

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

Adopted on 13 December 2012

OPINION

This opinion of the Member State Committee on the fourth draft recommendation of European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV was adopted on 13 December 2012 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006¹.

PROCESS FOR ADOPTION OF THE OPINION

ECHA consulted the Member State Committee during the spring of 2012 on its draft 4th Recommendation of priority substances for inclusion in Annex XIV, including the results of the prioritisation of the SVHCs on the Candidate List and the proposed draft Annex XIV entries for the priority substances. The Committee further discussed the draft recommendation and draft Annex XIV entries of the substances suggested for inclusion in the recommendation on 6-8 June 2012. After that, ECHA published its draft recommendation on 20 June 2012 on its website for public consultation.

The Member State Committee appointed a Rapporteur for preparing its opinion on ECHA's draft recommendation for Annex XIV at its 24th meeting (6-8 June 2012) and, in addition, 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 approach² and its application to all substances on the candidate list not already included or recommended for inclusion in Annex XIV³
- General approach for defining the Annex XIV entries⁴
- ECHA's draft recommendation of priority substances for inclusion in the list of substances subject to authorisation (available for public consultation on 20 June 2012)⁵ and its updates (dated 19 October and 29 November 2012, respectively)

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

² http://echa.europa.eu/documents/10162/17232/axiv_prioritysetting_general_approach_20100701_en.pdf

³ http://echa.europa.eu/documents/10162/13640/prioritisation_results_4th_rec_en.pdf

⁴ http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_4th_en.pdf

⁵ <http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/consultation-on-the-draft-of-20-june-2012-of-echas-4th-recommendation>

- (Draft) Background documents for each substance summarising the available information used for priority setting and specification of draft Annex XIV entries prepared by ECHA (published 20 June 2012 on the ECHA website in the context of the public consultation and in updated version made available to the Committee on 29 November 2012)
- Comments of the interested parties provided during the public consultation period that started on 20 June 2012 and closed on 19 September 2012
- Draft responses to comments provided by the ECHA Secretariat (as meeting documents on 19 October 2012 and in updated version on 29 November 2012).

The draft opinion provided to the Committee by the Rapporteur was finalised and adopted on 13 December 2012 after discussion at the 27th meeting of the Member State Committee. The support document for the MSC opinion is attached to this opinion (Annex 1).

THE FOURTH DRAFT RECOMMENDATION OF ECHA AND FOCUS OF THE OPINION

The fourth draft recommendation prepared by ECHA for Annex XIV of the REACH Regulation specifies the following information for priority substances:

- The identity of the substance as specified in section 2 of Annex VI
- The intrinsic property(ies) of the substance referred to in Article 57
- Transitional arrangements
 - The sunset date
 - The latest 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
- PPORD exemptions

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

OPINION ON THE DRAFT RECOMMENDATION FOR PRIORITISATION OF SUBSTANCES

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

- Formaldehyde, oligomeric reaction products with aniline (technical MDA)
- Arsenic acid
- Dichromium tris (chromate)
- Strontium chromate
- Potassium hydroxyoctaoxidizincatedichromate
- Pentazinc chromate octahydroxide
- Bis(2-methoxyethyl) ether (Diglyme)
- N,N-Dimethylacetamide (DMAC)
- 1,2-Dichloroethane (EDC)
- 2,2-dichloro-4,4'-methylenedianiline (MOCA)

With respect to recommending N,N-Dimethylacetamide (DMAC) for inclusion in Annex XIV, one member of the MSC (UK member), while agreeing that the substance appears to meet the criteria for prioritisation, is of the opinion that authorisation may not be the most appropriate risk management measure for this substance. A declaration has been prepared separately on this issue by the UK MSC member and transmitted to the Commission for further consideration.

ANNEX XIV ENTRIES

Substance identities

Formaldehyde, oligomeric reaction products with aniline (technical MDA)

EC number 500-036-1

CAS Number 25214-70-4

Arsenic Acid

EC number 231-901-9

CAS Number 7778-39-4

Dichromium tris(chromate)

EC number 246-356-2

CAS Number 24613-89-6

Strontium chromate

EC number 232-142-6

CAS Number 7789-06-2

Potassium hydroxyoctaoxodizincatedichromate

EC number 234-329-8

CAS Number 11103-86-9

Pentazinc chromate octahydroxide

EC number 256-418-0

CAS Number 49663-84-5

Bis(2-methoxyethyl) ether (Diglyme)

EC number 203-924-4

CAS Number 111-96-6

N,N-Dimethylacetamide (DMAC)

EC Number 204-826-4

CAS Number 127-19-5

1,2-Dichloroethane (EDC)

EC Number 203-458-1

CAS Number 107-06-2

2,2'-dichloro-4,4'-methylenedianiline (MOCA)

EC number 202-918-9

CAS Number 101-14-4

Intrinsic properties

The intrinsic properties of all of the prioritised substances are as outlined in the relevant Annex XV dossier for each substance.

Transitional arrangements

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

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

Although Article 58(1)(c) provides the option for setting a sunset date and latest application date per use (category of use), the Member State Committee supports ECHA's present position not to differentiate the dates for various uses of prioritised substances. The Member State Committee agrees with the updated transitional arrangements as recommended by ECHA.

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 from authorisation for many uses of the prioritised substances, no existing specific community legislation imposing 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, was referred to in those comments.

The Member State Committee agrees with ECHA that no exemptions for any particular uses are warranted in the recommendation for Annex XIV inclusion. This issue is further elaborated on in Annex 1 of this opinion.

The Member State Committee supports the draft recommendation concerning exemptions from authorisation.

