**Recommendation of the European Chemicals Agency (ECHA)**

**of 1 June 2009**

**for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) of Regulation (EC) No 1907/2006**

The European Chemicals Agency,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Article 58 thereof,

Having regard to ECHA's decision ED/67/2008 of 28 October 2008 identifying and including fifteen substances to the Candidate List of Substances of Very High Concern for authorisation[1],

Having regard to the comments received from interested parties on the draft recommendation published on ECHA's website on 14 January 2009[2],

Having regard to the opinion of ECHA's Member State Committee of 20 May 2009 [3],

Whereas:

(1) This recommendation aims to assist the Commission in taking its decision pursuant to Article 58(1) of the REACH Regulation to include substances referred to in Article 57 in Annex XIV of the REACH Regulation.

(2) Pursuant to Article 58(3) of the REACH Regulation ECHA is required to make its first recommendation of priority substances to be included in Annex XIV by 1 June 2009.

(3) Pursuant to Article 58(4) of the REACH Regulation ECHA published on its website on 14 January 2009 a draft recommendation of substances to be included in Annex XIV and invited all interested parties to submit comments by 14 April 2009. ECHA has analysed and prepared responses to comments received and will make these publicly available[4].

[1] http://echa.europa.eu/chem_data/candidate_list_table_en.asp
[2] http://echa.europa.eu/consultations/authorisation/draft_recommendations_en.asp
[3] http://echa.europa.eu/doc/about/organisation/msc/opinion_draft_recommendation_annex_xiv.pdf
[4] http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec/subst_spec_docs_en.asp

(4) ECHA has developed a paper presenting ECHA's approach for prioritising, pursuant to Article 58(3) of the REACH Regulation, substances for inclusion in Annex XIV[5]. On the basis of this approach ECHA has prioritised the following seven substances for inclusion in Annex XIV:

- 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)
- 4,4'-Diaminodiphenylmethane (MDA)
- Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - SCCPs)
- Hexabromocyclododecane (HBCDD)
- Bis(2-ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)

(5) ECHA is required by Article 58(3) of the REACH Regulation to recommend for each priority substance an Annex XIV entry specifying its identity, its intrinsic properties referred to in article 57, the application deadline, the sunset date from which the placing of the market and use of a substance is prohibited unless an authorisation is granted, the review periods for certain uses, and uses or categories of uses to be exempted from the authorisation requirement.

(6) ECHA has developed a paper presenting ECHA's approach for determining the Annex XIV entries of prioritised substances[6]. On the basis of this paper ECHA has determined the specific Annex XIV entries for each substance.

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

(8) The intrinsic properties of the substances entered in Annex XIV pursuant to Article 58(1)(b) of the REACH Regulation should help to determine the possible authorisation route for each substance.

(9) For the transitional arrangements referred to in Article 58(1)(c) of the REACH Regulation ECHA has applied for each substance a standard time period of 18 months between the relevant application deadline and the sunset date.

(10) The application deadlines take account of ECHA's capacity to handle applications in the time provided for. On that basis the latest authorisation application dates for the prioritised substances are spread over a period of 6 months. The expected time required to prepare an application for authorisation is used as a basis to differentiate the application dates for the different substances.

(11) Neither the available information for priority substances nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods in accordance with article 58(1)(d) for any uses of the substances prioritised for inclusion in Annex XIV.

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[5] http://echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_prior_set_approach.pdf
[6] http://echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_rec_entries.pdf

(12) For exemptions of certain uses (or categories of uses) pursuant to Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation, an assessment needs to be made whether the risk is properly controlled under specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance.

(13) Recital 80 of the REACH Regulation requires that a proper interaction should be ensured between the provisions on authorisation and restriction. On that basis exemptions from restrictions of a specified use of a substance should also be exempted from authorisation.

(14) ECHA has received following its public consultation of 14 January 2009 numerous comments on exemptions of certain uses pursuant to article 58(1)(e) of the REACH Regulation, and ECHA has provided its responses to these comments which should assist the Commission in its assessment of the merits of such requests.

(15) In light of ECHA's Member State Committee opinion ECHA revised its draft recommendation in so far as it no longer recommends that an exemption should be granted for the use of CMR (Category 1 and 2) substances in artists' paints.

