20 December 2011

Responses to Comments Document (RCOM) on ECHA's Draft 3rd Recommendation for the Group of recommended Cobalt(II) Substances

	Substance	EC Number
I	Cobalt(II) sulphate	233-334-2
II	Cobalt dichloride	231-589-4
III	Cobalt(II) dinitrate	233-402-1
IV	Cobalt(II) carbonate	208-169-4
V	Cobalt(II) diacetate	200-755-8

This document provides ECHA's responses to comments received during the public consultation on the draft 3rd Recommendation for inclusion of substances in Annex XIV of REACH.

PUBLIC VERSION

CONTENT

About this response to comments document (RCOM)

This RCOM document is substance group specific. It provides ECHA's responses to the comments received during public consultation on its draft recommendation, to include the cobalt(II) compounds named on page 1 of this document in Annex XIV of the REACH Regulation.

Because

- - many of the comments address the same or similar issues and
- the comments provided and/or the issues raised most often do not refer to a particular substance but mainly are relevant for the entire group of compounds,

this RCOM provides responses to the specific issues raised in the comments but not to the individual comments.

The issues that were raised in the comments received have been assigned to 6 thematic blocks (tables) as follows:

A – COMMENTS ON SUBSTANCE IDENTIFICATION & INTRINSIC PROPERTIES
B – COMMENTS ON ECHA'S PRIORITISATION APPROACH, APPLICATION OF PRIORITISATION CRITERIA AND ASSIGNED SCORES
C – COMMENTS ON LATEST APPLICATION DATES, SUNSET DATES AND REVIEW PERIODS
D – COMMENTS ON USES / REQUESTS FOR EXEMPTIONS
E – EXEMPTION REQUESTS WITH REFERENCE TO EXISTING EU LEGISLATION
F – MISCELLANEOUS

In these tables, beside ECHA's responses, summaries of the issue addressed by a group of comments are given ("Issue(s) addressed" column) and examples of comments addressing this issue provided. Hence the "examples" column only provides some representative examples but no exhaustive list of all comments received on that issue. The comments/responses are numbered (first column - #) in order to allow cross-referencing.

In addition to this Response to Comments table (RCOM), which addresses all five Cobalt compounds included in ECHA's 3rd recommendation, on ECHA's website there is available for each substance i) a table containing all individual comments received (as far as not confidential) and ii) a zip-file including all attachments to the individual comments (as far as not confidential). To view these substance specific comments and information, please go to the specific site hosting ECHA's 3rd Recommendation at:
http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/3rd-recommendation

Scroll down to the "View Substances" section. In this section you find a table listing all thirteen substances included in the 3rd Recommendation. For each substance you have a link to this RCOM and to "Details" (button in the right column), which includes substance specific comments and attachements.

Click the button “Details” to open a new substance specific page. On this new page scroll down to the “Substance details” section. There, you find the comments and attachements received for the substance in the subsection “other Info”.

The numbers (e.g. #1234) provided in the “Comment examples” column will in the final version of this RCOM allow to retrace in the Annex the original comments from which the examples are taken.

A –Comments on Substance identification & Intrinsic Properties:

#	Issue(s) addressed	Comment example(s)	Response
AA1	**Comments on threshold mechanism**	Cobalt(II) carbonate #1719, 1827 The data in the registration dossier and updates to be submitted by the end of this year indicate that cobalt carbonate is non genotoxic in vivo, suggesting a threshold mode of action. Guideline compliant studies indicate it may not be genotoxic in vivo. No reports of carcinogenicity and genotoxicity associated with cobalt ingestion have been reported in humans or in animals. The Cobalt REACH Consortium has provided ECHA with information regarding a potential concentration threshold of cobalt salts for eliciting cancer effects. A conclusion has not yet been reached by the Risk Assessment Committee which reflects the current understanding of the hazards associated with cobalt carbonate.	Thank you for your comment. The question as to whether the carcinogenic effects of the cobalt substances are elicited by a mechanism for which it is possible to determine a no-effect threshold is an important issue, as only for substances fulfilling the criteria of Article 57 (a, b, c or f) for which it is possible to determine an effects threshold an authorisation can be granted on the basis of adequate control of risks. However ECHA does not assess at this stage of the authorisation process (i.e. recommendation for inclusion in Annex XIV) whether on the basis of the available scientific evidence it can be concluded that a no-effect level for the carcinogenic effects of the cobalt substances exists. This is an issue to be addressed in the authorisation applications and be scrutinised by the Risk Assessment Committee when preparing its opinions on the authorisation applications.
AA2	**Comment on intrinsic properties**	Cobalt(II) diacetate, # 830 Important remarks disputing the SVHC classification […] The sensitization and the toxicity in the case of repeated administration are not dealt with although indications about the toxicity vis-à-vis the immune system or chronic effects would have been important. Although it is always claimed that the anhydrous form of salts and the hydrated form of salts behave the same and with that, the same classification is justifiable, one can see that with in vitro mutagenicity, both substance forms have different characteristics (See p. 29). This alone already questions/challenges the conclusion by analogy. Human data that is specific to Cobalt Diacetate and its hydrates is not available!	Thank you for your comment. Your point in regard to the hazardous inherent properties of cobalt(II) diacetate is not relevant for this part of the authorisation process, as the identification of the substance (and its hydrates) as Substance of Very High Concern has already been agreed by the Member State Committee, based on the harmonised classification in force for this substance and listed in Annex VI of the CLP-Regulation (Regulation (EC) No 1272/2008). According to Article 37(6) of the CLP Regulation manufactures, importers and downstream users who have new information which may lead to a change of the harmonized classification and labelling elements of a substance in Annex VI shall submit a proposal […] to the competent authority in one of the member states in which the substance is placed on the market. The MSCA will then decide if it is appropriate to prepare a CLH dossier and submit it to the Agency in order to review/revise the existing

#	Issue(s) addressed	Comment example(s)	Response
		[…] The test results support our opinion that the cobalt salts show a different chemical and physical-chemical behavior and therefore we have to expect a different behavior in living processes, as shown in the results of the testing for cancer, germ cell mutagenicity or reproductive toxicology. Therefore read across from Cobalt Sulfate to Cobalt Diacetate is impossible. And the results of the testing of Cobalt Sulfate cannot be the basis for the classification of Cobalt Diacetate.	harmonised classification.

B – Comments on ECHA's Prioritisation Approach, application of Prioritisation Criteria and assigned Scores

During consultation on ECHA's 3rd draft Recommendation of substances to be included in Annex XIV numerous comments have been received, in particular from industry organisations such as the Cobalt Reach Consortium (CoRC) and the Cobalt Development Institute that the priority scoring of the cobalt substances included in ECHA's draft Recommendation is flawed, because allegedly wrong volumes of the substances have been considered or because the wide dispersivenes of the uses has not assessed properly. ECHA has carefully assessed these comments and in the following a short report on the outcome of this assessment is provided.

B1 Cobalt salts - Comments regarding volumes and uses in the scope of authorisation, and the associated priority score

The estimation of volumes in the scope of authorisation for priority setting relied on data from the registration dossiers as provided in section 3.2 of the IUCLID dossiers and/or in the CSRs, along with information (especially on allocation of tonnage to uses) submitted during public consultation on SVHC identification of the cobalt salts, already presented in the Annex XV reports, or provided by industry during MSC consultation on the prioritisation in April/May. In this exercise, the definition of intermediates as set out in Article 3(15) of the REACH Regulation and further elaborated in the 'Definition of Intermediates as agreed by Commission, Member States and ECHA'.[1] was used to assess on the basis of available use descriptions (in the registrations incl. CSRs, the Annex XV SVHC reports and information received in consultation) whether the identified uses are in the scope of authorisation.

During the public consultation on the draft recommendation, industry provided again information on the currently used annual volumes of the cobalt salts and their allocation to the uses, and argued on the intermediate status of some of the uses considered by ECHA to be in the scope of authorisation. Industry considers that the cobalt compounds used in surface treatment and in the use registered as "manufacture of inorganic pigments & frits, glass, ceramic ware, varistors and magnets (calcination/sintering processes)" are intermediates whereas according to ECHA's assessment, based on available information, uses in surface treatment processes, as well as several applications in the context of the manufacture / production of inorganic pigments & frits etc. area appear to be in the scope of authorisation. It is stressed that this assessment is done only for prioritisation purpose and it does not conclude or define the status of the use under the REACH Regulation. In general, in this prioritisation phase of the Authorisation process a conservative approach is taken in cases where clear conclusion on the intermediate (or other exemption) status is not possible on the basis of available data.

[1] Appendix 4 to the Guidance on Intermediates, version 2, December 2010: http://www.echa.europa.eu/documents/10162/17224/intermediates_en.pdf

On the basis of the new data provided by industry, and considering that surface treatment normally should be covered by the authorisation requirement, the ***scoring calculated initially for the volumes of cobalt(II) sulphate and cobalt dichloride in the scope of authorisation remains the same***. However, an update of the "volume" scoring appears to be justified for cobalt(II) diacetate and potentially also for cobalt dinitrate and cobalt(II) carbonate for the reasons outlined in the following. With regard to cobalt dinitrate and cobalt(II) carbonate it should however be noted that there is uncertainty associated with the scores as the acutal volumes, according to the available data, are close to the lower (in case of Co-dinitrate) or higher (Co-carbonate) borders of the scored tonnage ranges.

Cobalt(II) diacetate
For priority setting, volumes in the scope of authorisation were considered to be in the range 1,000 – 10,000 t/y. This was based on data on volumes from the registration dossiers and ECHA's assessment of the use descriptions.

New more detailed information provided by CoRC on tonnages allocated to the different uses and on export suggests that due to significant exports for cobalt(II) diacetate the tonnage in the scope of authorisation is in the range 100 – 1,000 t/y. This results in a change of the "Volume" score from originally 7 to now 5.

Cobalt(II) dinitrate
For prioritiy setting, volumes of cobalt dinitrate in the scope of authorisation were considered to be in the range 10 – 100 t/y. This was based on data on volumes from the registration dossiers and ECHA's assessment of the use descriptions, as well as on approximate allocation of tonnage per use provided by CoRC.

New more detailed information provided by CoRC on tonnages allocated to the different uses indicates that the volume of cobalt dinitrate allocated to uses in the scope of authorisation is rather in the range of 100 - 1,000 t/y (towards the lower end). This results in a change of the "Volume" score from originally 3 to now 5.

Cobalt(II) carbonate
For prioritiy setting, volumes of cobalt carbonate in the scope of authorisation were considered to be in the range 10 – 100 t/y. This was based on data on volumes from the registration dossiers and ECHA's assessment of the use descriptions, as well as on approximate allocation of tonnage per use provided by CoRC.

New more detailed information provided by CoRC on uses indicates that the volume of cobalt carbonate allocated to uses in the scope of authorisation is rather in the range of 1 -10 t/y (towards the upper end). This results in a change of the "Volume" score from originally 3 to now 1.

B2 Cobalt salts - Comments on wide dispersiveness of uses (number of sites and exposure / release potential), and the associated priority score

As laid down in section 3.1 b) of ECHA's document describing the applied prioritisation approach[2], several qualitative and (semi) quantitative parameters are being considered to assess whether a use can be considered wide dispersive. For scoring, the information available is integrated in the two parameters '#-Sites' and 'Release', which respectively stand for the 'number of point sources or number of sites from which a substance is potentially released' and the 'potential for releases to the environment, for worker exposure and for consumer exposure in all steps of the life-cycle'.
For CMR substances the focus of the use assessment is on human health aspects, i.e. mainly the potential for exposure of workers and of consumers. For consumers it has been agreed that consumer use can be considered as wide-dispersive if it can be reasonably assumed that this use results in non-negligible releases. Professional use can be wide dispersive as well if it takes place at many sites and is carried out by many workers and if it cannot be excluded that releases are not negligible. In this context use of a carcinogenic compound at 100 or more industrial sites is considered a high number and an indication for widespread use.

#-Sites
ECHA estimated uses in the scope of authorisation to occur at a medium to high number of sites, depending on the specific Co(II) substance. ECHA based its assessment on the information / estimations provided by industry (CoRC) on industrial sites per use as well as on some assumptions on supply chain structure considering all available information on uses regarded to be in the scope of authorisation. Industry claimed during the public consultation that the Co(II) substances in the scope of authorisation are only used at a small to medium number of industrial sites. It is noted, however, that IND considers some more uses than ECHA, *inter alia* surface treatment, as uses of the cobalt subsances as intermediates.