Exemptions for the use in product and process oriented research

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

Annex I: Support document for the opinion of MSC

Annex II: ECHA's draft recommendation for Annex XIV

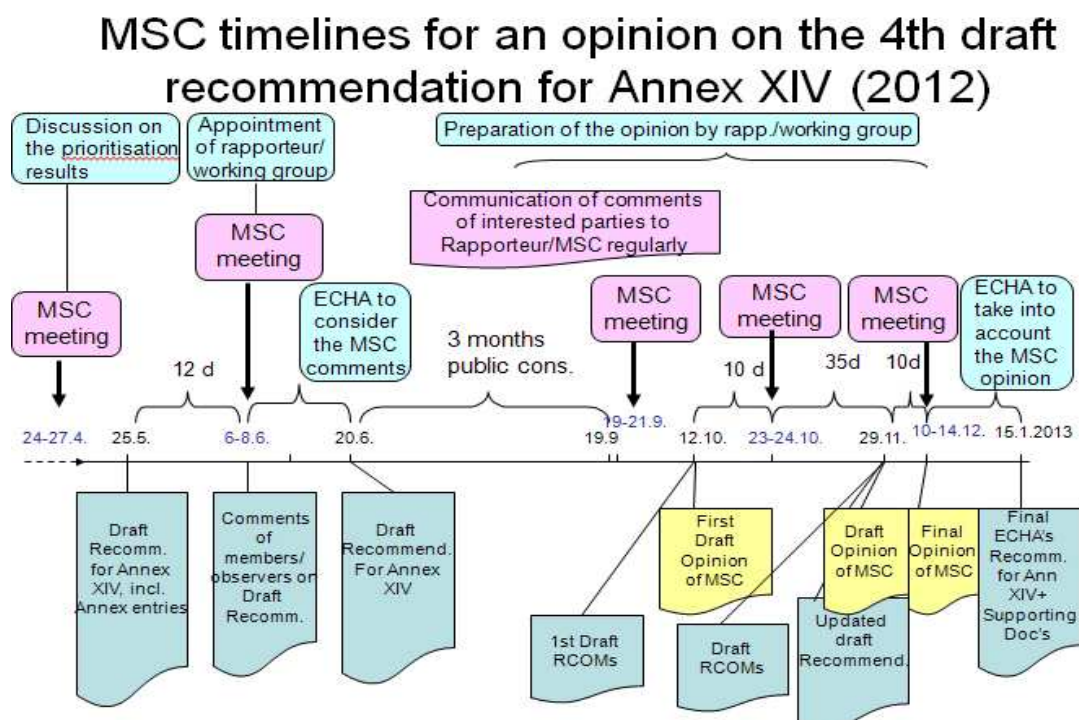
Support Document for the Opinion of MSC adopted on 13 December 2012 on ECHA's Draft fourth Recommendation of Substances for Inclusion in REACH Annex XIV

1. Introduction

In accordance with REACH Article 58(3), the Member State Committee (MSC) must provide an opinion on ECHA's draft recommendation for priority substances to be included in Annex XIV. The relevant Article 58(3) states:

"Prior to a decision to include substances in Annex XIV, the Agency shall, taking into account the opinion of the Member State Committee, recommend priority substances to be included [...]. Priority shall normally be given to substances with: (a) PBT or vPvB properties; or (b) wide dispersive use; or (c) high volumes. [...]"

For this fourth recommendation of substances, ECHA developed the following time-frame for the development of the MSC opinion:



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

During the three month public consultation on the draft recommendation, over 200 stakeholder comments were received. Stakeholders submitted a number of general comments and also comments on specific substances or specific issues. Some of these issues are summarised below, together with the views of the MSC.

2.1 Formaldehyde, oligomeric reaction products with aniline (technical MDA)

Justification for prioritisation

Formaldehyde, oligomeric reaction products with aniline (technical MDA) is classified as carcinogen, Carc. 1B in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) 1272/2008 and was identified as a substance of very high concern (SVHC) according to Article 57(a) of REACH. It was included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

The substance is used in relatively high volumes (100 – 1000 t/y) within the scope of authorisation. The main constituent of technical MDA is MDA (about 60 %), a substance already included in Annex XIV. Both MDA and technical MDA have the same functions as curing agent for polymers and hardener in epoxy resins and adhesives, (uses in the scope of authorisation), so that technical MDA may in some uses replace MDA. The uses of technical MDA in the scope of authorisation bear a high potential for significant exposure at a high number of sites in the EU. No conclusive information is available regarding the supply chain structure and the conditions of uses in the scope of authorisation. Full registration dossiers for technical MDA (similarly to the registrations of MDA) advise against the use of the substance by professionals or consumers.

Based on this, Formaldehyde, oligomeric reaction products with aniline (technical MDA) meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, no Member State Competent Authority (MSCA) opposed the prioritisation of Formaldehyde, oligomeric reaction products with aniline (technical MDA) for inclusion in Annex XIV; three MSCAs specifically supported the proposal. Two NGOs and one Trade Union Organisation expressed their support for the prioritisation.

Comments were received from one company on a specific use of the substance, which is subject of advanced research activities for its substitution and considered to be of utmost importance (constituent of a hardening agent for ion exchange resins in nuclear power plants).

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of Formaldehyde, oligomeric reaction products with aniline (technical MDA).

Transitional arrangements: Latest application date and sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for Formaldehyde, oligomeric reaction products with aniline (technical MDA):

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

During the public consultation one company requested an extension of the latest application date for a specific use of the substance as a constituent of a hardening agent for ion exchange resins in nuclear power plants, due to on-going research activities for substitution of the substance and expected completion slightly after the proposed latest application date.

On review of this comment, overall, MSC agrees with the response provided in ECHA's RCOM in that in general, the authorisation process does not mean that a substance cannot be subject to authorisation prior to the transition to the alternative substance or process. The application for authorisation should include the analysis of alternatives and this information will then be taken into account by the relevant ECHA committees and the Commission at the time of assessing/granting of the authorisation and it may have an impact on the length of the review period of the authorisation. In this specific case, it

appears that the timing of the proposed transitional arrangements is such anyways to allow the company in question to have the results of their testing in time to decide if they would have their alternative in place by the sunset date, and hence negate the need to apply for an authorisation.

MSC is of the opinion that longer transitional arrangements are not warranted for Formaldehyde, oligomeric reaction products with aniline (technical MDA). MSC therefore agrees with ECHA's recommendation for the transitional arrangements for this substance.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation.

During the public consultation no requests for review periods were submitted.

MSC supports ECHA's view that specified review periods are not warranted in the recommendation for the inclusion of Formaldehyde, oligomeric reaction products with aniline (technical MDA) in Annex XIV.

Proposed exempted (categories of) uses

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

During the public consultation, there was a request from one company to grant an exemption for the use of the substance in ion exchange resins in nuclear power plants, due to on-going research activities for substitution of the substance and based on the fact that measures to reduce employee exposure have been implemented for that use.

This comment is related to the comment submitted by the same company on the transitional arrangements above. MSC is of the opinion that no information was submitted during the public consultation that would warrant the inclusion of a specific exemption for Formaldehyde, oligomeric reaction products with aniline (technical MDA) for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were proposed by ECHA.

During the public consultation, there were no requests for PPORD exemptions.

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not warranted for Formaldehyde, oligomeric reaction products with aniline (technical MDA).

Other issues

The MSC briefly discussed the transitional arrangements for technical MDA and noted that ideally, it would be preferable to have transitional arrangements for this substance and those for MDA closely aligned. However, considering that the latest application date for MDA is already set for February 2013⁶, it was recognised that this is not feasible.

⁶ See entry 2 of Annex XIV to Regulation (EC) No 1907/2006 (REACH) as inserted by Commission Regulation (EC) No 143/2011 of 17 February 2011

2.2 Arsenic acid

Justification for prioritisation

Arsenic acid is classified as carcinogen category 1A in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 and was identified as a Substance of Very High Concern according to Article 57(a) of REACH. It was included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

According to information provided in the registrations, arsenic acid is imported between 100 – 1000 t/y. While it was manufactured previously in the EU, there is currently no EU manufacture. Arsenic acid may be used to replace diarsenic trioxide, a substance already included in Annex XIV. The main use, (about 97%), is in the industrial special glass sector. A second known use is in the manufacture of copper foil for printed circuit boards. Many uses within these sectors are considered to be within the scope of authorisation. Consumer exposure via articles resulting from the uses is considered to be insignificant, but there may be potentially significant occupational exposure.