(16) Neither the available information for priority substances nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

**HEREBY RECOMMENDS that on the basis of the reasons set out in the Annex to this recommendation the following entries are included in Annex XIV of the REACH Regulation (the list of substances subject to authorisation):**

| Entry n° | Substance | EC number | CAS number | Intrinsic property(ies) | Transitional arrangements | | Review periods | Exempted (categories of) uses | Exemptions for PPORD |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Latest application date | Sunset date | | | |
| 1 | 5-tert-butyl-2,4,6-trinitro-m-xylene **(musk xylene)** | 201-329-4 | 81-15-2 | vPvB<br><br>*(article 57(e)[1])* | [Date of inclusion in Annex XIV + 24 months] | [Date of inclusion in Annex XIV + 42 months] | None | None | None |
| 2 | 4,4'-Diaminodiphenyl-methane **(MDA)** | 202-974-4 | 101-77-9 | Carcinogenic - category 2<br><br>*(article 57(a)[2])* | [Date of inclusion in Annex XIV + 24 months] | [Date of inclusion in Annex XIV + 42 months] | None | None | None |
| 3 | Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - **SCCPs**) | 287-476-5 | 85535-84-8 | PBT and vPvB<br><br>*(article 57(d)&(e)[1])* | [Date of inclusion in Annex XIV + 27 months] | [Date of inclusion in Annex XIV + 45 months] | None | Placing on the market or use in preparations in concentrations at or lower than 1 % by weight, where the preparation is intended for:<br>▪ metalworking<br>▪ fat liquoring of leather | None |
| 4 | Hexabromocyclo-dodecane **(HBCDD)**<br><br>, and all major diastereoisomers identified, i.e.:<br><br>alpha-hexabromocyclo-dodecane<br><br>beta-hexabromocyclo-dodecane<br><br>gamma-hexabromo-cyclododecane | 247-148-4<br>221-695-9<br><br>134237-50-6<br><br>134237-51-7<br><br>134237-52-8 | 25637-99-4<br>3194-55-6 | PBT<br><br>*(article 57(d)[1])* | [Date of inclusion in Annex XIV + 27 months] | [Date of inclusion in Annex XIV + 45 months] | None | None | None |

[1] Pursuant to Article 60(3) of the REACH Regulation it would appear that an authorisation can only be granted 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, pursuant to Article 60(3) of the REACH Regulation it would appear that an authorisation can only be granted in accordance with Article 60(4) ('socio-economic route')

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5 | Bis(2-ethylhexyl) phthalate (**DEHP**) | 204-211-0 | 117-81-7 | Toxic to reproduction – category 2<br><br>*(article 57(c)[3])* | [Date of inclusion in Annex XIV + 30 months] | [Date of inclusion in Annex XIV + 48 months] | None | None | None |
| 6 | Benzyl butyl phthalate (**BBP**) | 201-622-7 | 85-68-7 | Toxic to reproduction – category 2<br><br>*(article 57(c)[3])* | [Date of inclusion in Annex XIV + 30 months] | [Date of inclusion in Annex XIV + 48 months] | None | None | None |
| 7 | Dibutyl phthalate (**DBP**) | 201-557-4 | 84-74-2 | Toxic to reproduction – category 2<br><br>*(article 57(c)[3])* | [Date of inclusion in Annex XIV + 30 months] | [Date of inclusion in Annex XIV + 48 months] | None | None | None |

Done at Helsinki, 1 June 2009

For the European Chemicals Agency,

Geert DANCET, Executive Director

[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').

**ANNEX I - Reasons for the prioritisation and Annex XIV recommendation for the prioritised substances**

Introduction:

The purpose if this Annex is to describe the reasons for prioritising and defining Annex XIV entries made for the following seven substances.

A. 5-tert-butyl-2,4,6-trinitro-m-xylene (**musk xylene**)
B. 4,4'-Diaminodiphenylmethane **(MDA)**
C. Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - **SCCPs**)
D. Hexabromocyclododecane (and all major diastereoisomers identified, i.e. alpha-, beta and gamma-hexabromocyclododecane) (**HBCDD**)
E. Bis(2-ethylhexyl) phthalate (**DEHP**)
F. Benzyl butyl phthalate (**BBP**)
G. Dibutyl phthalate (**DBP**)

For the preparation of this recommendation ECHA has used the following documents[10,11]:

- "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*" document
- "*General approach for defining the Annex XIV entries*" document
- Substance-specific background documents
- Substance-specific technical report on manufacture, import, export, uses, releases and alternatives
- Substance-specific "*Responses to comments*" documents
- Opinion of the Member State Committee of 20 May 2009

[10] http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec_en.asp#back_doc
[11] http://echa.europa.eu/doc/about/organisation/msc/opinion_draft_recommendation_annex_xiv.pdf

## Annex I.A. - 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)

**Reasons for prioritising musk xylene**

To determine whether musk xylene should be prioritised at this stage pursuant to Article 58(3) of the REACH Regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*". ECHA concluded that musk xylene, in addition to being a vPvB substance, is supplied for uses and applications that must be considered as wide dispersive, although in presumably relatively low volumes.

