

Recommendation of the European Chemicals Agency (ECHA) of 20 December 2011 for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) of Regulation (EC) No 1907/2006

The European Chemicals Agency,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (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 $^{\rm 1}$, (the REACH Regulation), and in particular Article 58 thereof,

Having regard to the Candidate List of Substances of Very High Concern for authorisation as last amended by $ED/95/2010^2$,

Having regard to the opinion of ECHA's Member State Committee of 19 December 2011^3 ,

Whereas:

- (1) This Recommendation aims to assist the Commission in taking its decision pursuant to Article 58(1) of the REACH Regulation to include substances referred to in Article 57 in Annex XIV of the REACH Regulation.
- (2) Pursuant to Article 58(3) of the REACH Regulation, ECHA is required to make at least every second year a Recommendation of priority substances to be included in Annex XIV.
- (3) Pursuant to Article 58(4) of the REACH Regulation ECHA published on its website on 15 June 2011 a draft Recommendation of substances to be included in Annex XIV and invited all interested parties to submit comments by 14 September 2011. ECHA has analysed and prepared responses to comments received and will make these publicly available⁴.

¹ OJ L 396, 30.12.2006, p 1

² http://echa.europa.eu/web/guest/candidate-list-table

http://echa.europa.eu/documents/10162/17087/opinion draft recommendation annex xiv third en.pdf

http://echa.europa.eu/documents/10162/17232/rcom trichloroethylene en.rtf http://echa.europa.eu/documents/10162/17232/rcom cobalt compounds en.pdf http://echa.europa.eu/documents/10162/17232/rcom chromium compounds en.pdf



(4) ECHA has developed a paper presenting ECHA's approach for prioritising, pursuant to Article 58(3) of the REACH Regulation, substances for inclusion in Annex XIV⁵. On the basis of this approach ECHA has prioritised the following thirteen substances from the Candidate List of Substances of Very High Concern for inclusion in Annex XIV⁶:

Group	#	Substance name	EC
	1	Trichloroethylene	201-167-4
Chromium(VI)	2	Chromium trioxide	215-607-8
compounds	3	Acids generated from chromium trioxide and their oligomers	
		Group containing:	
		Chromic acid, Dichromic acid Oligomers of chromic acid and dichromic acid	231-801-5 236-881-5 not yet assigned
	4	Sodium dichromate	234-190-3
	5	Potassium dichromate	231-906-6
	6	Ammonium dichromate	232-143-1
	7	Potassium chromate	232-140-5
	8	Sodium chromate	231-889-5
Cobalt(II) compounds	9	Cobalt(II) sulphate	233-334-2
	10	Cobalt dichloride	231-589-4
	11	Cobalt(II) dinitrate	233-402-1
	12	Cobalt(II) carbonate	208-169-4
	13	Cobalt(II) diacetate	200-755-8

(5) ECHA is required by Article 58(1) of the REACH Regulation to recommend for each priority substance an Annex XIV entry specifying its identity, its intrinsic properties referred to in Article 57, the date by which an application should be received where the applicant wishes to continue to use the substance or place the substance on the market according to Article 58(1)(c)(ii) of the REACH Regulation ("latest application date"), the date according to Article 58(1)(c)(i) of the REACH Regulation from which the placing of the market and use of a substance is prohibited unless an authorisation is granted ("sunset date"), the review periods for certain uses, and uses or categories of uses to be exempted from the authorisation requirement.

http://echa.europa.eu/documents/10162/17232/axiv priority setting gen approach 20100701 en.pdf

http://echa.europa.eu/documents/10162/17232/prioritisation results 3rd rec en.pdf



- (6) ECHA has developed a paper presenting ECHA's approach for determining the Annex XIV entries of prioritised substances⁷. On the basis of this paper ECHA has determined the specific Annex XIV entries for each substance.
- (7) In order to identify the substances pursuant to Article 58(1)(a) of the REACH Regulation ECHA provides the names of the substances, their EC numbers and CAS numbers.
- (8) For the transitional arrangements referred to in Article 58(1)(c) of the REACH Regulation ECHA has applied for each substance a standard time period of 18 months between the suggested application date and the sunset date because neither the available information for the recommended substances nor the comments received during public consultation provide information that would support the recommendation of longer periods.
- (9) The recommended latest application dates are based on the assumption that the substances listed in this Recommendation will be included in Annex XIV in February 2013. The latest application dates have been set having regard to (i) the estimate by the stakeholder expert group that was following the development of the guidance for including substances in Annex XIV regarding the time that normally should be given for preparing authorisation applications (18 months), (ii) factors which indicate that more time than 18 months may be needed to prepare the authorisation applications, such as complexity of the supply-chain, (iii) ECHA's capacity to handle applications in the time provided for and (iv) application dates stipulated for the substances in the Commission Regulation amending Annex XIV of the REACH Regulation for the first time and in the draft Commission Regulation amending Annex XIV for the second time. On this basis the application dates for the recommended substances are spread in three lots over a period of 6 months.
- (10) The information available for the recommended substances, including the comments received during the public consultation (15 June to 14 September 2011), does not provide information that would support the definition of review periods in accordance with article 58(1)(d) for any uses of the substances.
- (11) Article 58(1)(e) in conjunction with Article 58(2) of Regulation (EC) 1907/2006 provides for the possibility of exemptions of uses or categories of uses in cases where there is specific Community legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks.
- (12) ECHA has received during the public consultation of 15 June to 14 September 2011 numerous comments requesting exemptions of many uses. Based on its assessment of these exemption requests⁸, ECHA does not recommend any exemptions from the authorisation requirement on the basis of Article 58(1)(e) in conjunction with Article 58(2) of the REACH Regulation.

http://echa.europa.eu/documents/10162/17232/draft axiv entries gen approach en.pdf

See response to comments (RCOM) documents http://echa.europa.eu/documents/10162/17232/rcom_trichloroethylene_en.rtf http://echa.europa.eu/documents/10162/17232/rcom_cobalt_compounds_en.pdf http://echa.europa.eu/documents/10162/17232/rcom_chromium_compounds_en.pdf



(13) Article 56(3) of the REACH Regulation requires Annex XIV to specify if it applies to product and process orientated research and development. The information available for the recommended substances, including the comments received during public consultation, does not provide grounds to recommend exemptions from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.