Based on this, arsenic acid meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation no MSCA opposed the prioritisation for inclusion of arsenic acid in Annex XIV. Two MSCAs, two NGOs and one Trade Union Confederation expressed their support for the prioritisation. Claims were made by industry similar to those made previously during the public consultation for the prioritisation of diarsenic trioxide that the use of arsenic acid in glass production is an intermediate use. It is possible that some uses in glass production are intermediate ones, whereas others are not.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of arsenic acid.

Transitional arrangements: Latest application date/sunset date

ECHA proposed the following transitional arrangements for arsenic acid:

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

During the public consultation, one NGO requested to set the latest application and sunset dates as soon as possible. One statement from the glass industry indicated that there are no real alternatives available that would be less harmful than arsenic acid, but did not request changes to the transitional arrangements. One company, who requested an exemption, also requested that if the exemption was not granted for their use, then the sunset date should be set to 48 months.

Regarding the point on the lack of suitable alternatives, MSC agrees with the response provided in ECHA's RCOM that information on alternatives should be provided as part of the application for authorisation and will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision.

MSC is of the opinion that no new information was submitted during the public consultation that would support changes to the proposed transitional arrangements and therefore MSC agrees with ECHA's recommendation for the transitional arrangements for arsenic acid.

Proposed review period for certain uses

No review period was suggested by ECHA.

No comments were received during the public consultation on review periods.

MSC is of the opinion that review periods are not warranted in the recommendation for inclusion of arsenic acid in Annex XIV.

Proposed exempted (categories of) uses

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

During the public consultation, one trade association indicated that there are no alternatives to arsenic acid in glass production, but did not specifically request an exemption. That trade association had also claimed that this use is an intermediate one. Another company specifically asked for an exemption for the use in the production of copper foil, owing to limited worker exposure. There were also requests for exemptions for equipment calibration and as analytical standards. Additionally, one company requested an exemption for the use of filling arsenic acid into small packages for laboratory use.

MSC generally agrees with the response provided in ECHA's RCOM that the arguments provided for the exemption for the use in the production of copper foil are not sufficient to justify an exemption under Article 58(2) of REACH. Regarding the exemption request for equipment calibration and analytical standards, these uses are considered as scientific research and development and so already exempt.

Overall, MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for PPORD were suggested by ECHA in their draft recommendation.

There were no requests for PPORD exemptions submitted during the public consultation.

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not warranted for arsenic acid.

Other issues

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

2.3. Dichromium tris (chromate)

Justification for prioritisation

Dichromium tris(chromate), is classified as carcinogen 1B, in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 and was identified as a Substance of Very High Concern according to Article 57(a) of REACH. It was included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

According to the registration information the volume manufactured in the EU is in the range of 10 – 100 t/y. Dichromium tris(chromate) is mainly used for surface treatment of metals due to its corrosion inhibiting properties. Almost the entire amount of the 10-100 t/y of dichromium tris(chromate) is allocated to uses in the scope of authorisation (uses outside the scope of the authorisation may only include minor uses such as scientific research and development (SRD)).

Uses of the substance may take place at a medium to high number of industrial sites. Releases and exposure to workers may be controlled in most instances, however some of the uses have a potential for significant worker exposure.

While dichromium tris(chromate) has a medium prioritisation score, there are other chromium (VI) compounds recommended for inclusion in Annex XIV, e.g. sodium dichromate and potassium dichromate, which potentially could be replaced by dichromium tris(chromate) in surface treatment. This adds to the argument for the prioritisation of dichromium tris(chromate).

Based on this, dichromium tris(chromate) meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, two Member State Competent Authorities (MSCAs) supported the prioritisation of dichromium tris(chromate) for inclusion in Annex XIV. One MSCA expressed its concerns over the priority given to the substance and asked for clarification regarding the existence of a substance-specific risk that requires control. Their concern centred around the fact that the priority given to the substance appears to be based on an analogy to the use and exposure levels of chromium trioxide and there were concerns that this was not sufficiently justified. Two NGOs and one Trade Union Confederation expressed their support for the prioritisation.

Many comments were received from industry associations, individual companies and one individual. The arguments put forward for not prioritising dichromium tris(chromate) included points such as the unavailability of alternatives despite intensive searches, the specific safety obligations that apply to the aerospace industry and the fact that alternatives will not be compatible with existing products for repair or overhaul purposes, the burden to specific industry sectors, and especially SMEs, resulting from the regulation of many chromates within a short timeframe, that the use of the substance is adequately controlled under existing occupational worker protection and environmental protection legislation and economic reasoning based on presumed transfer of use processes to non-EU companies. Aerospace industry groups also raised concern that the authorisation process is an unknown and untested one so far, and they are concerned as regards what they see as the testing of their safety-critical substances in such an unknown process, especially with no guarantee that authorisations will be granted. Due to the poor solubility of dichromium tris(chromate) the inter-changeability with other chromium compounds was also questioned.

Regarding the points on the technical feasibility of alternatives MSC is of the same opinion for this substance as expressed previously in this document for other substances. Regarding the arguments provided by industry on the socio-economic benefits of using this substance and of the potential effect of authorisation on EU business, while the MSC considers that these issues are very important and relevant, it generally agrees with the

responses provided by ECHA in the RCOM documents on them. Overall, MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of dichromium tris(chromate).

Transitional arrangements: Latest application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for dichromium tris(chromate):

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

During the public consultation, there were many comments from industry requesting that the prioritisation be delayed as long as possible, to allow time for alternative solutions to become fully tested and accepted and to allow sufficient time for the formation of suitable consortia. The requests were based on lack of available alternatives, long periods of time (15 to 20 years) required for approval of new safe alternatives and socio-economic reasons. It is also claimed by industry that preparing the authorisation applications would dilute resources currently focused on development of alternatives. Additionally, some specific supply chain complexity arguments were provided by the aerospace industry. They also requested that the transitional arrangements be as long as possible to allow them to gain from work done and lessons learned from the authorisation applications of the chromate substances contained in ECHA's third recommendation for Annex XIV. Suggested sunset dates ranged from 8 to 18 years.

One NGO requested to set the latest application and sunset dates as close as possible.

In its November 2012 meeting, the REACH committee agreed that the latest application dates for the chromates in ECHA's 3rd recommendation for Annex XIV should be 35 months from entry into force of the Regulation. Following this, ECHA updated its recommendation and proposed that the latest application date for all 11 prioritised chromates (7 in the third recommendation and 4 in the fourth recommendation) should be the same. Based on the current working assumption that the Commission Regulation including the substances of the third recommendation will enter into force in March 2013, this would mean that the latest application date for all 4 chromates in the fourth recommendation should be set at 24 months after entry into force of the Regulation. MSC agrees with ECHA's recommendation and is of the opinion that the latest application date for dichromium tris(chromate) should be 24 months from entry into force.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation.

During the public consultation, comments received from industry suggested review periods between 5-10 and 15 years, depending on the transitional arrangements.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion of dichromium tris(chromate).

