ECHA/MSC-15/2010/029 - Adopted

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

**Adopted on 3 December 2010**

## OPINION

This opinion of the Member State Committee on the draft recommendation of the European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV was adopted on 3rd December 2010 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006.

## THE PROCESS FOR ADOPTION OF THE OPINION

ECHA consulted the Member State Committee 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 1 July 2010 on its website for public consultation.

The Member State Committee appointed a Rapporteur for preparing its opinion on ECHA's recommendation for Annex XIV at its 12th meeting (9-11 June 2010) and a Working Group to support the Rapporteur.

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

- ECHA's priority setting approach[1] and its application to all substances on the candidate list not already recommended for inclusion in Annex XIV[2]
- General approach for defining the Annex XIV entries[3]
- ECHA's draft recommendation of priority substances for inclusion in the list of substances subject to authorisation (available for public consultation on 1 July 2010) and its update (19 November 2010)
- Background documents for each substance summarising the available information used for priority setting and specification of items for Annex XIV entries prepared by

[1] http://echa.europa.eu/doc/consultations/recommendations/axiv_priority_setting_gen_approach_20100701.pdf
[2] http://echa.europa.eu/doc/consultations/recommendations/prioritisation_results_2nd_rec_20100701.pdf
[3] http://echa.europa.eu/doc/consultations/recommendations/draft_axiv_entries_gen_approach_20100701.pdf

ECHA (as published on ECHA website in the context of the public consultation and later updated as meeting documents on 19 November 2010)
- Comments of the interested parties provided during the public consultation period started on 1 July 2010 and closed on 30 September 2010
- Draft responses to comments provided by the ECHA Secretariat (as meeting documents on 19 November 2010).

The draft opinion provided to the Committee by the Rapporteur was finalised and adopted at the meeting of the Member State Committee (MSC) on 3rd December 2010. 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 made by ECHA for Annex XIV of the REACH Regulation specifies the following information for priority substances:

- The identity of substance as specified in section 2 of Annex VI
- The intrinsic properties 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.

In its draft recommendation addressed in the public consultation, ECHA did not recommend any uses or categories of uses that should be exempted from authorisation pursuant to Article 58(2). Moreover, in its recommendation ECHA did not recommend any exemptions from authorisation requirements for uses in the product and process oriented research and development (PPORD), as provided for in Article 56(3). Additionally no exemptions were proposed in the updated draft recommendation in which ECHA proposed some changes in the transitional arrangements.

The updated ECHA draft recommendation is attached to this opinion as Annex II.

## THE OPINION ON RECOMMENDED SUBSTANCES

The Member State Committee supports the recommendation of ECHA, as published on 1 July 2010, to include the following substances in Annex XIV:

Diisobutyl phthalate (DIBP)
EC number: 201-553-2, CAS number: 84-69-5

Diarsenic trioxide
EC number: 215-481-4, CAS number: 1327-53-3

Diarsenic pentaoxide
EC number: 215-116-9, CAS number: 1303-28-2

Lead chromate
EC number: 231-846-0, CAS number: 7758-97-6

Lead sulfochromate yellow (C.I. Pigment Yellow 34)
EC number: 215-693-7, CAS number: 1344-37-2

Lead chromate molybdate sulfate red (C.I. Pigment Red 104)
EC number: 235-759-9, CAS number: 12656-85-8

Tris (2-chloroethyl) phosphate (TCEP)
EC number: 204-118-5, CAS number: 115-96-8

2,4-dinitrotoluene (2,4-DNT)
EC number: 204-450-0, CAS number: 121-14-2

***Intrinsic properties***

Intrinsic properties have remained as agreed.

***Transitional arrangements***

The Member State Committee discussed the general approach to the transitional arrangements proposed by ECHA. One Competent Authority and one NGO proposed in the public consultation a 12 month period as the default time to prepare the applications for authorisation that may be applied from the date of entry into force of the updated version of Annex XIV until the application date. This is proposed where no relevant information on the production cycle for a specific use is available (Article 58(1)(c)(i)). According to some competent authorities it can be reasonably expected that once ECHA submits its recommendation concerning Annex XIV to the Commission, the industry will anticipate this decision or even already have anticipated the decision, since both the candidate list and the criteria for prioritisation are publicly available. Thus the companies would have had a possibility to start preparing the applications well in advance of adoption of the updated Annex XIV by the Commission. In the situations where the production and marketing cycle for a specific use is known and complex, a longer period from the entry into force to the application date could be considered. The Member State Committee is of the opinion that the application dates should be established as close as possible to the entry into force of the updated Annex XIV, normally not more than 12 to a maximum of 18 months.

Article 58(1)(c)(ii) provides that the application date should be set at least 18 months before the sunset date. The Member State Committee advises that the application dates should be set at 18 months before the sunset dates.

Although Article 58(1)(c) provides the option for setting a sunset date and application date per use (category of use), the Member State Committee supports ECHA's position not to differentiate the dates for various uses of prioritised substances. There were no comments requesting later dates for specific uses.

***Review periods for certain uses***

The Member State Committee agrees with ECHA's position that specified review periods are not warranted in the recommendation for Annex XIV inclusion. The review periods should be set up in accordance with Article 60(8) only after consideration of all the elements listed in Article 60(4).

***Uses or categories of uses exempted from the authorisation requirement***

Although there were comments requesting exemption of some uses of some prioritised substances from the authorisation, no existing specific Community legislation imposing the minimum requirements relating to the protection of human health or the environment against the use of these substances, which proves that the risk is properly controlled, were recalled in those comments. The Member State Committee agrees with ECHA that the exemptions for certain uses are not warranted in the recommendation for Annex XIV inclusion.

***Exemptions for the use in product and process oriented research***

Due to the comments received from one company, the Member State Committee discussed exemptions from authorisation for PPORD uses of small amounts of lead chromate pigments (C.I. Pigment Yellow 31 and C.I. Pigment Red 104). The Member State Committee supports ECHA's proposal that the PPORD exemption for these substances in Annex XIV should not be recommended.

