OPINION OF THE MEMBER STATE COMMITTEE ON ECHA´S 3RD DRAFT RECOMMENDATION OF PRIORITY SUBSTANCES FOR ANNEX XIV ENTRIES

Adopted on 19 December 2011

OPINION

This opinion of the Member State Committee (MSC) on the 3rd draft recommendation of the European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV was adopted on 19 December 2011 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006.

THE PROCESS FOR ADOPTION OF THE OPINION

ECHA consulted the Member State Committee during the spring of 2011 on the preliminary draft recommendation and justification for Annex entries for priority substances to be included in REACH Annex XIV. The Committee provided its first comments on the general approach for priority setting and principles to be applied for specification of Annex XIV entries. After that, ECHA published its draft recommendation on 15 June 2011 on its website for public consultation.

The Member State Committee appointed a Rapporteur for preparing its opinion on ECHA's draft recommendation for Annex XIV at its 18th meeting (25-27 May 2011) and, in addition, a Working Group to support the Rapporteur.

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

- ECHA's priority setting approach[1] and its application to all substances on the candidate list not already included or recommended for inclusion in Annex XIV[2]
- General approach for defining the Annex XIV entries[3]
- ECHA's draft recommendation of priority substances for inclusion in the list of substances subject to authorisation (available for public consultation on 15 June 2011)[4] and its update (dated 25 November, 2011)

[1] http://echa.europa.eu/documents/10162/17232/axiv_prioritysetting_general_approach_20100701_en.pdf
[2] http://echa.europa.eu/documents/10162/17232/prioritisation_results_3rd_rec_en.pdf
[3] http://echa.europa.eu/documents/10162/17232/draft_axiv_entries_gen_approach_en.pdf
[4] http://echa.europa.eu/web/guest/draft-recommendation-of-priority-substances-for-inclusion-in-the-list-of-substances-subject-to-authorisation

- Background documents for each substance summarising the available information used for priority setting and specification of items for Annex XIV entries prepared by ECHA (also published on the ECHA website in the context of the public consultation)

- Comments of the interested parties provided during the public consultation period that started on 15 June 2011 and closed on 14 September 2011

- Draft responses to comments provided by the ECHA Secretariat (as meeting documents on 25 November 2011).

The draft opinion provided to the Committee by the Rapporteur was finalised and adopted on 19 December 2011 after discussion at the 21st meeting of the Member State Committee and a subsequent written procedure. The support document for the MSC opinion is attached to this opinion (Annex 2).

THE DRAFT RECOMMENDATION OF ECHA

ECHA´s draft recommendation for new entries in REACH Annex XIV specifies the following information for each priority substance:

- The identity of the substance as specified in section 2 of Annex VI
- The intrinsic property/properties of the substance referred to in Article 57
- Transitional arrangements
    - The sunset date
    - The application date
- Review periods for certain uses, if appropriate
- Uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

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

The updated ECHA draft recommendation is attached to this opinion as Annex 3.

THE OPINION ON RECOMMENDED SUBSTANCES FOR INCLUSION IN ANNEX XIV

The *majority of the members of the Member State Committee support* the draft recommendation of ECHA, first published on 15 June 2011 and as updated on 25 November 2011, to include the 13 substances below 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*.

1. Chromium trioxide
   EC: 215-607-8, CAS: 1333-82-0

2. Acids generated from chromium trioxide and their oligomers
   Group containing:

Chromic acid	EC: 231-801-5	CAS 7738-94-5
Dichromic acid	EC: 236-881-5	CAS 13530-68-2
Oligomers of chromic acid and dichromic acid	EC: not yet assigned	CAS not yet assigned

3. Sodium dichromate
   EC: 234-190-3, CAS: 7789-12-0 and 10588-01-9

4. Potassium dichromate
   EC: 231-906-6, CAS: 7778-50-9

5. Ammonium dichromate
   EC: 215-693-7, CAS: 1344-37-2

6. Potassium chromate
   EC: 232-140-5, CAS: 7789-00-6

7. Sodium chromate
   EC: 231-889-5, CAS: 7775-11-3

8. Trichloroethylene
   EC: 201-167-4, CAS: 79-01-6

9. Cobalt (II) sulphate
   EC: 233-334-2, CAS: 10124-43-3

10. Cobalt dichloride
    EC: 231-589-4, CAS: 7646-79-9

11. Cobalt (II) dinitrate
    EC: 233-402-1, CAS: 10141-05-6

12. Cobalt (II) carbonate
    EC: 208-169-4, CAS: 513-79-1

13. Cobalt (II) diacetate
    EC: 200-755-8, CAS: 71-48-7

Regarding the prioritisation of the five cobalt salts – cobalt (II) sulphate, cobalt dichloride, cobalt (II) dinitrate, cobalt (II) carbonate and cobalt (II) diacetate – some MSC members [LV, UK, FR] disagreed with the prioritisation and provided a minority view, as expressed in Annex 1A.

Another group of MSC members [PL, LT, SK, ES, IT] disagreed with the prioritisation of cobalt (II) diacetate and provided minority views, as expressed in Annex 1B.

Intrinsic properties

The intrinsic properties of all of the substances are as indicated in the respective Annex XV SVHC dossiers.

Transitional arrangements

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

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

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

In the updated draft recommendation ECHA modified the proposed transitional arrangements for trichloroethylene and for the chromium(VI) compounds as compared to the draft version subject to the public consultation. Trichloroethylene is now given a slightly shorter application period and the chromium (VI) compounds a slightly longer one, while the transitional regime for the cobalt salts is left unchanged. In all cases the sunset date is proposed to follow 18 months after the respective application date.

By this modification of the transitional arrangements ECHA considers that due account has been taken of the comments received in the public consultation: the structure of the supply chain for trichloroethylene appears to be less complicated than for the cobalt and chromium compounds. Therefore, the standard application period of 18 months appears to be sufficient for trichloroethylene. Since the public consultation has suggested that a longer application period than the standard would be justified for the chromium compounds ECHA suggests 21 months to be more appropriate. For the cobalt compounds, the application period originally suggested (24 months) is already six months longer than the standard and no further prolongation is regarded by ECHA to be warranted.

While MSC agrees to the general line of reasoning offered by ECHA in the updated draft recommendation the majority of members do not believe that the later application dates suggested for the chromium compounds are sufficient to address the argumentation brought forward by several commenters in the public consultation. According to some MSC members, a longer period of time than suggested by ECHA before the application deadline would be warranted – e.g. an application date 48 months after entry into force of an updated Annex XIV might be more appropriate.

The Member State Committee agrees to ECHA´s proposal as given in the updated draft recommendation regarding trichloroethylene. Those members that agreed on the prioritisation of the cobalt salts also agree to ECHA´s proposal as given in the updated draft recommendation. Application and sunset dates should thus be set at 18/36 and 24/42 months after the date of inclusion in Annex XIV, for trichloroethylene and for the cobalt salts, respectively. However, for the chromium(VI) compounds substantially later application dates are recommended by most of the MSC members.

Review periods for certain uses

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

Uses or categories of uses exempted from the authorisation requirement

Although there were many comments requesting exemption from authorisation for many uses of all the prioritised substances, no existing specific community legislation imposing minimum requirements relating to the protection of human health or the environment against the use of these substances, which proves that the risk is properly controlled, was referred to in those comments.

The *Member State Committee agrees* with ECHA that no exemptions for any particular uses are warranted in the recommendation for Annex XIV inclusion. This issue is further elaborated on in Annex 2 of this opinion.

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

The Member State Committee discussed two types of requests for exemptions for use in product and process oriented research and development received during the public consultation, one specific for a particular use of chromium trioxide and one general proposal for exemption of all PPORD activities submitted for chromic acids, cobalt dichloride and cobalt diacetate. Following discussion, *MSC is of the opinion* that it supports ECHA's view that PPORD exemptions in Annex XIV are not warranted. Further information is provided in Annex 2 of this opinion.

ANNEX 1A

MINORITY POSITIONS

As the representatives of France, Latvia, and the United Kingdom in the Member State Committee, we would like to express our minority position to the decision regarding the opinion of the Member State Committee on the third recommendation of the European Chemicals Agency concerning priority substances to be included in Annex XIV adopted on 19th December 2011.

The information submitted during the consultation indicates that the relative priorities of the cobalt compounds may have been overestimated in the initial prioritisation. A large amount of information was submitted by industry during the consultation period and it appears that this has not been fully accounted for in the revised prioritisation. In particular, it has been claimed by industry that:

The different cobalt salts are not interchangeable in all their applications;

That the volumes used are not as high as initially indicated;

That the uses are not as widespread or dispersive as initially indicated;

That some of the uses currently being considered as within the scope of authorisation may be intermediate uses (e.g., manufacture of frits, glasses, pigments).

The merits of these claims need to be fully assessed before we move forward. This could be done by a MSC/ECHA working group working in collaboration with the relevant industry groups and independent experts. Further analysis would hopefully remove the uncertainties there are currently and would provide a firm basis upon which to make any reccomendations. If the industry claims of non-interchangability of the cobalt salts are substantiated, then this would mean that the whole group should not be prioritised.

In addition, the scores assigned to the cobalt compounds appear to be inconsistent when compared to those assigned to 2-methoxyethanol (which was also assessed in this prioritisation round). The uses of this substance would appear to be equivalent in terms of how widespread and disperse they are, yet it was given a much lower score.

Of particular note is the use of cobalt diacetate as a catalyst in the manufacturing process for polyethylene terephthalathese (PET) and related polymers. For the reasons expressed by the minority position of Poland, Lithuania, Slovakia, Spain and Italy, it seems inappropriate to take this substance forward for prioritisation to Annex XIV. However, this needs to be balanced against the possibility that the substance could be an alternative to the other inorganic cobalt salts in aplications such as surface treatment. If cobalt diacetate is not a viable substitute for the other cobalt salts, then it should not be prioritised for inclusion in Annex XIV.

In summary, we recommend that the new information gained as a result of the consultation be investigated further with a view to providing a firm basis upon which to draw conclusions. Until this has been done, we cannot support the inclusion of the cobalt group of substances.

MINORITY POSITIONS

MINORITY POSITION OF LITHUANIA, POLAND AND SLOVAKIA ON PRIORITISATION OF COBALT DIACETATE FOR INCLUSION INTO ANNEX XIV OF REACH

As representatives of *Lithuania, Poland and Slovakia* in Member State Committee (MSC) we would like to express our minority position to the decision regarding opinion of the Member State Committee on the 3rd draft recommendation of the European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV adopted on 19 December 2011 by MSC-21.

Taking into account General Approach for Prioritisation of Substances of Very High Concern for Inclusion in the List of Substances Subject to Authorisation" as well as available information on production volume and uses of cobalt (II) diacetate (CodiAc) we would like to express the opinion that high priority should not be given to this substance and as the consequence it should not be recommended for inclusion to Annex XIV.

We agree, regarding inherent properties, that CodiAc fulfils the criteria SVHC. It is classified as carcinogen category 1B; H350i (may cause cancer by inhalation) and toxic for reproduction category 1B; H360F (may damage fertility). However, it should be underlined that the carcinogenicity classification is linked with the exposure by inhalation route. Additionally CodiAc can be regarded as a threshold carcinogen, so, for it the threshold level can be obtained (the information from the Cobalt Development Institute - Threshold Mechanism for Cobalt Compounds). According to the "General Approach for Prioritization of Substance of Very High Concern (SVHC) for Inclusion in the List of Substances Subject to Authorisation" scoring approach method should be used in order to make a prioritisation. Three aspects need to be taken into account:

a) intrinsic properties,

b) volume,

c) wide dispersive use.

According to Article 58(3) of REACH priority shall normally be given to substances with:

a) PBT or *v*P*v*B properties; or

b) wide dispersive use; or

c) high volumes.

a) The CodiAc is not PBT nor *v*P*v*B substance. It doesn't meet the criteria of Article 57(d) and (e) of REACH.

b) Annual volume of production should be taken into account as well. CodiAc is not a high production volume (HPV) chemical. According to information obtained from Cobalt REACH Consortium, annual production of CodiAc is below 1000 t/y and its principal use within the scope of potential authorisation is as a catalyst (> 90 % of in-scope use).

c) "Wide-dispersive use":

The term „wide-dispersive use" is explained in Chapter R.16.2.1.6 of the Guidance on Information Requirements and Chemical Safety Assessment as follows: *„Wide-dispersive use refers to many small point sources or diffuse release by for instance the public at large or sources like traffic. … Wide-dispersive use can relate to both indoor and outdoor use"*. Consumer use can be considered

as wide-dispersive. Professional use can be wide-dispersive if it takes place at many sites and it is carried out by many workers and if it cannot be excluded that releases are negligible. Diffuse release means releases to the environment from a high number of sources and non-diffuse release means release to the environment from small or medium number of sources. Small sites are connected to tens of sources and medium to hundred sites where substance is being released.