Proposed exempted (categories of) uses

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

During the public consultation, industry requested exemption for the uses in aerospace industry and for oil and gas pipe-line coating. Some companies suggested an exemption for all uses of dichromium tris(chromate). The arguments put forward included existing occupational worker protection, existing environmental protection legislation and national occupational exposure limits in some Member States, as well as the arguments already mentioned in the priority setting section above.

In addition to the points made on the priority setting above, MSC generally agrees with the response provided by ECHA in the RCOM documents that the arguments put forward

by industry are not sufficient to justify an exemption under Article 58(2) of REACH. Overall, MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were proposed by ECHA in its draft recommendation.

During the public consultation, there were no requests for PPORD exemptions.

The Member State Committee supports ECHA's view that PPORD exemptions in Annex XIV are not warranted.

Other issues

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

2.4 Strontium chromate

Justification for prioritisation

Strontium chromate is classified as carcinogen 1B in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 and was identified as a Substance of Very High Concern according to Article 57(a) of REACH. It was included in the candidate list for authorisation on 20 June 2011, following ECHA's decision ED/31/2011.

According to the registrations the substance is manufactured or imported in the EU in a tonnage range of 1,000 – 10,000 t/y. The volume imported (range 100 - 1,000 t/y) is quite low compared to the volume manufactured. The main application of strontium chromate is in coil coated galvanised steel. Smaller quantities are used in processes such as anti-corrosion primers and sealants in equipment maintenance, such as within the aerospace sector. The entire manufactured or imported amount of strontium chromate is allocated to uses in the scope of authorisation.

Uses of the substance take place at a high number of industrial sites but also in workshops during vehicle and equipment repair and refurbishing activities. Although exposure of workers may be controlled in most industrial applications, there is potential for significant worker exposure, in particular during repair and refurbishing activities.

Based on this, strontium chromate meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, two Member State Competent Authorities (MSCAs) supported the prioritisation of strontium chromate for inclusion in Annex XIV. The MSCA that expressed concern over the prioritisation of dichromium tris(chromate) as described above raised the same concern for strontium chromate. Two NGOs and one Trade Union Confederation expressed their support for the prioritisation.

Many comments were received from industry associations, individual companies and individuals. The arguments put forward for not prioritising strontium chromate were generally the same as those raised for dichromium tris(chromate) and included points such as the unavailability of alternatives despite intensive searches, the specific safety obligations that apply to the aerospace industry and the fact that alternatives will not be compatible with existing products for repair or overhaul purposes, the burden to specific industry sectors, and especially SMEs, resulting from the regulation of many chromates within a short timeframe, that the use of the substance is adequately controlled under existing occupational worker protection and environmental protection legislation and economic reasoning based on presumed transfer of use processes to non-EU. Additionally, the same concerns around authorisation being an unknown process, as outlined above for dichromium tris(chromate), were also raised in comments submitted for strontium chromate. Due to the poor solubility of strontium chromate the interchangeability with other chromium compounds is questioned.

As with dichromium tris(chromate) described above, MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of strontium chromate.

Transitional arrangements: Latest application date and sunset date

ECHA initially proposed the following transitional arrangements for strontium chromate:

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

During the public consultation, as with dichromium tris(chromate), there were many comments from industry requesting that the prioritisation be delayed as long as possible, again for the same arguments outlined above, particularly for the aerospace sector.

Suggested sunset dates ranged from 8 to 18 years. One company, outside of the aerospace sector, asked for sector relevant transitional periods, taking into account the efforts of industry sectors to validate alternatives within the transitional periods. One NGO requested to set the latest application and sunset dates as close as possible

As previously described, following the November 2012 REACH Committee meeting ECHA proposed that the latest application date for the 4 chromates be set at 24 months from entry into force. MSC agrees and is of the opinion that the latest application date for strontium chromate should be 24 months from entry into force.

Proposed review period for certain uses

No review period was suggested by ECHA.

The comments received suggested review periods between 5-10 and 15 years, depending on the transitional arrangements.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories of) uses

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

During the public consultation, similar to dichromium tris(chromate) outlined above, industry requested exemptions for uses of strontium chromate in the aerospace industry. Some companies suggested an exemption for all uses. The arguments put forward were the same as those for dichromium tris(chromate), including existing occupational worker protection, existing environmental protection legislation and national occupational exposure limits in some Member States as well as the arguments already mentioned above in the priority setting section.

As for dichromium tris(chromate) described above, MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were proposed by ECHA in its draft recommendation.

During the public consultation, there were no requests for PPORD exemptions.

The Member State Committee supports ECHA's view that PPORD exemptions in Annex XIV are not warranted.

Other issues

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

2.5 Potassium hydroxyoctaoxodizincatedichromate

Justification for prioritisation

Potassium hydroxyoctaoxodizincatedichromate is classified as carcinogen category 1A in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 and was identified as a Substance of Very High Concern according to Article 57(a) of REACH. It was included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

It is used in volumes between 100 and 1000 t/y. The entire tonnage is allocated to uses within the scope of authorisation. The substance is used as an anti-corrosion agent for the formulation of primers and is further used in sealants. Uses of the substance are considered to be widespread, with a potential for significant worker exposure. Potassium hydroxyoctaoxodizincatedichromate can be used to replace other hexavalent chromium compounds with similar uses.

Based on this, potassium hydroxyoctaoxodizincatedichromate meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, two Member State Competent Authorities (MSCAs) supported the prioritisation of potassium hydroxyoctaoxodizincatedichromate for inclusion in Annex XIV. The MSCA that expressed concern over the prioritisation of dichromium tris(chromate) and strontium chromate as described above also raised the same concern for potassium hydroxyoctaoxodizincatedichromate. Two NGO's and one Trade Union Confederation expressed their support for the prioritisation.

Many comments were received from industry associations, individual companies and individuals. The arguments put forward for not prioritising potassium hydroxyoctaoxodizincatedichromate were the exactly the same as those raised for dichromium tris(chromate) and strontium chromate, already described above – arguments including the unavailability of substitutes with equivalent performance despite intensive searches, the specific safety obligations and critical performance criteria requirements that apply to the aerospace industry, economic reasonings about the potential cessation of aviation business in Europe if authorisation is not granted. Other arguments for not including potassium hydroxyoctaoxodizincatedichromate into Annex XIV included strictly controlled conditions of aerospace manufacturing, maintenance and repair processes, safe working environments and absence of any release to the environment.

As for the two chromate substances described above, MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of Potassium hydroxyoctaoxodizincatedichromate

Transitional arrangements: Latest application date/sunset date

ECHA initially proposed the following transitional arrangements for potassium hydroxyoctaoxodizincatedichromate:

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

As with the two chromates already described above, many comments were received during the public consultation relating to the transitional arrangements. All of the comments were identical to those already received on the other two substances and will not be repeated in full here.

As previously described, following the November 2012 REACH Committee meeting ECHA proposed that the latest application date for the 4 chromates be set at 24 months from entry into force. MSC agrees and is of the opinion that the latest application date for

potassium hydroxyoctaoxodizincatedichromate should be 24 months after entry into force.