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

				Draft Annex	Draft Annex XIV entries				
#	Substance	numper	CAS Number	SVHC-relevant intrinsic properties*	Latest application date	Sunset date	Review	Exempted (categories of) uses	Exemptions for PPORD
- -I	Trichloroethylene	201-167-4	79-01-6	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 18 months 1)	Latest application date plus 18 months	None	None	None
2	Chromium trioxide	215-607-8	1333-82-0	Art. 57 (a) & (b); Carcinogen 1A, Mutagen 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
m	Acids generated from chromium trioxide and their oligomers			Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
***************************************	Group containing: Chromic acid Dichromic acid Oligomers of chromic acid and dichromic	231-801-5 236-881-5 not yet assigned	7738-94-5 13530-68-2 not yet assigned		,				
4	Sodium dichromate	234-190-3	7789-12-0	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
ഹ	Potassium dichromate	231-906-6	7778-50-9	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None



# Substance EC CAS Number SVHC-relevant Latest application Sunset date Periode (categories) Intrinsic Intrinsi					Draft Annex	Draft Annex XIV entries				
Ammonium dichromate 232-143-1 7789-09-5 Art. 57 (a), (b) & Date of inclusion in Platest Carcinogen 1B; Poxic Chromate Annex XIV plus 21 plus 18 months Plus	#	Substance	number	A SANTASARAN SANTARA	SVHC-relevant intrinsic properties*	Latest application date	Sunset date	Review periods	Exempted (categories of) uses	Exemptions for PPORD
cobalt(II) sulphate 232-140-5 7789-00-6 Art. 57 (a) & (b); Annex XIV plus 21 plus 18 months 21 application date months 22 art. 57 (a) (b); Annex XIV plus 21 application date months 21 art. 57 (a) & (c); Annex XIV plus 21 application date months 21 art. 57 (a) & (c); Annex XIV plus 21 application date months 21 art. 57 (a) & (c); Annex XIV plus 22 application date months 21 art. 57 (a) & (c); Annex XIV plus 24 application date months 21 art. 57 (a) & (c); Annex XIV plus 24 application date months 21 art. 57 (a) & (c); Annex XIV plus 24 application date months 21 application date months 21 art. 57 (a) & (c); Annex XIV plus 24 application date months 21 art. 57 (a) & (c); Annex XIV plus 24 application date months 21 art. 57 (a) & (c); Annex XIV plus 24 application date months 21 art. 57 (a) & (c); Annex XIV plus 24 application date months 21 art. 57 (a) & (c); Annex XIV plus 24 application date application date months 21 art. 57 (a) & (c); Annex XIV plus 24 application date application	9	Ammonium dichromate	232-143-1		Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
Sodium chromate 231-889-5 7775-11-3 Art. S7 (a), (b) & Date of inclusion in months 2) Date of inclusion in months 2) Date of inclusion in months 3) Latest puls 18 months application date puls 18 months 2) None Cobalt (II) sulphate 233-334-2 10124-43-3 Art. S7 (a) & (c); Annex XIV plus 24 puls 18 months 3) Annex XIV plus 24 puls 18 puls 18 months 3) Annex XIV plus 24 puls 18 puls 18 months 3) Annex XIV plus 24 puls 18 puls 18 puls 18 puls 18 puls 18 months 3)	7	Potassium chromate	232-140-5	7789-00-6	Art. 57 (a) & (b); Carcinogen 1B, Mutagen 1B	Date of inclusion in Annex XIV plus 21 months 2)	Latest application date plus 18 months	None	None	None
Cobalt(II) sulphate233-334-210124-43-3Art. 57 (a) & (c); Annex XIV plus 24 months application date date dichlorideNoneCobalt dichloride231-589-47646-79-9Art. 57 (a) & (c); Annex XIV plus 24 months application date arbonateNoneCobalt(II) dinitrate233-402-110141-05-6Art. 57 (a) & (c); Annex XIV plus 24 months application date arbonateNone	8	Sodium chromate	231-889-5	7775-11-3	Art. 57 (a), (b) & (c); Carcinogen 1B, Mutagen 1B, Toxic for Reproduction 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
Cobalt dichloride231-589-47646-79-9Art. 57 (a) & (c); Carcinogen 1B; reproduction 1BDate of inclusion in months 3)Latest plus 18 months months 3)NoneCobalt(II) dinitrate233-402-110141-05-6Art. 57 (a) & (c); reproduction 1BDate of inclusion in months 3)Latest plus 18 months months 3)NoneCobalt(II)208-169-4513-79-1Art. 57 (a) & (c); reproduction 1BDate of inclusion in months 3)Latest plus 18 months plus 24NoneCarcinogen 1B; months plus 18 months monthsLatest plus 18 months plus 18 monthsNone	6	Cobalt(II) sulphate	233-334-2	10124-43-3	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months ³⁾	Latest application date plus 18 months	None	None	None
Cobalt(II) dinitrate233-402-110141-05-6Art. 57 (a) & (c);Date of inclusion in months 30Latest Annex XIV plus 24 plus 18 months 30 plus 18 months 30NoneCobalt(II)208-169-4513-79-1Art. 57 (a) & (c);Date of inclusion in months 30 plus 18 monthsNone	10	Cobalt dichloride	231-589-4	7646-79-9	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months ³⁾	Latest application date plus 18 months	None	None	None
Cobalt(II)208-169-4513-79-1Art. 57 (a) & (c);Date of inclusion in carbonateLatest Annex XIV plus 24 months 30 plus 18 monthsNone application date application date months		Cobalt(II) dinitrate	233-402-1	10141-05-6	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months ³⁾	Latest application date plus 18 months	None	None	None
	12	Cobalt(II) carbonate	208-169-4	513-79-1	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	Date of inclusion in Annex XIV plus 24 months ³⁾	Latest application date plus 18 months	None	None	None



				Draft Annex	Draft Annex XIV entries				
#	# Substance	EC	CAS Number	elevant	Latest application Sunset date	Sunset date	Review	Exempted	Exempted Exemptions
		number		intrinsic properties#	date		periods	(categories for PPORD of) uses	for PPORD
13	13 Cobalt(II) diacetate 200-755-8 71-48-7	200-755-8	71-48-7	Art. 57 (a) & (c);	Date of inclusion in	Latest	None	None	None
	•			Carcinogen 1B; Toxic for	Annex XIV plus 24 months ³⁾	application date plus 18 months			
				reproduction 1B					

- 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. #
- Assuming the Commission Regulation including the substances of this third Recommendation in Annex XIV would enter into force in February 2013, the latest application date would be August 2014 7
- Assuming the Commission Regulation including the substances of this third Recommendation in Annex XIV would enter into force in February 2013, the latest application date would be November 2014 7
- Assuming the Commission Regulation including the substances of this third Recommendation in Annex XIV would enter into force in February 2013, the latest application date would be February 2015 3

Done at Helsinki, 20 December 2011

For the European Chemicals Agency,



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 thirteen substances for inclusion in Annex XIV and the determination of their draft Annex XIV entries.