Hence, ECHA has prioritised 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) for inclusion in Annex XIV.

**Reasons for the specific items in the Annex XIV entry**

1) *Identity of the substance*

| | |
|---|---|
| Chemical name: | musk xylene |
| EC Number: | 201-329-4 |
| CAS Number: | 81-15-2 |
| IUPAC Name: | 1-tert-butyl-3,5-dimethyl-2,4,6-trinitrobenzene |

2) *Intrinsic properties of the substance*

Musk xylene was identified as a Substance of Very High Concern (SVHC) meeting the criteria of a vPvB substance pursuant to Article 57(e) and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

Possible route for authorisation:
The substance meets the criteria in Article 57(e).
Therefore, pursuant to Article 60(3) of the REACH Regulation, it would appear that an authorisation can only be granted in accordance with Article 60(4) of the REACH Regulation ('socio-economic route').

3) *Transitional arrangements*

Based on the available information, it is anticipated that the preparation of applications for authorisation would be facilitated by the relative homogeneity and the limited number of actors in the supply chains.

Furthermore, the available information indicates an already ongoing substitution of musk xylene with alternative substances as an autonomous process (due to pressure by consumers). There appears also to be information on the limitation of the currently available alternatives for certain uses. Therefore, the available information on

potential alternatives facilitates preparing an analysis of alternatives for uses for which actors wish to apply for.
Consequently, the available information suggests that potential applicants would be well prepared to develop an application, in particular with respect to the analysis of alternatives.

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

- *Latest application date*:
  24 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  42 months after the entry into force of the Decision to include the substance in Annex XIV

4) *Review periods for certain uses*

Neither the available information for musk xylene nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of musk xylene.

5) *Exempted (categories of) uses*

During the public consultation of 14 January 2009 no requests were made for exempting certain uses of musk xylene.

On the basis of the available information, ECHA does not see any grounds for recommending any exemptions of uses for musk xylene.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

Neither the available information for musk xylene nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of musk xylene in PPORD from authorisation.

## Annex I.B. - 4,4'-Diaminodiphenylmethane (MDA)

**Reasons for prioritising MDA**

To determine whether MDA should be prioritised at this stage pursuant to Article 58(3) of the REACH Regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*". ECHA concluded that MDA is supplied for uses and applications that must be considered as wide dispersive, in relatively high volumes.

Hence, ECHA has prioritised 4,4'-Diaminodiphenylmethane (MDA) for inclusion in Annex XIV.

**Reasons for the specific items in the Annex XIV entry**

1) *Identity of the substance*

| | |
|---|---|
| Chemical name: | 4,4'-Diaminodiphenylmethane (MDA) |
| EC Number: | 202-974-4 |
| CAS Number: | 101-77-9 |
| IUPAC Name: | Bis (4-aminophenyl)methane |

2) *Intrinsic properties of the substance*

MDA was identified as a Substance of Very High Concern (SVHC) pursuant to Article 57(a) as it is classified as Carcinogenic, Category 2[12] and it was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

Possible route for authorisation:
The substance meets the criteria in Article 57(a) and according to available information, it is not possible to determine a toxicological threshold in accordance with section 6.4 of Annex I.
Therefore, pursuant to Article 60(3) of the REACH Regulation, it would appear that an authorisation can only be granted in accordance with Article 60(4) of the REACH Regulation ('socio-economic route').

3) *Transitional arrangements*

Based on the available information, it is anticipated that the preparation of applications for authorisation would be facilitated by rather short supply-chains, which consist of actors from a limited number of relatively similar industrial sectors and professional user groups.

[12] This document refers (here and in its other parts) to classification in accordance with Directive 67/548/EEC to keep the references in line with the entry in the published Candidate list. ECHA will update the Candidate list to follow the CLP Regulation ((EC) No 1272/2008) in future.

Furthermore, the available information indicates an already ongoing substitution of MDA with alternative substances. There appears also to be information on the limitation of the currently available alternatives for certain uses. Therefore, the available information on potential alternatives facilitates preparing an analysis of alternatives for uses for which actors wish to apply for.
Consequently, the available information suggests that potential applicants would be well prepared to develop an application, in particular with respect to the analysis of alternatives.

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

- *Latest application date*:
  24 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  42 months after the entry into force of the Decision to include the substance in Annex XIV

4) *Review periods for certain uses*

Neither the available information for MDA nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of MDA.

5) *Exempted (categories of) uses*

ECHA does not recommend any exemptions of uses for MDA. ECHA arrived to this conclusion on the basis of the considerations set out below.

