.

2.8 Lead Hydrogen Arsenate

Priority setting

The majority of the comments agree with the ECHA recommendation that lead hydrogen arsenate is not prioritised for the recommendation for inclusion into Annex XIV. A few issues were raised on which the MSC holds the opinion that they could be considered in the next round(s) of prioritisation.

Volume and use

One comment questions if the volume of lead hydrogen arsenate is as low as expected and suggests to prioritise the substance if it is registered in 2010.

For the current prioritisation, this comment is not relevant. The registration of all SVHC in 2010 will be closely monitored by ECHA and considered in the following recommendations.

Occupational disease as an additional prioritisation criterion

A commenter indicated that occupational disease due to exposure to the substance should be considered as an additional prioritisation criterion. If such a situation would arise for a substance, it is considered to be due to significant worker exposure. This criterion can be considered in the next round of prioritisation.

Cumulative risk assessment/grouping of substances

One comment requests to conduct a cumulative risk assessment for lead compounds. Since lead hydrogen arsenate is the only lead compound currently on the candidate list, a grouping approach would not be possible for the current prioritisation. Furthermore, it may be difficult to summarize lead compounds with different chemical structures and different uses in one group. Nevertheless, the issue of cumulative risk assessment might be considered in future prioritisations.

Exemptions

A comment was received that the analytical use of lead hydrogen arsenate is exempted from authorisation (if the substance is prioritised). In our view, this use does not need a specific exemption in the Annex XIV entry. It is either covered by the general R&D exemption of Article 56(3) or an exemption is not possible because a specific Community legislation that covers this use is not available. However, this is a general issue that is addressed by several commenters for different chemicals. The MSC would like to refer to the general comments of ECHA on this issue.

Conclusions

At this moment the MSC recommends not to include lead hydrogen arsenate for the next public consultation based on the current information in the background reports. This should be reconsidered when new information has become available that affects the weighting of the prioritisation criteria as done by ECHA[14].

[14] Prioritisation of Substances of Very High Concern (SVHC) for Inclusion in the List of Substances Subject to Authorisation: http://echa.europa.eu/doc/consultations/recommendations/gen_approach_prioritisation.pdf. See also ECHA website for update: General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for inclusion in the list of Substances Subject to Authorisation

European Chemicals Agency

ANNEX II

Helsinki, 8th May 2009
ECHA/MSC-8/2009/020

***Draft* Recommendation of priority substances to be included in Annex XIV of the REACH Regulation**

Substance	Intrinsic property(ies)	Transitional arrangements		Review periods	Exempted (categories of) uses
		Application date	Sunset date		
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) EC number: 201-329-4 CAS number: 81-15-2	vPvB *(article 57(e[1]))*	[Date of inclusion in Annex XIV + 24 months]	[Date of inclusion in Annex XIV + 42 months]	-	-
4,4'-Diaminodiphenylmethane (MDA) EC number: 202-974-4 CAS number: 101-77-9	Carcinogenic - category 2 *(article 57(a)[2])*	[Date of inclusion in Annex XIV + 24 months]	[Date of inclusion in Annex XIV + 42 months]	-	Placing on the market in preparation for supply to the general public for the use as artists' paints which are covered by Directive 1999/45/EC
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - SCCPs) EC number: 287-476-5 CAS number: 85535-84-8	PBT and vPvB *(article 57(d)&(e)[1])*	[Date of inclusion in Annex XIV + 27 months]	[Date of inclusion in Annex XIV + 45 months]	-	Placing on the market as in preparation in concentration at or lower than 1 % by weight for a use in - metalworking - fat liquoring of leather

[1] An authorisation may be granted only in accordance with Article 60(4) ('socio-economic route')
[2] According to available information it is not possible to determine a threshold in accordance with Section 6.4 of Annex I. Therefore, an authorisation may be granted only in accordance with Article 60(4) ('socio-economic route')

Substance	Intrinsic property(ies)	Transitional arrangements		Review periods	Exempted (categories of) uses
		Application date	Sunset date		
Hexabromocyclododecane (and all major diastereoisomers identified, i.e. alpha-, beta- and gamma-hexabromocyclododecane) (HBCDD) EC number: 247-148-4 and 221-695-9 CAS number: 25637-99-4 and 3194-55-6 (diastereoisomers, respectively: 134237-50-6, 134237-51-7, 134237-52-8)	PBT (*article 57(d)*[1])	[Date of inclusion in Annex XIV + 27 months]	[Date of inclusion in Annex XIV + 45 months]	-	-
Bis(2-ethylhexyl) phthalate (DEHP) EC number: 204-211-0 CAS number: 117-81-7	Toxic to reproduction – category 2 *(article 57(c)*[3]*)*	[Date of inclusion in Annex XIV + 30 months]	[Date of inclusion in Annex XIV + 48 months]	-	Placing on the market in preparation for supply to the general public for the use as artists' paints which are covered by Directive 1999/45/EC
Benzyl butyl phthalate (BBP) EC number: 201-622-7 CAS number: 85-68-7	Toxic to reproduction – category 2 *(article 57(c)*[3]*)*	[Date of inclusion in Annex XIV + 30 months]	[Date of inclusion in Annex XIV + 48 months]	-	Placing on the market in preparation for supply to the general public for the use as artists' paints which are covered by Directive 1999/45/EC
Dibutyl phthalate (DBP) EC number: 201-557-4 CAS number: 84-74-2	Toxic to reproduction – category 2 *(article 57(c)*[3]*)*	[Date of inclusion in Annex XIV + 30 months]	[Date of inclusion in Annex XIV + 48 months]	-	Placing on the market in preparation for supply to the general public for the use as artists' paints which are covered by Directive 1999/45/EC

[3] According to available information it is possible to determine a threshold in accordance with Section 6.4 of Annex I. Therefore, if the risk to human health from the use of the substance arising from intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report, an authorisation will be granted in accordance with Article 60(2) ('adequate control route'); if not, an authorisation may be granted in accordance with Article 60(4) ('socio-economic route').