- 1. Trichloroethylene
- 2. Chromium trioxide
- 3. Acids generated from chromium trioxide and their oligomers (group containing: chromic acid, dichromic acid, oligomers of chromic acid and dichromic acid)
- 4. Sodium dichromate
- 5. Potassium dichromate
- 6. Ammonium dichromate
- 7. Potassium chromate
- 8. Sodium chromate
- 9. Cobalt(II) sulphate
- 10. Cobalt dichloride
- 11. Cobalt(II) dinitrate
- 12. Cobalt(II) carbonate
- 13. Cobalt(II) diacetate

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 (dated 28 May 2010)¹
- Results of the prioritisation of the SVHCs on the Candidate List with the objective to recommend priority substances for inclusion in Annex XIV (dated 15 June 2011)²
- Preparation of draft Annex XIV entries for the third Recommendation of substances to be included in Annex XIV – General approach (dated 15 June 2011)³

http://echa.europa.eu/documents/10162/17232/axiv priority setting gen approach 20100701 en.pdf

http://echa.europa.eu/documents/10162/17232/prioritisation results 3rd rec en.pdf

http://echa.europa.eu/documents/10162/17232/draft axiv entries gen approach en.pdf



- Substance-specific background documents (dated 20 December 2011)⁴
- Substance specific (trichloroetylene) or substance group specific (chromium(VI) compounds and cobalt(II) compounds) "Responses to comments" (RCOM) documents (dated 20 December 2011)⁵
- Opinion of the Member State Committee of 19 December 2011⁶

Prioritisation of cobalt(II) substances

The majority of the members of the Member State Committee (MSC) support the position of ECHA to include all 13 recommended substances in Annex XIV. They agree that these substances should be prioritised in accordance with Art. 58(3) following application of ECHA's General approach for prioritisation of substances of very high concern (SVHCs) for inclusion in the list of substances subject to authorisation.

Regarding the prioritisation of the five cobalt(II) substances – cobalt(II) sulphate, cobalt dichloride, cobalt(II) dinitrate, cobalt(II) carbonate and cobalt(II) diacetate – some MSC members disagree with the prioritisation of the entire group of cobalt(II) salts whereas some other MSC members only disagree with the prioritisation of cobalt(II) diacetate.

Reasons for these disagreements with ECHA's prioritisation are provided in the minority positions (Annexes IA and IB to the MSC-opinion). In these minority positions it is stated that ECHA does not seem to have applied the agreed prioritisation methodology correctly, and in particular, that volumes within the scope of authorisation are lower and that the uses are not as wide dispersive than assumed by ECHA in its prioritisation. It is put forward that the different cobalt salts are not interchangeable in all their applications. Furthermore, one of the minority views claims that information provided by industry appears to not have been fully accounted for and potentially not assessed properly.

Similar comments were brought forward by some cobalt industry associations during or after public consultation. The comments in the minority positions do not appear to include further information or assessment of the information provided earlier by industry.

In this context, it is emphasised that the intial prioritisation of the cobalt(II) substances was nearly exclusively based on information provided by industry. Information from the registration dossiers including the chemical safety reports (CSRs) has been considered in addition to comments submitted by industry during discussion of the prioritisation by the MSC in April/May 2011. Information

^{4 &}lt;a href="http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/3rd-recommendation
1 http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/3rd-recommendation

http://echa.europa.eu/documents/10162/17232/rcom trichloroethylene en.rtf http://echa.europa.eu/documents/10162/17232/rcom cobalt compounds en.pdf http://echa.europa.eu/documents/10162/17232/rcom chromium compounds en.pdf

http://echa.europa.eu/documents/10162/17087/opinion_draft_recommendation_annex_xiv_third_en.pdf



provided by industry has as well been the basis for the reassessment of the prioritisation after public consultation. For this reassessment the comments submitted during public consultation on the $3^{\rm rd}$ Recommendation (plus several summaries 7 of these comments submitted by industry after closure of the consultation) and updates of the registrations / CSRs have been taken into account.

In particular it is noted that all these cobalt(II) substances are registered for uses (e.g. surface treatment) which, according to the use descriptions and exposure scenarios provided in the registrations, include process steps with potential for exposure of workers through the respiratory route and which are carried out, according to information provided by industry for the different cobalt(II) substances, at tens to potentially thousands of sites in the EU. The tonnages allocated annually to surface treatment are, depending on the substance, in the tens to the (low) hundreds⁸.

ECHA carefully (re-)assessed all these comments against the prioritisation criteria of the agreed prioritisation approach and provided extensive responses as to how the new information provided by industry has been used to adapt the priority scoring for Co-diacetate, Co-dinitrate and Co-carbonate. However, these adaptations do not significantly change the overall priority of the group of cobalt compounds for inclusion in Annex XIV.

In one of the minority positions it is suggested to further assess the information provided during the consultation period. As explained above, all information provided on the cobalt(II) substances has been assessed and taken into account by ECHA for the present Recommendation. Based on this information it can be concluded with a sufficient degree of certainty that there is potential for worker exposure, especially as some of these uses take place on many sites. As substances are included in Annex XIV and not individual uses of these substances, more information and elaboration on differences in the likelihood of releases or exposures between the uses of a substance or between individual companies would not help to determine whether a substance should be included in Annex XIV. It should be further noted that a more in-depth assessment of potential risks associated with the uses of a substance would result in carrying out risk assessment at the prioritisation step, which would not be in line with the agreed approach nor with the role that the legal text foresees for this prioritisation step in the authorisation procedure. Carrying out risk assessments and demonstrating control of risks for uses applied for is part of the obligations of future applicants that may apply for authorisation.