Exemption for use in artists' paints:
Directive 76/769/EEC sets out the restrictions on the uses of substances as well as specific exemptions to these restrictions. These restrictions (and their exemptions) are incorporated in Annex XVII of the REACH Regulation which will replace the entries in Directive 76/769/EEC from 1 June 2009. The recitals of Directive 76/769/EEC and the directives amending it provide that these restrictions have an objective to protect human health and/or the environment. Directive 76/769/EEC could therefore constitute specific Community legislation imposing minimum requirements relating to the protection of human health and the environment for the use of a substance within the meaning of Article 58(2) of the REACH Regulation.

On this basis, ECHA considers that where an entry in Annex XVII exempts a specific use of a substance from the restrictions, Article 58(2) could be used to exempt that specific use from authorisation in the two following situations:

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.

Entries 28 to 30 of Annex XVII provide that all substances classified as CMR (Category 1 and 2) may not be used in substances and mixtures placed on the market for sale to the general public. However, these entries exempt from restriction the use of such substances in artists' paints.

In the draft recommendation published by ECHA on 14 January 2009 ECHA considered that as MDA is one of the CMR substances concerned by entries 28 to 30 of Annex XVII and that recital (80) of the REACH Regulation requires that a proper interaction should be ensured between the provisions of authorisation and restriction, an exemption from the authorisation requirement should be granted pursuant to Article 58(2) of the REACH Regulation for the use of MDA in artists' paints on the basis that this use has been specifically exempted in Annex XVII.

In its opinion of 20 May 2009 ECHA's Member State Committee (the MSC) considered that no exemption should be granted from the authorisation requirement for the use of MDA in artists' paints. This opinion was based on the following considerations.

First, some members of the MSC expressed doubts as to whether the exemption from restrictions of the use in artists' paints could be regarded as meeting the criteria for exemption from authorisation set out in Article 58(2) as the exemption to the restriction was based on socio-economic grounds rather than on health and risk considerations.

On this point ECHA considers that in determining whether an exemption to a restriction should benefit from an exemption from the authorisation requirement it is not possible to simply dissociate the exemption from the restriction. The restriction and its related exemptions must be examined as a whole in order to determine whether an exemption under Article 58(2) of the REACH Regulation should be granted.

Second, all members of the MSC considered that an exemption should not be granted for the use of artists' paints on the basis that the exemption from the restriction requirement of that use in entries 28 to 30 of Annex XVII covers a category of substances (i.e., all CMRs) rather than a specific substance (i.e., only MDA or group of specified substances). In the MSC's view an exemption to a restriction covering a wide range of substances may not necessarily meet the requirements from exemption from authorisation under Article 58(2) of the REACH Regulation.

On this latter point ECHA shares the MSC's concern. On the basis of the information available ECHA cannot determine whether such an exemption can be justified under Article 58(2) of the REACH Regulation.. ECHA therefore decided on the basis of the MSC's opinion and the deliberations leading to that opinion to amend its

recommendation and not propose an exemption from the authorisation requirement for the use of MDA in artists' paints.

ECHA however urges the European Commission to examine on the basis of the information at its disposal whether such exemption should be introduced after all, and to further clarify under what conditions specific exemptions to restrictions set out in Annex XVII should be taken into account when determining exemptions from the authorisation requirement under Article 58(2) of the REACH Regulation.

Exemptions requested by third parties:
During the public consultation on the draft recommendation, ECHA received a number of requests for use-specific exemptions of MDA.

ECHA did not see grounds for recommending general exemptions for MDA for the reasons set out in the "*Responses to comments*" document.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

Neither the available information for MDA nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of MDA in PPORD from authorisation.

## Annex I.C. - Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - SCCPs)

**Reasons for prioritising SCCPs**

To determine whether SCCPs should be prioritised at this stage pursuant to Article 58(3) of the REACH Regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*". ECHA concluded that SCCPs, in addition to being a PBT and vPvB substance, is supplied for uses and applications that must be considered as wide dispersive, in relatively high volumes.

Hence, ECHA has prioritised alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - SCCPs) for inclusion in Annex XIV.

**Reasons for the specific items in the Annex XIV entry**

1) *Identity of the substance*

| | |
|---|---|
| Chemical name: | alkanes, $C_{10-13}$,chloro (SCCPs) |
| EC Number: | 287-476-5 |
| CAS Number: | 85535-84-8 |
| IUPAC Name: | alkanes, $C_{10-13}$, chloro |

2) *Intrinsic properties of the substance*

Alkanes, $C_{10-13}$,chloro was identified as a Substance of Very High Concern (SVHC) meeting the criteria of a PBT and vPvB substance pursuant to Article 57 (d) and (e) and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

Possible route for authorisation:
The substance meets the criteria in Article 57(d) and (e).
Therefore, pursuant to Article 60(3) of the REACH Regulation, it would appear that an authorisation can only be granted in accordance with Article 60(4) of the REACH Regulation ('socio-economic route').