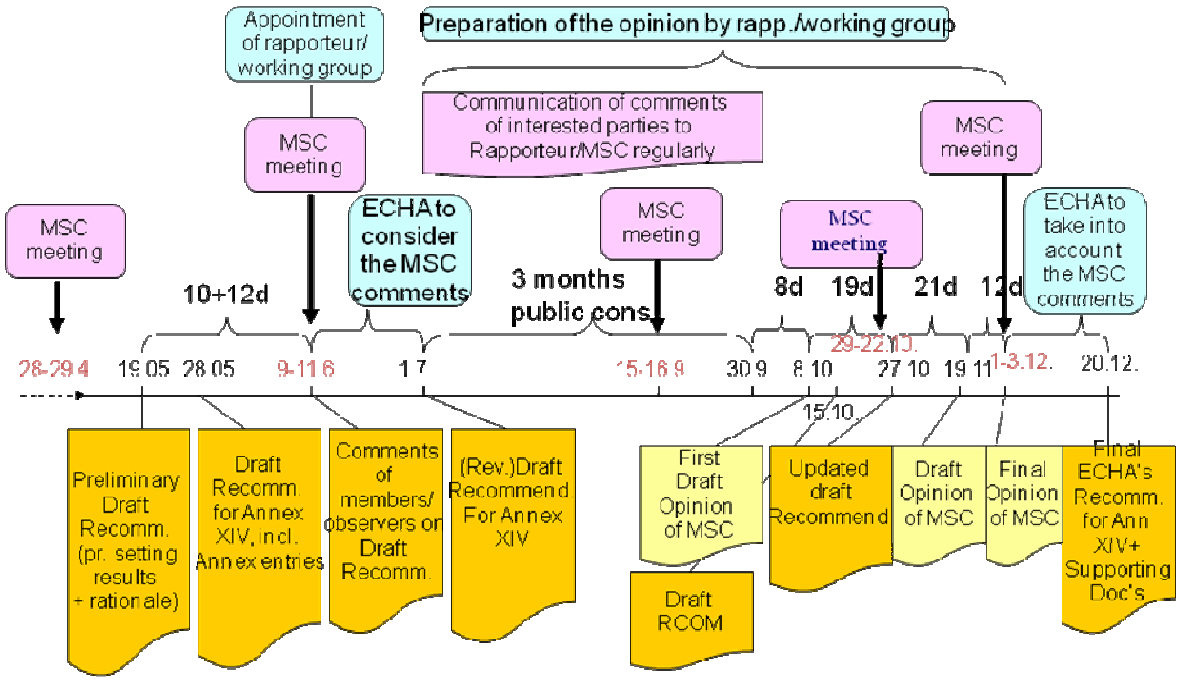
**Annex 1**

# SUPPORT DOCUMENT FOR THE OPINION OF THE MSC ADOPTED ON 3rd DECEMBER 2010 ON ECHA's DRAFT RECOMMENDATION OF SUBSTANCES FOR INCUSION IN ANNEX XIV

## 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, i.e. the Annex containing the list of 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 second round recommendation, ECHA developed the following timeframe that the MSC agreed to:




Approximately 60 comments concerning the priority substances were received under the public consultation.

## 2. The MSC Views on General Comments Received from Stakeholders

During the consultation period stakeholders submitted a number of general comments and a number of comments on specific substances or specific issues which however were, general in nature. These views or the MSC's opinions on those comments are summarised below.

**Prioritisation process**

The Arsenic Consortium hosted by the German Association WVM submitted additional data on the use of arsenic oxides, proving that the volume of diarsenic trioxide used is much lower than it was estimated in the background document. A number of uses that were regarded as uses of diarsenic trioxide turned out to be uses of metallic arsenic. The total estimated volume used in the EU is therefore lower than the volume anticipated in the background document subject to public consultation, and should be around 690-850 t/y. Manufacture of ultra pure arsenic or other arsenic compounds and applications in the enamel, glass and crystal sector and industrial use in the Zinc metal sector are, according to information provided by industry, the only remaining uses in Europe. The industry claims that diarsenic trioxide is used in these processes as an isolated intermediate or a transported isolated intermediate. Although the industry has presented arguments for considering these uses as intermediate, it is difficult to assess claims for zinc production on the basis of the available information. After initial analysis ECHA considers the use of diarsenic trioxide in the glass industry to be an end use, not intermediate use.

The use of diarsenic trioxide in the glass industry causes risk for humans and the environment only during the manufacture of glass. Consumers or general public will not be exposed to diarsenic trioxide as it is not present (as the original compound) in glass. Although the production of glass containing arsenic can be considered widespread, based upon available information, it is assumed that the release of arsenic compounds from those matrices/articles is most probably (very) low.

As regards occupational exposure, the information provided by the Italian Competent Authority indicates that there seem to be severe problems with preventing such exposure in the manufacturing of hand-made decorative glass for arts and crafts. However it is not clear whether insufficient control of occupational exposure is a problem for the entire glass production industry or only of this specific part of it, i.e., artisanal glass production.

Information on the use of the substance in the production of zinc suggests that widespread use may be questioned in this application. Further information suggests that exposure of workers could be limited, while the exposure of consumers is unlikely.

This information was provided by the industry well after closure of the public consultation, which has made it impossible to check properly the information provided.

Taking into account the lower volume, less wide dispersive use of diarsenic trioxide and a probable lack of exposure of consumers to diarsenic trioxide, which were then described in the background document subject to public consultation, the MSC discussed the following general issues whether there would still be grounds to prioritise the substance for Annex XIV.

The two following options were discussed:

Option 1: Diarsenic trioxide should be prioritised for Annex XIV, even though emissions to the environment are probably small and exposure of consumers is unlikely, given the fact that:

1) a relevant tonnage is used in the glass industry and zinc industry and these uses may not be regarded as intermediate and
2) considerable workers exposure in the (artisanal) glass industry cannot be excluded.

Option 2: Diarsenic trioxide should not be prioritised for Annex XIV until more information is available on worker exposure in the relevant uses (zinc production, artisanal and industrial glass production). This information would allow the MSC to assess the relevant tonnages that

lead to exposure/emissions to the environment, and to assess the widespread use of the substance. Arsenic trioxide could then be prioritised after the registration information is available (i.e., after 1 December 2010 at the earliest), however the information may be limited if diarsenic trioxide is registered as an intermediate.

In the discussion the MSC also considered the following arguments:

Even if there is no consumer or general public exposure, diarsenic trioxide is extensively used in part of the glass industry and its use may be considered as a wide dispersive use for workers. Considerable workers exposure was proven in the recent past in case of artisanal glass production in the Murano District (Italy), and it may occur in some other similar sites throughout the EU. On the other hand, there is no exposure data for the industrial glass production with the use of diarsenic trioxide. The obligation of authorisation will certainly improve conditions in the whole glass production industry, as granting the authorisation requires compliance with the conditions specified according to Article 60(9) of REACH.

In conclusion for diarsenic trioxide, the MSC decided to support ECHA in its prioritisation.

**Transitional arrangements**

One MSCA and one NGO suggested to shorten the application dates and the sunset dates as much as possible and practically viable, taking into account the chains of marketing and use of the substance. It was proposed that the default application date should be set at 12 months after entering into force of the Commission decision on including the substance into Annex XIV. Later application dates should be applied only when complex or complicated chains of distribution of the substance exist and industry needs more time for preparation of the application. It was also proposed to set the application date as early as possible (12 months to a maximum of 18 months) and to set the sunset dates at the intervals longer than 18 months.

The MSC agreed to set the application dates uniformly 18 months before the sunset dates.