As mentioned, ECHA regards surface treatment uses as uses in the scope of authorisation and has considereded this use and the structure of the respective industry sector for estimating per substance the number of sites at which uses in the scope of authorisation may be carried out. ***Taking away challenges on the #sites on the basis of this intermediate status interpretation, the scoring calculated for the #-sites for cobalt(II) carbonate, cobatt(II) dinitrate, and cobalt dichloride (i.e. 2, medium) was otherwise agreed by industry.*** Claims were though made to lower the score for cobalt(II) diacetate and cobalt(II) sulphate from high (3) to medium (2) #-sites.

As regards cobalt(II) sulphate, the number of industrial sites for uses originally provided by CoRC and considered by ECHA to be in the scope of authorisation summed up to above 100, although the number of sites had been provided merged with some intermediate uses for confidentiality reasons. New, more specific data/estimations provided during public consultation sum up below 100 sites for uses in the

[2] http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf

scope of authorisation, although for some of those uses no information on sites has been provided by industry. On the basis of all information available there is relatively high uncertainty on the #-sites at which surface treatment is carried out, as explained below.

According to CoRC, cobalt(II) substances are used for surface treatment in small quantities and in highly specialised applications at some 10s of sites. However, other industry organisations stated that cobalt compounds are widely used by SMEs in many surface treatment processes and that these applications are becoming increasingly important. For example, as regards passivation of zinc or zinc alloy plating with Co(II) compounds, more than 3 billion pieces p.a. alone in Germany are treated for the automotive industry. Therefore, extrapolating on the European scale, there is uncertainty as to whether surface treatment in such dimensions could take place at less than 100 sites (not taken into account formulator sites and other uses in the scope of authorisation). The amounts of the Co(II) substances used for surface treatment seem to be as well high, given the claimed specialty of the surface treatment uses and the relatively small amounts of cobalt needed per treated object. ***Therefore, in view of the information and evidence available ECHA considers to maintain its original scoring for the number of sites (> 100, score 3) for cobalt(II) sulphate.***

Regarding cobalt(II) diacetate, CoRC provided during public consultation new information on the tonnage allocated to the different uses and associated number of sites, which in total has been indicated to be below 100 (20 - 75). As apparently the use as catalyst is by far the main use for cobalt diacetate and surface treatment only amounts to approximately 5% of the volume in the scope of authorisation (whereas for other Co-substances surface treatment is the use where most of the volume is allocated to[3]), the number of sites where the acetate salt is used may indeed be lower than originally assumed and remain below 100. **Therefore, *ECHA considers that decreasing the score (i.e. from 3 to 2) for #-sites may be justified in the case of cobalt diacetate. However, high uncertainty regarding the #-sites and the correct scoring remains.***

It should be noted that, in contrast to the comments received during public consultation on the number of sites where cobalt salts are used in surface treatment processes, the Cobalt Reach Consortium, in a communication to the 21st meeting of the Member State Committee[4], reported that there are many more facilities than expected (potentially thousands) involved in surface treatment with cobalt salt (mainly passivation treatment). CoRC further commented that use for passivation treatment is declining due to the availability of cobalt free alternatives and therefore the total number of sites is expected to decrease in the next years.

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[3] The volume of cobalt diacetate used for surface treatment amounts to approximately 25% - 30% of the volumes of Co-sulfate and Co-dinitrate used for surface treatment.

[4] Cobalt REACH Consortium, Summary information: Cobalt Salts and Inter-changability, ECHA/MSC-21/040/Room document. https://circabc.europa.eu/d/d/workspace/SpacesStore/a4957da8-73ac-4e0b-9a07-333a437c6636/AP08%20and%2009%20Room%20doc_Summary%20Information%20-%20Cobalt%20Salts%20%20Interchangeability.pdf (Only accessible for Members of the CIRCABC Member State Committee interest group)

Release
CoRC and other industry organisations commented during public consultation that risks are controlled and that identification of a few cases having a potential for high exposure does not justify the classification as wide dispersive use.

It is stressed that the aim of the authorisation process is not only to ensure that risks from SVHC substances are properly controlled, but also that these substances are progressively replaced by suitable alternatives where these are technically and economically viable. Furthermore, the control of the risks related to a particular use should be documented by the applicants and consequently evaluated by the Risk Assessment Committee when preparing its opinion on the application and taken into account by the Commission in the final decision making on the application. Consequently, the prioritisation step in the authorisation process does not comprise an assessment of the exposure or risks arising from the particular uses of a substance (at specific installations/sites), but is rather intended to provide a very basic and general evaluation of the use pattern and exposure potential a substance may have (mainly for workers and consumers in the case of CMR).

The inclusion in Annex XIV is per substance and not per use (or installation). Therefore screening of release potential in the prioritisation phase does not assess the exposure levels from single uses (at specific sites), but aims to deduce whether there are uses/situations where exposure may potentially not be controlled. The use and user specific conditions can be reflected in the authorisation application and they will be taken into account by ECHA's Committees when developing their opinions on the applications and by the Commission when taking the final decisions. Therefore, ECHA's conclusion that some of the uses of the Co(II) substances, in particular in surface treatment, appear to have a potential for significant worker exposure[5] - in combination with a scoring of 3 - is in line with the agreed prioritisation approach (although exposure to workers might be controlled in many instances – which needs to be documented in the applications for authorisation).
In conclusion, in view of the information and evidence available ECHA considers to maintain its original scoring of release potential (3) for all assessed cobalt(II) salts.

[5] 'Significant' here refers to the description given in the scoring part of the General approach document (section 2.2.2. b): "Significant means non-negligible releases in relation to the likelihood that these releases could cause environmental or health effects"
In the surface treatment use descriptions provided in the registrations there are process steps listed with potential for emissions and exposure.

Overview on the priority scoring of the 5 cobalt salts before and after considering the information received during public consultation on the 3rd Recommendation.

	Co-diacetate	Co-sulphate	Co-dinitrate	Co-dichloride	Co-carbonate
Original prioritisation					
Properties	**0 - 1**	**0 - 1**	**0 - 1**	**0 - 1**	**0 - 1**
Volume	**7**	**5**	**3**	**3**	**3**
#-Sites	**3**	**3**	**2**	**2**	**2**
Release	**3**	**3**	**3**	**3**	**3**
Overall score	**16 - 17**	**14 - 15**	**9 - 10**	**9 - 10**	**9 - 10**
Revised prioritisation					
Properties	**0 - 1**	**0 - 1**	**0 - 1**	**0 - 1**	**0 - 1**
Volume	**5**	**5**	**5**	**3**	**1**
#-Sites	**2 - 3**	**3**	**2**	**2**	**2**
Release	**3**	**3**	**3**	**3**	**3**
Overall score	**11 - 15**	**14 - 15**	**11 - 12**	**9 - 10**	**7 - 8**

TABLE B: Comments on ECHA's Prioritisation Approach, application of Prioritisation Criteria and assigned Scores

#	Issue(s) addressed	Comment example(s)	Response
BB1	**Disagreement with ECHA's interpretation of intermediates**	Cobalt(II) sulphate, #1231 The use of Cobalt(II) salts by the plating industry should be regarded as an intermediate in accordance with the definition of Article 3(15) of REACH. ECHA's interpretation of the concept of 'intermediate' (as given in its June 2010 clarification document) excludes substances used as surface treatments, e.g. Cobalt(II) salts used in metal finishing. However, the conclusion reached in the clarification document of June 2010 cannot be supported. The abovementioned clarification document was reviewed by two independent legal experts at the request of Industry. In Cefic's position paper of December 2010, the followed was reported. Both legal advisory statements conclude that the interpretations for intermediates as elaborated in the [clarification] document go far beyond the Article 3 (15) of the REACH Regulation and therefore the concept of intermediates was narrowed tremendously by ECHA, Commission and the Member States. That position was subsequently endorsed by Cefic itself (see December 2010 document) and supported in a number of recent petitions made by Industry associations, such as AIAS and the Institute of Metal Finishing.	Thank you for your comment. In assessing the priority of substances in the Candidate List ECHA uses the definition of intermediates as defined in Art. 3(15) of REACH and further elaborated in the 'Definition of Intermediates as agreed by Commission, Member States and ECHA'.6. One obligation arising from inclusion of a substance in Annex XIV is the responsibility of actors to assess whether their uses of the substance are in the scope of authorisation (e.g. whether the use fulfils the definition of an intermediate as set out in Art. 3(15) of REACH) and to keep all relevant documentation supporting their respective conclusion. This information may be requested by any competent authority of the Member State in which he is established or by the Agency. Non compliance with the requirements of REACH may result in enforcement actions by the competent authority of the Member State in which the actor is established.
BB2	**Suggestion that substance doesn't fulfil the prioritisation criteria, but no specific justification provided as to why the criteria are not fulfilled.**		Thank you for your comment. The prioritisation approach applied by ECHA was discussed with the Member State Committee and has been agreed by this Committee and it has been followed by ECHA for prioritising the substances now included in the draft 3rd Recommendation of substances to be included in Annex XIV. Please refer to the description of the prioritisation approach (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf) and the justification provided for your substance in the report on the results obtained (http://echa.europa.eu/documents/10162/17232/prioritisation_results_3rd_rec_en.pdf) for more details on the priority of your substance. See also

[6] Appendix 4 to the Guidance on Intermediates, version 2, December 2010: http://www.echa.europa.eu/documents/10162/17224/intermediates_en.pdf

#	Issue(s) addressed	Comment example(s)	Response
			above our response B1 'Cobalt salts - Comments regarding volumes and uses in the scope of authorisation, and the associated priority score'.
BB3	**Disagreement with the prioritisation approach applied**	Cobalt(II) carbonate, #1114 Comment on the applied approach of prioritization Article 58 paragraph 3 of the REACH regulation defines 3 criteria for the substances to be prioritized for inclusion in Annex XIV: (a) PBT or vPvB properties or (b) Wide dispersive use or (c) High volumes. To (a) None of the proposed Cobalt salts has PBT or vPvB properties. ECHA uses a scoring system for the determination of substances for prioritization of SVHC for inclusion in the List of Substances Subject for Authorization taking into account the aforementioned 3 criteria. The weighting of the single scoring results is as follows: - PBT or vPvB properties: 18% - Wide dispersive use: 41% - Volumes: 41%. There is no justification for this weighting based on the REACH regulation. Following ECHA's explanation for the weighting, the substances on the Candidate List are a defined as a selection of substances with very severe hazard properties. However the European Commission chose to highlight PBT and vPvB properties over e.g. CMR properties in the REACH regulation	Thank you for your comment. The prioritisation approach applied by ECHA was discussed with the Member State Committee and has been agreed by this Committee. Article 58(3) indeed requires to take the mentioned 3 criteria 'normally' into account, but there is no provision how this should be done, e.g. with respect to evaluating, weighting or scoring of the criteria. Moreover, consideration of further aspects and criteria for priority setting is not excluded. Hence, it can be assumed that Article 58(3) leaves discretion regarding the development and design of a prioritisation approach that in the end provides the Candidate Substances for which the recommendation to include them in Annex XIV is relevant (both in terms of potential risk and regulatory effectiveness). It is noted that all priority setting approaches are conventions on how to systematically use the information available on the chosen or given prioritisation criteria (i.e. how to weight and combine the criteria in qualitative and/or quantitative terms). These conventions can be science based with regard to the selection and combination of relevant criteria. To draw overall conclusions there is a need to integrate complex bits of all relevant kinds of information. Therefore the assignment of weighting factors and scores remains to be done by expert judgement. In case of the applied prioritisation approach this has been done in discussion with the MSC. The currently used prioritisation approach requires the application of two methods, a scoring method and the so called verbal-argumentative method. Whereas the outcome of the scoring method is expressed in quantitative terms (scores) the verbal argumentative method provides rather a more qualitative valuation. However, although the result of the scoring method is expressed in quantitative terms, it should be considered that the information basis (and the data requirements) for both the scoring method and the verbal-argumentative method are the same and that the assignment of scores bears the same uncertainties regarding the reliability