CodiAc is used mainly in production process of PTA/IPA/DMT as catalyst (> 90 % of UE production), in other production process as catalyst (4 %) and in manufacture of chemicals, catalysts, organic pigments and animal food supplements exempted from Authorisation Procedure. It should also be noted that Co(II) is an essential element needed for biotechnological processes. If CodiAc is used as catalyst in plastic and PET production it shouldn't be regarded as intermediate substance because in this process CodiAc doesn't meet the criteria for intermediate. However, it should be noted that PET produced with CodiAc as catalyst can be used as pharmaceutical and feed packaging material. The production of plastic must be done under strictly controlled conditions because of CodiAc classification. In effect the release is extremely small and non dispersive. Additionally, exposure of workers has to be insignificant.

Moreover, we cannot agree with prioritisation of CodiAc together with other cobalt salts under grouping approach. According to our knowledge CodiAc is used mainly as a catalyst in strictly controlled conditions in a very limited number of processes and sites. Due to that a potential consumer exposure to this substance is insignificant. Consequently, grouping approach is not justified in this case.

Therefore, we are of the opinion that CodiAc should not be prioritised for inclusion into Annex XIV.

Italian and Spanish position regarding prioritisation of cobalt diacetate

The Italian and Spanish members of the Member State Committee would like to express their position on the decision for including cobalt diacetate in the recommendation of priority substances to be included in Annex XIV.

We consider that the result of applying the scoring method provided in the general approach for prioritization of substances of very high concern is exaggerated for cobalt diacetate. Even though new information on volumes and number of sites has been considered by ECHA resulting in an updated score we think that uncontrolled releases cannot be assumed for this substance.

According to the description of uses, exposure seems to be well controlled. In our opinion these uses fits well the definition used for controlled releases provided in general approach.

On the other hand, regarding information provided in this process it seems difficult to substitute other inorganic cobalt salt for cobalt diacetate. Therefore, regulatory efficiency arguments would not apply in this case.

Annex 2

Support Document for the Opinion of MSC adopted on 19th December 2011 on ECHA's Draft Recommendation of Substances for Inclusion in REACH Annex XIV

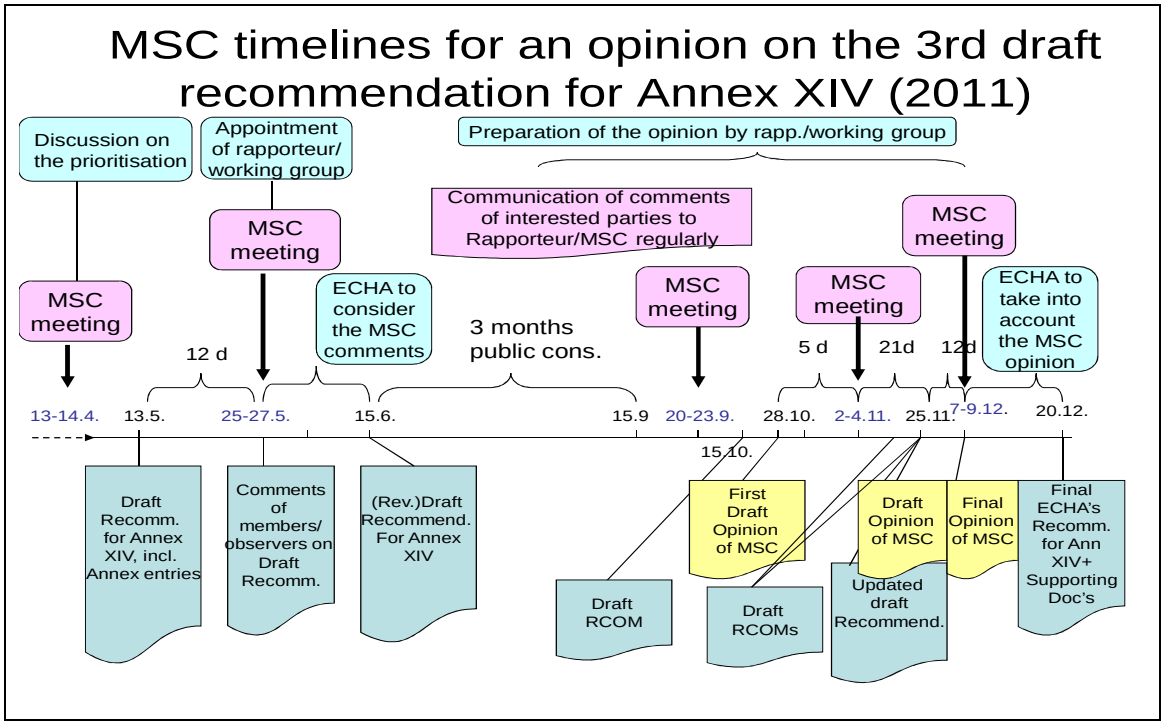
1. INTRODUCTION

According to REACH Article 58(3) the Member State Committee (MSC) needs to provide an opinion on ECHA's draft recommendation for priority substances to be included in Annex XIV, i.e. the Annex containing the list of substances subject to authorisation.

The relevant Article 58(3) states:

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

For this third (draft) recommendation of substances, ECHA developed the following timeframe that MSC agreed to follow.



2. **MSC VIEWS ON GENERAL COMMENTS RECEIVED FROM STAKEHOLDERS**

During the three month public consultation on this draft recommendation approximately 1400 stakeholder responses were received. Most of the comments were submitted by downstream users and their sector organisations and covered many aspects of the ECHA draft recommendation. The comments mostly addressed the *prioritisation* of individual substances, *exemptions* of uses or groups of uses from the authorisation provisions and *transitional arrangements*.

On a group basis the chromium(VI) compounds (e.g. chromic trioxide and sodium dichromate) received the highest number of comments followed by the cobalt salts (e.g. cobalt sulphate) and lastly trichloroethylene.

The high number of comments during the public consultation was of course welcome, but posed a considerable work-load issue in ECHA´s responding to the comments and in MSC´s deliberations for the present opinion. Since many comments were posted by lots of individual enterprises with the same or at least very similar content it may be worth while for future consultations to encourage stakeholder organisations such as associations, federations or sector groups of various types of downstream user businesses to try to coordinate the responses from individual companies and preferably submit collective answers whenever feasible.

During the consultation period stakeholders submitted a number of general comments and also comments on specific substances or specific issues which, however, may have wide-ranging consequences and be of general interest. Some of these issues are summarised below together with MSC's reflections and views.

Priority setting

To be prioritised or not to be prioritised – that is the question

To facilitate the selection and prioritisation of substances from the candidate list to Annex XIV ECHA has developed a qualitative/semi-quantitative prioritisation system. This two-way approach, comprising of a "verbal argumentative approach" and a "semi-quantitative scoring approach" has been discussed and agreed in MSC.

Both approaches aim to capture the essence of the legal text in Art. 58(3) which states that priority for inclusion in Annex XIV shall normally be given to substances with PBT/vPvB properties or wide dispersive use or high volumes. In addition, aspects of "regulatory effectiveness" are to be taken into account.

The results from the application of the semi-quantitative scoring approach for prioritising individual substances have been questioned by many commenters. For many of the substances a lot of effort has been put into scrutinising ECHA´s scoring of the degree of "wide dispersive use" and the projected volumes within the scope of authorisation. Recalculations provided suggest that the prioritisation of individual substances is unwarranted.

In this context it must be emphasised that the prioritisation of substances for Annex XIV inclusion is not strictly a risk based process. It is not intended to provide a comparative risk assessment amongst the SVHC substances included in the candidate list at the time of each prioritisation effort. Overall, prioritisation should be seen as a weight of evidence process where the legal text, the selection/prioritisation tools and regulatory effectiveness is taken into account.

The potential inter-changeability of groups of very similar chemicals, such as different salts of metal cations, has been recognised by ECHA as an important "regulatory effectiveness" aspect to take into account when prioritising substances for authorisation.

This "grouping approach" has been applied for some of the substances prioritised by ECHA that otherwise might have been less strong candidates for prioritisation.

The majority of the MSC members support the view taken by ECHA to take a conservative/inclusive position when assessing what to take into account when applying the "grouping approach" and its potential importance with regard to regulatory efficiency. Other members thought that the "grouping approach" may not be valid in all cases.

In order to gain wider acceptance, or at least better understanding, of the factors underpinning ECHA´s prioritisation efforts it may be worthwhile trying to further clarify this process to stakeholders and interested parties. Besides guidance improvements, ECHA may want to use more informal means of communication such as brochures or fact sheets.

At the same time it might be valuable to explain why s*ocio-economic arguments, lack of alternatives, "safe use – no exposure - no risk","strictly controlled conditions", etc.* are normally not relevant arguments against prioritisation of substances for Annex XIV inclusion. Such issues are to be taken into account in the Commission decisions on the granting of authorisations based on stakeholder applications and the opinions from ECHA´s risk assessment and socio-economic committees.

What is "intermediate use" and how does this issue influence prioritisation?

During the public consultation numerous commenters argued that many uses of the chromium(VI) and particularly the cobalt salts should be considered as intermediate uses. Since all intermediate uses would be exempt from authorisation, the commenters have scrutinised ECHA´s calculations of the volumes used as a basis for the scoring of the "Volume" aspect in the grounds for prioritisation. They often came to the conclusion that ECHA incorrectly included some intermediate uses of the substances when calculating the volume score and that therefore the prioritisation should be lower than that concluded by ECHA.

In the response to the comments received during the public consultation ECHA has maintained its original view and stressed that the assessment of the relevant volumes eligible for eventual authorisation is done only for prioritisation purposes and that it does not conclude or define the status of a use under the REACH Regulation. In ECHA´s view a conservative/inclusive approach should be taken in the prioritisation phase in cases where a clear conclusion on the intermediate (or other exemption) status is not possible on the basis of available data.

The majority of the MSC members agrees with ECHA`s views on how this issue should be dealt with when prioritising substances for Annex XIV inclusion. In the end, it is for individual enterprises to assess whether they need to submit applications for authorisation for their particular uses of an Annex XIV substance. Since there seems still to be questions on how to interprete the legal definition of an "intermediate" more information may lessen the need for future enforcement.

Transitional arrangements

The Member State Committee discussed the general approach to the transitional arrangements proposed by ECHA. In this, as in previous public consultations, an NGO proposed a 12 month period as a default time to prepare the applications for authorisation implying a sunset date 30 months later. This would apply when no relevant information on the production cycle for a specific use is available (c.f. Article 58(1)(c)(i)). According to some competent authorities it can be reasonably expected that once ECHA submits its recommendation concerning new Annex XIV entries to the Commission, the industry will anticipate this decision or even already have anticipated the decision, since both the candidate list and the criteria for prioritisation are publicly available. Thus the

companies would have had a possibility to start preparing the applications well in advance of the adoption of an updated Annex XIV by the Commission.

For already registered substances the availability of CSRs may be seen as a circumstance alleviating the work needed for an authorisation application and thereby argue against prolonged transitional periods. However, in situations where the production and marketing cycles for specific uses are known and complex, a longer period from the entry into force to the application date could be considered.

In the present opinion MSC agrees to ECHA´s proposal as given in the updated draft recommendation regarding trichloroethylene. Those members that agreed on the prioritisation of the cobalt salts also agree to ECHA´s proposal as given in the updated draft recommendation. Application and sunset dates should thus be set at 18/36 and 24/42 months after the date of inclusion in Annex XIV, for trichloroethylene and for the cobalt salts, respectively. However, for the chromium(VI) compounds substantially later application dates are recommended by most of the MSC members.

Review periods for certain uses

In the public consultation, there were requests for very long review periods once authorisation has been granted for economical and practical reasons. Commenters argued that e.g. closed systems may be very expensive and long review periods would be warranted for "adequate protection of investment". MSC considers that this issue is best addressed when the authorisation decision is taken as the review period will then be based on specific information provided in the application for authorisation.

Even though ECHA guidance has mentioned 18 months as the minimum length of a review period it should be realised that review intervals of about five years would normally be expected and in individual cases even longer review periods may be considered appropriate. Since several stakeholders have expressed strong concerns based on uncertainty regarding the length of future review periods more information in this area may be helpful.

Proposed exempted (categories of) uses

A multitude of commenters requested exemptions for many uses of the substances. However, after discussions within MSC and based on the Article 58(2) provisions and previous MSC decisions/opinions, all of these requests can be considered as not relevant.

REACH Art. 58(2) reads as follows:

> *Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled….*

Furthermore, in the general approach[5] for defining the Annex XIV entries the following explanation can be found:

[5] http://echa.europa.eu/documents/10162/17232/draft_axiv_entries_gen_approach_en.pdf

Accordingly, in light of this provision and the *Guidance on inclusion of substances in Annex XIV*, in order to exempt a use of a substance to be included in Annex XIV the following elements should be considered:

- There is existing Community legislation addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definitions. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed;

- This Community legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the use in question should also specifically refer to the substance to be included in Annex XIV either by naming the substance specifically or by referring to the group the substance belongs to e.g. by referring to the classification criteria or the Annex XIII criteria;

- This Community legislation imposes minimum requirements[1] for the control of risks of the use. Legislation setting only the aim of measures or not clearly specifying the actual type and effectiveness of measures required is not sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid on whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s) as relevant) are covered in the existing legislation.