3) *Transitional arrangements*

Based on the available information, it is anticipated that the preparation of applications will require a collaborative effort by a number of actors. Supply chains related to some of the uses are fairly simple while others include more levels. The affected actors represent several different industry sectors and professional user groups. However, most of the uses are highly specialised.

Furthermore, the available information on potential alternatives facilitates preparing an analysis of alternatives for uses for which actors wish to apply for. On the other hand, some of the available information on alternatives suggests that the potential

applicants may need to assess more complicated situations to conclude whether or not transfer to alternatives is feasible.

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

- *Latest application date*:
  27 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  45 months after the entry into force of the Decision to include the substance in Annex XIV

4) *Review periods for certain uses*

Neither the available information for SCCPs nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of SCCPs.

5) *Exempted (categories of) uses*

ECHA recommends to exempt from the authorisation requirement the placing on the market and use of SCCPs in preparation in concentrations at or lower than 1 % by weight where the preparation is intended for a use in metalworking or fat liquoring of leather.

Exemption for use in metalworking or fat liquoring of leather:
Directive 76/769/EEC sets out the restrictions on the uses of substances as well as specific exemptions to these restrictions. These restrictions (and their exemptions) are incorporated in Annex XVII of the REACH Regulation which will replace the entries in Directive 76/769/EEC from 1 June 2009. The recitals of Directive 76/769/EEC and the directives amending it provide that these restrictions have an objective to protect human health and/or the environment. Directive 76/769/EEC could therefore constitute specific Community legislation imposing minimum requirements relating to the protection of human health and the environment for the use of a substance within the meaning of Article 58(2) of the REACH Regulation. Furthermore, recital 80 of the REACH Regulation requires that a proper interaction should be ensured between the provisions of authorisation and restriction.

On this basis, ECHA considers that where an entry in Annex XVII exempts a specific use of a substance from the restrictions, Article 58(2) could be used to exempt that specific use from authorisation in the two following situations:

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.

Entry 42 of Annex XVII provides that SCCPs may not be placed on the market as substances or constituent of other substances or in preparations for use in metalworking or in fat liquoring of leather when the concentration is greater than 1 % by weight. Thus, use of SCCPs in these applications in preparation in concentrations at or lower than 1 % is permitted.

In its draft recommendation ECHA considered that as the restriction in Directive 76/769 permits the use of SCCPs in these applications in preparations in concentrations at or lower than 1 %, such use should be exempted from authorisation pursuant to Article 58(2) of the REACH Regulation.

In its opinion of 20 May 2009 ECHA's Member State Committee (MSC) considered that further legal interpretation is required in order to take a position whether this use of SCCP should be exempted from authorisation.

Having examined the opinion of the MSC ECHA still considers that from a legal point of view this use should be exempted from authorisation pursuant to Article 58(2) of the REACH Regulation. Indeed, unlike the exemption from restrictions for use of substances in artists' paints which addressed a category of substances, the restriction (and conditions for exemption) of the use of SCCPs specifically identified the substance that is subject to the restriction.

ECHA however urges the European Commission to review this analysis made by ECHA and to clarify under what conditions specific exemptions to restrictions set out in Annex XVII should be taken into account when determining exemptions from the authorisation requirement under Article 58(2) of the REACH Regulation.

Exemptions requested by third parties:
During the public consultation on the draft recommendation, ECHA received a number of requests for use-specific exemptions of SCCPs.

ECHA did not see grounds for recommending general exemptions for SCCPs for the reasons set out in the "*Responses to comments*" document.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

Neither the available information for SCCPs nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of SCCPs in PPORD from authorisation.

## Annex I.D. - Hexabromocyclododecane (and all major diastereoisomers identified, i.e. alpha-, beta and gamma-hexabromocyclododecane) (HBCDD)

**Reasons for prioritising HBCDD**

To determine whether HBCDD should be prioritised at this stage pursuant to Article 58(3) of the REACH Regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*". ECHA concluded that HBCDD, in addition to being a PBT substance, is supplied for uses that must be considered as wide dispersive, in very high volumes.

Hence, ECHA has prioritised hexabromocyclododecane (and all major diastereoisomers identified, i.e. alpha-, beta and gamma-hexabromocyclododecane) (HBCDD) for inclusion in Annex XIV.

