ANNEX I - Reasons for the recommendation to include the prioritised substances in Annex XIV

Introduction:

The purpose of this Annex is to describe the reasons for recommending the following ten substances for inclusion in Annex XIV and the determination of their draft Annex XIV entries.

1. Formaldehyde, oligomeric reaction products with aniline (technical MDA)
2. Arsenic Acid
3. Bis(2-methoxyethyl) ether (Diglyme)
4. N,N-Dimethylacetamide (DMAC)
5. 1,2-Dichloroethane (EDC)
6. 2,2'-dichloro-4,4'-methylenedianiline (MOCA)
7. Dichromium tris(chromate)
8. Strontium chromate
9. Potassium hydroxyoctaoxodizincatedichromate
10. Pentazinc chromate octahydroxide

For the preparation of this Recommendation ECHA has used the following documents:

- *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation.* Document developed in the context of ECHA's second Recommendation of substances for inclusion in Annex XIV (list of substances subject to authorisation) (28 May 2010)[1]
- *Draft results of the 4th prioritisation of the SVHCs on the Candidate List with the objective to recommend priority substances for inclusion in Annex XIV* (20 June 2012)[2]
- *Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach* (20 June 2012)[3]
- Substance-specific background documents (29 November 2012)[4]

[1] http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf
[2] http://echa.europa.eu/documents/10162/13640/prioritisation_results_4th_rec_en.pdf
[3] http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_4th_en.pdf
[4] See link to substance-specific background documents in overview table: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

- Substance specific or substance group specific (for the chromium(VI) compounds) "*Responses to comments*" (RCOM) documents (29 November 2012)[5]
- Opinion of the Member State Committee on the fourth draft recommendation of the priority substances and Annex XIV entries (Adopted on 13 December 2012[6])

[5] See link to responses to comments (RCOM) documents in overview table: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

[6] http://echa.europa.eu/documents/10162/13576/opinion_draft_recommendation_annex_xiv_fourth_en.pdf

Annex I.1. - Formaldehyde, oligomeric reaction products with aniline (technical MDA)

Reasons for prioritising formaldehyde, oligomeric reaction products with aniline (technical MDA)

Formaldehyde, oligomeric reaction products with aniline (technical MDA) is supplied to uses in the scope of authorisation in relatively high to high volumes at a high number of sites. Most uses have a high potential for significant exposure to workers.[7,8] Furthermore, a very similar substance with similar uses, namely MDA (main constituent of technical MDA), is already included in Annex XIV.

Hence, ECHA has prioritised formaldehyde, oligomeric reaction products with aniline (technical MDA) for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	formaldehyde, oligomeric reaction products with aniline
EC Number:	500-036-1
CAS Number:	25214-70-4

2) *Intrinsic properties of the substance*

Formaldehyde, oligomeric reaction products with aniline (technical MDA)[9] was identified as a Substance of Very High Concern (SVHC) pursuant to Article 57(a) as it is classified according to Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen 1B, H350 ("May cause cancer"), and was therefore included in the Candidate List for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on technical MDA does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

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7 The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

8 The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

9 "Technical MDA" is used in the remainder of the document when referring to "formaldehyde, oligomeric reaction products with aniline".

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 18 months

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received no comments on including review periods for certain uses in Annex XIV.

ECHA therefore does not recommend to include in Annex XIV review periods for any uses of technical MDA.

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of technical MDA on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received one request for a use-specific exemption of technical MDA based on on-going research into alternatives.

As documented in the *'Response to Comments Document for technical MDA'* (RCOM 2012), the anticipated Latest Application Date and Sunset Date for technical MDA of mid 2015 and beginning of 2017, respectively, should allow enough time for assessing the alternative which the requesting company assumed to be available by end of 2015.

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of technical MDA on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA did not receive requests for exemption of technical MDA from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of technical MDA for PPORD from authorisation.

Annex I.2. – Arsenic acid

Reasons for prioritising arsenic acid

Arsenic acid is supplied to uses in the scope of authorisation in relatively high volumes and presumably at a high number of sites. Potentially significant exposure to workers may occur in parts of the glass industry. [10,11] Furthermore, arsenic acid can be used to replace As_2O_3 in some of its applications. As_2O_3 has already been included in Annex XIV.

Hence, ECHA has prioritised arsenic acid for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	arsenic acid
EC Numbers:	231-901-9
CAS Number:	7778-39-4

2) *Intrinsic properties of the substance*

Arsenic acid was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57(a) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen 1A (H350: "May cause cancer") and was therefore included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on arsenic acid does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

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

- *Latest application date:*

[10] The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

[11] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

Date of inclusion in Annex XIV plus 18 months.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received no comments on including review periods for certain uses in Annex XIV.