[1]Legislation imposing minimum requirements means that
- the Member States may adopt more stringent but not less stringent requirements when implementing the specific Community legislation in question.
- the piece of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the similar minimum level of control of risks throughout the EU and that this level can be regarded as proper.

However, some unclear/less obvious cases may deserve additional consideration. As an example that may have wider-ranging consequences and be of general interest the following issue may be chosen.

Several stakeholders have requested that the industrial use of trichloroethylene for surface cleaning in closed systems is listed as an exempted use in accordance with Art. 58(2). The commenters refer to "safe use" as required by e.g. the Chemical Agents Directive (CAD), Carcinogen/Mutagen Directive (CMD), the VOC & IPPC Directives and an expected forthcoming indicative or binding OEL via amendment of the CAD or the CMD directive, respectively. A 10 ppm OEL for trichloroethylene has already been proposed by the DG Employment expert committee SCOEL who furthermore has considered the substance to be a threshold carcinogen.

In this particular case it can be argued that an indicative OEL would not suffice to fulfil the requirement of *Community legislation imposing minimum requirements* since Member States would be free to adopt both higher and lower national OELs and thus not forced to introduce minimum requirements.

If, however, a binding OEL would be implemented via an adaptation of the Carcinogen/Mutagen directive it might be argued that more than minimum requirements have been achieved. Even in this case it could still be rightfully questioned if "proper control" is at hand since the binding OEL would only regard inhalation exposure and it is known that dermal uptake of trichloroethylene is not negligible. Furthermore, arguments for exemptions based on future, anticipated Community legislation should not be taken

into account when ECHA recommends new entries in Annex XIV. On the other hand could forthcoming new Community legislation provide grounds for revision or deletion of individual entries in REACH Annex XIV once adopted and entered into force.

In this particular case, MSC does not believe that an exemption from authorisation (for industrial use of trichloroethylene for surface cleaning in closed systems) is legally warranted. MSC thus agrees with the analysis provided by ECHA on this issue. A similar line of argumentation may also apply when/if binding or indicative OELs are introduced for other substances prioritised for inclusion in Annex XIV.

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

As indicated in the MSC opinion, there were two types of requests for PPORD exemptions submitted in the public consultation, one being specific request in relation to chromium trioxide and the other was a general proposal for exemption of all PPORD activities. The latter was submitted for the chromic acids, cobalt dichloride and cobalt diacetate. The information provided in each case did not fully indicate that the activities described could be viewed as PPORD. Additionally, in general, MSC considers that there is an apparent inconsistency between the possibility of optional PPORD exemptions and the aims of authorisation formulated in Article 55 of REACH (i.e. that these substances are progressively replaced by suitable alternative substances or technologies). These apparent conflicting objectives of the legislation to substitute a substance subject to authorisation and at the same time to allow the use of such a substance for the development of new uses are difficult to address. Based on all of these considerations, MSC is of the opinion that PPORD exemptions are not warranted in this recommendation.

3. MSC VIEWS ON SPECIFIC COMMENTS RECEIVED FROM STAKEHOLDERS

3.1 ***CHROMIUM TRIOXIDE***

Justification for prioritisation – short summary

Chromium trioxide is classified as carcinogenic, CLP category 1A (corresponding to the former category 1) and mutagenic, CLP category 1B (corresponding to the former category 2). Chromium trioxide was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (b) of REACH.

The amount used in the EU is in the range 1,000 – 10,000 t/y. Most of this tonnage is for uses within the scope of authorisation and spread over a large number of sites, with the potential for significant worker exposure. Based on this, chromium trioxide meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

No Member State Competent Authority opposed the prioritisation of chromium trioxide for inclusion in Annex XIV; two MSs specifically supported the proposal. Two NGOs expressed their support for the prioritisation.

Many comments were received from industry representatives and individual companies generally challenging the prioritisation of chromium trioxide for inclusion in Annex XIV. The arguments put forward included points such as lower worker exposure in some sectors compared to what is included in the Annex XV dossier, claims that the use of the substance is tightly controlled under existing occupational worker protection and environmental protection legislation, that an OEL for hexavalent chromium is being

proposed (expected in 2013), that the substance is essential to many processes and is a critical substance in some safety applications such as in the aerospace industry, despite years of research and development, no suitable alternatives have been identified for many uses and the possible loss of employment in the EU as a result of the requirement for authorisation for chromium trioxide.

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

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for chromium trioxide:

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

Many comments were received requesting extensions to the applications dates and the sunset dates. The main reasons for requesting longer transitional arrangements are that no alternatives are currently available and that as all applications for authorisation will need a socio-economic analysis, this will take a long time to complete (some estimated that it could take five years to complete the SEA).

Requests for longer transitional periods ranged from 24 months to 36 months after EIF for the application date. Regarding the sunset date, there were many requests for an extension to this, with some companies requesting a date up to ten years after entry into force.

One NGO requested that the transitional arrangements be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date

In its updated recommendation, dated November 25, 2011, ECHA proposed to amend the application date for chromium trioxide from 18 months after EIF of the Regulation to 21 months. This new proposal takes into account the comments received during the public consultation and the fact that several of the comments appear to indicate that a longer latest application date than the standard 18 months is justified for the chromium compounds.

While MSC agrees to the general line of reasoning offered by ECHA in the updated draft recommendation the majority of members do not believe that the longer application dates suggested for the chromium compounds are sufficient to address the argumentation brought forward by several commenters in the public consultation. According to some MSC members, a longer period of time than suggested by ECHA before the application deadline would be warranted – e.g. an application date 48 months after entry into force of an updated Annex XIV might be more appropriate.

Proposed review period for certain uses

No review period was suggested by ECHA.

Some comments were received indicating that no review periods should be set, with some stakeholders indicating their agreement with ECHA that it is difficult to define review periods upfront for certain uses, while others suggested review periods of between 5 and 15 years.

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

strong concerns based on uncertainty regarding the length of future review periods more information in this area may be helpful.

Proposed exempted (categories) of uses

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

Many comments were received requesting exemptions for many different uses of chromium trioxide in accordance with Article 58(2) of REACH. The main basis for this request was that it is considered that the substance is adequately controlled by existing measures in place in the workplace as regards worker protection and environmental protection. Apart from general applications such as that in chromium plating and rotogravure printing and use in automated and enclosed processes, many exemptions were requested for uses in the aerospace and defence industry for safety critical applications (required to meet specific safety standards). In addition exemptions were requested for uses which may already be outside the scope of authorisation such as in the analysis of chemical oxygen demand, use in detector tubes, as an analytical reagent, use in the R&D, manufacture and analysis of medicinal products, use as a fixative in wood preservative (biocidal product). Additionally, an exemption for reported intermediate use in surface treatment was requested[6].

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

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for the PPORD were suggested by ECHA.

There was one request for a PPORD exemption submitted during the public consultation.

The request is in relation to the use in semiconductor companies who need to determine the potential impact of crystal defects during processing on device yield and performance, which they have indicated is essential for the development of new manufacturing processes in this industry. This is done in 'failure analysis' process developmental labs. The defects are typically analysed by means of preferential etch followed by microscopy and the industry has indicated that the use of chromium trioxide in these etches is essential. Individual companies would use a few grams to a few hundred grams per year, while the industry itself would use less than 2kg per year.

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

Other issues

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

[6] Surface treatment is not recognised as an intermediate use according to ECHA's guidance on intermediates

3.2 ACIDS GENERATED FROM CHROMIUM TRIOXIDE AND THEIR OLIGOMERS, GROUP CONTAINING: CHROMIC ACID, DICHROMIC ACID, OLIGOMERS OF CHROMIC ACID AND DICHROMIC ACID[7]

Justification for prioritisation – short summary

Chromic acids are spontaneously generated products of the reaction of chromic trioxide with water.

Chromic acids are classified as carcinogenic, CLP category 1B (corresponding to the former category 2). Chromic acids were identified as a Substance of Very High Concern (SVHC) according to Article 57(a) of REACH.

No registration was submitted for this group of compounds and therefore information on tonnages and uses in the EU refers to chromium trioxide. Most of this tonnage is for uses within the scope of authorisation and spread over a large number of sites, with the potential for significant worker exposure. This substance could be used as a replacement for other hexavalent chromium compounds with similar hazard profile and similar uses. Therefore it is proposed to recommend the chromic acids for inclusion in Annex XIV.

Priority setting

No Member State Competent Authority opposed the prioritisation of the chromic acids for inclusion in Annex XIV.

Some comments received from industry and their associations objected to the prioritisation of the chromic acids for inclusion into Annex XIV. The basis for the objections were that exposure to chromic acids in many sectors was lower than had been reported in the Annex XV dossier. Comments included claims that chromic acids are already tightly controlled by other Community legislation and that inclusion into Annex XIV would not improve worker health and safety or environmental protection. Many comments stressed the importance of the chromic acids in safety critical applications in the aerospace/defence industry and the lack of proven alternatives being of significant concern.

Further comments received related to the potential loss of jobs in the EU as a result of chromic acid being subjected to authorisation.

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

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for chromic acid

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

Comments requesting extensions to the transitional dates were received in large numbers. Also calls for the deferral of the prioritisation and the extension of the sunset dates by up to ten years. The main reasons for requesting longer transitional arrangements are that no alternatives are currently available and that as all applications

[7] The term "Chromic acids" is used throughout the rest of the document for easier readability.

for authorisation will need a socio-economic analysis, this will take a long time to complete (some estimated that it could take five years to complete the SEA).

Requests for longer transitional periods ranged from 24 months to 36 months after EIF for the application date. Regarding the sunset date, there were many requests for an extension to this, from 48 months up to ten years after entry into force.

One NGO requested that the transitional arrangements be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date

In its updated recommendation, dated November 25, 2011, ECHA proposed to amend the application date for chromic acid from 18 months after EIF of the Regulation to 21 months. This new proposal takes into account the comments received during the public consultation and the fact that several of the comments appear to indicate that a longer latest application date than the standard 18 months is justified for the chromium compounds.

While MSC agrees to the general line of reasoning offered by ECHA in the updated draft recommendation the majority of members do not believe that the longer application dates suggested for the chromium compounds are sufficient to address the argumentation brought forward by several commenters in the public consultation. According to some MSC members, a longer period of time than suggested by ECHA before the application deadline would be warranted – e.g. an application date 48 months after entry into force of an updated Annex XIV might be more appropriate.

Proposed review period for certain uses

No review period was suggested by ECHA.

Some comments were received indicating that no review periods should be set, with some stakeholders indicating their agreement with ECHA that it is difficult to define review periods upfront for certain uses, while others suggested review periods of between five and ten years.

MSC is of the opinion that upfront specified review periods for chromic acid are not warranted in the recommendation for Annex XIV inclusion. Since several stakeholders have expressed strong concerns based on uncertainty regarding the length of future review periods more information in this area may be helpful.

Proposed exempted (categories) of uses

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

Many comments were received requesting exemptions for many different uses of chromic acid in accordance with Article 58(2) of REACH. The main basis for this request was that it is considered that the substance is adequately controlled by existing measures in place in the workplace as regards worker protection and environmental protection. Apart from general applications such as that in chromium plating and rotogravure printing and use in automated and enclosed processes, many exemptions were requested for uses in the aerospace and defence industry for safety critical applications (required to meet specific safety standards).

Specific exemptions were requested for use in bright/decorative chromium plating on plastics and metals as existing EU legislation provides for suitable control. In addition, exemptions were requested for uses which may already be outside the scope of

authorisation such as in the analysis of chemical oxygen demand, use in detector tubes, as an analytical reagent, use in scientific R&D, manufacture and analysis of medicinal products, use as a fixative in wood preservative (biocidal product). Additionally, an exemption for reported intermediate use in surface treatment was requested[8].

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

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for the PPORD were suggested by ECHA.

There was one request for a PPORD exemption submitted during the public consultation.

The request argued that all PPORD activity should be exempted on the basis of the development of alternative technologies and the development of new risk mitigation measures for SVHCs.

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

Other issues

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

3.3 ***SODIUM DICHROMATE***

Justification for prioritisation – short summary

Sodium dichromate is classified as carcinogenic, CLP category 1B (corresponding to the former category 2), mutagenic, CLP category 1B (corresponding to the former category 2) and as toxic for reproduction, CLP category 1B (corresponding to the former category 2). Sodium dichromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a), (b) and (c) of REACH.

Sodium dichromate is used in volumes between 1,000 and 10,000 t/y within the scope of authorisation. Most of this tonnage is used in a large number of sites with potentially a significant worker exposure. Based on this, sodium dichromate meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

No Member State Competent Authority opposed the prioritisation of sodium dichromate for inclusion in Annex XIV. Two member states and two NGOs supported the ECHA proposal.

Many comments were received from industry or trade organisations, from companies and from individuals in general challenging the prioritisation of sodium dichromate for inclusion in Annex XIV.