**Reasons for the specific items in the Annex XIV entry**

1) *Identity of the substance*

| | |
|---|---|
| Chemical name: | hexabromocyclododecane (Hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane) and all major diastereoisomers identified |
| EC Numbers: | 221-695-9, 247-148-4 |
| CAS Numbers: | 3194-55-6, 25637-99-4 |
| IUPAC Name: | hexabromocyclododecane |

2) *Intrinsic properties of the substance*

HBCDD was identified as a Substance of Very High Concern (SVHC) meeting the criteria of a PBT substance pursuant to Article 57(d) and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

Possible route for authorisation:
The substance meets the criteria in Article 57(d).
Therefore, pursuant to Article 60(3) of the REACH Regulation, it would appear that an authorisation can only be granted in accordance with Article 60(4) of the REACH Regulation ('socio-economic route').

3) *Transitional arrangements*

Based on the information available, it is anticipated that the preparation of applications for authorisation will require some collaborative efforts by a potentially large number of actors, even though they represent a rather limited number of different industries.

The available information also suggests that, even though fairly much work has already been done to identify and assess potential alternatives, the preparation of the analysis of alternatives may require some additional time for certain uses, and in particular where the potential alternatives are changing the key materials rather than only replacing HBCDD by another substance in the same polymer.

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

- *Latest application date*:
  27 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  45 months after the entry into force of the Decision to include the substance in Annex XIV

4) *Review periods for certain uses*

Neither the available information for HBCDD nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of HBCDD.

5) *Exempted (categories of) uses*

During the public consultation on the draft recommendation, ECHA received a number of requests for use-specific exemptions of HBCDD.

ECHA did not see grounds for recommending general exemptions for HBCDD for the reasons set out in the "*Responses to comments*" document.

Hence, ECHA does not recommend any exemptions of uses for HBCDD.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

Neither the available information for HBCDD nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of HBCDD in PPORD from authorisation.

## Annex I.E. - Bis(2-ethylhexyl) phthalate (DEHP)

**Reasons for prioritising DEHP**

To determine whether DEHP should be prioritised at this stage pursuant to Article 58(3) of the REACH Regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*". ECHA concluded that DEHP is supplied for uses and applications that must be considered as wide dispersive, in very high volumes.

Hence, ECHA has prioritised bis(2-ethylhexyl) phthalate (DEHP) for inclusion in Annex XIV.

**Reasons for the specific items in the Annex XIV entry**

*1) Identity of the substance*

| | |
|---|---|
| Chemical name: | bis(2-ethylhexyl) phthalate (DEHP) |
| EC Number: | 204-211-0 |
| CAS Number: | 117-81-7 |
| IUPAC Name: | Bis(2-ethylhexyl) phthalate |

*2) Intrinsic properties of the substance*

DEHP was identified as a Substance of Very High Concern (SVHC) pursuant to Article 57(c) as it is classified as Toxic to Reproduction, Category 2[13] and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

Possible route for authorisation:
The substance meets the criteria in Article 57(c) and according to available information, it seems to be possible to determine a toxicological threshold in accordance with section 6.4 of Annex I.
Therefore, pursuant to Article 60(2) of the REACH Regulation, if the risk to human health from the use of the substance arising from its toxicity to reproduction is adequately controlled in accordance with Section 6.4 of Annex I and this is documented in the applicant's chemical safety report, an authorisation will be granted ('adequate control route'); if not, pursuant to Article 60(4) of the REACH Regulation, an authorisation may be granted ('socio-economic route').

*3) Transitional arrangements*

Based on the available information, it is anticipated that the preparation of applications for authorisation will require a considerable collaborative effort by

[13] This document refers (here and in its other parts) to classification in accordance with Directive 67/548/EEC to keep the references in line with the entry in the published Candidate list. ECHA will update the Candidate list to follow the CLP Regulation ((EC) No 1272/2008) in future.

various actors. Many different types of industries and activities involving a large number of actors may be affected by the possible authorisation requirement and may need to get involved directly or indirectly in the preparation of applications.

Furthermore, the available information indicates that, even though substitution has already started for some specific applications, the preparation of the analysis of alternatives may require some time for many applications of DEHP, in particular the assessment of the risks of alternative substances and the technical feasibility of alternative materials.

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

- *Latest application date*:
  30 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  48 months after the entry into force of the Decision to include the substance in Annex XIV

4) *Review periods for certain uses*

Neither the available information for DEHP nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of DEHP.

5) *Exempted (categories of) uses*

ECHA does not recommend any exemptions of uses for DEHP. ECHA arrived to this conclusion on the basis of the considerations set out below.