#	Issue(s) addressed	Comment example(s)	Response
		(e.g. Art. 58, para. 3) as risks of first mentioned substances are deemed to be higher. Keeping this in mind the weighting should be equal throughout the 3 criteria as otherwise the hazard (PBT and vPvB) properties would be underestimated against the volume and the wide dispersive use. To (b) 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'. In the Technical Guidance Document for Risk Assessment of new and existing substances and biocides (2003, Chapter 5) this term is defined as follows: 'Wide-dispersive use refers to activities which deliver uncontrolled exposure. Examples relevant for occupational exposure: Painting with paints; spraying of pesticides. Examples relevant for environmental/consumer exposure: Use of detergents, cosmetics, disinfectants, household paints.' In addition, the ECETOC Report No. 93 on Targeted Risk Assessment (Appendix B) states: 'A substance marketed for wide-dispersive use is likely to reach consumers, and it can be assumed that such a substance will be emitted into the environment for 100% during or after use.' Definitions above do clearly not apply for the use of cobalt containing solutions in industrial application. Such applications are strictly controlled equipment-technology-wise, personnel-training-wise, safety-wise and personnel-safety wise respectively. Furthermore strict requirements apply for waste water and exhaust air cleaning technology. Consequently the use is absolutely not comparable with "sources like traffic", "painting with uncontrolled exposure" or (outdoor) "spraying of pesticides". In contrary to the definition of ECETOC Report No. 93 the substance never reach consumers and exposure to environment	of the data and a similar level of subjectivity as the verbal conclusions drawn with the verbal-argumentative method. This means that although the results are expressed in numbers the outcome of the scoring method is not necessarily more precise or correct than an argumentative verbal conclusion. The scoring of the inherent properties considers that priority shall normally be given to substances with PBT or vPvB properties as substances with PBT/vPvB properties are indeed scored higher than substances with CMR properties. With regard to the weighting of the 3 criteria 'inherent properties', 'volume' and 'wide dispersive use' it should be considered that the substances on the Candidate List are already a selection of substances with very severe hazard properties and that for a prioritisation that is intended to consider the potential risks arising from the uses of a substance not too much weight can again be given to these hazard properties. Therefore, the relative maximum weight of the 'inherent properties' criterion has been set to approximately 50% of the weights of the 'volume' and 'wide dispersive use' criteria (i.e. 18:41:41 %). Further increasing the weight for the 'PBT/vPvB-inherent properties' criterion towards equity with the other criteria would result in an unjustified, mainly hazard driven high ranking of PBT/vPvB substances although the risk arising from such substances may potentially be low because of low volumes used and low releases. In ECHA's document describing the prioritisation approach applied, explicit reference is made to the definitions of wide dispersive use in Chapter R.16 of the Guidance on information requirements and chemical safety assessment, the TGD for new and existing substances and biocides (2003) and the ECETOC Report No 93. These definitions have been considered in determining which parameters to assess in order to conclude on the potential wide dispersiveness of a use. As laid down in section 3.1 b) of ECHA's document a lot of qualitative and (semi) quantitative parameters are being considered to assess whether a use can be considered wide dispersive. Parameters are, for example, number and size of sites, form of the substance on the market, potential for releases in different steps of its

#	Issue(s) addressed	Comment example(s)	Response
		is minimal as a result of aforementioned measures. ECHA disregards the given definitions of wide dispersive use and postulates that this criterion can be regarded as directly driven by the number of sites. ECHA defines already a number of 100 sites in Europe where cobalt salts are used as "high" (maximum scoring = 3). The "Guidance on Information Requirements and Chemical Safety Assessment" gives traffic as an example for "many small point sources" with 240 million point sources in total. […] In addition the approach of ECHA disregards the fact that the number if sites is not relevant for exposure of workers but the number of workers in contact with the concerned substance. For surface treatment application in industrial settings the number of persons working near the process solutions is very low. It can be estimated by 1-2 persons per site for automated systems and 4-5 persons per site for non-automated systems.	lifecycle, potential for occupational and consumer exposure and information on operational conditions and risk management measures. For scoring, the information available is integrated in the two parameters 'Site-#' and 'Release', which respectively stand for the 'number of point sources or number of sites from which a substance is potentially released' and the 'potential for releases to the environment, for worker exposure and for consumer exposure in all steps of the life-cycle'. For CMR substances the focus of the use assessment is on human health aspects, i.e. mainly the potential for exposure of workers and of consumers. For consumers it has been agreed that consumer use can be considered as wide-dispersive if it can be reasonably assumed that this use results in non-negligible releases. Professional use can be wide dispersive as well if it takes place at many sites and is carried out by many workers and if it cannot be excluded that releases are negligible. In this context we consider use of a carcinogenic compound at 100 or more industrial sites indeed as a high number and an indication for widespread use. In the case of the use of Co(II) compounds for example in surface treatment, consumer exposure to Co(II) seems to be no issue, but there appears to be a potential for significant worker exposure, as in use descriptions provided in the registrations there are process steps listed with potential for emissions and exposure. Based on this and in line with the agreed approach some of the uses have a potential for significant[7] worker exposure. Note that the agreed prioritisation approach is not intended to assess the risks exerted by particular applications of a substance at particular sites (in particular Member States) but to provide a very basic and general assessment of the use pattern and exposure potential a substance may have for humans (workers, consumers) or/and the environment. By doing so a precautionary approach needs to be taken and in particular uses/situations be considered in which risks may potentially not be controlled. Therefore the conclusion that some of the uses appear to have a potential for significant worker exposure in combination with a scoring of 3 is in accordance with the agreed approach although exposure to workers

[7] In the given context 'significant' means non-negligible releases in relation to the likelihood that these releases could cause adverse effects (focus on health effects in the case of CMR substances and on environmental effects in the case of PBT/vPvB substances).

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			may be controlled in many instances.
BB4	**The information used in support of the prioritisation is not up to date** **/ Information from the registrations was not taken into account**	Cobalt(II) carbonate, #536 In the registration dossier more recent exposure data are provided, this should be analysed instead of relying on published information only that may be already out of date. Releases and occupational exposure data of the catalyst industry are available and were considered in the registration dossier and CSR. According to this assessment the exposures are well controlled and would not constitute a relevant risk for humans and the environment.	For the purpose of priority setting we have taken all information that was available to us into account. In particular, this was information from the registration dossiers including the CSRs, the Annex XV reports and from the comments received during public consultation on the SVHC identification of the substances. Further, for some substances consultation of industry regarding their market volumes, uses, potential releases/exposure and alternatives have been commissioned by ECHA. In addition, comments by industry associations that have been submitted during MSC discussion of the prioritisation have been carefully considered. Nevertheless, as it is stated in the Background Documents of the individual Co(II) substances, information comprising confidential comments submitted during public consultation, or relating to content of Registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, was provided in a confidential annex to these documents. On the other hand, in the public Background Documents, reference for example to previous comments of the Cobalt REACH Consortium, which refer to Exposure Scenarios in the Registration Dossiers, were also present, reflecting such confidential information. ECHA often cannot provide more precise information as this information is confidential. New information provided during the public consultation on ECHA's 3rd Recommendation of substances to be included in Annex XIV will also be considered for inclusion in the background documents, if relevant, and according to its confidentiality status.
BB5	**Disproportionate regulation is being applied to the catalyst use compared to an intermediate**	Cobalt(II) diacetate, # 865 Given that the major use of cobalt diacetate (70-80%) is as a catalyst for the manufacture of PTA, IPA and DMT, that less than 500 tonnes/a are used in this application, that the powder	We note that the use of cobalt(II) diacetate as catalyst is the main use of this substance in the scope of authorisation. There are however further identified uses of this substance in the scope of authorisation for which a potential for widespread use and significant worker exposure (≈ wide-dispersive use as defined in the prioritisation approach) has been identified on the basis of the available information (e.g. registration dossiers and

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	substance handled under the same strictly controlled conditions	form is not handled and that these operations are carried out under strictly controlled conditions, cobalt diacetate is clearly NOT a high volume dispersive use substance as proposed by ECHA. This use does not give rise to any significant level of occupational exposure in our experience. It is noted that in this catalyst application the substance is handled in the same manner as an intermediate under strictly controlled conditions but because it is a catalyst use and does not meet the REACH definition of an intermediate it is not exempt from authorisation as an intermediate would be. This suggests that disproportionate regulation is being applied to this catalyst use compared to an intermediate substance handled under the same strictly controlled conditions.	information submitted by the cobalt industry on volumes and uses of the substance). Note that inclusion in Annex XIV is per substance and not per use. Therefore, a precautionary approach needs to be taken and in particular uses/situations be considered in which risks may potentially not be controlled. Therefore, ECHA's conclusion that some of the uses of the Co-compounds, in particular in surface treatment, appear to have a potential for widespread and significant worker exposure is in line with the agreed prioritisation approach (although exposure to workers might be controlled in other uses in most instances).
BB6	**Comments on the content / format of the Background Documents in releation to information relevant for prioritisation.**	Cobalt(II) sulphate, #721 Data on tonnages from registration information presented in the consultation document indicates a volume range of 1 000 – 10 000 t/y manufactured/imported into the EU. Although it is mentioned that volumes reported by the CoRC are in the same range it would be correct to indicate that the CoRC volumes (corrected for export) actually are less than a third of the maximum range 10 000 t/y (i.e. less than 3 300 t/y). In addition this section may give the impression that the mentioned volume (or volume range 1 000 -10 000 t/y) is expected to fall within the scope of Authorisation. It is our understanding that volumes subjected to authorization should be indicated in this section. This would give the public an overview of the tonnages and help them to take part in the public consultation	Thank you for your comment. Please note that the volume ranges are provided for confidentiality reasons. Tonnage information was submitted by CoRC as confidential. In such cases, ECHA uses tonnage bands for referring to the volumes, unless it has specific information from the submitter on a non-confidential range that can be used for publication. We agree that information provided in the Background Documents could benefit from narrow ranges and therefore we encourage submitters of confidential information to provide, for reasons of transparency, also a non-confidential version of their information. Information on the volume assumed to be in the scope of authorisation is provided in the document containing the results of the applied prioritisation approach for the substances in the Candidate List (http://echa.europa.eu/documents/10162/17232/prioritisation_results_3rd_rec_en.pdf), as well as in brief in the "Prioritisation" section of the Background Documents. The Background Document intends to give also an overview on identified uses of the substance. The section you mention refers clearly to "the volume manufactured / imported in the EU". Nevertheless, we'll endeavour to reflect more clearly to which uses the

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		Cobalt(II) sulphate, #643 It is critical for the integrity of the Prioritisation process that assumptions used for value judgments on wide dispersive use, non-intermediate status, etc. in the supporting document MUST be based on data, and not the absence of data, as seems to be the case here. [...] The lack of detailed information in the documentation is exemplified by the widespread use of "appear to be", "seem to be", etc. prefacing the key statements about tonnages, uses, and what is in, and what is out, of the scope of Authorisation. Given the very significant economic impact on companies and employees of a decision to place substances on Annex XIV, we would strongly recommend that more time is taken to improve the quality of the data used to make the Prioritisation determination for this substance, particularly at this time of economic hardship across Europe. This important decision must be based on facts and not speculation. Cobalt(II) carbonate, #641 We are concerned that the credibility of the REACH and Authorisation process could be put at risk by decisions taken on incomplete and, in some cases, misleading information. Political expediency is no substitute for good, data based, decision-making particularly where people's livelihood is at risk. Cobalt(II) carbonate, #1205 « No data available »: we would like to recall that other community legislation exists. For example the French regulation N° 2001-97 lays down specific rules for the prevention of carcinogenic, mutagenic or toxic for reproduction (CMR regulation) risks for any use of CMR products. Also suspected CMR are under other regulatory requirements (Regulation 2003-1254 of 23 December 2003 on the prevention of chemical risks). In Europe, all the activities related to the use of CMR compounds must follow EEC regulations since 1998 : Directive 98/24/CE then in 2004 Directive 2004/37/CE. In France, these texts were enforced by the French authority DRIRE, which has	given ranges in the different sections of the Background Documents refer to. ECHA assesses all the available information for applying its prioritisation approach. In this context, information collected during the development of the Annex XV Dossier, from the Registration Dossiers incl. the CSRs and data submitted during the public consultations is taken into account and summarised in the Background Document, in case the substance is included in ECHA's recommendation. Nonetheless, ECHA often cannot provide more precise information e.g. on tonnages or on uses as this information is confidential or because there is diverging information available, which requires to express uncertainties in the text. Furthermore, the purpose of the recommendation process is not to conclude whether the identified uses are in the scope of authorisation but to assess the priority of substances in the Candidate List for inclusion into Annex XIV on the basis of the agreed prioritisation approach and the available data. Same response as just above.