The arguments put forward included points such as the unavailability of alternatives despite intensive searches, the specific safety obligations that apply to the aerospace industry and the fact that alternatives will not be compatible with existing products for repair or overhaul purposes, that the risks are already adequately controlled and good

[8] Surface treatment is not recognised as an intermediate use according to ECHA's guidance on intermediates

workplace practices are already in place, the search for alternatives that is ongoing under existing substitution plans, economic reasoning based on presumed transfer of use processes to developing countries where workers and the environment would be less protected, loss of employment, etc.

Specific comments on the scoring were that the priority score should be lower. The volume range according to the comments should be 100-1000 t/a and the exposure is expected to be low. Comments were received that UK HSE monitoring shows that median levels measured for surface plating are equivalent to background levels.

Comments were received on ECHA's background document raising the fact that the use of sodium dichromate in the manufacturing of sodium chlorate has not been referenced.

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

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for sodium dichromate

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

Many comments were received related to the transitional arrangements.

One NGO requested that the transitional arrangements be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date.

Many request for longer transitional periods were based on lack of available alternatives, on existing substitution programs and on socio-economic reasons. It is also claimed by industry that applying for authorisation would dilute resources currently focused on development of alternatives (under the existing chromate substitution program) and result in substantial extension of chromate use.

Specific supply chain arguments:
It was stated many times that the supply chains in the aerospace industry are very complex, with thousands (some say around 200) companies and six or more layers/levels between chemical manufacturer/importer and the manufacturer of the final product. These include parts suppliers, assemblers, processing companies, formulators and distributers in addition to the manufacturers and importers of the substances themselves. This would create substantial complexity in the process of authorisation, which is expected to take a substantial period of time to manage.

Further supply chain arguments for long transitional periods are the fact that a commitment needs to be gained from chemical/formulation manufacturers and importers, including any commercial agreements relating to fees and costs. The need to examine the non-use impact on companies at every level and context in the supply chain to support socio-economic analysis is also mentioned. Many of these companies are SMEs with a poor working knowledge of REACH. They also need to ensure that any additional RMM identified in an authorisation application dossier is practical to implement. It is said that the upstream suppliers will not push for authorisation, meaning that the downstream users would have to establish a consortium, together with its surface treatment suppliers (>500) in order to prepare an application for authorisation.

Based on all the above arguments (with some differences in levels of argumentation), revised application dates are requested for the aerospace industry ranging from 42 to 78

months after entry into force, resulting in sunset dates of 60 to 96 months after entry into force.

The packaging steel industry requests to prolong the application date to at least 42 months after entry into force of the inclusion in Annex XIV as this would allow for avoiding non cost-effective authorisation applications for a short period of time. According to the current ongoing substitution plan the most optimistic timeline for market implementation of the alternative substance would be the beginning of 2018.

In its updated recommendation, dated November 25, 2011, ECHA proposed to amend the application date for sodium dichromate from 18 months after EIF of the Regulation to 21 months. This new proposal takes into account the comments received during the public consultation and the fact that several of the comments appear to indicate that a longer latest application date than the standard 18 months is justified for the chromium compounds.

While MSC agrees to the general line of reasoning offered by ECHA in the updated draft recommendation the majority of members do not believe that the longer application dates suggested for the chromium compounds are sufficient to address the argumentation brought forward by several commenters in the public consultation. According to some MSC members, a longer period of time than suggested by ECHA before the application deadline would be warranted – e.g. an application date 48 months after entry into force of an updated Annex XIV might be more appropriate.

Proposed review period for certain uses

No review period was suggested by ECHA.

Some commenters proposed not to have review periods for certain uses, others suggested review periods of 5-10 year.

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

Proposed exempted (categories) of uses

No exemptions of uses or categories of uses were proposed by ECHA.

Many comments were received for many different uses of sodium dichromate. The main basis for this request was that it is considered that the substance is adequately controlled by existing measures in place in the workplace as regards worker protection and environmental protection (Art. 58(2)). Furthermore some specific exemptions were requested for the aerospace industry, for automatic processes and enclosed processes in surface treatment using Cr(VI) compounds.

Additionally, exemptions for reported intermediate use were requested. It is the responsibility of the actors to assess whether the use fulfils the definition of an intermediate use.

Other requests for exemptions were made for which industry should further identify whether their use can benefit from the exemption of scientific R&D from authorisation as set out in Article 56(3) or falls within the provisions of Article 2 (5a).

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

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for PPORD were suggested by ECHA.

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

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

Other issues

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

3.4. POTASSIUM DICHROMATE

Justification for prioritisation – short summary

Potassium dichromate is classified as carcinogenic, CLP category 1B (corresponding to the former category 2), mutagenic, CLP category 1B (corresponding to the former category 2) and as toxic for reproduction, CLP category 1B (corresponding to the former category 2). Potassium dichromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a), (b) and (c) of REACH.

The major use of potassium dichromate is as an intermediate in the synthesis of fine and bulk large scale chemicals. Furthermore it is used in metal surface treatment products, formulation of mixtures and as a processing aid, as well as a laboratory chemical and as intermediate in the manufacture of basic metals. The tonnage of this substance allocated to uses within the scope of authorisation is assumed to be low. However this substance could be used to replace other hexavalent chromium compounds with a similar hazard profile and similar uses. Therefore, the substance qualifies for prioritisation.

Priority setting

No Member State Competent Authority opposed the prioritisation of potassium dichromate for inclusion in Annex XIV; three MS specifically supported the proposal.

Two NGOs expressed their support for the prioritisation. One of the NGOs expressed their support specifically due to the fact that potassium dichromate could be used to replace other hexavalent chromium compounds.

In most of the comments received industry did not challenge the prioritisation of potassium dichromate for inclusion into Annex XIV. However, industry is asking to delay or defer prioritisation for as long as possible, to allow time for alternative solutions to become fully tested and accepted and to allow sufficient time for the formation of suitable consortia, involving actors from all parties concerned in the supply chain. It was mentioned in the comments that with proper control and adherence to good workplace safety practices, possible risks can be adequately controlled. It was also stressed that the substance is essential to many processes and is a critical substance in some safety applications such as in the aerospace industry, and that a requirement for authorisation might result in loss of employment in the EU and in substantial economic losses in some fields.

There were also many comments received from industry representatives, individual companies and individuals challenging the prioritisation of potassium dichromate, doubting the claimed widespread use as well as level of exposure, or expressing overall dissagreement with inclusion of potassium dichromate in Annex XIV.

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

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for potassium dichromate:

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

Many comments were received requesting extensions to the applications dates and the sunset dates. The main reasons for requesting longer transitional arrangements are that: no alternatives are currently available and proposed dates represents insufficient time to complete the necessary R&D programmes required to produce qualified alternatives to potassium dichromate (expecially in aerospace industry to assure that the rigorous safety and airworthiness criteria can be met); complexity in the supply chains; need to establish a consortium in order to prepare applications for authorisation and thus improving the quality of the dossier as well as lowering the administrative burden for the evaluation.

Requests for prolongation of proposed application date ranged from an additional 12 months to 48 months, which transfers to 30 – 66 month after entering into force of the Regulation.

Regarding the sunset date, there were many requests for an extension to this date, with some companies requesting an extension up to eight years after application date.

One company suggested to set the application date by 2021 and subsequently the sunset date 18 months later with the motivation that national and international standards most likely can not be changed in a shorter period of time.

One company expressed their disagreement with the proposed dates, however did not elaborate on possible alternative dates.

One NGO requested that the timelines foreseen for transitional arrangements should be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date

One member state expressed their agreement with the proposed transitional arrangements for potassium dichromate.

In its updated recommendation, dated November 25, 2011, ECHA proposed to amend the application date for potassium dichromate from 18 months after EIF of the Regulation to 21 months. This new proposal takes into account the comments received during the public consultation and the fact that several of the comments appear to indicate that a longer latest application date than the standard 18 months is justified for the chromium compounds.

While MSC agrees to the general line of reasoning offered by ECHA in the updated draft recommendation the majority of members do not believe that the longer application dates suggested for the chromium compounds are sufficient to address the argumentation brought forward by several commenters in the public consultation. According to some MSC members, a longer period of time than suggested by ECHA before the application deadline would be warranted – e.g. an application date 48 months after entry into force of an updated Annex XIV might be more appropriate.

Proposed review period for certain uses

No review period was suggested by ECHA.

Most comments received were related to the aerospace and defence industry. In those comments it was suggested that the review periods should allow suitable time for the completion of the necessary R&D and qualification programmes, enable to establish whether suitable alternatives have been introduced or whether additional time is still required and should range between two and ten years. However it should be mentioned, that some comments were received indicating that no review periods should be set.

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

Proposed exempted (categories) of uses

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

Many requests for exemptions were received for activities covered by the Directive on industrial emissions (IED) 2010/75/EU, automated and enclosed processes in surface treatment, chemical surface treatment, gloss and black chrome plating, for hard chromium plating in appropriate installations.

It should also be noted that a lot of exemptions were requested for uses in the aerospace and defence industry for safety critical applications (required to ensure product quality, reliability and safety).

Quite a few comments were received requesting exemptions for different uses of potassium dichromate in accordance with Article 58(2) of REACH. The main basis for this request was that it is considered that the substance is adequately controlled by existing measures in place in the workplace as regards worker protection and environmental protection.

Additionally, an exemption for an intermediate use in surface treatment was requested[9].

It should be mentioned that a lot of exemptions were requested for uses which may already be outside the scope of authorisation such as: in the analysis of chemical oxygen demand; use in routine analytics for preserving milk investigation samples; use as an analytical reagent; use for scientific R&D, which is done in the pharmaceutical industry, in laboratories of waste water treatment plants, and in routine analytics; use in manufacture and analytical control of medicinal products and their ingredients and for any corresponding uses in relation to medical devices.

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

Information on the need to exempt PPORD from the authorisation requirement

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

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

Other issues

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

[9] Surface treatment is not recognised as an intermediate use according to ECHA's guidance on intermediates.

3.5 ***AMMONIUM DICHROMATE***

Justification for prioritisation – short summary

Ammonium dichromate (ADC) is classified as carcinogenic, CLP category 1B (corresponding to the former category 2), mutagenic, CLP category 1B (corresponding to the former category 2) and as toxic for reproduction, CLP category 1B (corresponding to the former category 2). Ammonium dichromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a), (b) and (c) of REACH.

There is no indication that there is any manufacture of ADC in the EU. The substance has been registered as a transported isolated intermediate in the tonnage band 1 - 1000 t/y. According to the registration information ADC is used as an intermediate in the synthesis of fine and bulk large scale chemicals. Furthermore it is used as a laboratory chemical. In the registrations, there were no uses identified within the scope of authorisation.

On the basis of the prioritisation criteria, ammonium dichromate gets very low priority for inclusion in Annex XIV. However, this substance could be used to replace other hexavalent chromium compounds with a similar hazard profile and similar uses. Therefore, it is proposed to recommend ammonium dichromate for inclusion in Annex XIV.

Priority setting

No Member State Competent Authority opposed the prioritisation of ADC for inclusion in Annex XIV and three MSCAs specifically supported the proposal. Two NGOs expressed their support for the prioritisation.

Few comments were received from individual companies challenging the prioritisation of ADC for inclusion in Annex XIV. They claim that the substances in the chromate group are already subject to tight control under many pieces of legislation; the worker exposure is adequately controlled; consumers are not exposed as the substances are converted to metallic chrome during processing; authorisation will not improve worker health and safety nor environmental protection; significant loss of manufacturing will occur because the substances will still be available for use outside of the EU.

One company questioned the consistency of the ECHA's prioritisation approach for inclusion of substances with low score for prioritisation.

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

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for ammonium dichromate:

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

One company requested a five-year extension of the application/sunset dates based on the complexity of the regulatory process in the aerospace industry and the absence of substitutes.

One NGO requested that the transitional arrangements be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date

One MSCA specifically supported the proposed transitional arrangements.

In its updated recommendation, dated November 25, 2011, ECHA proposed to amend the application date for ammonium dichromate from 18 months after EIF of the Regulation to 21 months. This new proposal takes into account the comments received during the public consultation and the fact that several of the comments appear to indicate that a longer latest application date than the standard 18 months is justified for the chromium compounds.

While MSC agrees to the general line of reasoning offered by ECHA in the updated draft recommendation the majority of members do not believe that the longer application dates suggested for the chromium compounds are sufficient to address the argumentation brought forward by several commenters in the public consultation. According to some MSC members, a longer period of time than suggested by ECHA before the application deadline would be warranted – e.g. an application date 48 months after entry into force of an updated Annex XIV might be more appropriate.

Review periods for certain uses

No review periods were suggested by ECHA

One NGO proposed short review periods (e.g. five years) without any argumentation.

One company suggested a review period of 5-7 years in the context of the requested exemption for authorisation for the use of ADC in the aerospace industry (no specific argumentation was provided).

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

Proposed exempted (categories of) uses

A few comments were received on behalf of the EU based gas turbine and engine manufacturers, requesting exemptions for use of ADC in scientific R&D for gas turbines for aeronautic and industrial engine development, due to controlled conditions of use and very low quantity of the substance (c.f. general exemption under Article 56(3)).