Proposed review period for certain uses

No review period was suggested by ECHA.

Again, as with the previous two chromates described above, the comments received suggested review periods between 5-10 and 15 years, depending on the transitional arrangements.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories of) uses

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

During the public consultation, one NGO expressed agreement with the proposal. As with the two chromates already described above, general exemptions were requested for uses in the aerospace industry based on air safety reasons.

As with the two chromate substances described above, MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA in its draft recommendation.

There were no requests for PPORD exemption submitted during the public consultation.

The Member State Committee supports ECHA's view that PPORD exemptions in Annex XIV are not warranted.

Other issues

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

2.6 Pentazinc chromate octahydroxide

Justification for prioritisation

Pentazinc chromate octahydroxide is classified as carcinogen category 1A in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 and was identified as a Substance of Very High Concern according to Article 57(a) of REACH. It was included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

Pentazinc chromate octahydroxide is manufactured within the EU and is used in volumes between 100 and 1000 t/y. It is used in the aerospace sector as an anti-corrosion agent for the formulation of primers and sealants, uses within the scope of authorisation and with the potential to occur at a high number of industrial sites. Potential for significant worker exposure at least in some processes cannot be excluded. Pentazinc chromate octahydroxide can be used to replace other hexavalent chromium compounds with similar uses.

Based on this, pentazinc chromate octahydroxide meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, two Member State Competent Authorities (MSCAs) supported the prioritisation of pentazinc chromate octahydroxide for inclusion in Annex XIV. The MSCA that expressed concern over the prioritisation of the other three chromates outlined above also raised the same concern for pentazinc chromate octahydroxide. Two NGO's and one Trade Union Confederation expressed their support for the prioritisation.

Many comments were submitted during the public consultation on the general prioritisation. All of these comments are identical to the ones also submitted for the other 3 chromates described above and will not be repeated here.

As for the chromate substances already described above, MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritization of pentazinc chromate octahydroxide.

Transitional arrangements: Latest application date/sunset date

ECHA initially proposed the following transitional arrangements for pentazinc chromate octahydroxide:

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

As with the other chromate substances, many comments were received related to the transitional arrangements. One Member State Competent Authority agreed with the proposed transitional arrangements. One NGO requested to set latest application and sunset dates as close as possible. Comments received from the aerospace sector were identical to the ones also submitted for the other 3 chromates and will not be repeated here.

As previously described, following the November 2012 REACH Committee meeting, ECHA proposed that the latest application date for the 4 chromates be set at 24 months from entry into force. MSC agrees and is of the opinion that the latest application date for pentazinc chromate octahydroxide should be 24 months from entry into force.

Proposed review period for certain uses

No review period was suggested by ECHA.

Again, as with the previous 3 chromates described above, the comments received suggested review periods between 5-10 and 15 years, depending on the transitional arrangements.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories of) uses

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

As with the three chromates already described above, general exemptions were requested for uses in the aerospace industry based on air safety reasons.

And as for the chromates already described, MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA.

There were no requests for PPORD exemptions submitted during the public consultation.

The Member State Committee supports ECHA's view that PPORD exemptions in Annex XIV are not warranted.

Other issues

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

2.7 Bis(2-methoxyethyl) ether (Diglyme)

Justification for prioritisation

Bis(2-methoxyethyl)ether (Diglyme, DEGDME) is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as toxic for reproduction 1B, H360D ("May damage the unborn child") and was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c). It was included in the Candidate List for authorisation on 19 December 2011 following ECHA's decision ED/77/2011.

According to registration information, the amount of Diglyme manufactured and/or imported into the EU in 2009 was in the range 100-1000t/y. It is produced in a small number of companies in the supply chain. Most of the uses are expected to be in closed systems, although worker exposure cannot be excluded. The main uses appear to be as a solvent for the synthesis of chemicals and pharmaceuticals. There is uncertainty whether for example paints or coatings contain the substance. ECHA concludes that the substance is used in high volumes and that applications exist with potential significant occupational exposure: cleaning, maintenance, sampling, and transfer operations. Based on the Risk Characterization Ratios in the CSRs being close to 1, ECHA concludes that risks are possible and ECHA therefore proposes to prioritise the substance.

Based on this, Bis(2-methoxyethyl)ether (Diglyme, DEGDME), meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, one Member State Competent Authority (MSCA) expressed concerns as to whether a substance evaluation should be started before prioritising the substance for inclusion in Annex XIV, as there are many uncertainties related to the actual exposure. Two MSCAs supported the prioritisation. Two environmental NGOs and a Trade Union Confederation supported the recommendation for inclusion of the substance in Annex XIV.

One company claimed that there are no alternatives and therefore prioritisation is not recommended. This company suggested that an Annex XVII entry be developed instead. Another company doubted the number of sites where Diglyme is used according to ECHA, but did not indicate whether ECHA under- or over-estimated this. In other comments companies claimed that the number of sites is lower than assumed in the background document. Comments from registrants indicated that there is no consumer exposure. Some companies claimed that the substance is used in adequate controlled processes, with limited worker exposure. It was also pointed out that national and EU legislation is in place to minimise the exposure of workers, consumers and the environment. These arguments were used to contest the prioritisation of the substance or to exempt industrial use of the product (also addressed in the exemption section below).

On the issue of lack of alternatives available, MSC is of the same opinion for this substance as expressed previously in this document for other substances. MSC is also of the same general opinion as ECHA, as noted in ECHA's RCOM, regarding the fact that having general national and EU legislation in place is not a valid argument for contesting the prioritisation of the substance.

Several registrants expressed the opinion that a restriction, would in their view, be a more suitable risk management option than authorisation. Depending on the registrant, restrictions were proposed for uses identified as dangerous for workers, consumers, or for the environment. However, as there is currently no proposal for a restriction dossier in place, MSC is of the opinion that the current recommendation process should not be delayed.

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

Transitional arrangements: Latest application date/sunset date

ECHA initially proposed the following transitional arrangements for Diglyme:

- i. Latest application date: 21 months after entry into force of the Regulation
- ii. Sunset date: Latest application date plus 18 months

During the public consultation, one MSCA agreed to the proposed dates. One company proposed 60 months after entry into force, while one NGO proposed the shortest possible application date.

As described already, following the REACH Committee meeting in November 2012, ECHA revised its recommendation on the transitional arrangements for the 4 chromate substances. In order to maintain evenly aligned groups of substances and giving consideration to workloads, the proposed latest application date for Diglyme has been changed from 21 months to 18 months. MSC agrees with this and so is of the opinion that the latest application date for Diglyme should be 18 months after entry into force.

Proposed review period for certain uses

No review period was suggested by ECHA. There were no comments submitted on review periods during the public consultation.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses or any exemption of uses or categories of uses.