A further issue raised is the alleged unclarity on the interchangeability of the cobalt(II) substances and thus whether grouping of these substances is justified in order to prevent potential replacement of those cobalt substances included in Annex XIV by others with the same hazard potential but not subject to the authorisation requirement. ECHA agrees that any of the grouped cobalt(II) substances may in some of its uses hardly be replaceable by another substance of the group. However, considering the chemistry of these compounds and general knowledge on the chemical processes taking place, it appears to be very

These documents repeat part of the information provided and also provide some new and partly conflicting pieces of information.

⁸ For cobalt(II) carbonate: < 10 t/y.

See Section B (Comments on ECHA's Prioritisation Approach, application of Prioritisation Criteria and assigned Scores) of the Responses to Comments Document (RCOM) on ECHA's Draft 3rd Recommendation for the Group of recommended cobalt(II) substances.

http://echa.europa.eu/documents/10162/17232/rcom cobalt compounds en.pdf



improbable that it would be technically not possible to replace any of these cobalt(II) substances in at least some of their uses by another substance of the cobalt group. A careful and consistent approach is therefore necessary to prevent unjustified differences in regulating the substances, in particular, bearing in mind that the aims of authorisation are to ensure proper control of risks of substances of very high concern and their progressive substitution with suitable alternatives where they are economically and technically viable while ensuring good functioning of the internal market. If a technical possibility of replacement cannot be excluded grouping should be applied.

Therefore, ECHA agrees with the opinion of the MSC and recommends the inclusion of all thirteen substances for inclusion in Annex XIV.

Transitional arrangements

With respect to the recommended latest application dates for each substance, ECHA has worked on the assumption that the substances of the second Recommendation will be included in Annex XIV by a Commission Regulation amending Annex XIV for the second time in February 2012 and that the substances in the present 3rd Recommendation will be included in Annex XIV in February 2013.

In its 3rd recommendation ECHA uses a latest application date (LAD) of 18 months from the inclusion of substances in Annex XIV as the starting point. This time has been estimated by the stakeholder expert group that was following the development of the guidance for including substances in Annex XIV ¹⁰ for preparing in standard cases an authorisation application of sufficient quality¹¹. In addition, the latest application dates for the groups of substances (trichloroethlylene, chromium(VI) substances and cobalt(II) substances) have been spread over a period of 6 months to distribute more evenly the workload of ECHA (RAC, SEAC and secretariat), and eventually the Commission, with the expected incoming applications for authorisation.

Although the information provided in the comments is not sufficient to allow proper assessment of the time needed for preparing an adequate application for authorisation, and thereby setting LADs ¹², several factors put forward in the comments, when evaluated in their entirety, appear to indicate that:

- The structure of the supply chain for trichloroethylene is less complicated than for the chromium(VI) and cobalt(II) substances. Therefore, the

¹⁰ The guidance has been replaced by the documents describing the general approaches and the working procedures of the MSC.

The time needed for preparing the application was estimated to be 12 months and another 6 months were foreseen to be needed for consulting the required expertise.

Aspects which could be considered when assessing whether the development of an authorisation application would appear to require more time than the standard 18 months include e.g. structure and complexity of supply chains, production cycles, number and size of manufactures / importers, pro-activeness of main manufacturer / importer, number of SMEs involved, whether a SEA may be required. See further details and considerations on this issue in the introduction to sections C "Comments on Latest Application Dates, Sunset Dates and Review Periods" in the Responses to Comments Documents (RCOM) on ECHA's Draft 3rd Recommendation for the Group of recommended chromium(VI) or cobalt(II) compounds or in Annex II of the Responses to Comments Document for trichloroethylene.



standard period of 18 months is suggested for the latest application date of trichloroethylene.

- Slightly longer LADs than the standard 18 months would be justified for the chromium(VI) and cobalt(II) substances.

It was on this basis that ECHA decided to change in its recommendation the LAD for chromium(VI) substances from 18 months (as initially proposed in the draft recommendation issued for public consultation) to 21 months and the LAD for trichloroethylene from 21 months to 18 months. Furthermore, considering that the LADs for the chromium(VI) and cobalt(II) substances groups should not be set on the same date considering the capacity of ECHA (secretariat, RAC and SEAC) to handle incoming applications for authorisation in the time provided for, it was suggested to set the LAD for the group of cobalt(II) substances to 24 months.

In its opinion of 19 December 2011 the Member State Committee notes that it has previously agreed that, in general, the application dates should be established as close as possible to the date of the entry into force (EiF) of the updated Annex XIV and that the LADs should normally not be set more than 12 to 18 months after EiF. MSC noted that, if justified in individual cases, longer application periods may however be acceptable.

The Member State Committee further agreed to the latest application dates and sunset dates for trichloroethylene now set out in the present recommendation. Those members that agreed to the prioritisation of the cobalt salts also agree to ECHA's proposal as given in the present recommendation. However, the majority of members do not believe that the extended application dates suggested for the chromium(VI) substances are sufficient to address the arguments brought forward by several commenters in the public consultation. According to some MSC members a longer period of time than suggested by ECHA – e.g. an application date of 48 months after entry into force of an updated Annex XIV might be more appropriate.

ECHA has carefully assessed the arguments brought forward in the public consultation 13 which could be relevant for considering longer than standard latest application dates due to longer time needed to prepare authorisation applications, including e.g., the complexity of supply chains, number and size of suppliers, the time required to accomplish analyses of alternatives and/or socio economic In addition several industry representatives submitted comments requesting later LADs to ensure that the transfer to alternatives can be finalised before the latest application date and by that there would be no need to apply for authorisation. ECHA does not consider these arguments relevant for setting LADs but finds that these aspects should be taken into account in the next phase of the process. In other words the time needed to develop alternatives and to take the necessary measures to transfer to them should be documented in the authorisation applications and taken into account in the opinion forming and final authorisation decision. Comments received during the public consultation seem to indicate that the supply chains and uses of the chromium(VI) substances, including uses further down the supply chains which do not themselves require authorisation but for which information is needed for the socio-economic

See Section C (Comments on Latest Application Dates, Sunset Dates and Review Periods) in the Responses to Comments Document (RCOM) on ECHA's Draft 3rd Recommendation for the Group of recommended chromium(VI) Substances. http://echa.europa.eu/documents/10162/17232/rcom chromium compounds en.pdf



assessment, are comparable to the complexity of the supply chains and uses of the cobalt(II) substances. However, suppliers of the chromium(VI) substances could potentially be less organised. On the other hand information on research and availability of alternatives for the chromium(VI) substances seems to be available for most uses and of higher quality than for the cobalt(II) substances. Hence, this should facilitate the preparation of authorisation applications for the chromium(VI) substances by the latest application date of 21 months proposed by ECHA.