Another exemption was requested for the use of ADC in electroplating processes (chromating of aircraft engine parts made of magnesium) in the aviation sector due to existing restrictive national requirements under environmental legislation; protection of employees ensured; safety of some aircraft engine components no longer guaranteed; safety maintaining processes to be relocated outside of the Community.

Request for exemption were also received for specific use of ADC as photosensitiser in water based photoresist-systems in low concentrations due to controlled conditions of use and lack of alternatives;

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

Information on the need to exempt PPORD from the authorisation requirement

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

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

Other issues

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

3.6 ***POTASSIUM CHROMATE***

Justification for prioritisation – short summary

Potassium chromate is classified as carcinogenic, CLP category 1B (corresponding to the former category 2) and mutagenic, CLP category 1B (corresponding to the former category 2). Potassium chromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (b) of REACH.

Potassium chromate is mostly used for metal surface treatment but can also be used as an intermediate in the synthesis of other substances and as a laboratory agent.

Potassium chromate is used in low volumes; however it could be used to replace other hexavalent chromium compounds with similar uses. Therefore, the substance qualifies for prioritisation.

Priority setting

No Member State Competent Authority opposed the prioritisation of potassium chromate for inclusion in Annex XIV. Three MSCAs specifically supported the proposal.

One NGO expressed support for the prioritisation, specifically due to the fact that potassium chromate could be used to replace other hexavalent chromium compounds.

In most of the comments received, industry did not challenge the prioritisation of potassium chromate for inclusion into Annex XIV. However industry is asking to defer prioritisation for as long as possible, to allow time for alternative solutions to become fully tested and accepted and to allow sufficient time for the formation of suitable consortia, involving actors from all parties concerned in the supply chain.

There was one comment received from an industry association challenging the prioritisation of potassium chromate, doubting the claimed widespread use as well as levels of exposure.

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

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for potassium chromate:

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

Few general comments were received requesting extensions to the applications dates and the sunset dates. The main reasons for requesting longer transitional arrangements are that: no alternatives are currently available and proposed dates represents insufficient time to complete the necessary R&D programmes required to produce qualified alternatives to potassium chromate (expecially in aerospace industry to assure that the rigorous safety and airworthiness criteria can be met); complexity in the supply chains; need to establish a consortiums in order to prepare applications for authorisation and thus improving the quality of the dossier as well as lowering the administrative burden for the evaluation.

In their comments a few companies proposed specific timing for the application and sunset dates. One company suggested to set the application date at 2021 and subsequently the sunset date 18 months later with the motivation that national and international standards most likely can not be changed in a shorter period of time.

Another company asked for prolongation of the proposed application date for 12 months, which transfers to 30 month after entering into force of the Regulation and for the extension of sunset date for an additional 12 month after the application date.

One NGO requested that the timelines foreseen for transitional arrangements should be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date.

One member state expressed their agreement with the proposed transitional arrangements for potassium chromate.

In its updated recommendation, dated November 25, 2011, ECHA proposed to amend the application date for potassium chromate from 18 months after EIF of the Regulation to 21 months. This new proposal takes into account the comments received during the public consultation and the fact that several of the comments appear to indicate that a longer latest application date than the standard 18 months is justified for the chromium compounds.

While MSC agrees to the general line of reasoning offered by ECHA in the updated draft recommendation the majority of members do not believe that the longer application dates suggested for the chromium compounds are sufficient to address the argumentation brought forward by several commenters in the public consultation. According to some MSC members, a longer period of time than suggested by ECHA before the application deadline would be warranted – e.g. an application date 48 months after entry into force of an updated Annex XIV might be more appropriate.

Proposed review period for certain uses

No review period was suggested by ECHA.

Only two comments were received concerning review periods.

There was a recommendation not to include review periods for uses related to aerospace and defence industry, however if they must be included then they should be many years apart in order to reflect the complex nature of developing and obtaining approval for alternatives. In a comment from another company there was a suggestion to set a review period of ten years.

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

Proposed exempted (categories) of uses

Most of the exemptions were requested for uses which may already be outside the scope of authorisation such as: in the analysis of chemical oxygen demand; use in routine analytic measurement and control of chlorides in process waters; use as an analytical reagent; use for scientific R&D, which is done in the pharmaceutical industry, in laboratories of waste water treatment plants, and in routine analytics; use in manufacture and analytical control of medicinal products and their ingredients and for any corresponding uses in relation to medical devices; use in laboratory measurments for quality reasons and/or monitoring of releases.

It should also be noted that some exemptions were requested for uses in the aerospace and defence industry for safety critical applications (required to ensure product quality, reliability and safety).

One industry association suggested that hard chromium plating in appropriate installation should be given a generic exemption. The main basis for this request was that exposure in the workplace is low to non-existing, the general public is not exposed at all given that the end product is not containing any chromium VI component, only a chrome metal plating and there is no suitabble alternatives. The same industry association believes that for for hard chromation potassium chromate is to be seen as an intermediate as it is transformed during the production process and a general exemption for reported intermediate use in surface treatment was requested[10].

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

Information on the need to exempt PPORD from authorisation:

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

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

Other issues

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

3.7 ***SODIUM CHROMATE***

Justification for prioritisation – short summary

Sodium chromate is classified as carcinogenic, CLP category 1B (corresponding to the former category 2), mutagenic, CLP category 1B (corresponding to the former category 2) and as toxic for reproduction, CLP category 1B (corresponding to the former category 2). Sodium chromate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a), (b) and (c) of REACH.

Sodium chromate is used in low volumes. Potential for significant worker exposure at least in some processes cannot be excluded. As sodium chromate could be used to replace other hexavalent chromium compounds with similar uses it qualifies for prioritisation.

Priority setting

No Member State Competent Authority opposed the prioritisation of sodium chromate for inclusion in Annex XIV.

Three Member States and two NGOs supported the ECHA proposal.

Requests were received from the aerospace industry on delaying or deferring prioritisation based on low volumes and well controlled exposure, no alternatives

[10] Surface treatment is not recognised as an intermediate use according to ECHA's guidance on intermediates.

available despite intensive searches and the specific safety critical performance criteria applying to their industry. Other statements for not prioritising were socio-economic benefits and limited worker exposure.

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

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for sodium chromate

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

Extensions of application dates were requested based on the need to first find alternatives and on the need for more time to bring together different industry sectors.

One MSCA specifically supported the proposed transitional arrangements.

One NGO requested that the transitional arrangements be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date.

In its updated recommendation, dated November 25, 2011, ECHA proposed to amend the application date for sodium chromate from 18 months after EIF of the Regulation to 21 months. This new proposal takes into account the comments received during the public consultation and the fact that several of the comments appear to indicate that a longer latest application date than the standard 18 months is justified for the chromium compounds.

While MSC agrees to the general line of reasoning offered by ECHA in the updated draft recommendation the majority of members do not believe that the longer application dates suggested for the chromium compounds are sufficient to address the argumentation brought forward by several commenters in the public consultation. According to some MSC members, a longer period of time than suggested by ECHA before the application deadline would be warranted – e.g. an application date 48 months after entry into force of an updated Annex XIV might be more appropriate.

Proposed review period for certain uses

Proposals were received to set a 2 or 4 year review period without further justification.

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

Proposed exempted (categories) of uses

Exemptions were requested for the placing on the market or use as substance or in preparations for some specific aerospace manufacturing and maintenance applications, for the use as a corrosion inhibitor in carbon steel cooling systems, in absorption refrigerators based on no available alternatives, based on existing exemptions under two other EU legislations (RoHS and End of Life Vehicles), for automated processes and enclosed systems in surface treatment, as well as activities covered by the IED directive and for hard chromium plating (intermediate use claimed) and use for laboratory measurements for quality reasons and/or monitoring.

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

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for PPORD were suggested by ECHA.

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

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

Other issues

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

*3.8 **TRICHLOROETHYLENE***

Justification for prioritisation – short summary

Trichloroethylene is classified as carcinogenic, CLP category 1B (corresponding to the former category 2). Trichloroethylene was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) of REACH.

The substance is used in very high volume (> 10,000 t/y) for applications within the scope of authorisation and the use is spread over a large number of sites, with the potential for significant worker exposure. Based on this, trichloroethylene meets the criteria for prioritisation for inclusion in Annex XIV.

Priority Setting

Three MSCAs and two international NGOs expressed agreement with ECHA's draft prioritisation of trichloroethylene. Three manufacturers/importers also supported the prioritisation. One national NGO questioned the prioritisation as did several downstream users. No formally valid arguments against prioritisation were brought forward by the opposing commenters.

The arguments put forward against prioritisation included points such as low worker exposure due to closed/enclosed processes, that the substance is essential to many processes and is a critical substance in some safety applications such as in the aerospace industry, no suitable alternatives available, loss of employment in the EU etc.

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

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for trichloroethylene:

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

Two MSCAs agreed to the dates as proposed by ECHA. Two green NGOs proposed shortening of the transitional regimen while an European safety agency in the aviation area argued for delayed time points. Several downstream users ask for delayed application date/sunset dates to at least 30/48 months after EIF. The main reasons for requesting longer transitional arrangements are that no alternatives are currently

available and that the use of trichloroethylene is mandatory in manufacture and repair in e.g. the aerospace industry.

In its updated recommendation, dated November 25, 2011, ECHA proposed to amend the application date for trichloroethylene from 21 months after EIF of the Regulation to 18 months. This new proposal takes into account the comments received during the public consultation and the fact that no comments appear to indicate that a longer latest application date than the standard 18 months is justified for the substance.

MSC is in agreement with ECHA's updated recommendation and is of the opinion that the application date should be set 18 months after entry into force of the decision on the inclusion of trichloroethylene in Annex XIV and the sunset date should fall 18 months later.

Proposed review period for certain uses

No review period was suggested by ECHA. Some industry commenters suggested very long review periods once authorisation has been granted, e.g. for uses as surface cleaning/degreasing in closed systems for economical and practical reasons – closed systems are very expensive and long review periods are warranted for "adequate protection of investment".

MSC does not see any relevant arguments for setting upfront review periods in the Annex XIV entry for trichloroethylene.

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

Proposed exempted (categories) of uses

No exemptions of uses or categories of uses were proposed by ECHA. Lots of comments were received in the public consultation arguing for exemptions in several areas. Two opposing comments were received from two MSCAs in relation to the feasibility of the proposed exemptions for the use in surface cleaning/degreasing in closed systems. This issue is further discussed above, under heading *2. MSC Views on General Comments Received from Stakeholders, Proposed exempted (categories of) uses*.

Several individual enterprices as well as sector organisations argued for exemptions such as: Industrial use as *surface cleaning/degreasing* in closed systems (aerospace industry, all applications in aero-engine fuel systems - not restricted to closed processes, mechanical industry etc.), use in repair and cleaning agents for *rubber conveyor belts* in underground mining, use as *process solvent*, use in manufacture of pharmaceuticals and medicinal products, uses in relation to medical devices – in medical devices or in their manufacture, use as a solvent in manufacturing of PPO polymer (= poly-p-phenylene-oxide) hollow fibre gas separation membranes, uses as solvent of polymers in closed-loop systems, use for manufacture of polyethylene "separator sheets" for lead battery manufacture, use as a processing aid/solvent in closed systems, *asphalt analysis* (for extraction of bitumen to analyse ballast composition/quality), in *recycling* (argumentation: exempt from full registration requirements on the basis of Article 2(7)(d) of REACH. If authorisation of trichloroethylene was required for recycled products, recyclers would be duplicating this process).

The requests for exemption of the uses above were submitted mostly by downstream users. The main manufacturers/importers of trichloroethylene argued exclusively for an exemption of *Industrial use as surface cleaning/degreasing in closed systems.*

In MSC´s opinion none of the commenters provided adequate arguments to fulfil the provisions in REACH Art. 58(2) for an exemption to be feasible – EU minimum legislation, properly controlled use, etc.

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

Information on the need to exempt PPORD from the authorisation requirement

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

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

Other issues

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

3.9 COBALT (II) SULPHATE

Justification for prioritisation - short summary

Cobalt sulphate is classified as carcinogenic by inhalation, CLP category 1B (corresponding to the former category 2) and as toxic for reproduction, CLP category 1B (corresponding to the former category 2). Cobalt (II) sulphate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (c) of REACH.

The total volume manufactured/imported in the EU is in the range of 1,000 – 10,000 t/y according to the registration information; volume produced within EU (corrected for export) was declared in the same range by the Cobalt REACH consortium (CoRC).

Reported uses are the manufacture of chemicals (including other cobalt compounds, catalysts, organic textile dyes, pigment formulation and other active substances by wet chemical processes), of pigments & frits - ceramic ware - glass - varistors and magnets, of coatings and inks (as drier and pigments), of feed grade material and the use in surface treatment processes (plating and passivation) and as a water treatment chemical / oxygen scavenger / corrosion inhibitor.