Regarding the application dates, the MSC members were of the opinion that the periods between entering into force of the decision to include the substance into Annex XIV, as well as the sunset date and the application date, should be as short as possible to meet the goals formulated in Article 55 of REACH. The default value for not complex (i.e., relatively simple) chains of the marketing and use of the substance for that period may be set at 12 months. For more complex chains the period could be longer[4]. However, the argument was

[4] From the Guidance on inclusion of substances in Annex XIV: *The time needed for the preparation of a new application for authorisation will probably vary from case to case depending on, e.g., how complicated supply chain (up and down from the applicant) is related to the use(s) applied for, how specific are the use conditions, what is the status of the development of alternatives, how straightforward or complicated are the considerations related to the alternatives and who possesses the relevant information on alternatives. The Commission Services estimated that the average time needed amounts to roughly 12 months. With time, experience on the preparation of an authorisation application will become available enabling more appropriate estimates. Furthermore, an applicant may not be able to consult the expertise required for certain issues of the application in a short time frame. Therefore a time period of 18 months (an additional time buffer of 6 months on top of the 12 months required for the preparation itself), should be given to prepare a well documented application for authorisation.*

raised that stakeholders could not comment upon such a short time scale, much shorter than periods proposed by ECHA so far. It was concluded that the outcomes of this discussion will be taken into account by ECHA in the next recommendations and where possible, in this round of prioritisation.

For this second prioritisation, the MSC recommends application dates between 12 and 18 months after the entry into force (EiF).

**Proposed exempted (categories of) uses**

The exemption of uses or categories of uses was thoroughly discussed in the first round of recommendation and it was not necessary to discuss it during this round.

**Exemptions for PPORDs**

Due to the comments received from one company, the Member State Committee discussed the exemptions from authorisation for PPORD uses of small amounts of lead chromate pigments (CI Pigment Yellow 31 and CI Pigment Red 104). After analysis of the justification for this exemption ECHA has encouraged this company to examine whether the specific use of the substances could fall in the scope of the Scientific Research and Development (SRD). The MSC shares ECHA's view and does not see a reason to provide an exemption for the PPORD use of C.I. Pigment Yellow 34 and C.I. Pigment Red 104.

## 3. The MSC Views on Specific Comments Received from Stakeholders

### *3.1. Diisobutyl phthalate (DIBP)*

**Justification for prioritisation – short summary**

DIBP is classified as toxic for reproduction, category 1B[5] (corresponding to classification as toxic for reproduction category 2[6]). It is used in very high volume. On the basis of the prioritisation criteria, the substance qualifies for prioritisation.

**Priority setting**

Four MSCAs supported or did not object to prioritisation of diisobutyl phthalate (DIBP). Prioritisation of this substance was also supported by two NGOs. One of these NGOs additionally stressed the simultaneous exposure caused by DIBP and other phthalates, which may contribute to the overall anti-androgenic effects, even if exposure to any particular phthalate is below its effective concentration. Also the wide dispersive use of DIBP was stressed, as this substance is being used in plastics, paints, lacquers, varnishes, paper pulps, softeners, viscosity adjusters and others. One MSCA proposed some minor comments to the background document.

[5] Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

[6] Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC)

There were no comments objecting to prioritisation of DIBP.

**The MSC is of the opinion that the prioritisation criteria (CMR properties, high volume, type of uses and wide-dispersive use) of DIBP were adequately demonstrated in the background document compiled by ECHA to support the prioritisation process.** No new information has been brought forward during the stakeholder consultations to challenge the criteria of prioritisation**.**

**Transitional arrangements: Application date/Sunset date**

ECHA proposed the following transitional arrangements for diisobutyl phthalate:

(i) The application date: 18 months before the sunset date,
(ii) Sunset date: as close as possible to the sunset dates established by the European Commission for phthalates that were included in ECHA´s first recommendation of 1 June 2009 - minimum 30 months after entering into force of the decision to include this substance in Annex XIV.

After closing the consultation period ECHA updated the transitional arrangements in the draft recommendation. For diisobutyl phthalate ECHA recommends the application date and the sunset date to be respectively, 12 months and 30 months from entry into force of the Commission Regulation on update to Annex XIV. ECHA also proposes that always (taking into account the uncertainty of the time of adoption of the Commission Regulation) there should be 18 months time between the date of entry into force and application date.

One company proposed uniform wording in the background document considering defining the sunset date and first application date, as different wording may cause ambiguity. An environmental NGO asked for earlier application and sunset dates arguing that diisobutyl phthalate can be used to replace dibutyl phthalate and other phthalates already recommended for inclusion in Annex XIV. It asked for the application date to be exactly 12 months and the sunset date as close as possible to the sunset date of the other phthalates listed in Annex XIV.

One MSCA proposed to set the application date 12 months after the decision on including DIBP into Annex XIV enters into force and the sunset date should fall 18 months later. Similar sunset date and application date were proposed by this MSCA for other prioritised substances. In justification of this proposal the MSCA argued that shortest realistic and pragmatic dates should be applied.

**The MSC is of the opinion that the application date should be set 12 months after entering into force of the decision on including DIBP into Annex XIV and the sunset date should fall 18 months later. The MSC also supports ECHA's recommendation to set only one application date and one sunset date.**

**Proposed review period for certain uses**

No review period was 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 inclusion of DIBP in Annex XIV.**

**Proposed exempted (categories) of uses**

ECHA did not propose any exemption of uses or categories of uses. One MSCA and one NGO supported the ECHA proposal not to exempt any (category of) use.

**The MSC supports ECHA's proposal not to exempt any use or category of uses.**

**Information on the need to exempt PPORD from the authorisation requirement**

No exemptions for the PPORD were suggested by ECHA, and no comments were received during the stakeholder consultations.

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

**Other issues**

There were no other comments nor did the MSC discuss other issues.

### *3.2. Diarsenic trioxide*

**Justification for prioritisation – short summary**

Diarsenic trioxide is classified as a carcinogen, category $1A^5$ (corresponding to classification as carcinogen category $1^6$). The volume of the use of diarsenic trioxide is high, although consumer exposure via articles is unlikely as diarsenic trioxide is present in (very) low quantities in articles and exposure of humans via the environment can be considered low. On the basis of the prioritisation criteria the substance qualifies for prioritisation.

**Priority setting**

Two MSCAs, one trade union and two NGOs argued that diarsenic trioxide should be prioritised for inclusion into Annex XIV. Several industry representatives referred to the tonnages as mentioned in the background document. It now seems that the relevant tonnage is probably between 690-850 t/y, and that this compound is used in the enamel, glass and crystal sector and in the zinc metal production processes. Contrary to what had been described in the initial background document the use in battery grids, special alloys and ammunition, turned out to be the use of the metallic arsenic instead of diarsenic trioxide.