Annex I.1. - Trichloroethylene

Reasons for prioritising trichloroethylene

To determine whether trichloroethylene should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that the volumes of trichloroethylene allocated to uses in the scope of authorisation are very high and at least some of the described uses bear potential for significant exposure of industrial workers and professionals and can be considered wide dispersive.

Hence, ECHA has prioritised trichloroethylene for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

Trichloroethylene

EC Number:

201-167-4

CAS Number:

79-01-6

2) Intrinsic properties of the substance

Trichloroethylene 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 18 June 2010, following ECHA's decision ED/30/2010.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on trichloroethylene does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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

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 comments on setting review periods in accordance with article 58(1)(d) for several uses of trichloroethylene. Some comments received agreed with ECHA's approach not to set upfront review periods whereas others suggested that such upfront review periods could take into account the long product life cycles (up to 40 years) and security of investments for SMEs. However no specific proposal for an upfront review periods was made. 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.

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

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of trichloroethylene 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 numerous requests for use-specific exemptions of trichloroethylene. Some requests refer to uses of the substance as analytical agent or standard under conditions that may be covered by the exemption of scientific research and development from authorisation pursuant to Article 56(3) 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in Annex I to the 'Response to Comments Document for Trichlorethylene' (RCOM 2011). In this RCOM document also ECHA's responses to the requests are documented.

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

However, one request for exemption of trichloroethylene for industrial use for surface cleaning in closed systems brought forward by the European manufacturers and importers of trichloroethylene¹⁴, makes a reference to ongoing activities potentially resulting in inclusion of a binding Occupational Exposure Limit (bOEL) for trichloroethylene in Directive 2004/37/EC (Carcinogens and

See comment 1221 and ECHA's response in Section i of the RCOM for trichloroethylene http://echa.europa.eu/documents/10162/17232/rcom_trichloroethylene_en.rtf



mutagens at work). If a bOEL for workers would be included in this Directive, the conclusion that existing EU legislation aimed at protection of workers against risks to their health (including Directives 98/24/EC and 2004/37/EC) currently does not impose binding minimum requirements for controlling risks to workers health during the use phase or throughout the life cycle of trichloroethylene may need to be revisited.

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA did not receive requests for exemption of trichloroethylene 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 trichloroethylene for PPORD from authorisation.



Annex I.2. - Chromium trioxide

Reasons for prioritising chromium trioxide

To determine whether chromium trioxide should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that chromium trioxide is supplied to uses in the scope of authorisation in high volumes and at a high number of sites. Significant exposure to workers may occur in a number of uses with releases to the workplace. Some uses could therefore be considered as wide-dispersive.

Hence, ECHA has prioritised chromium trioxide for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

Chromium trioxide

EC Numbers:

215-607-8

CAS Number:

1333-82-0

2) Intrinsic properties of the substance

Chromium trioxide was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (b) 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 category 1A (H350: "May cause cancer") and mutagen category 1B (H340: "May cause genetic defects") and was therefore included in the candidate list for authorisation on 15 December 2010, following ECHA's decision ED/95/2010.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on chromium trioxide does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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

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 chromium trioxide. Some comments received agreed with ECHA's approach not to set upfront review periods whereas others suggested review periods of at least 5 years or much longer periods (e.g. at least 10 to 15 years or no clear timeframe). 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.

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

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of chromium trioxide 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 very many requests for use-specific exemptions of chromium trioxide. Some requests refer to uses of the substance as analytical agent or standard under conditions that may be covered by the exemption of scientific research and development from authorisation pursuant to Article 56(3) 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of chromium(VI) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA received two requests for exemption from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. The first one was a general request stating that in general all PPORD activities should be exempted based on the need to develop alternatives and referred to the low exposure of workers dealing with PPORD. 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 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.

The other request concerned the use of chromium trioxide in failure analysis of new semi-conductor manufacturing processes and products. Based on the information submitted, it was however concluded that this might under certain conditions fulfil the definition of scientific research and development (SRD) in Article 3(23), in which case it would be exempted from authorisation in accordance with Article 56(3).

Therefore, ECHA does not recommend exempting the use of chromium trioxide for PPORD from authorisation.



Annex I.3. – Acids generated from chromium trioxide and their oligomers

Reasons for prioritising Acids generated from chromium trioxide and their oligomers

To determine whether Acids generated from chromium trioxide and their oligomers should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). Chromic acid, dichromic acid and oligomers of chromic and dichromic acid are spontaneously generated products of the reaction of chromium trioxide with water. They are carcinogenic and identified as SVHC. Acids generated from chromium trioxide and their oligomers can be used to replace chromium trioxide in many of its uses and potentially as well other chromium(VI) substances. If not included in Annex XIV the substance could potentially be used to replace those chromium(VI) substances that will be included in Annex XIV.

Hence, ECHA has prioritised Acids generated from chromium trioxide and their oligomers for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

•

Acids generated from chromium trioxide and their oligomers

Names of the acids and their oligomers

Chromic acid

Chemical name:

EC Numbers: 231-801-5

CAS Number: 7738-94-5

IUPAC Name: Dihydroxy(dioxo)chromium

Dichromic acid

EC Numbers: 236-881-5

CAS Number: 13530-68-2

IUPAC Name: hydroxy-(hydroxy(dioxo)chromio)oxy-

dioxochromium

Oligomers of chromic acid and dichromic acid

EC Numbers: not yet assigned CAS Number: not yet assigned

2) Intrinsic properties of the substance

Acids generated from chromium trioxide and their oligomers was identified as a Substance of Very High Concern (SVHC) according 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 a carcinogen category 1B (H350i: "May cause cancer by inhalation")



and was therefore included in the candidate list for authorisation on 15 December 2010, following ECHA's decision ED/95/2010.