The main uses appear to be intermediate. Volume related to uses considered in the scope of authorisation and taken into account for the prioritisation is estimated in the range 100-1000 t/y. The substance is used at a high number of industrial sites and by a large number of workers. Releases at workplaces appear to be controlled in most cases but significant worker exposure through inhalation cannot be excluded for some processes with high potential for emission involving powders, dusts, fumes, aerosols, mists etc. Consumer exposure is guessed possible especially through coated articles that may be sanded or ground. Uses are thus considered wide dispersive.

It has been reasonably assumed that other cobalt salts could replace cobalt sulphate and *vice versa* in some of its applications (the grouping approach applies).

Based on this, cobalt sulphate qualifies for prioritisation for inclusion in Annex XIV according to the view of the majority of MSC members[11].

Priority setting

[11] See the minority views expressed in Annex 1A and 1B

During the public consultation, no Member State Competent Authority submitted comments that opposed the prioritisation of cobalt sulphate for inclusion in Annex XIV. Four MSCAs and two NGOs expressed their support.

New uses have been described in the comments: drying agent in paints (as for printing inks), manufacturing of fertilizers, hardener and alloy metal in gold electrolytes, deposition of cobalt phosphorus coatings on metal surfaces, catalytic element for cobalt-based enzymes biochemical reactions in sewage treatment and biogas production plants, nutrient supply to microbial cultures in fermentation processes to produce biochemical substances. For these new uses no volumes have been specified.

Almost all comments received from industry representatives and individual companies challenge the prioritisation for inclusion in Annex XIV, especially the accuracy of the data used and the worst case scenario applied to each criterion. Updated data has been proposed by industry with respect to each of ECHA's prioritisation criterion and industry has requested ECHA to recalculate the scoring on this basis. Comments are very similar suggesting a common and organised approach to answer the public consultation. Most positions and data from comments are summarised and aggregated in a confidential document for cobalt sulphate from CoRC. Arguments put forward regarding the scoring include:

- the low total tonnage on the EU market;
- the low volume in the scope of authorisation (from <<1% up to 5% of the total tonnage according to the interpretation of the intermediate status) given that all uses are considered as intermediate by industry and exempted from authorisation requirements (including the manufacturing of other chemicals, 95% of the total tonnage) except the use as corrosion prevention;
- the low number of sites dealing with uses in the scope of authorisation (in the tens), compared to the total EU downstream facilities using the substance;
- the low number of workers exposed at these facilities in the scope of authorisation (not known) compared to the number of workers in downstream facilities using the substance;
- the reduced exposure by inhalation given that cobalt sulphate is supplied in either solid, usually crystalline form or as solution for most uses and that it is handled under closed and "tightly" controlled conditions because of existing occupational worker protection and environmental protection legislations, thereby minimizing or eliminating the risk; the irrelevancy to consider exposure data from companies outside EU; consumer exposure through ceramic wares and any other article is strongly denied.

Other arguments put forward against prioritisation include

- the importance of use of cobalt sulphate by some manufacturer/importer/users considered as critical because essential and highly efficient to many processes especially in the electronic sector, in the metal surface treatment and catalyst sector, including the gasoline refining industry,
- the severe consequence for the availability of this crucial raw material if listed in Annex XIV without exempted uses
- the reduced economical and environmental efficiency of catalysts without cobalt (higher pollutants SO_2 and NO_x emissions and higher energy consumption, that is not compliant with other EU legislations),
- the expected loss of employment in the EU as a result of relocation and/or companies shutdown, the distortion of competition with non European countries with same uses,
- the absence of alternatives in brass/zinc/zinc-nickel/zinc alloy surface treatment where cobalt is required in the end product (plating as metal, coatings as salts) and the very low volumes used compared to other metals; the efficiency of available cobalt free alternatives for passivation processes is either confirmed

either denied according to comments (depending of the final use indoor/outdoor and function);
- the use of cobalt salts as a recent alternative (Co-Cr[III], Co-tungsten, etc) to hexavalent chromium (and to cadmium compounds)

Note that some comments show that substitution of hexavalent chromium based passivation (using chromium trioxide) can now be achieved in 95% of the uses by a Cr(III)-Co process. The remaining 5% of uses that still need hexavalent chromium concerns the aerospace sector.

The inter-changeability principle between cobalt compounds is also strongly questioned. Even if cobalt compounds may be interchangeable to a certain extent (case by case) and even if common uses are identified in generic scenarios for several substances, a cobalt compound cannot be "simply" replaced by another one because of technical and economical reasons. No efficient interchange would be possible without development work and costs. Research has been conducted on interchanging cobalt salts in the production of textile dyes (using Co sulphate) without success. However cobalt sulphate may be replaced in certain processes (not specified) by cobalt oxide.

MSC agrees that some new information has been submitted during the public consultation that might slightly lower the scoring depending on the interpretation of the intermediate status of individual uses and the grading of wide-dispersiveness.

However, the majority of MSC members are of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of cobalt sulphate

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for cobalt sulphate:

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

One MSCA agreed to the proposed transitional arrangements. One NGO requested that the transitional arrangements be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date.

Many comments from industry were received requesting extensions to the transitional dates. The main reasons for requesting longer transitional arrangements are

- the time needed to prepare an application for authorisation regarding the complexity of requirements, of the supply chain and the drafting of a socioeconomic analysis (depending on the potential threshold mechanism of Co salts proposed by industry);
- the difficulty to mobilise companies in time in a common approach, especially small and medium size facilities (especially in the surface treatment sector) that do not have the capacity to handle regulatory requirements alone;
- the technical and economical difficulty to handle applications for chromium salts and cobalt salts in same uses at the same time;
- the lack of available alternatives and the time and investments needed to develop, agree and implement transition technologies.

Commenters have proposed 36 months as the latest application date and 48 months for the sunset date. Some others ask for six additional months or even ten additional years in order to achieve substitution first. One commenter suggested either to extent applications date or to allow specific exemptions.

In its updated recommendation, dated November 25, 2011, ECHA maintained its original proposal of transitional arrangements. Due account has been taken to the comments received during the public consultation and for the cobalt compounds, the application period originally suggested (24 months) is already six months longer than the standard and no further prolongation seems warranted.

MSC is in agreement with ECHA's updated recommendation and is of the opinion that the application date should be set 24 months after entry into force of the decision on the inclusion of cobalt sulphate in Annex XIV and the sunset date should fall 18 months later.

Proposed review period for certain uses

No review period was proposed by ECHA. Several companies and CoRC urged to not set review periods until suitable robust data are available from the supply/value chain.

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

Proposed exempted (categories) of uses

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

Many comments were received requesting exemptions for many different and specific uses[12] of cobalt sulphate in accordance with Article 58(2) of REACH. The main basis for the requests was that the substance is considered adequately controlled by existing measures in place in the workplace as regards worker protection and environmental protection.

In addition exemptions or "exception to the rules" were requested for

- uses in very small amounts,
- uses already covered by specific regulations and exempted from authorisation (manufacturing of feed grade material as an example),
- uses exempted from authorisation (R&D as catalyst, analytical reagent for routine analyses in laboratories),
- uses for which no alternatives are yet available (surface treatments, fermentation processes etc.),
- uses considered outside the scope of authorisation because of intermediate status (manufacturing of other chemicals).

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

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for PPORD were suggested by ECHA and no comment was received on this issue.

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

Other issues

[12] Surface treatments (plating and passivating activities, galvanic industry, operating bath to produce Co-W alloy, anticorrosion processes, bright cobalt alloy plating), fermentation processes, all aerospace applications, manufacturing of batteries, manufacturing of flat glass)

Cobalt has been identified as a critical raw material by the European Commission in 2010. Industry considers the prioritisation not to be in line with this European strategy.

The Member State Committee does not believe that this European Commission position would affect the prioritisation of cobalt compounds for authorisation and any inclusion of such substances in Annex XIV.

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

3.10 ***COBALT DICHLORIDE***

Justification for prioritisation – short summary

Cobalt dichloride is classified as carcinogenic by inhalation, CLP category 1B (corresponding to the former category 2) and as toxic for reproduction, CLP category 1B (corresponding to the former category 2). Cobalt dichloride was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (c) of REACH.

The use of the substance in the scope of authorisation is relatively low. The substance is used in a medium number of industrial settings and releases at workplaces can lead to significant exposure of industrial and professional workers. On the basis of the prioritisation criteria, the substance has a moderate priority.

As there are other cobalt (II) compounds on the candidate list which could be replaced by the substance in some of their uses cobalt dichloride should be grouped together with the other substances and included in Annex XIV according to the view of the majority of MSC members[13].

Priority Setting

During the public consultation, no Member State Competent Authority submitted comments that opposed the prioritisation of cobalt dichloride into Annex XIV but one MSCA requested more information about the possibility to interchange three substances of the Co-group (i.a. cobalt dichloride). Three other MSCAs specifically supported the proposal and two of them also agreed to the grouping approach for the cobalt substances. Two NGOs expressed their support for the prioritisation and one of them also supported the grouping approach. There was also one comment from industry confirming the inter-changeability of the Co(II) salts for metal surface passivation.

There were comments from industry, associations and individuals which challenged the need for prioritisation of cobalt dichloride as in their view all registered uses are effectively controlled and can be considered as safe.

Many comments from industry associations or individual companies also questioned the possibility to interchange the different candidate cobalt substances. It was stated, that a change of the process, even if chemically possible, would involve extensive costs. Industry claimed that – as the grouping approach was the core assumption for the prioritisation of cobalt dichloride and as this assumption is wrong - the prioritisation should be reconsidered.

[13] See the minority views expressed in Annex 1A & 1B

The majority of MSC members are of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of cobalt dichloride.

Transitional arrangements: application date and sunset date

For the public consultation ECHA proposed the following transitional arrangements for cobalt dichloride:

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

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

Industry claimed that the transitional periods were too short, e.g. because the socio-economic route of application has to be taken for cobalt dichloride as a non-threshold carcinogen, and such applications would need much time for complex supply chains.

Latest application dates between 36 and 60 month were claimed to be reasonable by industry. A common justification for prolonging of the transitional dated is the absence of alternatives.

In some cases industry seems not to have fully understood ECHA´s proposals for transitional arrangements.

In its updated recommendation, dated November 25, 2011, ECHA maintained its original proposal of transitional arrangements. Due account has been taken to the comments received during the public consultation and for the cobalt compounds, the application period originally suggested (24 months) is already six months longer than the standard and no further prolongation seems warranted.

The *MSC is in agreement* with ECHA's updated recommendation and is of the opinion that the application date should be set 24 months after entry into force of the decision on the inclusion of cobalt dichloride in Annex XIV and the sunset date should fall 18 months later.

Proposed review period for certain uses

No review period was suggested by ECHA.

There were some comments in favour of review periods but in other comments industry proposed not to suggest review periods because the supply chains are not yet fully understood.

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

Proposed exempted (categories) of uses

No exemptions of uses or categories of uses were proposed by ECHA.

Many comments were received requesting exemptions for many different (almost all) uses of cobalt dichloride. The justification for the request of an exemption was quite similar for the different uses - it was mainly stated that cobalt dichloride is regulated in the EU by various laws and regulations, the processes are well controlled and that there

is no risk. For some uses the argumentation for a request for exemption was that there are no alternatives at the moment.

There were also requests for exemption of uses potentially outside the scope of authorisation, like intermediate use, scientific R&D and use an analytical agent.

One MSCA and one NGO supported the recommendation not to exempt any uses from authorisation.

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

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for the PPORD were suggested by ECHA.

One company claimed for general exemption of all PPORD activity using cobalt dichloride arguing that (i) alternative technology has to use Co salts and the proposed regulation would hinder this, (ii) to reduce risks from SVHCs PPORD is necessary, (iii) personal´s exposure to PPORD is generally reduced as time of exposure is short and latest safety equipment is used.

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

Other issues

Cobalt has been identified as a critical raw material by the European Commission in 2010. Industry considers the prioritisation not in line with this European strategy.

The Member State Committee does not believe that this EC position would affect the prioritisation of cobalt compounds for authorisation and any inclusion of such substances in REACH Annex XIV.

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

3.11 COBALT (II) DINITRATE

Justification for prioritisation - short summary

Cobalt dinitrate is classified as carcinogenic by inhalation, CLP category 1B (corresponding to the former category 2) and as toxic for reproduction, CLP category 1B (corresponding to the former category 2). Cobalt dinitrate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (c) of REACH.

Total volume manufactured/imported in the EU is in the range of 1,000 – 10,000 t/y according to the registration information, whereas volume produced within EU (corrected for export) was estimated in the range of 100-1,000 t/y by the Cobalt Reach consortium (CoRC).

Reported uses are the manufacture of chemicals (including other cobalt compounds, catalysts, and other active substances by wet chemical processes), as catalyst (not confirmed), surface treatments (electro and non-electrodeposition, colour anodizing, welding and soldering processes) and water treatment chemical / oxygen scavenger / corrosion inhibitor.

Few uses (and their related volumes) are considered in the scope of authorisation, others being considered as intermediate. The related volume taken into consideration for the

prioritisation is in the range 10-100 t/y. Releases at workplace appear to be controlled in most cases but significant workers exposure through inhalation cannot be excluded for some applications (water treatment, weldering/soldering materials) and processes with high potential for emission involving powders, dusts, fumes, aerosols, mists etc.