General exemptions were requested for uses in the production of medicinal products and pharmaceuticals, as well as in the fine chemicals production. This exemption request was based on the critical nature of the use of this aprotic solvent in these processes, as well as claims that the use of solvents is covered specifically under the medical products legislation, with specific limits for specified substances referred to in relevant guidelines. Additionally, one company requested an exemption for the use of filling Diglyme into small packages for laboratory use, as competitors importing small bottles will have lower costs. One NGO requested that no general exemptions should be granted.

Exemptions were requested based on several EU Regulations: e.g. 2001/83/EC and (EC) 726/2004 relating to medicinal products for human use, 1999/13/EC Solvent Emissions Directive, 2004/37/EC Carcinogens and Mutagens Directive as well as 2000/76/EC Waste Incineration Directive. As these Directives do not impose binding minimum requirements for imposing risks to workers health and/or the environment for this substance, the MSC is of the opinion that a specific exemption is not warranted in accordance with Article 58(2) of REACH.

Regarding the request for an exemption for uses in the production of medicinal products, MSC is of the opinion that while an exemption in accordance with Article 2(5)(a) of REACH is unlikely considering that the substance is not used in the medicinal product itself, but rather further back in the production cycle, for example, in the production of the API, some companies may benefit from the exemption if the conditions of Article 2(5)(a) are met. This would need to be examined on a case-case basis by individual companies. Regarding claims for an exemption based on EMA guidelines for residual solvents, MSC considers that as these guidelines are directed towards the safety of the final medicinal products, they do not necessarily provide protection for human health or the environment from the use of the substance and so the grounds for an exemption are not considered to be valid.

Overall, MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA.

No requests for PPORD exemptions were brought forward during the public consultation.

MSC supports ECHA's view that upfront specified PPORD exemptions in Annex XIV are not warranted.

Other issues

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

2.8 N,N-Dimethylacetamide (DMAC)

Justification for prioritisation

N,N-Dimethylacetamide (DMAC) is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as toxic for reproduction 1B, H360D ("May damage the unborn child") and was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c). It was included in the Candidate List for authorisation on 19 December 2011 following ECHA's decision ED/77/2011.

According to registration information, in 2012, the total manufactured volume was in the range 15,000-20,000 t/a while import was in the range 1,000-2,000 t/a. DMAC has widespread uses and at least some uses have a high likelihood for releases and exposure. The main use is as an aprotic solvent in the production of agrochemicals, pharmaceuticals and fine chemicals. It is also used in the manufacture of man-made fibres, along with other smaller uses. Worker exposures (dermal and by inhalation) during the main industrial uses of DMAC are likely to occur during mixing and blending of DMAC in batch formulation processes. According to the background document worker exposure may also take place during automated filling, maintenance, and lab analysis. Industrial and in some cases professional workers might – according to the background document - also be exposed to low amounts of DMAC found as residues in fibers.

Based on this, N,N-Dimethylacetamide (DMAC), meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, one Member State Competent Authority (MSCA) expressed concerns whether authorisation is the most appropriate risk management route. That MSCA argued that there is a lack of suitable alternatives. It also questioned whether authorisation would be the most appropriate route as imported articles may still contain DMAC in concentration levels > 0.1%. Two MSCAs supported the prioritisation. Several NGOs and a Trade Union Confederation supported the recommendation for inclusion of the substance in Annex XIV.

The main comments received from individual companies and sector organisations were related to the production of fibres and production and development of medicinal products. Several companies claimed that the substance is used in adequately controlled processes with limited workers exposure, with some reporting to work under the IPPC Directive. It was also pointed out that national and EU legislation is in place to minimise the exposure of workers, consumers and the environment, with some emphasis placed on adherence to the indicative OEL for the substance. These arguments were used to contest the prioritisation of the substance or to exempt industrial use of the product for the production of fibres and the use in the production of API's or as analytical standards (exemptions also dealt with in the exemptions section below).

Several companies claimed that there are less companies working with the substance than indicated in the ECHA background document; however these claims were not substantiated.

Many companies suggested not to prioritise the substance for authorisation, but instead requested a restriction on the use of the substance, for uses other than industrial fibre production.

Several companies indicated that there are no alternatives for the substance or only alternatives with a lower performance. This is due to the specific properties of DMAC and the comparable hazard profile of potential alternative solvents. Substitution would therefore not lead to lower risks for workers, consumers or the environment, according to these companies.

Companies using DMAC for the production of fibres state that the concentrations in the end-product are less than the max. 3% mentioned in the background document, and indicate that the concentrations are rather 0.1 – 0.6%. Therefore, they argue that exposure of workers to DMAC in the finished product is not a relevant risk.

The main use of DMAC is as a polar aprotic solvent. There is a limited number of polar aprotic solvents in use and industry claims that these substances all have a more or less similar toxicological profile. Industry suggests that substitution between these substances will therefore have limited possibilities, and some companies argue that the most appropriate risk management option would be a restriction. However, as there is currently no proposal for a restriction dossier in place, MSC is of the opinion that the current recommendation process should not be delayed.

Transitional arrangements: Latest application date/sunset date

ECHA initially proposed the following transitional arrangements for DMAC:

- i. Latest application date: 24 months after entry into force of the Regulation
- ii. Sunset date: Latest application date plus 18 months

Several companies indicated that longer transitional periods would be needed, to optimise the process for suitable alternative solvents. However, given the fact that this is very difficult anyway due to the specificity of the substance, longer transitional periods would not seem to solve this problem.

As described already, following the REACH Committee meeting in November 2012, ECHA revised its recommendation on the transitional arrangements for the 4 chromate substances. In order to maintain evenly aligned groups of substances and giving consideration to workloads, the proposed latest application date for DMAC has been changed from 24 months to 21 months. MSC agrees with this and is of the opinion that the latest application date for DMAC should be 21 months after entry into force.

Proposed review period for certain uses

No review period was suggested by ECHA.

During the public consultation, one proposal was received to set a review period of 10 years or more as there is no alternative available.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses or any exemption of uses or categories of uses.

General exemptions were requested for uses in the fibre production, production of membranes, medical devices, medical products and pharmaceuticals. These were mainly based on an argument of low worker exposure and low emissions and that the use of solvents in the production of medicinal products is covered by the medical products Directive and controlled by guidelines on the presence of residual solvents in medicinal products, as discussed previously for Diglyme. One company requested an exemption for refilling from bulk to small packaging, as for some other prioritised substances previously described.

Exemptions were requested based on some EU Regulations: e.g. 2001/83/EC and 726/2004 relating to medicinal products for human use, Chemical Agents Directive 98/24/EC, 1999/13/EC Solvent Emissions Directive, 2004/37/EC Carcinogens and Mutagens Directive, as well as 2000/76/EC Waste Incineration Directive. Additionally, an exemption request was made based on Directive 2000/39/EU establishing an indicative occupational exposure limit value (i-OEL) for DMAC. As these Directives do not impose binding minimum requirements for imposing risks to workers health and/or the

environment for this substance, the MSC is of the opinion that a specific exemption is not warranted in accordance with Article 58(2) of REACH.

Regarding the request for an exemption for uses in the production of medicinal products, MSC is of the same opinion for this substance as expressed for Diglyme above.