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		now become DREAL, and is in charge of REACH enforcement as well. Cobalt(II)sulphate, #798 2.2.2.3 Geographical distribution and conclusions in terms of (organisation and communication in) supply chains Since this part of background is crucial to the scoring on cobalt sulphate priority to be authorised, the presentation of supply chains must be made clear and more precise. This description seems like there is no actual data where this is based. And the data here does not take into account the uses that will fall into the scope of authorisation, it merely looks on the all uses and sites. Therefore this paragraph should only contain the sites per uses that are likely to fall in to the scope of Authorisation. Any other data should be removed.	Please note that the specific section refers to the "Existing specific Community legislation relevant for possible exemption". Therefore, national legislation, or community legislation that does not fulfil the requirements of Art. 58(2) of REACH, or legislation on the basis of which generic exemptions from the authorisation requirement have been included in the REACH Regulation, are not to be listed in this section of the Background Document. With respect to the assessment as to whether Community legislation referred to in the comments requesting exemptions is regarded to fulfil the requirements of Art. 58(2) please see the responses in table E. Please note that only information on the sites involved in uses in the scope of authorisation is used in the context of prioritisation - but no information on the organisation and communication in the supply chains. Information on the supply chains of the uses in the scope of authorisation may be used for determining the latest application dates for a substance. The section on 'geographical distribution and conclusions in terms of supply chains' is intended to provide an overview on the available information on the structure of the supply chains of all uses. To populate this section, ECHA considers all available relevant information, e.g. from the registrations, the Annex XV dossiers, from comments received during public consultation and, where relevant, from reports prepared by consultants at the request of ECHA on market volumes, uses, releases and alternatives for a substance. The latter reports again consider and reflect largely information provided by industry.

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			Nonetheless, it will be considered to improve the clarity of this section.
BB7	**Comments on grouping / interchangeability (cobalt salts)**	➢ **CoRC and other IND organisations claim that interchange between the 5 cobalt salts in their specific applications is not possible due to either technical or economical reasons** ➢ **A MSCA has asked ECHA to provide evidence that the Co salts are compatible to justify / support their grouping**	Grouping of chemically and in terms of their hazard potential similar substances is an important strategy to prevent evasion of the authorisation requirement *(by replacing one Co-salt on Annex XIV by another one not on this Annex)*. Therefore, a precautionary approach is necessary to prevent loopholes. If it is technically possible that a particular substance can replace any of the other substances of the group in any of their uses the grouping is used. It is in practice impossible and not necessary to provide positive evidence for the compatibility of the substances in all their particular uses as this would require knowledge about all the concrete processes and possible alternative processes, which appears impossible to achieve and not necessary at this stage of the authorisation process. In order to challenge the grouping concept in case of the 5 cobalt salts in question, it is therefore deemed more appropriate that IND would document that it is technically not possible to replace a particular substance in any of its uses by another substance of the group. Complementary, it would as well be necessary to demonstrate that the substance in question cannot replace any other substance of the group in any of its uses.
BB8	**Further information on tonnages, sites, uses, exposure, alternatives**		Thank you for the provided information, which will be considered for updating the Background Document as necessary.
BB9	**Some uses listed in the Background Document are not specific to this cobalt salt / Information on further uses / Details on uses**	Cobalt(II) carbonate, #641 Many of the uses listed in the document are not specific to cobalt carbonate, and relate to applications of other cobalt chemicals, and even cobalt metal and alloys (welding/soldering). This is inaccurate and misleading,	Thank you for your comment. For the purpose of priority setting we have taken all information that was available to us into account. In particular, this was information from the registration dossiers including the CSRs, the Annex XV reports and from the comments received during public consultation on the SVHC identification of the substances. Further, for some substances consultation of industry regarding their market volumes, uses, potential releases/exposure and alternatives have been commissioned by ECHA. In

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		especially where these uses are then stated to be related to high exposures and wide dispersive use. These statements are then inappropriately reflected in the ranking score for these criteria. Only uses of the compound in question should be considered in the Prioritisation process in line with the legislation.	addition, comments by industry associations that have been submitted during MSC discussion of the prioritisation have been carefully considered. In case information was already available that there is uncertainty regarding the actual use of a specific cobalt salt for a particular application, those uncertainties were already reflected in the Background Documents for consultation, including the respective references. New information provided during the public consultation on ECHA's 3rd Recommendation of substances to be included in Annex XIV will be considered for inclusion in the background documents, if relevant. In this context, uses in welding/soldering, which indeed seem to be uses of cobalt metal and alloys, will accordingly not be considered for the finalisation of ECHA's Recommendation.
BB10	**Mainly used as intermediate, therefore no regulatory effectiveness of inclusion into Annex XIV.**	Cobalt(II) sulphate, #967 An authorisation requirement for these substances will not prevent their use, as it is our understanding that they are widely used as intermediates in various industries as is the case in the battery industry, but will surely hamper the production of mixtures in the EU. […] In order to allow the future production of mixtures used by the battery industry in Europe, we therefore recommend that Cobalt (II) dinitrate and Cobalt (II) sulphate should not be included under Annex XIV of the REACH Regulation. […] We believe it is critical for the security of supply of the European battery industry to ensure that production capacity of the substances we use remains operational in Europe. Cobalt(II) carbonate, #536 Although the use of Cobalt carbonate as intermediate for the manufacture of other cobalt compounds in the catalyst industry is exempted from authorisation, a listing in Annex XIV could have serious consequences for the availability of this crucial raw material and the subsequent availability of cobalt containing catalysts in the EU and worldwide. This possible consequence should be considered carefully before the final	Thank you for your comment. As you correctly state, uses of a substance as intermediate in the scope of Article 3(15) of the REACH Regulation are exempted from authorisation whereas formulation of mixtures is not. Formulation of mixtures containing cobalt salts will in the future, i.e. after the sunset date, still be possible provided that an authorisation is applied for and granted.

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		decision on inclusion of Cobalt carbonate in Annex XIV.	
BB11	**Identified as a critical raw material by the European Commission, therefore no regulatory effectiveness of inclusion into Annex XIV.**	Cobalt(II) carbonate, #1047 The socio-economic impact of the authorization is clearly underestimated. First of all, we are confused of the diverging signals given, taken into account that cobalt was identified as a critical raw material within the Raw Materials Initiative of the European Commission linked to the economic importance in different future technologies such as batteries, combating air pollution. In this report the substitution potential is described as: "Substitutes for cobalt are constantly being sought mainly because of the metal price volatility. However, due to the unique properties of cobalt, there are limited options for substitution and ***almost all substitutes result in reduced product performance***." This seems a conflicting signal with this proposal to prioritize cobalt salts for authorization and thus affecting even further the long term availability for cobalt salts.	Thank you for your comment. Although the substance is of high economic importance and apparently difficult to substitute in a range of its uses, it is also carcinogenic and toxic for reproduction. Hence there is as well a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses. Taking account of these conflicting areas, authorisation appears to be an appropriate risk management measure. It does not restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are properly controlled or that there are no alternatives available and the socio-economic benefits are outweighing the risks arising from the uses. Concomitantly, the obligation to apply for authorisation is a strong incentive (or duty) to search for and develop suitable alternatives, which is also one of the recommendations given in the referred to Commission report.
BB12	**No risk for cancer from oral exposure of man via ENV, based on estimated exposure and health effects / Co essential for human body**	Cobalt(II) carbonate, #474 I advice you to read the position of your Canadian colleagues (at http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=8E18277B-1, after a complete and serious study, confirmed that: "There are limited health effects data on the chronic effects of oral exposure to cobalt; however, there is no evidence in the available short-term and subchronic studies that would indicate cancer as a potential endpoint following oral exposure. and concluded that "On the basis of the adequacy of the margins between upper-bounding estimates of exposure and critical effect levels in humans, it is concluded that elemental cobalt, cobalt chloride, and cobalt sulfate are not entering the environment in a quantity or concentration or	Thank you for your comment. Please note that the assessment you are referring to does not cover health risks for workers potentially arising from releases at the workplace during the uses of the substances but only potential risk from exposure of man via the environment For CMR substances it is however important to assess their potential for exposure to humans in a lifecycle perspective in order to identify all life stages that may pose a risk for human health.

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		under conditions that constitute or may constitute a danger in Canada to human life or health." Question: is there, for ECHA and European competent authorities, a diffecrence between Candian and European human health and environment? Cobalt(II) carbonate, #1855 Cobalt is a natural element that is essential in humans and some animal species, who are unable to synthesise sufficient quantities of Vitamin B12. While low levels of Vitamin B12 intake can be associated with diseases of deficiency, the ingestion of large amounts of Vitamin B12 has not been reported to be toxic to humans. Its ubiquitous and constant presence in the body tissues is indicative of the fact that low dietary levels of cobalt have no health impact. The main source of exposure to cobalt for the general population is through their diet. [...]Although there is variability depending on the type of diet, humans ingest 0.1-1.0 µg Co/kg body weight on a daily basis.[...] There is considerable experience and clinical evidence of safety with oral intakes of 3000 µg per day. Cobalt(II) carbonate, #595 Also need the human body thes metals as a trace element in his body, because wihout all these elemens the man will not survive! We need Cr-III, Co, Ni, As and all other elements of the periodic system!	

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BB14	**Different inherent properties between Cr and Co (reflected in classification category). Co replaced Cr, therefore Cr and Co should not have been recommended together.**	Cobalt dichloride, #1784 Despite inherent differences between the toxicity of hexavalent chromium and cobalt dichloride (as evidenced by their differing Inherent Properties categories as per draft background documentation for hexavalent chromium and cobalt dichloride), they have been grouped together, which has led to a great misunderstanding to intended users within the EU and impedes the acceptance of an alternative to hexavalent chromium.	Thank you for your comment. The Cr(VI) and the Co(II) substances included in ECHA's draft recommendation are not considered as one group and therefore not grouped together into one group. However, it appears that your concerns are rather referring to uses of Co(II)-substances as alternative for Cr(VI) substances in some uses. In this context please note that the Co-salts, although not having the same toxicity profiles than the Cr(VI) substances, are as well identified as SVHCs with carcinogenic and reprotoxic properties. Hence there is a strong societal interest to protect humans, in particular workers handling the substances, from risks potentially arising from both the uses of Cr(VI) and of Co(II) substances. Further note that the meaning of "(suitable) alternative" in the context of authorisation means the possibility of replacement of the substance in a particular use by another substance or technology which reduces the overall risk arising from the use in question and concomitantly is feasible in technical and economic terms.
BB15	**Other Co substances or more hazardous processes could replace cobalt(II) salts in some of their uses**	Cobalt dichloride, #541 Allowing cobalt dichloride to be used in the zinc cobalt plating process would reduce the demand for the more hazardous **cadmium plating**, for which it is an alternative. Cobalt(II) sulphate, #1831	Thank you for this information. Please note that authorisation does not restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are properly controlled or that there are no alternatives available and the socio-economic benefits are outweighing the risks arising from the uses. Concomitantly, the obligation to apply for authorisation is a strong incentive (or duty) to search for and develop suitable alternatives, which is also one of the recommendations given in the referred to Commission report. Further note that the meaning of "(suitable) alternative" in the context of authorisation means the possibility of replacement of the substance in a particular use by another substance or technology which reduces the

#	Issue(s) addressed	Comment example(s)	Response
			overall risk arising from the use in question and concomitantly is feasible in technical and economic terms. In the cases where you consider substitution, we would like to advise assessing the overall risk to human health and the environment related to the substance/technology you currently use and any potential substitute substance/technology.
BB16	**Proposal for other alternative measures instead of Authorisation, on the basis of Regulatory effectiveness**	Cobalt(II) carbonate, #1114 Considering that there are no existing alternatives for different uses of cobalt salts there will be no environmental or human health benefit as an authorization has to be granted for this specific technology. But this process will result in considerable costs and workload for the companies affected, resulting in downsides competition-wise on global level as other economies will simply continue using the substance without any bureaucratic hurdles. It should be the aim of European authorities that existing technology and operational conditions are optimized there where the exposition elevated. Please note here that this is only the case for some exceptions. **Regulatory effectiveness would be much higher if consistent exposure and emission standards are agreed throughout Europe and forcefully controlled by member states authorities**. Cobalt dichloride, #1182 Looking for **a harmonization of authorized processes at a world scale**, as it is carried out with CLP concerning the labeling of dangerous substances **would be a better solution** than including under authorisation cobalt salts at this point in time in Europe.	Thank you for providing your opinion.