ECHA therefore does not recommend to include in Annex XIV review periods for any uses of arsenic acid.

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of arsenic acid on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation ECHA received requests for use-specific exemptions of arsenic acid. These requests refer to uses of the substance as analytical standard for equipment calibration but also to the formulation of test kits or analytical standards with the intention to supply them for SRD purposes. A further exemption request referred to the use of arsenic acid in the production of copper foil based on low volume and limited occupational and environmental exposure.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2012). Further details can be found in the *'Response to Comments Document for Arsenic Acid'* (RCOM 2012).

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of arsenic acid on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA did not receive requests for exemption of arsenic acid from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of arsenic acid for PPORD from authorisation.

Annex I.3. – Bis(2-methoxyethyl) ether (Diglyme)

Reasons for prioritising bis(2-methoxyethyl) ether (Diglyme)

Bis(2-methoxyethyl) ether (Diglyme) is supplied to uses in the scope of authorisation in relatively high volumes. The number of sites is unknown but is assumed to be at least in the medium range. Exposure to workers seems to be controlled in many instances although certain operations bear the potential for significant exposure. [12,13]

Hence, ECHA has prioritised bis(2-methoxyethyl) ether (Diglyme) for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	bis(2-methoxyethyl)ether
EC Number:	203-924-4
CAS Number:	111-96-6

2) *Intrinsic properties of the substance*

Bis(2-methoxyethyl)ether (Diglyme) was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as toxic for reproduction 1B , H360FD ("May damage fertility. May damage the unborn child."), and was therefore included in the Candidate List for authorisation on 19 December 2011 following ECHA's decision ED/77/2011.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on bis(2-methoxyethyl)ether (Diglyme) does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

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[12] The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

[13] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 18 months.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received no comments on including review periods for certain uses in Annex XIV.

ECHA therefore does not recommend to include in Annex XIV review periods for any uses of bis(2-methoxyethyl) ether (Diglyme).

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of bis(2-methoxyethyl) ether (Diglyme) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During public consultation on the draft Recommendation ECHA received a few comments for use-specific exemptions of bis(2-methoxyethyl) ether (Diglyme), relating for example to its use in the production of medical products, or which are based on the argument that the use of the substance is sufficiently regulated by existing EU legislation.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2012). Further details can be found in the *'Response to Comments Document for bis(2-methoxyethyl) ether (Diglyme)'* (RCOM 2012).

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of bis(2-methoxyethyl) ether (Diglyme) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA did not receive requests for exemption of bis(2-methoxyethyl) ether (Diglyme) from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of bis(2-methoxyethyl) ether (Diglyme) for PPORD from authorisation.

Annex I.4. – N,N-Dimethylacetamide (DMAC)

Reasons for prioritising N,N-dimethylacetamide (DMAC)

N,N-Dimethylacetamide (DMAC) is supplied to uses in the scope of authorisation in very high volumes at a high number of sites. Some of the uses have high potential for exposure. [14,15]

Hence, ECHA has prioritised N,N-dimethylacetamide (DMAC) for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	N,N-dimethylacetamide (DMAC)
EC Number:	204-826-4
CAS Number:	127-19-5

2) *Intrinsic properties of the substance*

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

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on N,N-dimethylacetamide (DMAC) does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

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

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[14] The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

[15] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

- *Latest application date*:
  Date of inclusion in Annex XIV plus 21 months.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received comments on setting review periods in accordance with article 58(1)(d) for several uses of N,N-dimethylacetamide (DMAC). The comments received suggested review periods of at least 10 years. The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the *'Response to Comments Document for N,N-dimethylacetamide (DMAC)'* (RCOM 2012).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of N,N-dimethylacetamide (DMAC).

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of N,N-dimethylacetamide (DMAC)on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received a number of comments for use-specific exemptions of N,N-dimethylacetamide (DMAC). Some requests refer to uses that may be covered by existing exemptions from authorisation on the basis of the REACH Regulation. Other requests made reference to Article 58(2) of the REACH Regulation or did not cite a reference as basis.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2012). Further details can be found in the *'Response to Comments Document for N,N-dimethylacetamide (DMAC)'* (RCOM 2012).