In relation to the request for an exemption for the use of the substance in the production of medical devices, MSC notes that this exemption was already addressed in Recital 18 of Commission Regulation 143/2011 of 17 February 2011, amending Annex XIV to REACH for the first time,

MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA.

Requests for PPORD exemptions were made during the public consultation. Two pharmaceutical industry trade organisations requested a PPORD exemption for up to 10 t/a for use in medical products while 4 other individual pharmaceutical companies requested PPORD exemptions for either 10 t/a or 100 t/a.

Article 55 of REACH formulates one of the aims of REACH - that SVHCs are progressively replaced by suitable alternative substances or technologies. MSC considers that there is an apparent inconsistency between the possibility of optional PPORD exemptions and what is indicated in Article 55. This apparent conflicting objective of the legislation to substitute a substance subject to authorisation and at the same time to allow its use in product and process oriented research and development activity is difficult to address. It is also recognised by MSC that formulation of a PPORD exemption in such a way that it would be specific enough but applicable to all possible similar cases would be difficult. A PPORD exemption to be included in the legislation cannot be addressed only to one company. Based on the considerations above, MSC generally does not support the inclusion of PPORD exemptions in Annex XIV. However, MSC also agrees with ECHA's view on this specific case that, where there is no alternative, then PPORD activity with the aim to reduce the use of the substance could be justified. In such a case, the PPORD activity should be justified in the authorisation application and subsequently decided on during the granting process.

The Member State Committee supports ECHA's view that upfront specified PPORD exemptions in Annex XIV are not warranted.

Other issues

During the public consultation and MSC discussions, one MSC member (UK member) expressed concern as to whether authorisation is the most appropriate risk management measure for DMAC and was of the opinion that other risk management options should be considered. A declaration has been prepared separately on this issue by the UK MSC member and transmitted to the Commission for further consideration.

2.9 1,2-Dichloroethane (EDC)

Justification for prioritisation

1,2-dichloroethane or ethylene dichloride (EDC) is classified as a carcinogen, Carc. 1B in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 and was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) of REACH and was therefore included onto the Candidate List for authorisation on 19 December 2011 following ECHA's decision ED/77/2011.

According to the Annex XV report (ECHA 2011), the total amount of 1,2-dichloroethane (EDC) manufactured in the EU is between 1,000,000 and 10,000,000 t/a with a further 10,000 – 50,000 t/a imported into the EU. The main use of 1, 2-dichloroethane is in the production of Vinyl Chloride monomer and as on-site isolated intermediate. These uses representing > 99% of the total tonnage are therefore outside the scope of authorisation. ECHA concludes that while the exact total volume used within the scope of authorisation cannot be estimated based on available information, the remaining 0.2% corresponds to a tonnage of 2,000 – 20,000 t/a. Based on the available information, worker exposure to EDC is possible during batch processes, transfer, cleaning and maintenance activities, therefore ECHA proposes to prioritise this substance for inclusion in Annex XIV.

Based on this, 1,2-dichloroethane (EDC), meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation process, no Member State Competent Authority (MSCA) opposed the prioritisation of 1,2-dichloroethane for inclusion in Annex XIV. One MSCA supported the recommendation, along with two NGOs and one Trade Union Association

Comments were received from industry associations and individual companies. One trade association challenged the prioritisation score on the basis of information it received through a survey conducted of all the registrants of EDC. It is stated that the prioritisation score was overestimated, based on the total tonnage of non-intermediate use. It is claimed that the actual tonnage range is 1,000-10,000 t/a and therefore a lower prioritisation score is suggested. This suggestion was supported by several other companies and trade associations. Many companies and trade associations commented on the main use of the substance as a solvent under strictly controlled conditions in the manufacture of active ingredients for medical and veterinary products and therefore the exposure to workers is limited within the controlled processes. Companies also argue the difficulties associated with gaining approvals for use in pharmaceutical manufacture and the unavailability of suitable, non or less hazardous alternatives. Many comments further suggested that a restriction for uses with the highest impact on health or the environment would be a more appropriate risk management option. This would allow for the continued use of EDC as a solvent in the manufacture of pharmaceutical products and fine chemicals under strictly controlled conditions.

Regarding the proposed change to the prioritisation score, MSC notes that with the new information submitted during the public consultation, ECHA has revised its prioritisation score from 17-19 down to 14. However, even taking this into account, MSC is still of the opinion that 1,2-dichloroethane meets the criteria for prioritisation.

Regarding the points raised during the public consultation on restriction perhaps being a more suitable risk management option than authorisation, MSC is of the same opinion on the issue for this substance as was already expressed previously for Diglyme and DMAC

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of 1,2-dichloroethane (EDC).

Transitional arrangements: Latest application date and sunset date

For the public consultation ECHA initially proposed the following transitional arrangements for 1,2-dichloroethane (EDC):

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

One NGO commented that the proposed dates should be as soon as possible. One company proposed setting the latest application date 60 months after the entry into force.

As described already, following the REACH Committee meeting in November 2012, ECHA revised its recommendation on the transitional arrangements for the 4 chromate substances. In order to maintain evenly aligned groups of substances and giving consideration to workloads, the proposed latest application date for EDC has been changed from 24 months to 21 months. MSC agrees with this and so is of the opinion that the latest application date for EDC should be 21 months from entry into force.

Proposed review period for certain uses

No review period was suggested by ECHA.

No comments were submitted during the public consultation suggesting any review periods.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses.

During the public consultation, one NGO commented that no use should be granted a generic exemption. Many requests for general exemptions were submitted by industry for the use of the substance as a solvent in pharmaceutical processes carried out under strictly controlled conditions. The argument used for this exemption request was similar to that made for DMAC as outlined above, being based on an argument of low emissions and that the use of solvents in the production of medicinal products is covered by the medical products Directive and controlled by guidelines on the presence of residual solvents in medicinal products, as already also outlined for the substances Diglyme and DMAC above. One company requested an exemption for filling of 1, 2-dichloroethane into small packages for laboratory use (same request for other prioritised substances) and also requested an exemption for use in testing of residual solvents.

Regarding the requests for exemptions based on existing EU legislation, low emissions and low worker exposure, MSC is of the same opinion for this substance as already expressed for other substances in this document. Similarly, MSC's opinion on the use in the production of medicinal products is similar to that already expressed for Diglyme and DMAC.

MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were proposed by ECHA.

Two requests for PPORDs were received. One for activity related to the production of medicinal products for up to 10 t/a, the other did not specify the activity but was also for up to 10 t/a.

MSC is of the same view regarding PPORDs for this substance as expressed for DMAC above and so MSC is of the opinion that PPORD exemptions in Annex XIV are not warranted for 1,2-dichloroethane.