C – Comments on Latest Application Dates, Sunset Dates and Review Periods

C1
The estimated time needed to prepare an authorisation application has been used as the main factor to define the latest application date (LAD) for a substance The stakeholder expert group that was following the development of the guidance for including substances in Annex XIV estimated that the time needed for preparation of an authorisation application of sufficient quality might in standard cases require 18 months (roughly 12 months worktime for drafting the application plus an additional buffer of 6 months for consulting required external expertise). This standard time could be changed on the basis of information on aspects which have a considerable effect on the time needed to prepare an application. Some such aspects were discussed in the general approach document for the 1st recommendation[8] and in MSC20. Aspects included e.g. Structure and complexity of supply chains, production cycles, number and size of manufactures / importers, pro-activeness of main manufacturer / importer, number of SMEs involved, whether a SEA may be required.
Information on complexity of supply chains provided by industry in the public consultation does not appear to allow assessment against the criteria given. Many of the anticipated complications and difficulties in preparing authorisation applications will only materialise in case industry is not able to organise their communication and co-operation in an effective manner, however, the comments also indicate clear opportunities for effective preparation for applications. In addition requests for longer transitional periods appear in several cases be based on misunderstandings on the authorisation process, e.g.:

- There appear to be misunderstandings on i) who needs an authorisation for continued use, ii) who can apply for authorisation and for which uses, iii) what needs to be in an authorisation application
- Comments indicate that for a range of uses there is already a lot of information on potential alternatives and on lack of research for alternatives. Such information is the basis for preparing an Analysis of Alternatives as part of an application for authorisation and, according to the comments, potential demonstration that there are no suitable alternatives available.
- Many comments requesting longer latest application and sunset dates refer to aspects which need to be included in the authorisation application and will be taken into account by RAC and SEAC when they develop their opinions and by the Commission when taking their final decisions.

Conclusion based on overall reading of the comments received:

In the 3rd draft recommendation 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 secretariat, and eventually the Commission, more evenly. It was assumed that the number of applications on uses of trichloroethylene will likely be lower than for the five Cobalt and seven Chromium compounds. To get further spreading of the workload,

[8] http://echa.europa.eu/documents/10162/17232/annex_xiv_rec_entries_en.pdf

for trichloroethylene a LAD of 21 months was suggested while for the two groups of Chromium(VI) and Cobalt(II) metal compounds respectively 18 and 24 months were suggested.

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 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 observers 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.

#	Issue(s) addressed	Comment example(s)	Response
CC1	**Proposal to set upfront review periods for granted authorisations**	Cobalt(II) diacetate, #830 In view of production and use of Cobalt Diacetate Solution over three decades, review periods should at least be 5 years or more.	Thank you for your comment. Please note that setting 'upfront' review periods[9] for any uses requires that the Agency has access to adequate information on different aspects relevant for a decision on the review period. ECHA currently assessed that the information available is not sufficient to conclude upfront on specific review periods. Therefore, we have not proposed such review periods. It is to be stressed that all authorisation decisions will include specific review periods which will be based on concrete case specific information provided in the applications for authorisation.
CC2	**Request for longer application dates** **(I)** **because SME's in the field of metal surface**	Cobalt(II) carbonate, #1114 **Decouple Co(II) further from Cr(VI);** These salts **and chromium trioxide** are used for surface treatment, this sector	Thank you for your comment. Note that in accordance with Art. 62(1, 2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance and that they may be made for one or several substances that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Applications may be made for

[9] i.e. review periods already included as entry in Annex XIV and not decided upon, case by case, on the basis of information becoming available in the authorisation application phase of the process.

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	treatment may not be able to handle authorisation application processes for cobalt and chromium VI compounds simultaneously at a time.	of industry does **not have the capacity of handling two authorization processes at a time**. Surface treatment shops usually are **small to medium size companies** that do not have the capacity to handle regulatory requirements of this extent as dedicated personnel is required.	the applicant's own uses and/or for uses for which he intends to place the substance on the market. From these specifications of Art. 62 it is evident that not each actor on the market has to apply for authorisation of his use(s) because he can benefit from the authorisation granted to an actor up its supply chain. It is further possible to submit joint applications by a group of actors. To get the required application(s) ready in time is therefore rather a matter of communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of work than dependent on the size and expertise of individual enterprises in the supply chain.
CC3, CC4, CC5, CC6	**Request for longer application dates** **(II)** **due to the time required to organise and prepare an application, and to allow development of alternatives**	Co(II) carbonate, # 1114 18 months are not an appropriate timeframe considering that (i) small and medium users need external support for this process, (ii) users may wish to organize in groups for cost sharing, (iii) users have to select appropriate supporters, (iv) documents need to be finalized including reviews, (v) application for authorisation is a new process, (vi) REACH uses the word "progressively" implying that the users must be granted an appropriate timeframe for the transition from one technology/substance to another, where possible. etc., (vii) the capacity of supporting entities is limited.	Thank you for your comment. Note that in accordance with Art. 62(2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance (or any combination thereof) and that they may be made for one or several substances that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Applications may be made for the applicant's own uses and/or for uses for which he intends to place the substance on the market. From these specifications of Art. 62 it is evident that not each actor on the market has to apply for authorisation of his use(s).A supplier (manufacturer, importer or downstream user) may cover in his application use(s) of his downstream users. Furthermore, it is possible to submit joint applications by a group of actors. To get the required application(s) ready in time is therefore rather a matter of communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of work than dependent on the size and expertise of individual enterprises in the supply chain. The Authorisation title, inter alia, has the objective (Art. 55) to progressively replace SVHCs by suitable alternatives or technologies where these are economically and technically viable. This does however not mean that a substance cannot be subjected to authorisation before transition to alternative substances or processes has taken place. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in

#	Issue(s) addressed	Comment example(s)	Response
			accordance with Art. 62 (4e)). The availability of alternatives and the required transition period will then be considered in the process of assessing/granting the authorisation and may have an impact on the conditions of the authorisation and the length of the review period of the authorisation. Regarding the arguments that potential applicants wish to get organised in form of consortia etc. or may need to organise support and therefore need longer deadlines for the latest application dates, it is noted that the standard period of 18 months considered by ECHA as the shortest application date already considers a an additional time of 6 months for getting organised and contracting external expertise. The time required to prepare an authorisation application was discussed by the stakeholder expert group that was following the development of the guidance for including substances in Annex XIV. It was estimated that the time needed for preparation of an authorisation application of sufficient quality might require roughly 12 months worktime for drafting the application plus an additional buffer of 6 months for consulting. For the reasons explained above, the need for prolonging application dates because some actors in the supply chain may be SMEs with limited capacities and expertise or because transition to alternative substances or processes may need to continue beyond the latest application date or the sunset date seems questionable. Thank you for your comment. ECHA made its proposals for the latest application dates on the basis of discussions by the stakeholder expert group that was following the development of the Guidance for including substances in Annex XIV. This expert group estimated that the time needed for preparation of an authorisation application of sufficient quality might in standard cases require 18 months (roughly 12 months worktime for drafting the application plus an additional buffer of 6 months for consulting required external expertise). As there is yet no reliable information available that would suggest shortening or prolonging this time interval, we consider that

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		Co(II) carbonate, #547 **12 months** after the date of inclusion in Annex XIV. in order to encourage the replacement of this substance in its current uses. This corresponds with the Commission Service estimate that the average time needed (for the preparation of a new application for authorisation) amounts to roughly 12 months, as mentioned in the Guidance on inclusion of substances in Annex XIV (p.35).	a period of 18 months should normally be given to allow for the preparation of a well documented application for authorisation. The anticipated workload of the Agency with regard to processing of authorisation applications was accounted for by grouping the proposed substances in 3 groups and spreading the application and sunset dates over a period of six months, resulting in a combination of application/sunset dates of 18/36, 21/39 and 24/42 months for the three groups. Thank you for your comment. Please note that authorisation, inter alia, is a means to promote the development of alternatives. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance with Art. 62 (4e)). Therefore, the present lack of alternatives to (some of) the uses of a substance and the need to complete R&D programmes to get qualified alternatives to it is no viable reason for adjourning the subjection of a substance or some of its uses to authorisation. Information regarding lack of alternatives is however important information for inclusion in an authorisation application. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

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		Cobalt sulphate, #964 The aerospace industry requests the longest possible timescale to identify, test and qualify alternative substances capable of meeting the demanding corrosion protection requirements at high temperature. If ECHA follows previous practice, it is likely that cobalt sulphate will enter Annex XIV in January 2013, with a likely "Sunset date" of 3 years later, in January 2016. However, applications for Authorisation for the continued use of cobalt sulphate would have to be completed and submitted 18 months before the "Sunset date"; July 2014 by the latest. This represents insufficient time to complete the necessary R&D programmes required to produce qualified alternatives to cobalt sulphate. **An extension of several years is essential for all concerned**. Cobalt(II) sulphate, #890 This chemical substance is used in manufacturing and or maintenance of aviation products and parts. It might not be easy to find an alternative substance that would have the same attributes and or performance and the banning of such substance may therefore have a negative impact on aviation safety. We invite the ECHA to consider a possible exemption for the use in aviation applications or an appropriate transition period. Cobalt sulphate, #531	See response just above, to comment #964

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		Aufgrund der komplexen Zulassungsverfahren in der Luftfahrtindustrie sehen wir die-se Fristen als zu kurz an und schlagen **eine Verlängerung um bis zu 5 Jahren bzw. eine Verlängerung bis zum Vorliegen weiterer fundierter Daten und Untersuchungen** vor. Ziel sollte es selbstverständlich sein, weiter zu versuchen diesen Stoff bzw. die eingesetzten Verfahren zu substituieren.	
CC7, CC8	**Request for longer application dates** **(III)** **due to the complexity of supply chain and limited capacity of SMEs**	Co(II) carbonate, #719 **Latest application date: July 2015 (and then sunset date: January 2017)**; **no threshold** carcinogen → socioeconomic route applicable → due to **complexity of supply chain** of articles subject to surface treatment, more time is needed. Otherwise, Authorisation requirement equals in practice to Restriction (ban)	Thank you for your comment. We understand that you request an extension of the latest application dates for cobalt carbonate to July 2015 and of the Sunset date to January 2017 due to the complexity of the supply chain and the work associated with setting up authorisation applications. From the information available in the registration dossiers and the comments submitted during public consultation on the draft Annex XIV recommendation it appears that the parts of the supply chain that would require authorisation are not particularly long or overly complex. Moreover, note that from Art. 62 it is evident that not each actor on the market has to apply for authorisation of his use(s). A supplier (manufacture, importer or downstream user) may cover in his application use(s) of his downstream users. Furthermore, it is possible to submit joint applications by a group of actors. To get the required application(s) ready in time is therefore rather a matter of communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of work than dependent on the complexity of the supply chain and the expertise of individual enterprises in the supply chain.
		Cobalt dichloride, # 1182 **48 months for LAD, SD: 18 months later** **Cobalt salts are used in a very complex supply chain involving many SMEs. Substantial technical data need still** to be collected and reviewed to ensure complete understanding **of a complex supply chain and of the cobalt**	Thank you for your comment. We understand that you request an extension of the latest application dates to 48 months after potential inclusion of Cobalt dichloride in Annex XIV.

#	Issue(s) addressed	Comment example(s)	Response
		salts' numerous uses. The EU should not take any premature decision before we have this understanding. DUs are small companies, so not necessary technical, administrative and financial means to constitute a consortium, launch studies and complete an authorization file according to the ECHA's proposed dates.	From the information available in the registration dossiers and submitted during public consultation on the recommendation it appears that the parts of the supply chain that appear to be relevant for authorisation (e.g. uses in metal surface treatment, as drier or pigment in coatings, as oxygen scavenger for water treatment, as corrosion inhibitor or as catalyst) are not very long or overly complex, although in the case of surface treatment many actors may be involved. Moreover, note that from Art. 62 it is evident that not each actor on the market has to apply for authorisation of his use(s) but that it is possible to submit joint applications by a group of actors. To get the required application(s) ready in time is therefore rather a matter of communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of work than dependent on the structure (size) and expertise of individual enterprises in the supply chain. Therefore, the need for prolonging application dates because some actors in the supply chain may be SMEs with limited capacities to handle authorisation applications seems questionable.
CC9, CC10	**Request for longer sunset dates** **(I)** **to allow substitution**	Co(II) carbonate, # 613 **36 months** instead of the proposed 18 months. 18 months seems for sunset date extremely short considering the **time it would take to implement a change in industrial process or substitution at an industrial scale for the uses in scope of Authorisation**. 36 months would be reasonable, for any uses in the scope of A.	Thank you for your comment. It appears that a sunset date 36 months after the application date is requested (54 months after inclusion of the substance in Annex XIV) whereas ECHA suggested the sunset date to be set 42 months after inclusion of the substance in Annex XIV. Please note that the sunset date does not need to consider the timeframe in which it may be possible to substitute the substance in question in a particular use or in all of its uses. Authorisation, inter alia, is a means to promote the development of alternatives. Therefore, the present lack of alternatives to (some of) the uses of a substance or the time estimated to change industrial processes and finalise transition to alternatives is no viable reason for adjourning the subjection of a substance or of some of its uses to authorisation. Such (perceived) lack of alternatives and timeframes required for development of alternatives and adapting industrial process should be addressed in the authorisation application (e.g. in the analysis of alternatives and the socio economic analysis). Respective information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation.