The Arsenic Consortium hosted by the German Association WVM also claimed that the use of diarsenic trioxide in the glass industry should be regarded as a use of an intermediate. However, given the analogy with the discussion on metal salts used in metal plating, both ECHA and the MSC are of the opinion that the use of $As_2O_3$ in the glass industry should be considered to be non-intermediate use.

Furthermore, information from the Consortium indicated that occupational exposure cannot be excluded.

While using diarsenic trioxide in the glass industry the risk for humans and the environment arises only during the manufacture of glass involving the substance. During the use of articles made of glass, consumers or general public will not be exposed to diarsenic trioxide as it is not present (as the original compound) in the glass. Furthermore, arsenic binds into the glass matrix, thus the potential for migration and exposure is expected to be low. A study into elemental migration from glass in contact with food has revealed that, in general, accelerated migration testing did not result in detectable levels of various elements (including arsenic). Although the use of glass containing arsenic can be considered widespread, based upon available information, it is assumed that the release of arsenic compounds from those matrices/articles is most probably (very) low and hence they should not be regarded as wide dispersive.

As regards occupational exposure, the information provided by the Italian Competent Authority indicates that there are severe problems with preventing such exposure in the manufacturing of hand-made decorative glass for arts and crafts. Biological monitoring of workers in glass manufactories in the Murano District, which was carried out through urinary arsenic measurement, revealed that workers employed in the mixture preparation and in the furnace work are still significantly exposed to arsenic despite the technical preventive measures adopted (the mean concentrations of different As species in urine samples of workers are 2-3 times higher than the upper limit of reference for the non exposed population). Main problems may apparently be caused by the dustiness of $As_2O_3$, which is mixed with other glass raw materials in the form of fine powder, and the high volatility of $As_2O_3$ at the melting temperature (at least 20% loss of the As added), which lead to inhalation exposure. About 80 plants employing approx. 800 – 1,000 workers are manufacturing art glass containing As. The annual consumption of $As_2O_3$ for art glass manufacture is 8.2 t in the Murano District (the estimated volume for entire Italy is 12 t/yr). However it is not clear whether insufficient control of occupational exposure is a problem of the entire glass production industry or only of this specific part of it, i.e. artisanal glass production.

In the discussion of the information provided during the public consultation (and after its closure) the MSC also considered the following arguments:

Even if there is no consumer or general public exposure, diarsenic trioxide is extensively used in part of the glass industry and its use may be considered a wide dispersive use for workers. Considerable workers exposure was proven in the case of artisanal glass production in Murano District and it may occur in some other similar sites throughout the EU. On the other hand, there is no exposure data for industrial glass production which uses diarsenic trioxide. The obligation of authorisation will certainly improve conditions in the whole glass production industry, as granting the authorisation requires compliance with the conditions specified according to Article 60(9) of REACH.

**In conclusion for diarsenic trioxide, the MSC decided to support ECHA in its prioritisation of diarsenic trioxide.**

**Transitional arrangements: Application date/Sunset date**

ECHA proposed the following transitional arrangements for diarsenic trioxide:

(i) The application date: 18 months after entering into force of the Commission decision (Regulation amending Annex XIV) on inclusion of diarsenic trioxide into Annex XIV and 18 months before the sunset date,

(ii) The sunset date: 36 months after entering into force of the decision to include this substance in Annex XIV.

After closing the consultation period ECHA updated the transitional arrangements in the draft recommendation. For diarsenic trioxide ECHA recommends the application date and the sunset date to be respectively, 18 months and 36 months from entry into force of the Commission Regulation on update to Annex XIV. At the same time ECHA proposes that the application date should be 1 October 2013. ECHA also proposes that there should always be (taking into account the uncertainty of the time of adoption of the Commission Regulation) 18 months time between the date of entry into force and application date.

An environmental NGO asked for earlier application and sunset dates due to the relative simplicity of the supply chain. It asked for the application date to be exactly 12 months and the sunset date to fall 18 months later.

One MSCA proposed to set the application date at 12 months after the decision on including diarsenic trioxide into Annex XIV enters into force and the sunset date to fall 18 months later. Similar sunset date and application date were proposed by this MSCA for other prioritised substances. This MSCA argued that the problem is well defined and has been known for a long time, it affects only one sector of industry and the supply chain is short. However, there is no information on how advanced the research for alternatives is. In justification of this proposal the MSCA argued that the shortest realistic and pragmatic dates should be applied.

**The MSC is of the opinion that the application date should be set between 12 and 18 months after entering into force of the decision (Commission Regulation) on including diarsenic trioxide into Annex XIV and the sunset date should fall 18 months later. MSC also supports ECHA's recommendation to set only one application date and one sunset date.**

**Proposed review period for certain uses**

No review period was suggested by ECHA and no comments on this issue were received during the stakeholder consultation.

**The MSC agrees that review periods are not warranted in the recommendation for inclusion of diarsenic trioxide into Annex XIV.**

**Proposed exempted (categories) of uses**

ECHA did not propose any exemption of uses or categories of uses. One company remarked that an exemption for use in analysis of organic gases and vapors inside and outside of laboratories, by means of detector tubes which are calibrated, ready to use analytical devices. Such a use could be considered to be exempted as the scientific research and development thus it does not need to be specified in Annex XIV.

**The MSC supports ECHA's proposal not to exempt any use or category of uses.**

**Information on the need to exempt PPORD from the authorisation requirement**

No exemptions for PPORD were suggested by ECHA and no comments were received during the stakeholder consultations.

**The MSC agrees that exemptions for PPORD are not warranted in the recommendation for inclusion of diarsenic trioxide into Annex XIV.**

**Other issues**

There were no other comments nor did the MSC discuss other issues.

### *3.3 Diarsenic pentaoxide*

**Justification for prioritisation – short summary**

Diarsenic pentaoxide is classified as a carcinogen, category $1A^5$ (corresponding to classification as carcinogen category $1^6$). There seems to be no known manufacture or placing on the market of the substance. However, as diarsenic pentaoxide may replace diarsenic trioxide in most of its uses, there is a potentially significant exposure of workers during manufacture of As contained in glass.

**Priority setting**

Three MSCAs and two NGOs supported the prioritisation of diarsenic pentaoxide.
One comment has been received from an industry association indicating that the available information on diarsenic pentaoxide is limited and no data on manufacture and import has been notified, so that consortium does not intend to apply for registration of this substance . Another industry and trade organisation claimed that the use of the substance in the production of glass should be considered to be an intermediate and thus excluded from authorisation. The MSC discussed the possibility of replacement of diarsenic trioxide by diarsenic pentaoxide if the former is included in the Annex XIV. This was the most important argument for recommendation of diarsenic pentaoxide to be priritised.