It has been reasonably assumed that other cobalt salts could replace cobalt dinitrate and *vice versa* in some of its applications (the grouping approach applies).

Based on this, cobalt dinitrate qualifies for prioritisation for inclusion in Annex XIV according to the view of a majority of the MSC members[14].

Priority setting

During the public consultation, no Member State Competent Authority submitted comments that opposed the prioritisation of cobalt dinitrate for inclusion in Annex XIV. One however questioned the relevancy of the grouping approach. Three MS and two NGO expressed their support.

A new use with few quantities has been described in the nuclear sector where cobalt dinitrate is used as reagent by power plants laboratories to check the condition of fuel cladding.

Almost all comments received from industry representatives and individual companies challenge the prioritisation for inclusion in Annex XIV, especially the accuracy of data used and the worst case scenario applied to each criterion. Updated data has been shared with respect to each ECHA's prioritisation criterion and industry has requested ECHA to recalculate the scoring on this basis. Comments are very similar and point out a common and organized approach to answer the public consultation. Most positions and data from comments are summarized and aggregated in a confidential document from the CoRC.

Arguments put forward regarding the scoring include

- the lower total tonnage on the EU market (around 100-1000 t/y);
- the low volume considered in the scope of authorisation (from <1% up to 10% of the total tonnage according to the interpretation of the intermediate status for some uses; i.e. 1-10 t/y) given that most uses are considered as intermediate by industry and exempted from authorisation requirements (including the manufacturing of other chemicals, main use as non isolated or on-site isolated intermediate, 90% of the total tonnage) except use as oxygen scavenger / corrosion prevention;
- the use as catalyst itself is denied, cobalt dinitrate being used to manufacture catalysts;
- the expected low number of sites dealing with uses in the scope of authorisation (not known) compared to the total EU downstream facilities using the substance (1-10 without considering sites of surface treatment);
- the expected lower number of workers exposed at these facilities in the scope of authorisation (not known) compared to the number of workers in downstream facilities using the substance;
- no consumer exposure expected;
- the low exposure by inhalation given that cobalt dinitrate is supplied in either solid, usually crystalline form or as solution for most uses and that substance is handled under closed and "tightly" controlled conditions (effective control of

[14] See the minority views expressed in Annex 1A & 1B

exposure) because of existing occupational worker protection and environmental protection legislations, thereby minimizing or eliminating the risk.

Other arguments put forward against prioritisation include

- the importance of use of cobalt dinitrate by some manufacturer/importer/users considered as critical because essential, highly efficient to many processes and without alternative available yet especially in the electronic sector, the metal surface treatment and catalyst sector, including the gasoline refining industry;
- the severe consequence for the availability of this crucial raw material (if listed in Annex XIV without exempted uses);
- the reduced economical and environmental efficiency of catalysts without cobalt (higher pollutants SO_2 and NO_x emissions and higher energy consumption, that is not compliant with other EU legislations);
- the absence of alternative in surface treatment where cobalt is required in the end product (plating as metal, coatings as salts) and the very volumes used compared to other metals; the efficiency of available cobalt free alternatives for passivation processes is either confirmed either denied according to comments (depending of the final use indoor/outdoor and function);
- the use of cobalt salts as a recent alternative (Co-Cr[III], Co-tungsten, etc) to hexavalent chromium (and to cadmium compounds).

The interchangeability principle between cobalt compounds is also strongly questioned: even if cobalt compounds may be interchangeable to a certain extent (case by case) and even if common uses are identified in generic scenarios for several substances, a cobalt compound cannot be "simply" replaced by another one because of technical and economical reasons. No efficient interchangeability would be possible without development work and costs. Even if used in similar industrial sectors and similar ways, cobalt dinitrate and cobalt carbonate are not interchangeable in catalyst production because of different processes and equipments. The use of cobalt dinitrate requires an additional step of denitrifying.

MSC agrees that some new information was submitted during the public consultation that might slightly lower the scoring depending on the interpretation of the intermediate status of individual uses and the grading of wide-dispersiveness.

However, the majority of MSC members are of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of cobalt dinitrate.

Transitional arrangements: application date and sunset date

For the public consultation, ECHA proposed the following transitional arrangements for cobalt dinitrate:

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

One MSCA agreed the proposed transitional arrangements. One NGO requested that the transitional arrangements be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date.

Many comments from industry were received requesting extensions to the transitional dates. The main reasons for requesting longer transitional arrangements are

- the time needed to prepare an application for authorisation regarding the complexity of the requirements, of the supply chain and the drafting of a

socioeconomic analysis (depending on the potential threshold mechanism of Co salts proposed by industry);
- the difficulty to mobilize in time companies in a common approach, especially small and medium facilities (especially in the surface treatment sector) that do not have the capacity to handle regulatory requirements alone;
- the lack of available alternatives and the time and investments needed to develop, agree and implement transition technologies.

Commenters have proposed 36 months as the latest application date and 48 months for the sunset date. Some others asked for six additional months or even ten additional years in order to achieve substitution first.

In its updated recommendation, dated November 25, 2011, ECHA maintained its original proposal of transitional arrangements. Due account has been taken to the comments received during the public consultation and for the cobalt compounds, the application period originally suggested (24 months) is already six months longer than the standard and no further prolongation seems warranted.

MSC is in agreement with ECHA's updated recommendation and is of the opinion that the application date should be set 24 months after entry into force of the decision on the inclusion of cobalt dinitrate in Annex XIV and the sunset date should fall 18 months later.

Proposed review period for certain uses

No review period was proposed by ECHA. Two companies specified two specific uses in the "review period" part of the public consultation without justification and explanation, but possibly confused with exemption requests. Several companies and CoRC urged to not set review periods until suitable robust data are available from the supply/value chain.

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

Proposed exempted (categories) of uses

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

Many comments were received requesting exemptions for many different and specific uses[15] of cobalt dinitrate in accordance with Article 58(2) of REACH. The main basis for the requests was that the substance is considered adequately controlled by existing measures in place in the workplace as regards worker protection and environmental protection. In this context, exemptions were requested for automated and enclosed processes in surface treatment and activities covered by IED directive (Directive on industrial emissions 2010/75/EU).

In addition exemptions or "exception to the rules" were requested for

- uses in very small amounts,
- uses where cobalt salts replace hexavalent chromium,
- uses already covered by specific regulations and exempted from authorisation,
- uses exempted from authorisation (R&D as catalyst, analytical reagent for secure routine analytics in laboratories, fundamental research, manufacture and control of medicinal products and devices),
- uses for which no alternatives are yet available,

[15] Surface treatments (plating and passivating/galvanic activities, anticorrosion processes, bright cobalt alloy plating), all aerospace applications, manufacturing of batteries, R&D

- uses considered by industry outside the scope of authorisation because of the intermediate status.

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

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for the PPORD were suggested by ECHA. No comment was received on this item.

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

Other issues

Cobalt has been identified as a critical raw material by the European Commission in 2010. Industry considers the prioritisation not in line with this European strategy.

The Member State Committee does not believe that this European Commission position would affect the prioritisation of cobalt compounds for authorisation and any inclusion of such substances in Annex XIV.

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

3.12 COBALT (II) CARBONATE

Justification for prioritisation - short summary

Cobalt carbonate is classified as carcinogenic by inhalation, CLP category 1B (corresponding to the former category 2) and as toxic for reproduction, CLP category 1B (corresponding to the former category 2). Cobalt carbonate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (c) of REACH.

The total volume manufactured/imported in the EU is in the range of 1,000 – 10,000 t/y according to the registration information; volume produced within EU (corrected for export) was declared in the same range by the Cobalt REACH consortium (CoRC).

Reported uses are the manufacture of chemicals (including catalysts and other active substances by wet chemical processes), of pigments (colorant in ceramic applications) & frits - ceramic ware - glass - varistors and magnets, of feed grade material, of fertilizers and the use in surface treatment processes (electrodeposition, colour anodizing, non-electrodeposition, welding and soldering processes).

Few uses (and their related volumes) are considered in the scope of authorisation, others being considered as intermediate. The related volume taken into account for prioritisation is estimated in the range 10-100 t/y. The substance is considered used at presumably medium number of downstream user sites.

Release at workplaces is not known. Significant workers exposure through inhalation cannot be excluded for some processes with high potential for emission through powders, dusts, fumes, aerosols, mists etc. Professional applications using powders are particularly of concern. Environmental release from mixtures (e.g. fertilizers) may in most instances be low but possibly widespread.

It has been reasonably assumed that other cobalt salts could replace cobalt carbonate and *vice versa* in some of its applications (the grouping approach applies).

Based on this, cobalt carbonate qualifies for prioritisation for inclusion in Annex XIV according to the view of the majority of MSC members[16].

Priority setting

During the public consultation, no Member State Competent Authority submitted comments that opposed the prioritisation of cobalt carbonate for inclusion in Annex XIV. One however questioned the relevancy of the grouping approach. Three MS and one NGO expressed their support.

A new use has been described in the exemption part of the comments: catalytic element for cobalt-based enzymes biochemical reactions in agricultural manure treatment but without volume specified.

Almost all comments received from industry representatives and individual companies challenge the prioritisation for inclusion in Annex XIV, especially the accuracy of data used and the worst case scenario applied to each criterion. Updated data has been proposed by industry with respect to each ECHA's prioritisation criterion and industry has requested ECHA to recalculate the scoring on this basis. Comments are very similar and point out a common and organized approach to answer the public consultation. Most positions and data from comments are summarized and aggregated in a confidential document from CoRC.

Arguments put forward regarding the scoring include

- the low total tonnage on the EU market;
- the low volume considered in the scope of authorisation (manufacture of fertilizers and feed grade materials, 5% of the total tonnage) given that all other uses are considered intermediate and exempted from authorisation requirements (including the manufacturing of other chemicals-catalysts-pigments, main use as non isolated or on-site isolated intermediate, 95% of the total tonnage);
- the low number of sites dealing with the only use in the scope of authorisation, compared to the total EU downstream facilities using the substance,
- the low number of workers exposed at these facilities in the scope of authorisation compared to the number of workers in downstream facilities using the substance;
- no consumer exposure expected;
- occupational exposure concentrations that are reported do not correspond to cobalt carbonate but refers to cobalt metal, oxides and several other salts; updated exposure scenarios shared in the registration dossiers underline that exposure is well controlled and risk managed;
- the substance is handled under closed and "tightly" controlled conditions (effective control of exposure) because of existing occupational worker protection and environmental protection legislations, thereby minimizing or eliminating the risk; the irrelevancy to consider exposure data from companies outside EU.

Other arguments put forward against prioritisation include

[16] See the minority views in Annex 1A & 1B

- the importance of use of cobalt carbonate by some manufacturer/importer/users considered as critical because essential and highly efficient to many processes especially in the catalyst industry and the petrochemical industry;
- the severe consequence for the availability of this crucial raw material (if listed in Annex XIV without exempted uses);
- the reduced economical and environmental efficiency of catalysts without cobalt (higher pollutants SO_2 and NO_x emissions, higher energy consumption);
- high development costs for alternatives with a loss of performance and less socio-economical benefit of end-products;
- the lack of efficient alternatives in surface treatment where cobalt is required in the end product (plating as metal, coatings as salts) and the low volumes used compared to other metals; the efficiency of available cobalt free alternatives for passivation processes is either confirmed either denied according to comments (depending of the final use indoor/outdoor, the expected efficiency and functions);
- alternatives may be identified but are not yet ready: the adsorption properties of cobalt containing catalysts is related to the electronic structure of cobalt; close elements to cobalt in the periodic table may be considered as alternatives; such replacements are under investigation but costs are expected higher; for the current use as catalyst, industry concludes that few socio-economically viable alternative exist;
- in the automotive sector, the use of cobalt salts as a recent alternative (Co-Cr[III], Co-tungsten, etc) to hexavalent chromium (and to cadmium compounds).

The inter-changeability principle between cobalt compounds is also strongly questioned: even if cobalt compounds may be interchangeable to a certain extent (case by case, see infra) and even if common uses are identified in generic scenarios for several substances, a cobalt compound cannot be "simply" replaced by another one because of technical and economical reasons. Cobalt carbonate, acetate and hydroxide are interchangeable to a certain extent in some processes for the manufacture of chemicals (not specified) but cobalt dinitrate, chloride and sulphate are not interchangeable. Even if cobalt carbonate and cobalt dinitrate are used in sections of the catalyst industry, they are not interchangeable without changing the whole production process. Within the manufacture of catalysts, cobalt carbonate is transformed to an oxide (the active species) without leaving a residual anion, that isn't possible with another cobalt salts (dinitrate, chloride, sulphate: anions reduce the catalyst activity). Another key characteristic of cobalt carbonate is the management of its soluble or insoluble state in aqueous solution depending on the pH.

MSC agrees that some new information has been submitted during the public consultation that might slightly lower the scoring depending on the interpretation of the intermediate status of individual uses and the grading of wide-dispersiveness.