#	Issue(s) addressed	Comment example(s)	Response
		Cobalt diacetate, #945 The proposed sunset date would very likely not allow enough time to start a R&D program, identify an alternative, confirm its viability under production conditions and then to implement that new technology into plants that may need to be re-designed or newly built depending on the nature of the alternative. We cannot propose an implementation date, as the success of additional R&D cannot be predicted and furthermore a costly re-design / new build of plants in the EU is economically questionable.	Thank you for your comment. Please note that authorisation, inter alia, is a means to promote the development of alternatives. Therefore, the present lack of alternatives to (some of) the uses of a substance or the time and costs estimated to adapt industrial processes and finalise transition to alternatives is no viable reason for adjourning the subjection of a substance or of some of its uses to authorisation. Such (perceived) lack of alternatives and timeframes required for development of alternatives and for adapting industrial processes should be addressed in the authorisation. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.
CC11	**Request for longer sunset dates** **(II)** **due to lack of alternatives and socio-economic or practical considerations**	Cobalt dichloride, #683 **60 months should be the minimum sunset date**: No suitable alternative meeting all the requirements of humidity indicator card.R&D, and if successfull also capital expenditure cost and ramp out time is unknown. A Use Specific Exemption would be applied for and it would be reasonable to expect a decision on exemption prior to expending tremendous time and money to attempt (with no guarantee of success) to develop an alternative.	Thank you for your comment. The brought forward arguments as to why an exemption is requested for use of Cobalt dichloride in humidity indicator cards do not constitute a basis for exemption of this use from authorisation on the basis of Article 58(2)[10]. Please note that authorisation, inter alia, is a means to promote the development of alternatives. Therefore, the present lack of alternatives to (some of) the uses of a substance as well as the other socio-economic or practical considerations may be addressed in the authorisation application (e.g. in the analysis of alternatives and the socio economic analysis), further commented on in the context of the public consultation on possible alternatives, and reflected in the opinions of the Committees for Socio Economic Assessment and Risk Assessment (SEAC and RAC). The outcome of the analysis of alternatives is relevant for the decision on the authorisation application and may as well have an impact on the conditions applicable to the authorisation and on the length of the time limited review period.

[10] It is only possible to consider exemption of (categories of) uses from the authorisation requirement on the basis of Article 58 (2), unless the uses are a priori exempted from authorisation on the basis of other Articles of the REACH Regulation.

D – Comments on Uses / Requests for Exemptions:

#	Issue(s) addressed	Comment example(s)	Response
DD1	**Socioeconomic benefits of a use, no Alternatives on a use, Impact of ceasing a use**	Cobalt(II) sulphate, #1146 The electroplating and surface treatment industry is, at the same time, both a key technology and a cross technology and, as a result, a driving force for technological advancement. In the field of electroplating, cobalt salts are used in particular in the manufacture of coatings made of metallic cobalt-alloys. Within the overall field of electroplating, zinc and zinc alloys and their subsequent conversion layers for the cathodic corrosion protection of steel components represent also a particular area of focus which is of growing importance. Cobalt- and cobalt-alloy-plating is a field of special interest whose importance continues to grow from both an economic and technical point of view. The added value gained from refining surfaces contributes to a strengthening of Europe as an economic region and secures the competitive edge of European products on the world's markets. To save resources and reduce CO 2 one has to have durable products with optimised technical properties. Zinc and zinc alloy coatings with the conversion layers deposited on them make a considerable contribution to achieving these aims as a result of their corrosion-protection properties. It can be generally said that zinc & zinc alloys provide optimum corrosion protection for a minimum use of materials and at low costs. The need to save resources necessitates the ability to produce durable commodities which have optimised technical properties. As a result of their mechanical properties, e.g. high hardness levels in gold application, cobalt	Thank you for your comment. Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently information on topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for inclusion Annex XIV.

#	Issue(s) addressed	Comment example(s)	Response
		including coatings makes a crucial contribution to these aims. The use of cobalt (II) salts with its importance for the surface treatments industry, machine and plant engineering, automotive, improving the adhesion of paint layers when they are applied and other industrial sectors, such as the construction industry in Europe, must have a future in order to maintain the specific properties achieved with the application of electrochemical corrosion protection systems using zinc and zinc alloys with subsequent conversion layers. Further industries which are concerned are bathroom and furniture fittings, consumer articles, the watch and clockmaking and jewellery industries, medical technology and many other industrial fields in Europe will be referred to and the specific reasons explained as to why electrochemical cobalt- and cobalt-alloy-plating must remain an option in the future. Cobalt(II) diacetate, #1474 80% of the use of Cobalt Acetate is to be allocated on production of PTA, IPA, DMT and there is ***no suitable replacement*** for Cobalt Acetate in the manufacture of PTA. Numerous research programmes have been run to find a suitable replacement for CoAc – so far without success. Cobalt(II) carbonate, # 1181	
DD2	**Exemption(s) requested without specification of a legal basis permitting to consider such**	Cobalt dichloride, #1182 In surface treatment, closed processes like DALISTICK or	According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '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'.

#	Issue(s) addressed	Comment example(s)	Response
	exemptions	processes saving CO2 and energy like DALISTICK and BRUSH PLATING, should be exempted, as well as activities covered by the strict regulations concerning health & safety and environment in reason of the existing surveillance of companies by the states. This should apply in particular to companies, which have already provided great efforts to fulfill the requirements of these regulations. [...] Processes, like DALISTICK and BRUSH PLATING should be also exempted because they are sold (with solutions) and used in the whole world for local repair or local treatment on new parts (e.g. in railways, energy or print industry). Cobalt(II) sulphate, #890 This chemical substance is used in manufacturing and or maintenance of aviation products and parts. It might not be easy to find an alternative substance that would have the same attributes and or performance and the banning of such substance may therefore have a negative impact on aviation safety. We invite the ECHA to consider a possible exemption for the use in aviation applications or an appropriate transition period.	ECHA will consider the following elements when deciding whether to include an exemption of a use of a substance in its recommendation: - 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 legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance 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[11] for the control of risks of the use. Legislation setting only the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to 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 by the legislation. On the basis of the criteria above, we made the following observations on the argumentation brought forward by the commenting party: (i) Only existing Community legislation is relevant in the context to be

[11] Legislation imposing minimum requirements means that:
- The Member States may establish 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 same minimum level of control of risks throughout the EU and that this level can be regarded as proper.

#	Issue(s) addressed	Comment example(s)	Response
			assessed (no national legislation). (ii) Minimum requirements for controlling risks to human health or (and) the environment need to be imposed in a way that they cover the life cycle stages that are exerting the risks resulting from the uses in question. (iii) There need to be binding and enforceable minimum requirements in place for the substance(s) used. This means that solely national legislation or industry's voluntary actions in reducing releases cannot be considered as such as a reason to propose an exemption. From ECHA's assessment of the available information, there appears to be no Community legislation regulating the uses of the 5 Cobalt(II) substances. Therefore, on the basis of the available information, there seems to be no basis for proposing an exemption from authorisation for uses of the 5 Cobalt(II) substances (for further details see table E).
DD3	**Exemption for precursor uses to SRD.**	Cobalt(II) sulphate, #682 We suggest that all steps in the process of using cobalt sulfate in scientific R&D should be exempted from authorization. This should cover the steps starting from manufacture of the substance (already exempted), filling and refilling into packages, and preparation of formulations till the use in scientific R&D. The use of these formulations for scientific R&D (< 1t/a) is already exempted. Cobalt sulfate is a substance used for scientific R&D, e.g. as catalyst. The substance will only be supplied in packages used in laboratories, e.g. small bottles. Cobalt sulfate is used in the laboratory by industrial and professional users that are well-trained.	Thank you for your comment. Although uses for scientific research and development of a substance are exempted from the authorisation requirement in accordance with Article 56(3) this only applies to its final use for SRD purposes under the conditions defined in Article 3(23) (See also our response to issue DD8). However, use of a CMR substance included in Annex XIV, on its own or in a mixture (above the lowest of the concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No1272/2008), for e.g. formulation of test kits or analytical standards with the intention to supply them for SRD purposes, requires authorisation.

#	Issue(s) addressed	Comment example(s)	Response
DD4	**PPORD exemption**	Co(II) carbonate, #1114 PPORD (applied for Corrosion Protection Conversion Layers applications; specific sectors listed) should be clearly exempted from authorisation. Alternative technology development has to use cobalt salts in order to develop further. Restrictions would hinder PPORD from fulfilling his role in the REACH framework. b. Following Article 55, the aim of the authorization is to control the risks from SVHC. In order reduce the risks from SVHC the need for PPORD is evident, which may result in optimized processes reducing the risks for human health and the environment. c. Personnel's exposure in PPORD is significantly reduced against production processes as the time of exposure is reduced, the throughput is lower by decimal powers and usually equipment with latest safety measures is used.	Thank you for your comment. The authorisation title requests in Art. 55 the progressive replacement of SVHCs where this is technically and economically viable. Therefore, PPORD should in principle focus on alternative substances and technologies to replace the SVHC in question. However, we agree that in cases where no alternatives are available to replace the SVHC, PPORD with the aim to reduce the use of the substance or of its emissions could be justified. The pertinence of such a PPORD project with a substance identified as SVHC should however be justified in an authorisation application and be scrutinized and decided in the authorisation granting process in accordance with Article 60.
DD5	**Requests for confirmation that a specific use is exempted from authorisation / Explicit listing of exempted uses per Annex XIV entry**	Cobalt(II) dinitrate, #573 According to REACH Title 1, Chapter 1, Article 2, 8b all intermediate uses are exempted from Authorisation. We are therefore of the opinion that all supported uses to which PC19 is assigned (cfr. registration dossier) should be specifically listed as being exempted in the recommendation for prioritisation of ECHA. Cobalt(II) carbonate, #1663 According to Article 2 §5 and §6 of Regulation (EC) No 1907/2006 (the "REACH" Regulation), "feed additives" are exempted from the scope of REACH Regulation. Cobalt is an essential nutrient for livestock; without which animal welfare could be compromised in some circumstances. The use of	Thank you for your comment. A list of uses exempted from authorisation according to the REACH Regulation can be found in ECHA's General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation (see Appendix 1 therein): http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf It is the responsibility of companies to assess whether their use complies with the requirements relevant for each of the exempted uses. Further information on such requirements can be found in the legislation listed in the above cited appendix, as well as in response DD8 (on exemptions for Scientific Research & Development) or in the Guidance on intermediates

#	Issue(s) addressed	Comment example(s)	Response
		Cobalt salts used as additive in feedingstuffs are regulated by Regulation (EC) No 1831/2003 (the "Feed Additives Regulation"). Consequently, the provisions of Titles II (REGISTRATION OF SUBSTANCES), V (DOWNSTREAM USERS), VI (EVALUATION) and VII (AUTHORISATION) of REACH Regulation do not apply to the feed additive use of Cobalt salts; as well as to the manufacture of cobalt salts for use as feed additives. In the frame of Regulation (EC) No 1831/2003, FEFANA asbl initiated the formation of an European Economic Interest Grouping (EEIG) aiming at the re-authorization of Trace elements as feed additives, namely TREAC EEIG, the Trace Elements Authorization Consortium EEIG. [...] From the above, FEFANA asbl and TREAC EEIG would like to get reinsurance that the evaluation of Cobalt salts made by ECHA will not take into consideration the use of Cobalt salts as feed additives which is evaluated by another regulatory framework. Cobalt dichloride, #883 […] Much of the remaining humidity indicator card market that still uses Cobalt Dichloride is military related which is exempt from authorization.	(http://www.echa.europa.eu/documents/10162/17224/intermediates_en.pdf) As regards the obligations arising in case of the inclusion of a substance in Annex XIV, it is the responsibility of companies to assess whether their use is in the scope of authorisation and keep the relevant documentation available for enforcement authorities if wishing to continue that use / placing the substance on the market for that use after the sunset date. Explicit listing in Annex XIV of all identified uses for a particular substance, which are exempted from the authorisation requirement, would be inappropriate and in any case not possible, because i) the identified uses of a substance can change with time (therefore exhaustive up-to-date list not possible), ii) ECHA and the European Commission are not in the position to conclude whether a particular use is / is not in the scope of authorisation in this phase of the authorisation process. As for the military uses, please note that they are not generally exempted from authorisation. According to Art. 2(3) of REACH, Member States may allow for exemptions from REACH in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of defence.