**The MSC is of the opinion that diarsenic pentaoxide should be prioritised as long as diarsenic trioxide is prioritised, as these substances may be used alternatively.**

**Transitional arrangements: Application date/Sunset date**

ECHA has proposed the following transitional arrangements for diarsenic pentaoxide:

(i) The application date: 18 months after entering into force of the Commission decision (Regulation amending Annex XIV) on inclusion of diarsenic pentaoxide into Annex XIV and 18 months before the sunset date,
(ii) Sunset date: 36 months after entering into force of the decision to include this substance in Annex XIV.

After closing the consultation period ECHA updated the transitional arrangements in the draft recommendation. For diarsenic pentaoxide ECHA recommends the application date and the sunset date to be respectively, 18 months and 36 months from entry into force of the Commission Regulation on update to Annex XIV. At the same time ECHA proposes that the application date should be 1 October 2013. ECHA also proposes that there should always be

(taking into account the uncertainty of the time of adoption of the Commission Regulation) 18 months time between the date of entry into force and application date.

An environmental NGO asked for earlier application and sunset dates due to the relative simplicity of the supply chain. It asked for the application date to be exactly 12 months and the sunset date to fall 18 months later.

**The MSC is of the opinion that diarsenic pentaoxide should be treated in the same way as diarsenic trioxide and the application date should be set between 12 and 18 months after entering into force of the decision on including this substance into Annex XIV and the sunset date to fall 18 months later. The MSC also supports ECHA's recommendation to set only one application date and one sunset date.**

**Proposed review period for certain uses**

No review period was suggested by ECHA. One MSCA agreed that no review period was necessary.

**The MSC agrees that the review periods are not warranted in the recommendation for inclusion of diarsenic pentaoxide into Annex XIV.**

**Proposed exempted (categories) of uses**

ECHA did not propose any exemption of uses or categories of uses. One company remarked that an exemption for use in analysis of organic gases and vapors inside and outside of laboratories, by means of detector tubes which are calibrated, ready to use analytical devices. Such a use could be considered to be exempted as scientific research and development need not to be specified in Annex XIV.

**The MSC supports ECHA's proposal not to exempt any use or category of uses.**

**Information on the need to exempt PPORD from the authorisation requirement**

No exemptions for the PPORD were suggested by ECHA and no comments were received during the stakeholder consultations.

**The MSC agrees that the exemptions for PPORD are not warranted in the recommendation for inclusion of diarsenic pentaoxide into Annex XIV.**

**Other issues**

There were no other comments nor did the MSC discuss any other issues.

### *3.4. Lead chromate*

**Justification for prioritisation – short summary**

Lead chromate is classified as carcinogen, category 1B and as toxic for reproduction, category 1A[5] (These classifications correspond to classification as category 2 and category 1[6], respectively). The annual consumption volume in the EU is relatively low. Nevertheless, the

potential uses are widespread to wide dispersive. On the basis of the prioritisation criteria, lead chromate qualifies for prioritisation.

**Priority setting**

Four MSCAs supported prioritisation of lead chromate for inclusion into Annex XIV. Two of these MSCAs expressed some uncertainty about relevant volumes and uses leading to wide dispersive use, although they agreed to prioritisation. Prioritisation of lead chromate was also supported by two NGOs. No comments have been submitted by industry.

**The MSC is of the opinion that the wide dispersive use of lead chromate was adequately demonstrated to support the prioritisation process in the background document compiled by ECHA and in the report on the "Actual Data on the European Market, Uses and Releases/Exposures for Lead Chromate" commissioned by ECHA.**

**Transitional arrangements: Application date/Sunset date**

ECHA proposed the following transitional arrangements for lead chromate:

(i) The application date: 21 months after entering into force Commission's decision (Regulation amending Annex XIV) on inclusion of lead chromate into Annex XIV and 18 months before the sunset date,
(ii) Sunset date: 39 months after entering into force of the decision to include this substance in Annex XIV.

After closing the consultation period ECHA updated the transitional arrangements in the draft recommendation. For lead chromate ECHA recommends the application date and the sunset date to be respectively, 18 months and 36 months from entry into force of the Commission Regulation on update to Annex XIV. At the same time ECHA proposes that the application date should be 1 October 2013. ECHA also proposes that always (taking into account the uncertainty of the time of adoption of the Commission Regulation) there should be 18 months time between the date of entry into force and application date.

One MSCA agreed with ECHA's proposal. One MSCA proposed to set the application date 12 months after the decision on including lead chromate into Annex XIV enters into force and sunset date to fall 18 months later. Similar sunset date and application date were proposed by this MSCA for other prioritised substances. Shortening of the transitional arrangements for lead chromate to 12 and 30 months respectively, was also proposed by one NGO. In justification of this proposal the MSCA argued that the shortest realistic and pragmatic dates could be applied.

**The MSC is of the opinion that the application date should be set between 12 and 18 months after entering into force of the decision on including lead chromate into Annex XIV and the sunset date to fall 18 months later. The MSC also supports ECHA's recommendation to set only one application date and one sunset date.**

**Proposed review period for certain uses**

No review period was suggested by ECHA and no comments on this issue were received during the stakeholder consultation.

**The MSC agrees that the review periods are not warranted in the recommendation for inclusion of lead chromate into Annex XIV.**

**Proposed exempted (categories) of uses**

ECHA did not propose any exemption of uses or categories of uses. One MSCA and one NGO supported ECHA's proposal not to exempt any (category of) use.

**The MSC supports ECHA's proposal not to exempt any uses or categories of uses.**

**Information on the need to exempt PPORD from the authorisation requirement**

No exemptions for the PPORD were suggested by ECHA and no comments were received during the stakeholder consultation.

**The MSC agrees that the exemptions for PPORD are not warranted in the recommendation for inclusion of lead chromate into Annex XIV**.

**Other issues**

There were no other comments nor did the MSC discuss other issues.

### *3.5. Lead sulfochromate yellow (C.I. Pigment Yellow 34)*

**Justification for prioritisation – short summary**

Lead sulfochromate yellow is classified as a carcinogen, category 1B and as toxic for reproduction, category 1A[5] (These classifications correspond to classification as category 2 and category 1[6], respectively). It is used in high volumes and at a high number of sites, and may be released (presumably in relatively low amounts) at very many sites from articles during service life or (in potentially higher but unknown and uncontrolled amounts) after the end of the life cycle in the waste state or during recycling. On the basis of the prioritisation criteria, lead sulfochromate yellow qualifies for prioritisation.

**Priority setting**

Two comments from two different companies were received during the stakeholder consultation period. In one of them industry supported the principle of prioritisation based on classification in combination with the additional criteria of wide dispersive uses and high production volumes. In its comment, the other company, did not support the prioritisation of C.I. Pigment Yellow 34 (as well as C.I. Pigment Red 104), neither did it agree with the background document. However no new information has been brought forward during the stakeholder consultation to challenge the criteria of prioritisation.