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of N,N-dimethylacetamide (DMAC) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA received and assessed requests for exemption of N,N-dimethylacetamide (DMAC) from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. These requests mainly referred to PPORD activities for the production of medicinal products and asked for ≤10 t/a, or ≤100 t/a, respectively, to be exempted.

ECHA considers that in accordance with Article 55 of REACH one of the aims of Authorisation is progressive replacement of SVHCs where this is technically and economically viable. Therefore, PPORD should in principle focus on alternative substances and technologies to replace the SVHC in question. However, ECHA agrees that in cases where no alternatives are available to replace the SVHC, PPORD e.g. with the aim to reduce the use of the substance or of its emissions could be justified. The pertinence of such a PPORD activity with a substance identified as SVHC should however be justified in an authorisation application and be scrutinized and decided in the authorisation granting process in accordance with Article 60.

In conclusion, ECHA could not identify grounds to recommend exempting the use of N,N-dimethylacetamide (DMAC) for PPORD from authorisation.

Annex I.5. – 1,2-Dichloroethane (EDC)

Reasons for prioritising 1,2-dichloroethane (EDC)

1,2-Dichloroethane (EDC) is supplied to uses in the scope of authorisation in high volumes at a medium number of sites. There is potential for significant worker exposure. [16,17]

Hence, ECHA has prioritised 1,2-dichloroethane (EDC) for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	1,2-dichloroethane
EC Number:	203-458-1
CAS Number:	107-06-2

2) *Intrinsic properties of the substance*

1,2-Dichloroethane (EDC) was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57 (a) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen, Carc. 1B (H350: "May cause cancer"), and was therefore included in the Candidate List for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on 1,2-dichloroethane (EDC) does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

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

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[16] The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

[17] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

- *Latest application date*:
  Date of inclusion in Annex XIV plus 21 months.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received no comments on including review periods for certain uses in Annex XIV.

ECHA therefore does not recommend to include in Annex XIV review periods for any uses of 1,2-dichloroethane (EDC).

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of 1,2-dichloroethane (EDC) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received a number of requests for use-specific exemptions of 1,2-dichloroethane (EDC). Most of these requests made reference to Article 58(2) of the REACH Regulation.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2012). Further details can be found in the *'Response to Comments Document for 1,2-dichloroethane*' (RCOM 2012).

In conclusion, ECHA could not identify grounds to recommend exemption of uses of 1,2-dichloroethane (EDC) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA received and assessed requests for exemption of 1,2-dichloroethane (EDC) from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. These requests mainly referred to PPORD activities for the production of medicinal products and asked for ≤10 t/a, or ≤100 t/a, respectively, to be exempted.

ECHA considers that in accordance with Article 55 of REACH one of the aims of Authorisation is progressive replacement of SVHCs where this is technically and economically viable. Therefore, PPORD should in principle focus on alternative substances and technologies to replace the SVHC in question. However, ECHA agrees that in cases where no alternatives are available to replace the SVHC, PPORD e.g. with the aim to reduce the use of the substance or of its emissions could be justified. The pertinence of such a PPORD activity with a substance identified as SVHC should however be justified in an authorisation application and

be scrutinized and decided in the authorisation granting process in accordance with Article 60.

In conclusion, ECHA could not find grounds to recommend exempting the use of 1,2-dichloroethane (EDC) for PPORD from authorisation.

Annex I.6. – 2,2'-Dichloro-4,4'-methylenedianiline (MOCA)

Reasons for prioritising 2,2'-dichloro-4,4'-methylenedianiline (MOCA)

2,2'-Dichloro-4,4'-methylenedianiline (MOCA) is supplied to uses in the scope of authorisation in high volumes at a high number of sites. Significant releases of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) with high potential for worker exposure from a range of processes and applications may take place.[18,19]

Hence, ECHA has prioritised 2,2'-dichloro-4,4'-methylenedianiline (MOCA) for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	2,2'-dichloro-4,4'-methylenedianiline
EC Number:	202-918-9
CAS Number:	101-14-4

2) *Intrinsic properties of the substance*

2,2'-Dichloro-4,4'-methylenedianiline (MOCA) was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57 (a) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen, Carc. 1B (H350: "May cause cancer"), and was therefore included in the Candidate List for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on 2,2'-dichloro-4,4'-methylenedianiline (MOCA) does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

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

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[18] The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

[19] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

- *Latest application date*:
  Date of inclusion in Annex XIV plus 21 months.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received one comment for setting review periods in accordance with article 58(1)(d) for use of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) as curing agent. The comment suggested review periods of 6 and 12 years, respectively, for two different types of polyurethanes. The information available, including the information provided in the comment, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the *'Response to Comments Document for 2,2'-dichloro-4,4'-methylenedianiline (MOCA)'* (RCOM 2012).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of 2,2'-dichloro-4,4'-methylenedianiline (MOCA).