#	Issue(s) addressed	Comment example(s)	Response
DD6	**Proposal to exempt non-interchangeable uses (where grouping in the context of regulatory effectiveness is used for prioritising a substance)**	Cobalt(II) dinitrate, #1790 […] we understand the need for the authorization of cobalt (II) dinitrate (regulatory effectiveness) to prevent the switch from other cobalt salts, which are fulfilling the criteria of Art. 58 (3), to cobalt (II) dinitrate for some uses. However, this should not lead to authorization for uses of cobalt (II) dinitrate which are not related to this regulatory effectiveness and which would not have been in focus of authorization based solely on the criteria of Art. 58 (3).	Please note that inclusion in Annex XIV is per substance and not per use. Therefore, a conservative approach is taken and in particular uses/situations be considered in which interchangeability is technically feasible. If it is technically possible that a particular substance can replace any of the other substances of the group in any of their uses the grouping is used because Grouping of chemically and in terms of their hazard potential similar substances is an important strategy to prevent evasion of the authorisation requirement *(by replacing one Co-salt on Annex XIV by another one not on this Annex)*. See also response BB7 in table B. On the requirements for a specific exemption in Annex XIV, please see response to comment DD2 and table E.
DD7	**Application for authorisation not needed for use in in vitro diagnostic assays and in medical devices.**	Cobalt dichloride, #1085 A number of exemptions apply for the use of cobalt dichloride as a cofactor for the enzyme terminal transferase and as a trace element in fermentation. These exemptions are: […]***Specific exemption for use in in vitro diagnostic assays and in medical devices***: The use for the substance in medical device is regulated by Council Directive 90/385/EEC and Directive 98/79/EC for in vitro diagnostic medical devices. According to Article 60(2) the Commission should not consider the risks to human health, when granting authorisations, with the use of substances covered by the above directives. Therefore an application for authorisation is not needed. Cobalt(II) dinitrate, #1760	We wish here also to refer to recital 18 of Commission Regulation (EU) No 143/2011 of 17 February 2011, amending Annex XIV to REACH for the first time: *In accordance with Article 60(2) of Regulation (EC) No 1907/2006, the Commission should not consider, when granting authorisations, the human health risks associated with the use of substances in medical devices regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[12], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[13], or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[14]. In addition, Article 62(6) of Regulation (EC) No 1907/2006 provides that applications for authorisation should not include the risks to human health arising from the use of a substance in a medical device regulated under those Directives. It follows that an application for an authorisation should not be required for a substance used in medical devices regulated under Directives 90/385/EEC, 93/42/EEC, or 98/79/EC if such a substance has been identified in Annex XIV to Regulation (EC) No 1907/2006 for human health concerns only. […]*

[12] OJ L 189, 20.7.1990, p. 17
[13] OJ L 169, 12.7.1993, p. 1
[14] OJ L 331, 7.12.1998, p. 1

#	Issue(s) addressed	Comment example(s)	Response
		In the light of the above considerations, ABPI Recommends that cobalt (II) dinitrate be exempt from authorisation for any use in the research, development, manufacture or anlytical control of medicinal products and their ingredients and ***for any corresponding uses in relation to medical devices***. This should cover the steps starting from manufacture of the substance (already exempted), filling into packages, preparation of formulations described in standards (DIN, EN, ISO and ASTM), Pharmacopoeias (Reag. Ph. Eur. and ACS) till the use as calibration standard for ICP and AAS. The use of these formulations for scientific R&D (< 1t/a) is already exempted.	We would suggest that you examine whether the mentioned uses of your substance(s) can be regarded as uses in vitro diagnostic assays or uses in medical devices in accordance with the definitions set out in Council Directive 90/385/EEC and Council Directive 98/79/EC, respectively. Please see also response to issue EE14. Similarly, you should examine whether uses of your substance(s) fulfil the definition and conditions for scientific research and development (SRD) set out in Article 3(23) of the REACH Regulation. On exemptions for SRD, please see also responses DD3 and DD8.
DD8	**Exemptions for R&D**	Cobalt dichloride, #678 Cobalt dichloride is a compound that is used in laboratory analysis for different reaction. One main use is in the color analysis. Cobalt dichloride is an accepted standard substance for color standards in the color determination methods. The reagent is used for laboratory and field analysis, and ready for use. The advantage of the reagent set is, that the risk of contamination by the noxious substances, is low for the user. It is effectively a closed system. Accordingly, the risk of coming into contact with the reagent is very low. Compared with the conventional reference procedures, the regents set needs less pollutants, and a correspondingly smaller quantity of Cobalt dichloride. Therefore, it is essential to exempt the use of Cobalt dichloride	The uses of the referred to cobalt substances for analytical purposes may fall under the exemption of the use of substances in scientific research and development from the authorisation requirement in accordance with Art. 56(3). We would suggest that you examine whether the mentioned uses of your substance(s) can be regarded as SRD in accordance with the definition set out in Article 3(23). Article 3(23) defines SRD as "*any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year*". It is noted that • SRD activities can cover analysis for monitoring or quality controls purposes; • Therefore, in principle a substance may be exempt from authorisation if used, on its own or in a mixture, in analysis for monitoring and quality control purposes, for instance, in order to monitor the presence or

#	Issue(s) addressed	Comment example(s)	Response
		for "analysis purposes" respective "laboratory uses" from the requirement for approval, or it should be classified as an approved. Cobalt dichloride is a substance, that is mandatory in the ISO6271 (Clear liquids -- Estimation of colour by the platinum-cobalt scale) and ISO 4630 (Clear liquids -- Estimation of colour by the Gardner colour scale) Cobalt(II) dinitrate, #837 First of all, cobalt (II) dinitrate hexahydrate is used on EDF nuclear power plants within the monitoring laboratories to check the condition of fuel cladding, in order to determine the amount of caesium present in the water and in contact with the fuel assemblies. Cobalt (II) dinitrate is used as a reagent for the analysis tanks to the precipitation of cobalt process. Caesium-137 and caesium-134, generated by the radioactive fission during nuclear reactor operation, can be efficiently measured and monitored using this procedure. The use of cobalt (II) dinitrate by EDF is limited to in-laboratory measurement and monitoring procedures: · in the primary coolant liquid samples analyzed in the nuclear power plant laboratories, · in the liquid samples taken from spent fuel pools within the	concentration of that substance or other substances; • Nevertheless, this exemption only applies to the extent that the relevant operator uses that substance under controlled conditions[15] and in a volume less than 1 tonne per year. • Only substances used directly for research or analytical purpose, whether on their own, in mixture, or in conjunction with analytical equipments, can benefit from the SRD exemption. This excludes from the exemption any substances forming an integral part of an analytical device. If you conclude that your uses of the mentioned substances fulfil the above points, the uses can benefit from the exemption of SRD from authorisation as set out in Article 56(3) and no authorisation would be required to continue the use after the sunset date.

[15] In the absence of explicit requirements set out by the competent authorities, the controlled conditions must be appreciated in relation to different elements including the intrinsic properties of the substance at stake, but also risk management standards. Although such standards may contribute to the determination of controlled conditions, there implementation may not alone be sufficient to meet this condition. Analytical activities that are not run under controlled conditions cannot benefit from the SRD exemption.

#	Issue(s) addressed	Comment example(s)	Response
		fuel building in the nuclear power plant laboratories. In the presence of high cobalt (cobalt 58 and cobalt 60) isotope activities, caesium gamma rays are hidden. Using gamma ray spectroscopy, it is sometimes difficult to measure with sufficient accuracy the activities of caesium 134 and caesium 137 in order to be able to calculate their ratio. In such a case, it is of vital importance that precipitation of cobalt be carried out prior to the activity measurement using gamma-ray spectroscopy, with the device usually used on-site. The aim of this process is therefore to extract the cobalt isotopes of cobalt to be analysed by implementing precipitation using cobalt salts. The cases when a precipitation of cobalt process should be implemented prior to the measurement of caesium activity remain exceptional, making the implementation of this process particularly rare. The second use of cobalt (II) dinitrate is under a liquid form and only related to the analysis procedures carried out within the EDF corporate laboratory, i.e. the Ceidre/DLAB . A cobalt (II) dinitrate solution of 1000 mg/L is used as a calibrator in the procedures using inductively coupled plasma atomic emission spectroscopy (ICP/AES). These procedures simultaneously determine the quantity (amount) of various substances (phosphorous, chrome, molybdene, manganese, vanadium, copper, nickel, arsenic, tin, cobalt, iron, silicon, aluminium, titanium and boron) within alloyed or unalloyed, as well as in nickel-based alloys. The cobalt (II) dinitrate solution is used at a maximum dilution rate of 1mL per 100 mL. […] EDF uses only very small amounts of cobalt (II) dinitrate, and cases in which the substance is used remain rare. No substitute has, today, been discovered, and use is strictly covered by procedures guaranteeing risk control. EDF therefore considers that it would be particularly penalising	

#	Issue(s) addressed	Comment example(s)	Response
		to submit authorisation files for the little use made of the substance, if use of cobalt (II) dinitrate were to become subject to authorization.	
DD9	**Request for exemption for the use as trace element (essentiality)**	Cobalt dichloride, #562 Request for exemption of the authorisation requirement for the use of CoCl2 as a trace element in fermentation processes Cobalt dichloride, #1795 "Use as a biochemical substrate: Industrial and laboratory operations commonly use fermentation processes to produce valuable substances, such as pharmaceutical substances (i.e. proteins, peptides, etc.) and industrial enzymes. Many substances are manufactured in large, industrial scale fermenters (i.e. vessels which grow microorganisms under controlled conditions to produce a valuable compound of interest). In industrial scale fermentation processes, the production of organisms typically is conducted in a complex fermentation medium. A complex medium is understood to be a medium comprising a complex nitrogen and/or carbon source, such as soybean meal, cotton seed meal, corn steep liquor, yeast extract, casein hydrolysate, molasses, and mixtures of trace vitamins, minerals and elements.	Thank you for your comment. As regards your request for exemption of the described uses please note that (categories of) uses can only be exempted from the authorisation requirement on the basis of Article 58(2) of REACH, unless they are already explicitly exempted in REACH Art. 2(5 & 8) and Art. 56(3 – 6). A list of uses that in accordance with the REACH Regulation are exempted from authorisation can be found in ECHA's General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation (see Appendix 1 therein): http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf Use of substances as essential nutrient for micro-organisms is not among the uses that are explicitly empted in REACH from the authorisation requirement, unless the micro-organisms are cultivated for scientific research and development purposes in accordance with Art. 3(23) and 56(3) (regarding the applicable conditions see response DD8). Also Article 58(2) of REACH, according to which it is possible to exempt from the authorisation requirement uses or categories of uses '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', does not appear to provide a basis for exempting the referred to uses of substances as essential element in nutrient solutions for micro-organisms from the authorisation requirement because there seems to be no specific Community Legislation in place that would impose minimum requirements for proper control of risks arising from these uses, in particular in relation

#	Issue(s) addressed	Comment example(s)	Response
		One of the primary advantages of utilizing a complex media in fermentation is that offers a wide array of raw materials to be available to allow a complete or nearly complete nutrient source for specific microorganisms. However, some substances in a media may not be readily available for organisms. Within many industries, highly refined, high-producing microbial strains have been developed for industrial processes in complex media to maintain their good performance in media. Catalytic elements are commonly needed to utilize specific enzymes or enzyme cofactors in these processes. These elements can include substances such as magnesium, iron, copper, calcium, manganese, zinc, cobalt, molybdenum, selenium, barium. Cobalt dichloride is a commonly and safely utilized source of cobalt. In some cases, the use of cobalt dichloride can be specifically used to direct the forms of an active molecule or discourage the production of other substances generated in a fermentative process. Many pharmaceutical products derived from fermentation processes are used for human and animal health. No monetization of benefits has been provided in this analysis. We suggest that all steps for the use of Co salts as an essential trace element in fermentation processes and in the production of dehydrated culture media should be exempted from authorisation. Cobalt(II) sulphate, #1705	to worker health. Therefore, on the basis of the available information, there seems to be no basis for proposing an exemption from authorisation for uses of the referred to cobalt substances as essential nutrients for micro-organisms (for further details see response DD2 and table E).