3) <u>Transitional arrangements</u>

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Acids generated from chromium trioxide and their oligomers does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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

- 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 Acids generated from chromium trioxide and their oligomers. Some comments received agreed with ECHA's approach not to set upfront review periods whereas others suggested review periods of at least 5 years or even much longer periods (e.g. at least 10 to 15 years or no clear timeframe). 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.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of Acids generated from chromium trioxide and their oligomers.

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of Acids generated from chromium trioxide and their oligomers 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 many requests for use-specific exemptions of Acids generated from chromium trioxide and oligomers. Some requests refer to uses of the substance as analytical agent or standard under conditions that may be covered by the exemption of scientific research and development from authorisation pursuant to Article 56(3)



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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of chromium(VI) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of Acids generated from chromium trioxide and their oligomers on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA received one request for exemption from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. This was the same general request as received for chromium trioxide stating that in general all PPORD activities should be exempted based on the need to develop alternatives and because of the low exposure of workers dealing with PPORD.

For the same reasons as provide in section 6) of Annex I.2. - Chromium trioxide, ECHA does not recommend exempting the use of Acids generated from chromium trioxide and their oligomers for PPORD from authorisation.



Annex I.4. - Sodium dichromate

Reasons for prioritising Sodium dichromate

To determine whether Sodium dichromate should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that Sodium dichromate is supplied to uses in the scope of authorisation in high volumes and at a high number of sites. Although releases and exposure to workers might be controlled in most instances, some uses appear to have a potential for significant worker exposure.

Hence, ECHA has prioritised Sodium dichromate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

sodium dichromate

EC Number:

234-190-3

CAS Number:

10588-01-9 (anhydrous) and 7789-12-0

(dihydrate)

2) Intrinsic properties of the substance

Sodium dichromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a), (b) and (c) 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 category 1B (H350: "May cause cancer"), as mutagen category 1B (H340: "May cause genetic defects") and as toxic for reproduction category 1B (H360-FD: "May damage fertility. May damage the unborn child") and was therefore included in the candidate list for authorisation on 28 October 2008, following ECHA's decision ED/67/2008.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Sodium dichromate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.



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

- 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 for setting review periods in accordance with article 58(1)(d) for several uses of Sodium dichromate. These ranged from proposing to have none to suggesting review periods of 5 to 10 years. The information provided was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

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

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of Sodium dichromate 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 many requests for use-specific exemptions of Sodium dichromate. Some requests refer to uses of the substance as analytical agent or standard under conditions that may be covered by the exemption of scientific research and development from authorisation pursuant to Article 56(3) 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of chromium(VI) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA did not receive requests for exemption of Sodium dichromate 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 Sodium dichromate for PPORD from authorisation.



Annex I.5. - Potassium dichromate

Reasons for prioritising Potassium dichromate

To determine whether Potassium dichromate should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that Potassium dichromate is supplied to uses in the scope of authorisation in low volumes and at a medium number of sites. Although releases and exposure to workers might be controlled in most instances, some uses have potential for significant worker exposure. In addition, the substance could be used to replace other hexavalent chromium compounds.

Hence, ECHA has prioritised Potassium dichromate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

potassium dichromate

EC Number:

231-906-6

CAS Number:

7778-50-9

2) Intrinsic properties of the substance

Potassium dichromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a), (b) and (c) 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 a carcinogen category 1B (H350: "May cause cancer"), as mutagen category 1B (H340: "May cause genetic defects") and as toxic for reproduction category 1B (H360-FD: "May damage fertility. May damage the unborn child"), and was therefore included in the candidate list for authorisation on 18 June 2010, following ECHA's decision ED/30/2010.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Potassium dichromate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.



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

- 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 for setting review periods in accordance with article 58(1)(d) for several uses of Potassium dichromate. These ranged from proposing to have none to suggesting review periods of 2 to 10 years. The information provided was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

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

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of Potassium dichromate 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 Potassium dichromate. Some requests refer to uses of the substance as analytical agent or standard under conditions that may be covered by the exemption of scientific research and development from authorisation pursuant to Article 56(3) 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of chromium(VI) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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



6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA did not receive requests for exemption of Potassium dichromate 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 dichromate for PPORD from authorisation.



Annex I.6. - Ammonium dichromate

Reasons for prioritising Ammonium dichromate

To determine whether Ammonium dichromate should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that Ammonium dichromate has currently no uses of significance in the scope of authorisation. However, the substance could be used to replace other hexavalent chromium compounds.

Hence, ECHA has prioritised Ammonium dichromate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

ammonium dichromate

EC Number:

232-143-1

CAS Number:

7789-09-5

2) Intrinsic properties of the substance

Ammonium dichromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a), (b) and (c) 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 a carcinogen category 1B (H350: "May cause cancer"), as mutagen category 1B (H340: "May cause genetic defects") and as toxic for reproduction category 1B (H360-FD: "May damage fertility. May damage the unborn child"), and was therefore included in the candidate list for authorisation on 18 June 2010, following ECHA's decision ED/30/2010.

3) <u>Transitional arrangements</u>

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Ammonium dichromate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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



- 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 some few comments for setting review periods in accordance with article 58(1)(d) for Ammonium dichromate. The review periods suggested range from 5 to 7 years. The information provided was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

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

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of Ammonium dichromate 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 comments for use-specific exemptions of Ammonium dichromate. These requests refer to uses of the substance as analytical agent or in scientific research and development under conditions that may be covered by the exemption of scientific research and development from authorisation pursuant to Article 56(3) of the REACH Regulation.

ECHA has assessed these requests on the basis of the approach set out in the document 'Preparation of draft Annex XIV entries for the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of chromium(VI) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA did not receive requests for exemption of Ammonium dichromate 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 Ammonium dichromate for PPORD from authorisation.



Annex I.7. - Potassium chromate

Reasons for prioritising Potassium chromate

To determine whether Potassium chromate should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that Potassium chromate is supplied to uses in the scope of authorisation in low volumes. There is no detailed information on the uses but it seems that they mostly are carried in closed processes but with potential for significant worker exposure at least in some processes. In addition, the substance could be used to replace other hexavalent chromium compounds.