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received a few requests for use-specific exemptions of 2,2'-dichloro-4,4'-methylenedianiline (MOCA). Some requests refer to uses that may be covered by existing exemptions from authorisation on the basis of the REACH Regulation. Other requests made reference to already implemented measures for reducing employee exposure, or did not cite a reference as basis.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2012). Further details can be found in the *'Response to Comments Document for 2,2'-dichloro-4,4'-methylenedianiline (MOCA)'* (RCOM 2012).

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA did not receive requests for exemption of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) from the authorisation requirement for product and

process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) for PPORD from authorisation.

Annex I.7. – Dichromium tris(chromate)

Reasons for prioritising dichromium tris(chromate)

Dichromium tris(chromate) is supplied to uses in the scope of authorisation in relatively low volumes at medium to high number of sites. There is potential for significant worker exposure. [20,21]

In addition, if not included in Annex XIV the substance could potentially be used to replace some of those chromium(VI) substances of the 3rd Recommendation that will be included in Annex XIV in 2013.

Hence, ECHA has prioritised dichromium tris(chromate) for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	dichromium tris(chromate)
EC Number:	246-356-2
CAS Number:	24613-89-6

2) *Intrinsic properties of the substance*

Dichromium tris(chromate) was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57(a) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen 1B (H350: "May cause cancer") and was therefore included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on dichromium tris(chromate) does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recitals (9) and (10) of the Recommendation.
Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

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[20] The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

[21] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

- *Latest application date*:
  Date of inclusion in Annex XIV plus 24 months.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received comments on setting review periods in accordance with article 58(1)(d) for several uses of dichromium tris(chromate). The comments received suggested review periods of 5 to 10 years and 15 years. The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the substance-group specific *"Responses to comments Document for the Chromium(VI) compounds"* (RCOM 2012).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of dichromium tris(chromate).

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of dichromium tris(chromate) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received a number of requests for exemptions of dichromium tris(chromate), either use-specific or requesting to exempt all uses. The requests are, for example, based on arguments such as existing legislation, the strict control measures in place, the special requirements in the aerospace sector and the non-availability of suitable alternatives.

ECHA has assessed all these requests on the basis of the approach set out in the document *''Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2012). Further details can be found in the substance-group specific *"Responses to comments Document for the Chromium(VI) compounds"* (RCOM 2012).

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of dichromium tris(chromate) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA did not receive requests for exemption of dichromium tris(chromate) from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of dichromium tris(chromate) for PPORD from authorisation.

Annex I.8. – Strontium chromate

Reasons for prioritising strontium chromate

Strontium chromate is supplied to uses in the scope of authorisation in high volumes at a high number of sites. There is potential for significant worker exposure. [22,23]

In addition, if not included in Annex XIV the substance could potentially be used to replace other chromium(VI) substances included in this recommendation such as potassium hydroxyoctaoxodizincatedichromate and pentazinc chromate octahydroxide in some of their uses.

Hence, ECHA has prioritised strontium chromate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	strontium chromate
EC Number:	232-142-6
CAS Number:	7789-06-2

2) *Intrinsic properties of the substance*

Strontium chromate was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57(a) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen 1B (H350: "May cause cancer") and was therefore included in the candidate list for authorisation on 20 June 2011, following ECHA's decision ED/31/2011.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on strontium chromate does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

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[22] The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

[23] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

ECHA has determined the application dates as described in Recitals (9) and (10) of the Recommendation.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 24 months.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received comments on setting review periods in accordance with article 58(1)(d) for several uses of strontium chromate. The comments received suggested review periods of 5 to 10 years and 15 years. The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the substance-group specific *"Responses to comments Document for the Chromium(VI) compounds"* (RCOM 2012).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of strontium chromate.

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of strontium chromate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received a number of requests for exemptions of strontium chromate, either use-specific or requesting to exempt all uses. The requests are based on arguments such as existing legislation, the strict control measures in place, the special requirements in the aerospace sector and the non-availability of suitable alternatives.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2012). Further details can be found in the substance-group specific *"Responses to comments Document for the Chromium(VI) compounds"* (RCOM 2012).

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of strontium chromate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA did not receive requests for exemption of strontium chromate from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of strontium chromate for PPORD from authorisation.