**The MSC is of the opinion that the prioritisation criteria (CMR properties, high volume, type of uses and wide-dispersive use) of lead sulfochromate yellow were adequately**

**demonstrated in the background document compiled by ECHA to support the prioritisation process.**

**Transitional arrangements: Application date/Sunset date**

ECHA proposed the following transitional arrangements for lead sulfochromate yellow (C.I. Pigment Yellow 34):

(i) The application date: 21 months after entering into force the Commission decision (Regulation amending Annex XIV) on inclusion of lead sulfochromate yellow (C.I. Pigment Yellow 34) into Annex XIV and 18 months before the sunset date,

(ii) Sunset date: 39 months after entering into force of the decision to include this substance in Annex XIV.

After closing the consultation period ECHA updated the transitional arrangements in the draft recommendation. For lead sulfochromate yellow ECHA recommends the application date and the sunset date to be respectively, 18 months and 36 months from entry into force of the Commission Regulation on update to Annex XIV. At the same time ECHA proposes that the application date should be 1 October 2013. ECHA also proposes that there should always be (taking into account the uncertainty of the time of adoption of the Commission Regulation) 18 months time between the date of entry into force and application date.

One MSCA proposed to set the application date at 12 months after the decision on including lead sulfochromate yellow (C.I. Pigment Yellow 34) into Annex XIV enters into force and sunset date to fall 18 months later. Similar sunset date and application date were proposed by this MSCA for other prioritised substances. Similar shortening of transitional arrangements was proposed by one NGO. In justification of this proposal the MSCA argued that the shortest realistic and pragmatic dates should be applied. There was one comment from the industry claiming that there are no available substitutes, and timelines have to be extended to "allow for the analysis and substitution of thousands of products which will require many years to complete". There were no definite timelines proposed in the comment submitted by the industry.

**The MSC is of the opinion that the application date should be set between 12 and 18 months after entering into force of the decision on including lead sulfochromate yellow (C.I. Pigment Yellow 34) into Annex XIV and the sunset date should fall 18 months later. The MSC also supports ECHA's recommendation to set only one application date and one sunset date.**

**Proposed review period for certain uses**

No review period was suggested by ECHA and no comments on this issue were received during the stakeholder consultation.

**The MSC agrees that the review periods are not warranted in the recommendation for inclusion of lead sulfochromate yellow (C.I. Pigment Yellow 34) into Annex XIV.**

**Proposed exempted (categories) of uses**

No exemption of uses (categories of uses) were proposed by ECHA. During the stakeholder consultations, in the documents attached to one comment received, the industry proposed to

consider under Article 58 (2) of REACH the use of lead sulfochromate yellow in development, testing, and improvement of new, safe and efficient gas turbines for possible exemption from the authorisation requirement. In another comment a different company asked for exemption for all important existing uses of lead sulfochromate yellow, for silica-glass encapsulated pigments in particular. In their comment they claimed that these existing uses had already been well controlled by "existing and extensive" Community regulations. The company stated a number of Community acts regulating some aspects of the use of lead and chromium compounds. However, the MSC agreed with ECHA responses that these Community regulations do not fulfil the obligation formulated in Article 58(2) which reads as follows: "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 ...". The legislation stated in the company comments cover some parts of the life cycle of lead sulfochromate yellow, but are not sufficient to control the risk posed during the whole life cycle of the substance.

**In conclusion, the MSC agrees with ECHA's proposal not to include any exemptions in the recommendation for Annex XIV inclusion.**

**Information on the need to exempt PPORD from the authorisation requirement**

No exemption for the PPORD was suggested by ECHA. One company proposed exemption of the use of lead sulfochromate yellow (C.I. Pigment Yellow 34) as PPORD in development, testing, and improvement of new, safe and efficient gas turbines under Article 56(2). ECHA encourages the company to examine whether the specific use of the substance could fall in the scope of Scientific Research and Development (SRD).

**The MSC agrees that the exemptions for PPORD are not warranted in the recommendation for inclusion of lead sulfochromate yellow into Annex XIV**.

**Other issues**

There were no other comments and the MSC did not discuss other issues.

### *3.6 Lead chromate molybdate sulfate red (C.I. Pigment Red 104)*

**Justification for prioritisation – short summary**

Lead chromate molybdate sulfate red is classified as a carcinogen, category 1B and as toxic for reproduction, category 1A[5] (These classifications correspond to classification as category 2 and category 1[6], respectively). It is used in high volumes and at a high number of sites and may be released (presumably in relatively low amounts) at very many sites from articles during service life or (in potentially higher but unknown and uncontrolled amounts) after the end of the life cycle in the waste state or during recycling. On the basis of the prioritisation criteria, lead chromate molybdate sulfate red qualifies for prioritisation.

**Priority setting**

Commenting authorities and NGOs supported the proposal to prioritise lead chromate molybdate sulfate red (C.I. Pigment Red 104) based on its CMR properties, the volume and the wide dispersive use. One company supported prioritisation, while the other opposed. No new information was brought forward in the stakeholder consultation to challenge the criteria of prioritisation**.**

**The MSC is of the opinion that the prioritisation criteria (CMR properties, high volume, type of uses and wide-dispersive use) of lead chromate molybdate sulfate red (C.I. Pigment Red 104) were adequately demonstrated in the background document compiled by ECHA to support the prioritisation process.**

**Transitional arrangements**

ECHA proposed the following transitional arrangements for lead chromate molybdate sulfate red (C.I. Pigment Red 104):

(i) The application date: 21 months after entering into force of the Commission decision (Regulation amending Annex XIV) on inclusion of lead chromate molybdate sulfate red (C.I. Pigment Red 104) into Annex XIV and 18 months before the Sunset date,
(ii) Sunset date: 39 months after entering into force of the Decision to include this substance in Annex XIV.

After closing the consultation period ECHA updated the transitional arrangements in the draft recommendation. For lead chromate molybdate sulphate red ECHA recommends the application date and the sunset date to be respectively, 18 months and 36 months from entry into force of the Commission Regulation on update to Annex XIV. At the same time ECHA proposes that the application date should be 1 October 2013. ECHA also proposes that there should always be (taking into account the uncertainty of the time of adoption of the Commission Regulation) 18 months time between the date of entry into force and application date.

One MSCA proposed to set the application date 12 months after the decision on including lead chromate molybdate sulfate red (C.I. Pigment Red 104) enters into force and sunset date 18 months later. Similar sunset date and application date were proposed by this MSCA for other prioritised substances. Similar shortening of sunset date and application date was proposed also by one NGO. In justification of this proposal the MSCA argued that shortest realistic and pragmatic dates should be applied.

One company claimed generally that “in any way” timelines should be extended, because for many products substitutes have not yet been found and it would require many years to complete the search for substitutes. It is not clear if the transitional arrangements were meant there.