Exemption for use in artists' paints:
In the draft recommendation published by ECHA on 14 January 2009 ECHA considered that as DEHP is one of the CMR substances concerned by entries 28 to 30 of Annex XVII and that recital (80) of the REACH Regulation requires that a proper interaction should be ensured between the provisions of authorisation and restriction, an exemption from the authorisation requirement should be granted pursuant to Article 58(2) of the REACH Regulation for the use of DEHP in artists' paints on the basis that this use has been specifically exempted in Annex XVII. ECHA has now decided in light of the MSC opinion not to recommend this exemption for the same considerations set out in more detail for MDA in Annex I.B.

Exemptions requested by third parties:
During the public consultation on the draft recommendation, ECHA received a number of requests for use-specific exemptions of DEHP.

ECHA did not see grounds for recommending general exemptions for DEHP for the reasons set out in the "*Responses to comments*" document.

However, with regard to the use of the prioritised substances in medical devices and in primary/immediate packaging of medicinal products ECHA was not in a position to fully assess the possible consequences of the existing Community legislation on the implementation of the provisions in Title VII of the REACH Regulation. In particular in these cases, ECHA urges the European Commission to examine these requests for exemptions.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

Neither the available information for DEHP nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of DEHP in PPORD from authorisation.

## Annex I.F. - Benzyl butyl phthalate (BBP)

**Reasons for prioritising BBP**

To determine whether BBP should be prioritised at this stage pursuant to Article 58(3) of the REACH Regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*". ECHA concluded that BBP is supplied for uses and applications that must be considered as wide dispersive, in high volumes

Hence, ECHA has prioritised benzyl butyl phthalate (BBP) for inclusion in Annex XIV.

**Reasons for the specific items in the Annex XIV entry**

1) *Identity of the substance*

| | |
|---|---|
| Chemical name: | benzyl butyl phthalate (BBP) |
| EC Number: | 201-622-7 |
| CAS Number: | 85-68-7 |
| IUPAC Name: | benzyl butyl phthalate |

2) *Intrinsic properties of the substance*

BBP was identified as a Substance of Very High Concern (SVHC) pursuant to Article 57(c) as it is classified as Toxic to Reproduction, Category 2[14] and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

Possible route for authorisation:
The substance meets the criteria in Article 57(c) and according to available information, it seems to be possible to determine a toxicological threshold in accordance with section 6.4 of Annex I.
Therefore, pursuant to Article 60(2) of the REACH Regulation, if the risk to human health from the use of the substance arising from its toxicity to reproduction is adequately controlled in accordance with Section 6.4 of Annex I and this is documented in the applicant's chemical safety report, an authorisation will be granted ('adequate control route'); if not, pursuant to Article 60(4) of the REACH Regulation, an authorisation may be granted ('socio-economic route').

[14] This document refers (here and in its other parts) to classification in accordance with Directive 67/548/EEC to keep the references in line with the entry in the published Candidate list. ECHA will update the Candidate list to follow the CLP Regulation ((EC) No 1272/2008) in future

3) *Transitional arrangements*

Based on the available information, it is anticipated that the preparation of applications for authorisation will require a considerable collaborative effort by various actors, involved both within the same or different supply chains.

The information available also suggests that even though substitution has already started for several applications of BBP, the preparation of the analysis of alternatives may require some additional time for other uses, and in particular to conclude whether or not the transfer to alternatives is feasible. This is the case, for instance, where the identified potential alternative may have an impact on the specific properties that BBP confers to certain end products affecting, e.g., the maintenance.

Furthermore, some of the uses and potentially affected user groups are the same as for DEHP, which further supports the setting of the same application date for these substances.

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

- *Latest application date*:
  30 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  48 months after the entry into force of the Decision to include the substance in Annex XIV

4) *Review periods for certain uses*

Neither the available information for BBP nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of BBP.

5) *Exempted (categories of) uses*

ECHA does not recommend any exemptions of uses for BBP. ECHA arrived to this conclusion on the basis of the considerations set out below.

Exemption for use in artists' paints:
In the draft recommendation published by ECHA on 14 January 2009 ECHA considered that as BBP is one of the CMR substances concerned by entries 28 to 30 of Annex XVII and that recital (80) of the REACH Regulation requires that a proper interaction should be ensured between the provisions of authorisation and restriction, an exemption from the authorisation requirement should be granted pursuant to Article 58(2) of the REACH Regulation for the use of BBP in artists' paints on the basis that this use has been specifically exempted in Annex XVII. ECHA has now

decided in light of the MSC opinion not to recommend this exemption for the same considerations set out in more detail for MDA in Annex I.B.