Annex I.9. – Potassium hydroxyoctaoxodizincatedichromate

Reasons for prioritising potassium hydroxyoctaoxodizincatedichromate

Potassium hydroxyoctaoxodizincatedichromate is supplied to uses in the scope of authorisation in relatively high volumes at a high number of sites. There is potential for significant worker exposure. [24,25]

In addition, if not included in Annex XIV the substance could potentially be used to replace other chromium(VI) substances included in this recommendation such as strontium chromate and pentazinc chromate octahydroxide in some of their uses.

Hence, ECHA has prioritised potassium hydroxyoctaoxodizincatedichromate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	potassium hydroxyoctaoxodizincatedichromate
EC Number:	234-329-8
CAS Number:	11103-86-9

2) *Intrinsic properties of the substance*

Potassium hydroxyoctaoxodizincatedichromate was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57(a) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen 1A (H350: "May cause cancer") and was therefore included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on potassium hydroxyoctaoxodizincatedichromate does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

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[24] The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

[25] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

ECHA has determined the application dates as described in Recitals (9) and (10) of the Recommendation.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 24 months.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received comments on setting review periods in accordance with article 58(1)(d) for several uses of potassium hydroxyoctaoxodizincatedichromate. The comments received suggested review periods of 5 to 10 years and 15 years. The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the substance-group specific *"Responses to comments Document for the Chromium(VI) compounds"* (RCOM 2012).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of potassium hydroxyoctaoxodizincatedichromate.

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of potassium hydroxyoctaoxodizincatedichromate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received a number of requests for exemptions of potassium hydroxyoctaoxodizincate-dichromate, either use-specific or requesting to exempt all uses. The requests are based on arguments such as existing legislation, the strict control measures in place, the special requirements in the aerospace sector and the non-availability of suitable alternatives.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2012). Further details can be found in the substance-group specific *"Responses to comments Document for the Chromium(VI) compounds"* (RCOM 2012).

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of potassium hydroxyoctaoxodizincatedichromate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA did not receive requests for exemption of potassium hydroxyoctaoxodizincatedichromate from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of potassium hydroxyoctaoxodizincatedichromate for PPORD from authorisation.

Annex I.10. – Pentazinc chromate octahydroxide

Reasons for prioritising pentazinc chromate octahydroxide

Pentazinc chromate octahydroxide is supplied to uses in the scope of authorisation in relatively high volumes at a high number of sites. There is potential for significant worker exposure. [26,27]

In addition, if not included in Annex XIV the substance could potentially be used to replace other chromium(VI) substances included in this recommendation such as strontium chromate and potassium hydroxyoctaoxodizincatedichromate in some of their uses.

Hence, ECHA has prioritised pentazinc chromate octahydroxide for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) *Identity of the substance*

Chemical name:	pentazinc chromate octahydroxide
EC Number:	256-418-0
CAS Number:	49663-84-5

2) *Intrinsic properties of the substance*

Pentazinc chromate octahydroxide was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57(a) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen 1A (H350: "May cause cancer") and was therefore included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

3) *Transitional arrangements*

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on pentazinc chromate octahydroxide does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

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[26] The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

[27] The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/4th-recommendation

ECHA has determined the application dates as described in Recitals (9) and (10) of the Recommendation.

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

- *Latest application date*:
  Date of inclusion in Annex XIV plus 24 months.

- *Sunset date*:
  18 months after the application date.

4) *Review periods for certain uses*

During the public consultation on the draft Recommendation, ECHA received comments on setting review periods in accordance with article 58(1)(d) for several uses of pentazinc chromate octahydroxide. The comments received suggested review periods of 5 to 10 years and 15 years. The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the substance-group specific *"Responses to comments Document for the Chromium(VI) compounds"* (RCOM 2012).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of pentazinc chromate octahydroxide.

5) *Exempted (categories of) uses*

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of pentazinc chromate octahydroxide on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received a number of requests for exemptions of pentazinc chromate octahydroxide, either use-specific or requesting to exempt all uses. The requests are based on arguments such as existing legislation, the strict control measures in place, the special requirements in the aerospace sector and the non-availability of suitable alternatives.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2012). Further details can be found in the substance-group specific *"Responses to comments Document for the Chromium(VI) compounds"* (RCOM 2012).

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of pentazinc chromate octahydroxide on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

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

ECHA did not receive requests for exemption of pentazinc chromate octahydroxide from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of pentazinc chromate octahydroxide for PPORD from authorisation.