Other issues

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

2.10 2,2'-Dichloro-4,4'-methylenedianiline (MOCA)

Justification for prioritisation

2,2'-Dichloro-4,4'-methylenedianiline (MOCA) is classified as carcinogen, Carc 1B in Annex VI, part 3, table 3.1 of Regulation (EC) 1272/2008 and was identified as a substance of very high concern (SVHC) according to Article 57(a) of REACH. It was included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

According to the Annex XV report (ECHA, 2011), MOCA is not manufactured in Europe and import is between 1,000-10,000 t/y. The main use of MOCA is as a curing agent in the manufacture of polyurethane, a use that is within the scope of authorisation. Based on available information, significant releases of MOCA with high potential for worker exposure may occur at a high number of sites.

Based on this, MOCA meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, no Member State Competent Authority (MSCA) opposed the prioritisation of MOCA for inclusion in Annex XIV; three MSCAs specifically supported the proposal. Two NGOs and one Trade Union Association expressed their support for the prioritisation.

Comments were received from industry associations and individual companies that challenged the prioritisation of MOCA. Some of the comments indicated that there are guidelines and procedures already in place for the safe handling of this substance. Some companies made the point that there are no alternatives available to MOCA for their processes. In addition, a company challenged the priority score attributed by ECHA, indicating that there may be double counting of tonnages within the aggregated registration information, while also challenging the number of downstream user sites. Furthermore, the existence of professional uses was also questioned. Some companies also disagreed with ECHA's statement in the background document that un-reacted MOCA may be present in final articles (up to 4%).

For this substance, on issues such as guidelines and procedures in place to ensure safe use, in addition to existing community legislation, as well as a lack of alternatives, MSC is of the same general opinion, as with other substances already described in this document, that there are not enough grounds for de-prioritisation.

On the challenge to the priority score, MSC notes that ECHA's estimation of volumes is based on information currently available in the registration dossiers and generally agrees with ECHA's view as expressed in the RCOMs that it is this information that the estimation should be based on, as opposed to external estimates of the volumes submitted during the public consultation.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of 2,2'-dichloro-4,4'-methylenedianiline (MOCA).

Transitional arrangements: Latest application date and sunset date

In its draft recommendation, ECHA initially proposed the following transitional arrangements for 2,2'-dichloro-4,4'-methylenedianiline (MOCA)

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

No comments were received during the public consultation regarding the transitional arrangements.

As described already, following the REACH Committee meeting in November 2012, ECHA revised its recommendation on the transitional arrangements for the 4 chromate substances. In order to maintain evenly aligned groups of substances and giving consideration to workloads, the proposed latest application date for MOCA has been changed from 24 months to 21 months. MSC agrees with this and so is of the opinion that the latest application date for MOCA should be 21 months from entry into force.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation.

During the public consultation, one company requested a review period of 6 years for one type of foam and 12 years for another type, if their requested exemptions were not granted.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for the inclusion of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) in Annex XIV.

Proposed exempted (categories of) uses

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

During the public consultation, there was a request from an industry association to grant an exemption, due to the fact that measures to reduce employee exposure have been implemented within the industry. This request was echoed by another individual company. In addition, one other company requested an exemption based on its claims that the prioritisation score should be lower.

MSC considers that voluntary measures implemented by companies are not sufficient to justify an exemption. Regarding the request for an exemption based on claims that the prioritisation score should be lower, MSC, as already described above under the prioritisation score section, considers that the prioritisation score should remain as is.

MSC is of the opinion that no information was submitted during the public consultation that would warrant the inclusion of a specific exemption for 2,2'-dichloro-4,4'-methylenedianiline (MOCA) for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were proposed by ECHA in its draft recommendation.

During the public consultation, there were no requests for PPORD exemptions.

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not warranted for 2,2'-dichloro-4,4'-methylenedianiline (MOCA).

Other issues

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

4th Draft Recommendation of Priority Substances to be Included in Annex XIV of the REACH Regulation, as presented for public consultation
(List of Substances Subject to Authorisation)

Draft Annex XIV entries [§]									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties [#]	Latest application date pursuant to Art. 58 (1) (c) (ii) [@]	Sunset date	Review periods	Exempted (categories of) uses	Exemptions for PPORD
1	Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	25214-70-4	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 18 months ¹⁾	Latest application date plus 18 months	None	None	None
2	Arsenic Acid	231-901-9	7778-39-4	Art. 57 (a); Carcinogen 1A	Date of inclusion in Annex XIV plus 18 months ¹⁾	Latest application date plus 18 months	None	None	None
3	Dichromium tris(chromate)	246-356-2	24613-89-6	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 18 months ¹⁾	Latest application date plus 18 months	None	None	None
4	Strontium chromate	232-142-6	7789-06-2	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
5	Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9	Art. 57 (a); Carcinogen 1A	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
6	Pentazinc chromate octahydroxide	256-418-0	49663-84-5	Art. 57 (a); Carcinogen 1A	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
7	Bis(2-methoxyethyl) ether (Diglyme)	203-924-4	111-96-6	Art. 57 (c); Toxic for Reproduction 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None

Draft Annex XIV entries [§]									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties [#]	Latest application date pursuant to Art. 58 (1) (c) (ii) [@]	Sunset date	Review periods	Exempted (categories of) uses	Exemptions for PPORD
8	N,N-Dimethylacetamide (DMAC)	204-826-4	127-19-5	Art. 57 (c); Toxic for Reproduction 1B	Date of inclusion in Annex XIV plus 24 months ³⁾	Latest application date plus 18 months	None	None	None
9	1,2-Dichloroethane (EDC)	203-458-1	107-06-2	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 24 months ³⁾	Latest application date plus 18 months	None	None	None
10	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9	101-14-4	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 24 months ³⁾	Latest application date plus 18 months	None	None	None

[#] Reference is made to the identified SVHC properties in accordance with Article 57 of the REACH Regulation and to the corresponding classification in accordance with Annex VI, Table 3.1 (*List of harmonised classification and labelling of hazardous substances*) of REGULATION (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

[§] Description of the general approach for deriving the draft Annex XIV entries: http://echa.europa.eu/documents/10162/17232/draft_axiv_entries_gen_approach_4th_en.pdf

[@] The standard Latest Application Date (LAD) of 18 months is used as the starting point and the dates for the 10 substances are spread in three groups over a period of 6 months (LADs 18, 21 or 24 months from entry into force) to distribute the workload in the authorisation application and decision phase more evenly.

In the first group (substances 1-3) there are substances that are similar in their inherent properties and their uses to substances already recommended for inclusion in Annex XIV. The second group (substances 4 – 7) comprises Cr(VI) compounds with a limited spectrum of uses, mainly as corrosion inhibitor applied in coating matrices to metal surfaces. Diglyme has been assigned to this second group and the remaining three substances (8 - 10) to the third group based on available information on the range of uses and the complexity of the supply chains.

- 1) Assumed the Commission Regulation including the substances of this fourth Recommendation in Annex XIV would enter into force in February 2014, the latest application date would be August 2015
- 2) Assumed the Commission Regulation including the substances of this fourth Recommendation in Annex XIV would enter into force in February 2014, the latest application date would be November 2015
- 3) Assumed the Commission Regulation including the substances of this fourth Recommendation in Annex XIV would enter into force in February 2014, the latest application date would be February 2016