Exemptions requested by third parties:
During the public consultation on the draft recommendation, ECHA received a number of requests for use-specific exemptions of BBP.

ECHA did not see grounds for recommending general exemptions for BBP for the reasons set out in the "*Responses to comments*" document.

However, with regard to the use of the prioritised substances in medical devices and in primary/immediate packaging of medicinal products ECHA was not in a position to fully assess the possible consequences of the existing Community legislation on the implementation of the provisions in Title VII of the REACH Regulation. In particular in these cases, ECHA urges the European Commission to examine these requests for exemptions.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

Neither the available information for BBP nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of BBP in PPORD from authorisation.

## Annex I.G. - Dibutyl phthalate (DBP)

**Reasons for prioritising DBP**

To determine whether DBP should be prioritised at this stage pursuant to Article 58(3) of the REACH Regulation ECHA applied the principles contained in the document entitled "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*". ECHA concluded that DBP is supplied for uses and applications that must be considered as wide dispersive, in high volumes

Hence, ECHA has prioritised dibutyl phthalate (DBP) for inclusion in Annex XIV.

**Reasons for the specific items in the Annex XIV entry**

*1) Identity of the substance*

| | |
|---|---|
| Chemical name: | dibutyl phthalate (DBP) |
| EC Number: | 201-557-4 |
| CAS Number: | 84-74-2 |
| IUPAC Name: | dibutyl phthalate |

*2) Intrinsic properties of the substance*

DBP was identified as a Substance of Very High Concern (SVHC) pursuant to Article 57(c) as it is classified as Toxic to Reproduction, Category 2[15] and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

Possible route for authorisation:
The substance meets the criteria in Article 57(c) and according to available information, it seems to be possible to determine a toxicological threshold in accordance with section 6.4 of Annex I.
Therefore, pursuant to Article 60(2) of the REACH Regulation, if the risk to human health from the use of the substance arising from its toxicity to reproduction is adequately controlled in accordance with Section 6.4 of Annex I and this is documented in the applicant's chemical safety report, an authorisation will be granted ('adequate control route'); if not, pursuant to Article 60(4) of the REACH Regulation, an authorisation may be granted ('socio-economic route').

*3) Transitional arrangements*

Based on the information available, it is anticipated that the preparation of applications for authorisation will require a considerable collaborative effort by various actors, involved both within the same or different supply chains.

[15] This document refers (here and in its other parts) to classification in accordance with Directive 67/548/EEC to keep the references in line with the entry in the published Candidate list. ECHA will update the Candidate list to follow the CLP Regulation ((EC) No 1272/2008) in future.

The information available also suggests that even though substitution has already started for several applications of DBP, the preparation of the analysis of alternatives may require some additional time for other uses, and in particular for the assessment of the risks of alternative substances or the changes in the process and/or the material composition which the use of the alternative may require (technical/economic feasibility).

Furthermore, some of the uses and potentially affected user groups are the same as for DEHP, which further supports setting the same application date for these substances.

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

- *Latest application date*:
  30 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  48 months after the entry into force of the Decision to include the substance in Annex XIV

*4) Review periods for certain uses*

Neither the available information for DBP nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of DBP.

*5) Exempted (categories of) uses*

ECHA does not recommend any exemptions of uses for DBP. ECHA arrived to this conclusion on the basis of the considerations set out below.

Exemption for use in artists' paints:
In the draft recommendation published by ECHA on 14 January 2009 ECHA considered that as DBP is one of the CMR substances concerned by entries 28 to 30 of Annex XVII and that recital (80) of the REACH Regulation requires that a proper interaction should be ensured between the provisions of authorisation and restriction, an exemption from the authorisation requirement should be granted pursuant to Article 58(2) of the REACH Regulation for the use of DBP in artists' paints on the basis that this use has been specifically exempted in Annex XVII. ECHA has now decided in light of the MSC opinion not to recommend this exemption for the same considerations set out in more detail for MDA in Annex I.B.

Exemptions requested by third parties:
During the public consultation on the draft recommendation, ECHA received a number of requests for use-specific exemptions of DBP.

ECHA did not see grounds for recommending general exemptions for DBP for the reasons set out in the "*Responses to comments*" document.

However, with regard to the use of the prioritised substances in medical devices and in primary/immediate packaging of medicinal products ECHA was not in a position to fully assess the possible consequences of the existing Community legislation on the implementation of the provisions in Title VII of the REACH Regulation. In particular in these cases, ECHA urges the European Commission to examine these requests for exemptions.

6) *Application of authorisation to product and process oriented research and development (PPORD)*

Neither the available information for DBP nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of DBP in PPORD from authorisation.