**The MSC is of the opinion that the application date should be set between 12 and 18 months after entering into force of the decision on including lead chromate molybdate sulfate red (C.I. Pigment Red 104) in Annex XIV and the sunset date 18 months later. MSC also supports ECHA’s recommendation to set only one application date and one sunset date.**

**Proposed review period for certain uses**

No review period was 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 inclusion of lead chromate molybdate sulfate red (C.I. Pigment Red 104) into Annex XIV.**

**Proposed exempted (categories) of uses**

No exemption of uses (categories of uses) were proposed by ECHA. During stakeholder consultations in the documents attached to the one comment received, industry proposed to consider under Article 58 (2) of REACH the use of lead chromate molybdate sulfate red (C.I. Pigment Red 104) in development, testing, and improvement of new, safe and efficient gas turbines for possible exemption from the authorisation requirement. In another comment different company asked for exemption for all important existing uses of lead chromate molybdate sulfate red (C.I. Pigment Red 104) in particular for silica-glass encapsulated pigments. In their comment industry claims that these existing uses are already well controlled by "existing and extensive" community regulations. The company stated a number of Community acts regulating some aspects of the use of lead and chromium compounds. However, the MSC agreed with ECHA responses that these Community regulations do not fulfil the obligation formulated in Article 58(2) which reads as follows: "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 ...". The legislation stated in the company comments cover some parts of the life cycle of lead sulfochromate yellow, but are not sufficient to control the risk posed during the whole life cycle of the substance.

**In conclusion, the MSC agrees with ECHA proposal not to include any exemptions in the recommendation for Annex XIV inclusion.**

**Information on the need to exempt PPORD from authorisation:**

No exemption for PPORD was suggested by ECHA. One company proposed exemption of the use of lead chromate molybdate sulfate red (C.I. Pigment Red 104) as PPORD in development, testing, and improvement of new, safe and efficient gas turbines under Article 56(2). ECHA encourages the company to examine whether the specific use of the substances could fall in the scope of Scientific Research and Development (SRD).

**The MSC agrees that the exemptions for PPORD are not warranted in the recommendation for inclusion of lead chromate molybdate sulfate red into Annex XIV**.

**Other issues**

There were no other comments and the MSC did not discuss other issues.

### *3.7 Tris (2-chloroethyl) phosphate (TCEP)*

**Justification for prioritisation – short summary**

Tris (2-chloroethyl) phosphate is classified as toxic to reproduction, category 1B[5] (corresponding to classification as category 2[6]). The volume used is high and there are releases to workers, environment and consumers from widespread used articles. On the basis of the prioritisation criteria the substance qualifies for prioritisation.

**Priority setting**

One MSCA and two NGOs supported ECHA recommendation for prioritisation of TCEP for inclusion into Annex XIV, based on its CMR properties, the relevant volumes for the authorisation process and their wide-dispersive uses. One MSCA had no objection for prioritisation as a consequence that it did not receive any request for exemption of uses at the national level from stakeholders.

**The MSC is of the opinion that high volumes and wide dispersive use of TCEP were adequately demonstrated in the annex XV dossier on TCEP and in the background report compiled by ECHA to support the prioritisation process. No new information has been brought forward during the second public consultation to challenge this conclusion.**

**Transitional arrangements: Application date/Sunset date**

ECHA proposed the following transitional arrangements for TCEP:

(i) The application date: 24 months after entering into force the Commission decision (Regulation amending Annex XIV) on inclusion of TCEP into Annex XIV and 18 months before the sunset date,
(ii) Sunset date: 42 months after entering into force of the decision to include this substance in Annex XIV.

One MSCA supported transitional arrangements recommended by ECHA. One MSCA proposed to set the application date at 12 months after the decision on including TCEP into Annex XIV enters into force and the sunset date 18 months later. Similar sunset date and application date were proposed by this MSCA for other prioritised substances. In justification of this proposal the MSCA argued that shortest realistic and pragmatic dates should be applied. Also one NGO proposed to set the application date and the sunset date at 12 months and 30 months, respectively.

**The MSC is of the opinion that the application date should be set between 12 and 18 months after entering into force the decision on including TCEP in Annex XIV and the sunset date 18 months later. The MSC also supports the ECHA recommendation to set only one application date and one sunset date.**

**Proposed review period for certain uses**

No review period was suggested by ECHA nor requested by stakeholders in public consultations. Two MSCAs supported the ECHA decision not to recommend the review periods.

**The MSC agrees that review periods are not warranted in the recommendation for Annex XIV inclusion in the case of this substance**.

**Proposed exempted (categories) of uses**

No exemption of categories of uses was proposed by ECHA nor requested by stakeholders in public consultations. One MSCA and one NGO supported ECHA decision not to recommend exemptions under Article 58(2) of REACH Regulation.

**The MSC agrees that exemptions of categories of uses are not warranted in the recommendation for inclusion of TCEP into Annex XIV.**

**Information on the need to exempt PPORD from the authorisation requirement**

No exemption for PPORD was suggested by ECHA nor requested by stakeholders in public consultations.

**The MSC agrees that exemption for PPORD is not warranted in the recommendation for inclusion of TCEP Annex XIV.**

**Other issues**

There were no other comments nor did the MSC discuss other issues.

### *3.8. 2,4 - Dinitrotoluene*

**Justification for prioritisation – short summary**

2,4 - dinitrotoluene is classified as a carcinogen category 1B[5] (corresponding to classification as carcinogen category 2[6]). The substance is used in relatively high volume. On the basis of the prioritisation criteria, the substance qualifies for prioritisation.

**Priority Setting**

Three MSCAs and one international NGO expressed agreement with ECHA's recommendation that 2,4-DNT is prioritised for inclusion into Annex XIV. There were no objections to the prioritisation.

**MSC is of the opinion that the prioritisation criteria (CMR properties, high volume, type of uses and wide-dispersive use) of 2,4-DNT were adequately demonstrated in the background document compiled by ECHA to support the prioritisation process.**

**Transitional arrangements: Application date/Sunset date**

ECHA proposed the following transitional arrangements for 2,4-DNT:

(i) The application date: 24 months after entering into force of the Commission decision (Regulation amending Annex XIV) on inclusion of 2,4-DNT into Annex XIV and 18 months before the sunset date,

(ii) Sunset date: 42 months after entering into force of the decision to include this substance in Annex XIV.

After closing the consultation period ECHA updated the transitional arrangements in the draft recommendation. For 2,4-DNT ECHA recommends the application date and the sunset date to be respectively, 21 months and 39 months from entry into force of the Commission Regulation on update to Annex XIV. At the same time ECHA proposes that the application date should be 1 January 2014. ECHA also proposes that there should always be (taking into account the uncertainty of the time of adoption of the Commission Regulation) 18 months time between the date of entry into force and application date.