However, the majority of MSC members are of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of cobalt carbonate.

Transitional arrangements: application date and sunset date

For the public consultation, ECHA proposed the following transitional arrangements for cobalt carbonate:

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

One MSCA agreed the proposed transitional arrangements. One NGO requested that the transitional arrangements be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date.

Many comments were received requesting extensions to the transitional dates. The main reasons for requesting longer transitional arrangements are

- the time needed to prepare an application for authorisation regarding the complexity of the requirements, of the supply chain and the drafting of a socioeconomic analysis (depending on potential threshold mechanism of Co salts proposed by industry);
- the difficulty to mobilize in time companies in a common approach, especially small and medium facilities (especially in the surface treatment sector) that do not have the capacity to handle regulatory requirements alone;
- the lack of available alternatives and the time and investments needed to develop, agree and implement transition technologies.

Commenters have proposed 36 months as the latest application date and 48 months for the sunset date. One other asked for six additional months. One commenter suggested a postponement without specifying any delay.

In its updated recommendation, dated November 25, 2011, ECHA maintained its original proposal of transitional arrangements. Due account has been taken to the comments received during the public consultation and for the cobalt compounds, the application period originally suggested (24 months) is already six months longer than the standard and no further prolongation seems warranted.

MSC is in agreement with ECHA's updated recommendation and is of the opinion that the application date should be set 24 months after entry into force of the decision on the inclusion of cobalt carbonate in Annex XIV and the sunset date should fall 18 months later.

Proposed review period for certain uses

No review period was proposed by ECHA. One company specified a specific use in the "review period" part of the public consultation without justification and explanation, but possibly confused with exemption request. Several companies and CoRC urged to not set review periods until suitable robust data are available from the supply/value chain.

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

Proposed exempted (categories) of uses

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

Many comments were received requesting exemptions for many different and specific uses[17] of cobalt carbonate in accordance with Article 58(2) of REACH. The main basis for the requests was that the substance is considered adequately controlled by existing measures in place in the workplace as regards worker protection and environmental protection.

In addition exemptions or "exception to the rules" were requested for

- uses in very small amounts,
- uses already covered by specific regulations and exempted from authorisation (manufacturing of feed grade material as an example),

[17] Surface treatments (plating and passivating / galvanic activities, anticorrosion processes, decorative and bright cobalt alloy plating), manure treatment, automotive and aerospace applications.

- uses for which no alternatives are yet available (surface treatments, fermentation processes, etc),
- uses considered outside the scope of authorisation because of the intermediate status (i.e. manufacturing of other chemicals).

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

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for PPORD were suggested by ECHA. No comment was received on this item.

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

Other issues

Cobalt has been identified as a critical raw material by the European Commission in 2010. Industry considers the prioritisation not in line with this European strategy.

The Member State Committee does not believe that this EC position would affect the prioritisation of cobalt compounds for authorisation and any inclusion of such substances in Annex XIV.

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

3.13 COBALT (II) DIACETATE

Justification for prioritisation - short summary

Cobalt diacetate is classified as carcinogenic by inhalation, CLP category 1B (corresponding to the former category 2) and as toxic for reproduction, CLP category 1B (corresponding to the former category 2). Cobalt diacetate was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) and (c) of REACH.

The total volume manufactured/imported in the EU is in the range of 1,000 – 10,000 t/y according to the registration information, whereas volume produced within EU (corrected for export) was declared below 1,000 t/y by the Cobalt REACH consortium (CoRC).

Reported uses are the manufacture of chemicals, of pigments & frits, ceramic ware, glass, of TPA (terephtalic acid) as catalyst, of plastics and/or PET, of feed grade material and the use in surface treatment processes and rubber adhesion.

Except the manufacture of other chemicals, most uses (and their related high volumes) are considered in the scope of authorisation being non-intermediate uses. The volume taken into consideration for prioritisation is 1,000 – 10,000 t/y. The substance is used at a high number of sites by an expected high number of workers. The manufacture of chemicals (including catalysts) and pigments and the manufacture of feed grade material are considered as intermediate and outside the scope of authorisation respectively. Releases are expected controlled in most cases but significant exposure by inhalation may occur for some scenarios through powders, dusts, fumes, aerosols, mists etc.

It has been reasonably assumed that other cobalt salts could replace cobalt diacetate and *vice versa* in some of its applications (the grouping approach applies).

Based on this, cobalt diacetate qualifies for prioritisation for inclusion in Annex XIV according to the view of the majority of MSC members[18].

Priority setting

During the public consultation, no Member State Competent Authority submitted comments that opposed the prioritisation of cobalt diacetate for inclusion in Annex XIV. Four MSCAs and one NGO expressed their support.

A new use as catalytic element for cobalt-based enzymes biochemical reactions in the sector of waste treatment has been reported without volume specified.

Almost all comments received from industry representatives and individual companies challenge the prioritisation for inclusion in Annex XIV, especially the accuracy of data used and the worst case scenario applied to each criterion. Updated data has been proposed by industry with respect to each ECHA's prioritisation criterion and industry has requested ECHA to recalculate the scoring on this basis. Comments are very similar and point out a common and organized approach to answer the public consultation. Most positions and data from comments are summarized and aggregated in a confidential document from CoRC.

Arguments put forward regarding the scoring include

- the lower total tonnage on the EU market (less than 1,000 t/y);
- the low volume in the scope of authorisation (5% of 1000 t/y, i.e. 50 t/y) given that the main use as catalyst in the manufacture of other chemicals (70-80%), even if considered as non-intermediate, is "expected to be exempt from authorisation under a specific exemption" (according to industry); most other uses are either considered as intermediate and exempted from authorisation (10%), either not covered by REACh (feed grade material, 1%) either being phased out (pigment in PET bottles, 10%);
- the low number of total EU downstream facilities using the substance (and even the lower number regarding uses in the scope of authorisation),
- the low number of workers exposed at these facilities;
- the low exposure by inhalation given that major use handles the substance as a liquid (70-80%, the remaining 20-30% being as a powder) under closed and "tightly" controlled conditions thereby minimizing or eliminating the risk; consumer exposure through ceramic wares is strongly denied.

Other arguments put forward against prioritisation include

- the importance of use of cobalt diacetate by some manufacturer/importer/users considered as critical because essential to many processes, including the electronic sector, the metal surface finishing sector and the refining industry,
- the severe commercial consequences and the possible loss of employment in the EU as a result of relocation and/or companies shutdown,
- the absence of viable/suitable alternatives in the use as catalyst for PET manufacture and in the PTA industry,
- the absence of alternative in surface treatment where cobalt (as metal) is required in the end product (passivation processes may be covered by cobalt-free alternatives) and the very volumes used compared to other metals,
- the use of cobalt salts as a recent alternative to hexavalent chromium compounds.

[18] See the minority views expressed in Annexes 1A & 1B

The interchangeability principle between cobalt compounds is also strongly questioned: even if cobalt compounds may be interchangeable to a certain extent and even if common uses are identified in generic scenarios for several substances, a cobalt compound cannot be "simply" replaced by another one because of technical and economical reasons. No efficient interchangeability would be possible without development work and costs. More specifically, the use of cobalt acetate as catalyst appears to be very specific and essential in the processes.

MSC agrees that some new information has been submitted during the public consultation that might slightly lower the scoring depending on the interpretation of the intermediate status of individual uses and the grading of wide-dispersiveness.

However, the majority of MSC members are of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of cobalt diacetate.

Transitional arrangements: application date and sunset date

For the public consultation, ECHA proposed the following transitional arrangements for cobalt diacetate:

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

One MSCA agreed the proposed transitional arrangements. One NGO requested that the transitional arrangements be shortened to 12 months after entry into force for the application date, and 30 months after entry into force for the sunset date.

Many comments were received requesting extensions to the transitional dates. The main reasons for requesting longer transitional arrangements are

- the time needed to prepare an application for authorisation regarding the complexity of the supply chain and the drafting of a socioeconomic analysis if the potential threshold mechanism of Co salts proposed by industry is not agreed;
- the difficulty to mobilize in time companies in a common approach, especially small and medium facilities (especially in the surface treatment sector) that do not have the capacity to handle regulatory requirements alone;
- the technical and economical difficulty to handle applications for chromium salts and cobalt salts in same uses at the same times;
- the lack of available alternatives and the time and investments needed to develop, agree and implement transition technologies

Commenters have proposed 36 months as the latest application date and 48 months for the sunset date. Some others asked for six additional months.

In its updated recommendation, dated November 25, 2011, ECHA maintained its original proposal of transitional arrangements. Due account has been taken to the comments received during the public consultation and for the cobalt compounds, the application period originally suggested (24 months) is already six months longer than the standard and no further prolongation seems warranted.

MSC is in agreement with ECHA's updated recommendation and is of the opinion that the application date should be set 24 months after entry into force of the decision on the inclusion of cobalt diacetate in Annex XIV and the sunset date should fall 18 months later.

Proposed review period for certain uses

No review period was proposed by ECHA. Three companies urged to not set review periods until suitable robust data are available from the supply/value chain.

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

Proposed exempted (categories) of uses

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

Many comments were received requesting exemptions for many different and specific uses of cobalt diacetate in accordance with Article 58(2) of REACH. The main basis for the requests was that the substance is considered adequately controlled by existing measures in place in the workplace as regards worker protection and environmental protection.

In addition exemptions were requested for

- uses already covered by specific regulations and exempted from authorisation (manufacturing of feed grade material),
- uses exempted from authorisation (R&D, analytical reagent for secure routine analytics in laboratories),
- uses for which no alternatives are yet available (purposes of corrosion protection, decorative and bright cobalt alloy plating),
- uses considered outside the scope of authorisation because of the intermediate status (manufacturing of other chemicals).

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

Information on the need to exempt PPORD from the authorisation requirement

No exemptions for PPORD were suggested by ECHA. One company asked for a PPORD exemption without specifying the use and the content.

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

Other issues

Cobalt has been identified as a critical raw material by the European Commission in 2010. Industry considers the prioritisation not in line with this European strategy.

The Member State Committee does not believe that this European Commission position would affect the prioritisation of cobalt compounds for authorisation and any inclusion of such substances in Annex XIV.

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

Annex 3

3rd Draft Recommendation of Priority Substances to be Included in Annex XIV of the REACH Regulation

(List of Substances Subject to Authorisation)

25 November 2011

Information on how the draft Annex XIV entries have been set and may be modified on the basis of comments received during the public consultation is provided in the document *"Preparation of draft Annex XIV entries for the third Recommendation of substances to be included in Annex XIV - General Approach",* which is available at ECHA's website.

Draft Annex XIV entries									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties[#]	Latest application date pursuant to Art. 58 (1) (c) (ii) [@]	Sunset date	Review periods	Exempted (categories of) uses	Exemptions for PPORD
1	**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
3	**Acids generated from chromium trioxide and their oligomers** Group containing: Chromic acid Dichromic acid Oligomers of chromic	 231-801-5 236-881-5 not yet	 7738-94-5 13530-68-2	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None

Draft Annex XIV entries									
#	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties**[#]	**Latest application date pursuant to Art. 58 (1) (c) (ii)** [@]	**Sunset date**	**Review periods**	**Exempted (categories of) uses**	**Exemptions for PPORD**
	acid and dichromic acid	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
5	**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
6	**Ammonium dichromate**	232-143-1	7789-09-5	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
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
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
9	**Cobalt(II) sulphate**	233-334-2	10124-43-3	Art. 57 (a) & (c); Carcinogen 1B;	Date of inclusion in Annex XIV plus 24	Latest application date	None	None	None

Draft Annex XIV entries									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties[#]	Latest application date pursuant to Art. 58 (1) (c) (ii) [@]	Sunset date	Review periods	Exempted (categories of) uses	Exemptions for PPORD
				Toxic for reproduction 1B	months [3)]	plus 18 months			
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
11	**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
13	**Cobalt(II) diacetate**	200-755-8	71-48-7	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

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.

@ In the draft version of the 3rd recommendation subjected to public consultation ECHA used the standard latest application date (LAD) of 18 months from the inclusion of substances to Annex XIV as a starting point. The dates for the groups of substances were spread over 6 months only to distribute the workload of RAC, SEAC and ECHA secretariat, and eventually the Commission, more evenly.

Taking account of the comments received, the structure of the supply chain for Trichloroethylene appears to be less complicated than for the Cobalt and Chromium compounds. Therefore, the standard period of 18 months appears to be sufficient and is suggested for the latest application date of Trichloroethylene.

Although the evidence provided in the comments does not allow an assessment against the criteria (given in the general approach document for the 1st recommendation and listed by Members and Stakeholder oberservers in MSC20), several factors put forward in the comments, when evaluated in their entirety, appear to indicate that a longer LAD (e.g. 21 months) than the standard (18 months) would be justified to consider for the Chromium compounds.

As regards the Cobalt compounds, the LAD suggested (24 months) is already 6 months longer than the standard and no further prolongation deemed necessary.

1) Assumed 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

2) Assumed 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

3) Assumed 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