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

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

Potassium chromate

EC Number:

232-140-5

CAS Number:

7789-00-6

2) Intrinsic properties of the substance

Potassium chromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (b) 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 category 1B (H350i: "May cause cancer by inhalation") and mutagen category 1B (H340: "May cause genetic defects") and was therefore included in the candidate list for authorisation on 18 June 2010, following ECHA's decision ED/30/2010.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Potassium chromate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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



- 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 requesting a review period of 10 years for Potassium chromate. The information available, including the information provided in the consultation, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

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

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of Potassium chromate 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 few comments for use-specific exemptions of Potassium chromate. Some requests refer to uses of the substance as analytical agent or standard under conditions that may be covered by the exemption of scientific research and development from authorisation pursuant to Article 56(3) of the REACH Regulation. Other requests seem to refer to Article 58(2) of the REACH Regulation but 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of chromium(VI) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA did not receive requests for exemption of Potassium 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 Potassium chromate for PPORD from authorisation.



Annex I.8. - Sodium chromate

Reasons for prioritising Sodium chromate

To determine whether Sodium chromate should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that Sodium chromate is supplied to uses in the scope of authorisation in low volumes at a presumably low number of sites. There is no detailed information on the uses but it seems that they mostly are carried in closed processes. Potential for significant worker exposure at least in some processes cannot be excluded. The substance could be used to replace other hexavalent chromium compounds.

Hence, ECHA has prioritised Ammonium dichromate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

Sodium chromate

EC Number:

231-889-5

CAS Number:

7775-11-3

2) Intrinsic properties of the substance

Sodium chromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a), (b) and (c) 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 category 1B (H350: "May cause cancer"), as mutagen category 1B (H340: "May cause genetic defects") and toxic for reproduction category 1B (H360-FD: "May damage fertility. May damage the unborn child") and was therefore included in the candidate list for authorisation on 18 June 2010, following ECHA's decision ED/30/2010.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on Sodium chromate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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



- 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 proposals for review period between 2 and 4 years for Sodium chromate without further justification. The information available, including the information provided in these proposals, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

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

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of Sodium 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 few comments for use-specific exemptions of Sodium chromate. One request referred to uses of the substance as analytical agent that may be covered by the exemption of scientific research and development from authorisation pursuant to Article 56(3) 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of chromium(VI) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA did not receive requests for exemption of Sodium 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 Sodium chromate for PPORD from authorisation.



Annex I.9. - Cobalt(II) sulphate

Reasons for prioritising cobalt(II) sulphate

To determine whether cobalt(II) sulphate should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that cobalt(II) sulphate is supplied to uses in the scope of authorisation in relatively high volumes and at a high number of sites. Although releases and exposure to workers might be controlled in most instances, some uses have potential for significant worker exposure. Furthermore, the substance could be used to replace other cobalt(II) compounds in some of their uses.

Hence, ECHA has prioritised cobalt(II) sulphate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

cobalt(II) sulphate

EC Number:

233-334-2

CAS Number:

10124-43-3

2) Intrinsic properties of the substance

Cobalt(II) sulphate was identified as a Substance of Very High Concern (SVHC) according to Articles 57(a) and (c) as it is classified according to Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as a carcinogen category 1B, H350i (may cause cancer by inhalation), and as toxic for reproduction category 1B, H360F (may damage fertility), and was therefore included in the candidate list for authorisation on 15 December 2010, following ECHA's decision ED/95/2010.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on cobalt(II) sulphate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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



- 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 for setting review periods in accordance with article 58(1)(d) for some uses of cobalt(II) sulphate. Most comments received agreed with ECHA's approach not to set upfront review periods whereas some comments suggested review periods of 5 to 7 years or did not propose a concrete timeframe. The information available, including the information provided in these proposals, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of cobalt(II) sulphate.

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of cobalt(II) sulphate 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 many requests for use-specific exemptions of cobalt(II) sulphate. 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of cobalt(II) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA received one request for exemption from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. The was a general request stating that in general all PPORD activities should be exempted based on the need to develop alternatives and because of the low exposure of workers dealing with PPORD.



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 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.

Therefore, ECHA does not recommend exempting the use of cobalt(II) sulphate for PPORD from authorisation.



Annex I.10. - Cobalt dichloride

Reasons for prioritising cobalt dichloride

To determine whether cobalt dichloride should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that cobalt dichloride is supplied to uses in the scope of authorisation in relatively low volumes and at a medium number of sites, which though might be higher. Although releases and exposure to workers might be controlled in most instances, some uses have potential for significant worker exposure. Furthermore, the substance could be used to replace other cobalt(II) compounds in some of their uses.

Hence, ECHA has prioritised cobalt dichloride for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

cobalt dichloride

EC Number:

231-589-4

CAS Number:

7646-79-9

2) Intrinsic properties of the substance

Cobalt dichloride was identified as a Substance of Very High Concern (SVHC) according to Articles 57(a) as it is classified according to Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as a carcinogen category 1B, H350i (may cause cancer by inhalation), and was therefore included in the candidate list for authorisation on 28 October 2008, following ECHA's decision ED/67/2008. Pursuant to Commission Regulation (EC) No 790/2009 of 10 August 2009, cobalt dichloride is as of 1 December 2010 also classified in Annex VI, part 3, Table 3.1 as toxic for reproduction, Repr. 1B (H360F***: May damage fertility). An Annex XV dossier proposing the update of the entry of cobalt dichloride in the candidate list with its amended classification was prepared by ECHA upon request by the European Commission and submitted to the SVHC identification process in accordance with Art. 59 of the REACH Regulation. The entry for cobalt dichloride in the Candidate List has been updated accordingly in June 2011.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on cobalt dichloride does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.



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

- 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 for setting review periods in accordance with article 58(1)(d) for some uses of cobalt dichloride. Most comments received agreed with ECHA's approach not to set upfront review periods whereas some comments suggested review periods or did not propose a concrete timeframe. The information available, including the information provided in these proposals, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

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

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of cobalt dichloride 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 many requests for use-specific exemptions of cobalt dichloride. 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of cobalt(II) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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



6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA received one request for exemption from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. This was the same general request as received for cobalt(II) sulphate stating that in general all PPORD activities should be exempted based of the need to develop alternatives and referred to the low exposure of workers dealing with PPORD.

For the same reasons as provided in section 6) of Annex I.9. – Cobalt(II) sulphate, ECHA does not recommend exempting the use of cobalt dichloride for PPORD from authorisation.