One MSCA agreed with the dates proposed by ECHA. One MSCA proposed to set the application date 12 months after the decision on including 2,4-DNT into Annex XIV enters into force and the sunset date to fall 18 months later. Similar sunset date and application date were proposed by this MSCA for other prioritised substances. Similar transitional arrangements were proposed by one NGO. In justification of this proposal the MSCA argued that the shortest realistic and pragmatic dates should be applied.

**The MSC is of the opinion that the application date should be set between 12 and 18 months after entering into force of the decision on including 2,4-DNT into Annex XIV and the sunset date should fall 18 months later. The MSC also supports ECHA's recommendation to set only one application date and one sunset date.**

**Proposed review period for certain uses**

No review period was suggested by ECHA and no comments on this issue were received during the stakeholder consultation.

**The MSC agrees that the review periods are not warranted in the recommendation for inclusion of 2,4-DNT into Annex XIV.**

**Proposed exempted (categories) of uses**

No exemptions of uses or categories of uses were proposed by ECHA. Two comments were received in relation to this issue. One MSCA and one NGO supported the recommendation not to exempt any uses from authorisation.

**The MSC supports ECHA's proposal not to exempt from authorisation any uses or categories of uses in the case of 2,4-DNT.**

**Information on the need to exempt PPORD from the authorisation requirement**

No exemptions for the PPORD were suggested by ECHA and no comments were received during the stakeholder consultations.

**The MSC agrees that exemptions for the PPORD are not warranted in the recommendation for inclusion of 2,4-DNT into Annex XIV.**

**Other issues**

There were no other comments and the MSC did not discuss other issues.

**Annex 2**

# (2nd Updated draft) Recommendation of priority substances to be included in Annex XIV of the REACH-Regulation

**(List of substances subject to authorisation)**

NOTE: The reasoning for each item in the table can be found in the 'Specification Documents for the Recommended Annex XIV Entries' for each substance.

| # | Substance | EC number | CAS number | SVHC-relevant intrinsic properties | Transitional arrangements | | Review periods | Exempted (categories of) uses | Exemptions for PPORD |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Latest application date * | Sunset date | | | |
| 1 | **Diisobutyl phthalate (DIBP)** | 201-553-2 | 84-69-5 | *Article 57(c)*<br>Repr. 1B [#]<br>Repr. Cat. 2; R61 [##] | ** As close as possib-le to the application date of the already recommended phthalates but not earlier than<br>[Date of entry into force + 12 months] | Application date plus 18 months | None | None | None |
| 2 | **Diarsenic trioxide** | 215-481-4 | 1327-53-3 | *Article 57(a)*<br>Carc. 1A [#]<br>Carc. Cat. 1; R45 [##] | 01/10/2013 but not earlier than<br>[Date of entry into force + 18 months] | Application date plus 18 months | None | None | None |
| 3 | **Diarsenic pentaoxide** | 215-116-9 | 1303-28-2 | *Article 57(a)*<br>Carc. 1A [#]<br>Carc. Cat. 1; R45 [##] | 01/10/2013 but not earlier than<br>[Date of entry into force + 18 months] | Application date plus 18 months | None | None | None |
| 4 | **Lead chromate** | 231-846-0 | 7758-97-6 | *Article 57(a) and 57(c)* | 01/10/2013 but not | Application date plus 18 | None | None | None |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Carc. 1B<br>Repr. 1A [#]<br>Carc. Cat. 2; R45<br>Repr. Cat. 1; R61 [##] | earlier than<br>[Date of entry into force + 18 months] | months | | | |
| 5 | **Lead sulfochromate yellow (C.I. Pigment Yellow 34)** | 215-693-7 | 1344-37-2 | *Article 57(a) and 57(c)*<br>Carc. 1B<br>Repr. 1A [#]<br>Carc. Cat. 2; R45<br>Repr. Cat. 1; R61 [##] | 01/10/2013 but not earlier than<br>[Date of entry into force + 18 months] | Application date plus 18 months | None | None | None |
| 6 | **Lead chromate molybdate sulfate red (C.I. Pigment Red 104)** | 235-759-9 | 12656-85-8 | *Article 57(a) and 57(c)*<br>Carc. 1B<br>Repr. 1A [#]<br>Carc. Cat. 2; R45<br>Repr. Cat. 1; R61 [##] | 01/10/2013 but not earlier than<br>[Date of entry into force + 18 months] | Application date plus 18 months | None | None | None |
| 7 | **Tris (2-chloroethyl) phosphate (TCEP)** | 204-118-5 | 115-96-8 | *Article 57(c)*<br>Repr. 1B [#]<br>Repr. Cat 2; R60 [##] | 01/01/2014 but not earlier than<br>[Date of entry into force + 21 months] | Application date plus 18 months | None | None | None |
| 8 | **2,4 – Dinitrotoluene (2,4-DNT)** | 204-450-0 | 121-14-2 | *Article 57(a)*<br>Carc. 1B [#]<br>Carc. Cat. 2; R45 [##] | 01/01/2014 but not earlier than<br>[Date of entry into force + 21 months] | Application date plus 18 months | None | None | None |

# Classification in accordance with Annex VI, Table 3.1 (*List of harmonised classification and labelling of hazardous substances) of* REGULATION (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

## Classification in accordance with Annex VI, Table 3.2 *(The list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of* REGULATION (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

* The recommendation of the latest application dates is based on the assumption that the Commission Regulation amending Annex XIV to the REACH Regulation for the first time will enter into force in January 2011 and the Regulation amending it for the second time in January 2012.

The following general aspects should be considered when decisions on the transitional arrangements to be include in Annex XIV are taken in accordance with Art. 133(4):

i) Potential overlaps of the application dates between the 1st and 2nd amendmentn of Annex XIV should be accounted for in order to avoid overload of the Agency with authorisation applications.

ii) As there is no specific information available that would allow drawing the conclusion that shorter time intervals for preparing appropriate authorisation applications are sufficient, the standard time interval recommended in the guidance on inclusion of substances in Annex XIV should be respected in setting the latest application dates. Therefore, the time interval between entry into force of the inclusion of a substance in Annex XIV and its latest application date shall normally not be shorter than 18 months.

iii) The substances included in this second recommendation (apart from diisobutylphthalate, see **) may be grouped in 2 batches with a time interval of three months between the batches.

** The sunset date for diisobutyl phthalate should be set as close as possible to the sunset dates for the phthalates included in the Commission Regulation amending Annex XIV to the REACH Regulation for the first time. However, the minimum time interval between entry into force of the inclusion of diisobutylphthalate in Annex XIV and its latest application date should be no shorter than 12 months (In the particular case of DIBP it is not deemed necessary to concede 18 months for preparing the authorisation applications as for this case it appears possible to draw on the experience gained in preparing the applications of the other phthalates that will be earlier included in Annex XIV).