Annex I.11. - Cobalt(II) dinitrate

Reasons for prioritising cobalt(II) dinitrate

To determine whether cobalt(II) dinitrate should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that cobalt dichloride is supplied to uses in the scope of authorisation in relatively high volumes and at a medium number of sites, which though might be higher. Although releases and exposure to workers might be controlled in most instances, some uses have potential for significant worker exposure. Furthermore, the substance could be used to replace other cobalt(II) compounds in some of their uses.

Hence, ECHA has prioritised cobalt(II) dinitrate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

cobalt(II) dinitrate

EC Number:

233-402-1

CAS Number:

10141-05-6

2) Intrinsic properties of the substance

Cobalt(II) dinitrate was identified as a Substance of Very High Concern (SVHC) according to Articles 57(a) and (c) as it is classified according to Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as a carcinogen category 1B, H350i (may cause cancer by inhalation), and as toxic for reproduction category 1B, H360F (may damage fertility), and was therefore included in the candidate list for authorisation on 15 December 2010, following ECHA's decision ED/95/2010.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on C(II) dinitrate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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



- 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 for setting review periods in accordance with article 58(1)(d) for some uses of cobalt(II) dinitrate. Most comments received agreed with ECHA's approach not to set upfront review periods whereas some comments did not propose a concrete timeframe. The information available, including the information provided in these proposals, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of cobalt(II) dinitrate.

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of cobalt(II) dinitrate 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 many requests for use-specific exemptions of cobalt(II) dinitrate. 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of cobalt(II) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA received one request for exemption from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. This was the same general request as received for cobalt(II) sulphate stating that in general all PPORD activities should be



exempted based of the need to develop alternatives and referred to the low exposure of workers dealing with PPORD.

For the same reasons as provided in section 6) of Annex I.9. – Cobalt(II) sulphate, ECHA does not recommend exempting the use of cobalt(II) dinitrate for PPORD from authorisation.



Annex I.12. - Cobalt(II) carbonate

Reasons for prioritising cobalt(II) carbonate

To determine whether cobalt(II) carbonate should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that cobalt(II) carbonate is supplied to uses in the scope of authorisation in low volumes and at a medium number of sites. Although releases and exposure to workers might be controlled in most instances, some uses have potential for significant worker exposure. Furthermore, the substance could be used to replace other cobalt(II) compounds in some of their uses.

Hence, ECHA has prioritised cobalt(II) carbonate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

cobalt(II) carbonate

EC Number:

208-169-4

CAS Number:

513-79-1

2) Intrinsic properties of the substance

Cobalt(II) carbonate was identified as a Substance of Very High Concern (SVHC) according to Articles 57(a) and (c) as it is classified according to Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as a carcinogen category 1B, H350i (may cause cancer by inhalation), and as toxic for reproduction category 1B1, H360F (may damage fertility), and was therefore included in the candidate list for authorisation on 15 December 2010, following ECHA's decision ED/95/2010.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on cobalt(II) carbonate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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



- 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 for setting review periods in accordance with article 58(1)(d) for some uses of cobalt(II) carbonate. Most comments received agreed with ECHA's approach not to set upfront review periods whereas some comments did not propose a concrete timeframe. The information available, including the information provided in these proposals, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of cobalt(II) carbonate.

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of cobalt(II) carbonate 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 many requests for use-specific exemptions of cobalt(II) carbonate. 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of cobalt(II) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA received one request for exemption from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. This was the same general request as received for cobalt(II) sulphate stating that in general all PPORD activities should be



exempted based of the need to develop alternatives and referred to the low exposure of workers dealing with PPORD.

For the same reasons as provided in section 6) of Annex I.9. – Cobalt(II) sulphate, ECHA does not recommend exempting the use of cobalt(II) carbonate for PPORD from authorisation.



Annex I.13. - Cobalt(II) diacetate

Reasons for prioritising cobalt(II) diacetate

To determine whether cobalt(II) diacetate should be prioritised pursuant to Article 58(3) of the REACH Regulation, ECHA applied the principles contained in the document entitled "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (version 28/05/2010). ECHA concluded that cobalt(II) diacetate is supplied to uses in the scope of authorisation in relatively high volumes and at a medium to high number of sites. Although releases and exposure to workers might be controlled in most instances, some uses have potential for significant worker exposure. Furthermore, the substance could be used to replace other cobalt(II) compounds in some of their uses.

Hence, ECHA has prioritised cobalt(II) diacetate for inclusion in Annex XIV.

Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:

cobalt(II) diacetate

EC Number:

200-755-8

CAS Number:

71-48-7

2) Intrinsic properties of the substance

Cobalt(II) diacetate was identified as a Substance of Very High Concern (SVHC) according to Articles 57(a) and (c) as it is classified according to Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as a carcinogen category 1B, H350i (may cause cancer by inhalation), and as toxic for reproduction category 1B, H360F (may damage fertility), and was therefore included in the candidate list for authorisation on 15 December 2010, following ECHA's decision ED/95/2010.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The information available on cobalt(II) diacetate does not allow to discriminate sunset dates for different uses or to deviate from the 18 months set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation, taking into account the considerations set out in Annex I above on transitional arrangements.

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



- 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 for setting review periods in accordance with article 58(1)(d) for some uses of cobalt(II) diacetate. Most comments received agreed with ECHA's approach not to set upfront review periods whereas some comments suggested review periods of at least 5 years. The information available, including the information provided in these proposals, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of cobalt(II) diacetate.

5) Exempted (categories of) uses

In its draft recommendation, ECHA has not proposed any exemptions for (categories of) uses of cobalt(II) diacetate 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 many requests for use-specific exemptions of cobalt(II) diacetate. 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 the third Recommendation of substances to be included in Annex XIV – General approach' and as further explained in sections 'E' and 'D' of the 'Response to Comments Document for the Group of cobalt(II) Substances' (RCOM). In this RCOM document also ECHA's responses to the requests are documented.

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

6) <u>Application of authorisation to product and process oriented research and development (PPORD)</u>

ECHA received one request for exemption from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. This was the same general request as received for cobalt(II) sulphate stating that in general all PPORD activities should be



exempted based of the need to develop alternatives and referred to the low exposure of workers dealing with PPORD.

For the same reasons as provided in section 6) of Annex I.9. – Cobalt(II) sulphate, ECHA does not recommend exempting the use of cobalt(II) diacetate for PPORD from authorisation.