#	Issue(s) addressed	Comment example(s)	Response
		The use of cobalt(II) sulphate (as a water treatment chemical) in a formulated mixture for adding this mixture to process water as a nutrient solution should be exempted from the authorisation requirement. This use is also mentioned on page 3 of the draft background document for cobalt(II) sulphate. Cobalt is essential for the growth and activity of microorganisms that perform the purification processes, like the conversion of pollutants to methane. For further information we refer to the attached documents.	

E. Exemption Requests with reference to existing EU Legislation

INTRODUCTION

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses *'(…) provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled'.*

The following elements are considered when assessing whether to include an exemption of a use of a substance in its recommendation:

- There is existing EU 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 EU 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 to REACH; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to e.g. by referring to the classification criteria or the Annex XIII criteria;
- This EU legislation imposes minimum requirements[16] for the control of risks of the use. Legislation setting only the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2) REACH. Furthermore, it can be implied from the REACH Regulation that attention should be paid as to 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 by the legislation.

On the basis of the criteria above, ECHA has taken the following approach to assess argumentation brought forward by commenting parties in relation to exemption requests under Article 58(2). All of the cobalt (II) compounds recommended for Annex XIV were identified as Substances of Very High Concern (SVHC) and added to the Candidate List due to their carcinogenic and toxic for reproduction properties. Therefore, in the following it is

[16] Legislation imposing minimum requirements means that:
- The Member States may establish 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 same minimum level of control of risks throughout the EU and that this level can be regarded as proper.

- firstly assessed whether existing EU legislation imposes minimum requirements to control exposure of workers when the substances are used on their own or in mixture;
- subsequently, it is assessed whether exposure of workers is sufficiently covered by existing EU legislation throughout the steps in the life-cycle of the substance resulting from these uses;
- finally, it is assessed if there is sufficient coverage of man via the environment from the substances by existing EU legislation.

It is noted that the supply to the general public of these five Cobalt compounds on their own or in mixtures is prohibited by Annex XVII to the REACH Regulation (entries 28 and 30). Available information does not indicate exposure of consumers to these five specific Cobalt compounds during the service life or waste stage of articles. Therefore, no further specific assessment was carried out as to whether consumer exposure is covered by existing EU legislation.

Responses to individual/groups of exemption requests are further elaborated in the table below.

#	**Group of Exemption request** (comment example(s); legislation; use(s); any justification)	**Response**
Human health-based legislation		
EE1	**Cobalt(II) carbonate, #1827, #1199; Cobalt dichloride, #562, #1085; Directive 2004/37/EC** on the protection of workers from the risks related to exposure to **carcinogens or mutagens at work** (Sixth individual Directive within the meaning of Article 16(1) of Council **Directive 89/391/EEC; all uses / use in fermentation process / uses covered by that legislation** Industry must comply with its requirements, which sets out conditions for the strict control of occupational exposure. It aims at the reduction and replacement of carcinogens and mutagens in so far as technically possible and prevent and reduce the exposure to these products. **Also referred: Restriction of CMRs for**	**Carcinogens or Mutagens at Work Directive 2004/37/EC (CMD)** introduces a framework of general principles to protect workers against risks to their health (which includes prevention of risk) from exposure. The overriding principle is to replace CM substances (by using less hazardous substances) or, where this is not possible, to prevent/reduce workers exposure to CM substances as far as is technically possible. Where use remains, the principle is to use closed systems, where techically possible. Furthermore, a hierarchy of measures shall be applied when a CM is used. The Directive outlines a hierarchy of control and risk reduction measures (with substitution at the top), however, it leaves the determination of the measures to be imposed to the employer and does not provide sufficient indicators to be used to assess whether a measure higher up in the hierarchy would have been technically possible. On this basis it is not considered that Directive 2004/37/EC would impose binding minimum requirements for controlling risks to human health. Therefore, this Directive is not regarded as a sufficient basis for exempting uses of **cobalt (II) carbonate / cobalt dichloride** (/ cobalt(II) compounds) from authorisation in accordance with Article 58(2) of the REACH Regulation.

#	Group of Exemption request (comment example(s); legislation; use(s); any justification)	Response
	consumers	
EE2	**Co(II) carbonate, #719; Cobalt dichloride, #1085; The Carcinogens Directive (90/394/EEC) and the Directive 98/24/CE** apply to CMR compounds; **all uses** / **uses covered by that legislation**	**Council Directive 98/24/EC** on **the protection of the health and safety of workers from the risks related to chemical agents at work** (CAD) sets out a framework based on the determination and assessment of risk and general principles for the prevention of risk, associated with hazardous chemical agents. The **Carcinogens or mutagens at work Directive 2004/37/EC (CMD)** introduces a framework of general principles to protect workers against risks to their health (which includes prevention of risk) from exposure. The overriding principle is to replace CM substances (by using less hazardous substances) or, where this is not possible, to prevent/reduce workers exposure to CM substances as far as is technically possible. Where use remains, the principle is to use closed systems, where techically possible. Furthermore, a hierarchy of measures shall be applied when a CM is used. Both Directives outline a hierarchy of control and risk reduction measures (with substitution at the top), however, they leave the determination of the measures to be imposed to the employer and do not provide sufficient indicators to be used to assess whether a measure higher up in the hierarchy would have been technically possible. On this basis it is not considered that Directive 98/24/EC nor Directive 2004/37/EC impose binding minimum requirements for controlling risks to human health. Therefore, these Directives are not regarded as a sufficient basis for exempting uses of **cobalt (II) carbonate / cobalt dichloride** (/ cobalt(II) compounds) from authorisation in accordance with Article 58(2) of the REACH Regulation.
EE3	**Co(II) carbonate, #1205**; Also suspected CMR are under other regulatory requirements (**Regulation 2003-** **1254** of 23 December 2003 **on the prevention of chemical risks**)	As the exemption request is only based on national legislation there is no basis for an exemption on the basis of Article 58(2).
EE4	**Co(II) carbonate, #1199; Cobalt dichloride, #562**; **92/85/EEC Pregnant Workers Directive and Directive 94/33/EC Protection of** **Young Workers at the Workplace** (applying to carcinogens and mutagens); **use in fermentation process**	**Council Directive 92/85/EEC** (Pregnant Workers Directive) aims to encourage improvements in health and safety at the workplace, and in this case, for a defined sensitive group, through the assessment of risks at the workplace. In case the results of this assessment reveal the existence of a risk to the safety or health of the female worker, provision must be made for the worker to be protected. In addition, pregnant workers and workers who are breastfeeding must not be engaged in activities which have been assessed as revealing a risk of exposure, jeopardizing safety and health, to certain particularly dangerous agents or working conditions.

#	Group of Exemption request (comment example(s); legislation; use(s); any justification)	Response
		Whilst the Directive identifies substances with R-phrases relevant for carcinogenic potential for particular attention in an assessment, the Directive leaves the determination of the measures to be imposed to the employer. On this basis it is not considered that Directive **92/85/EEC** would impose binding minimum requirements for controlling risks to human health. Therefore, this Directive is not regarded as a sufficient basis for exempting uses of **cobalt (II) carbonate / cobalt dichloride** (/ cobalt(II) compounds) from authorisation in accordance with Article 58(2) of the REACH Regulation. **Council Directive 94/33/EC** on the protection of young people at work provides that the Member States shall take the necessary measures to prohibit the employment of children and shall ensure that the employment of adolescents is strictly controlled and they are protected under the conditions outlined in the Directive. This includes the requirement to take measures to prohibit the employment of young persons in work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health. The provision(s) refer to hazard classification. The Directive, where implemented fully, should prevent exposure to carcinogenic substances for this specific and sensitive group. However, the size of the population "at risk" is likely to be very low and therefore in itself, the Directive 94/33/EC is not regarded as a sufficient basis for exempting uses of **cobalt (II) carbonate / cobalt dichloride** (/ cobalt(II) compounds) from authorisation in accordance with Article 58(2) of the REACH.
EE5	**Cobalt dichloride, #1149; Use for production of cultured media to allow fermentation processes for production of proteins, and other biomolecules e.g. for pharmaceuticals, vaccines etc.** Following the fermentation process, the remaining cobalt dichloride, if any, is separated from the end products in a separation and purification process. Companies preparing or using cobalt dichloride for culturing media must comply with the industrial hygiene framework of **occupational exposure limits values recognized as good occupational hygiene practice (ECHA, 2009)**. (Examples of occupational exposure limit values, UK 0.1 mg/m3, Sweden 0.05 mg/m3. (+ very low amounts and exposure potential) The prohibition	References to the Council Directive 98/24/EC on **the protection of the health and safety of workers from the risks related to chemical agents at work** (CAD) and the **Carcinogens or mutagens at work Directive 2004/37/EC (CMD)** as outlined earlier in this Table apply. In this specific request, the respondent highlights their relatively small consumption of cobalt dichloride (50 gms per year) in their stated use. However, the CAD and CMD do not consider threshold quantities in their application. Furthermore, the authorisation requierment does not have a volume threshold.

#	Group of Exemption request (comment example(s); legislation; use(s); any justification)	Response
	or restriction on the use of cobalt dichloride for this use would most be disruptive to the pharmaceutical industry and innovation in the European Union.	
EE6	**Cobalt dichloride, #655; 67/548. Cobalt dichloride is the color reactive component of humidity indicators.** In our opinion this application fulfils an exemption from the authorisation requirement according to art. 58 (2). Max. tonnage 100 kg per year.	As the exemption request is only based on national legislation there is no basis for an exemption on the basis of Article 58(2).
Environment-based legislation		
EE7	**Co(II) carbonate, #1827, #1047;,Cobalt dichloride, #1085; Directive 96/61/EC** for ENV: concerning integrated pollution prevention and control / **the IPPC Directive (Dir. 2008/1/EC)**, **all uses / uses covered by that legislation** Industry must comply with its requirements	*Man via the environment* The substances have been identified as SVHC on the basis of Article 57(a) and 57(c). Nevertheless, release to the environment is potentially an important step in the life-cycle with respect to exposure of man via the environment. In relation to **Directive 2008/1/EC (IPPC**), Annex III is an indicative list of the main polluting substances and includes large groups of substances. The directive does not specify how to identify polluting substances for which a permit for an installation needs to include an emission limit value. For these reasons the substances for which the minimum requirements set out in the directive apply are not specified in a way that would allow the use of the IPPC Directive as a reason for exemption under Article 58(2) REACH. It is further noted that pursuant to Article 62(5)(b)(i) REACH an applicant may justify in his authorisation application that emissions from an installation for which an IPPC-permit has been granted do not need to be considered when deciding on an authorisation. This implies that a case specific consideration is needed to judge whether risks arising from IPPC installations are properly controlled. It is noted that the IPPC Directive will be repealed with effect from 7 Jan 2014 by the Industrial Emissions Directive (IED, 2010/75/EU) and that the same conclusions, as above, will still apply. See, also the replies to

#	Group of Exemption request (comment example(s); legislation; use(s); any justification)	Response
		questions directly referring to IED.
EE8	**Co(II) carbonate, #1827; Directive 96/82/EC on the control of major accident hazards** involving dangerous substances, which set out conditions for the strict control of environmental risk (for R50/53 substances); **all uses**	*Man via the environment* This substance has been identified as SVHC on the basis of Article 57(a) and 57(c). Nevertheless, release to the environment due to major accidents is an important potential source of exposure of man via the environment. The **Seveso II Directive 96/82/EC** aims at the prevention of major accident hazards involving dangerous substances and at the limitation of the consequences of such accidents for man and the environment. The Directive only applies to establishments where certain dangerous substances are present above specified tonnage thresholds. In addition, the focus of the Directive is relatively limited and does not address protection of man via the environment during normal operating conditions. In the absence of such controls, as outlined in the other responses to comments, it does not appear that there is adequate protection of man via the environment from this substance.
EE9	**Cobalt dichloride, #1690;** In the EU, the human health and environmental aspects for safe handling of Cobalt(II) salts are regulated the following laws and regulations: • **EG 1907/2006 (REACH-regulation) • EG/1272/2008 (GHS-regulation) • 2002/95/EG (ROHS) • 2002/96/EG (WEEE) • 196/82/EG (Seveso-II-RL) • 2010/75/EU (IVU) • 2000/60/EG (WRR) • 98/249/EG; use: plating**	The **ROHS Directive 2002/95/EC**, which is to be repealed on 3 Jan 2013 by **Directive 2011/65/EU,** restricts the levels of certain substances in electrical and electronic equipment with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE. However, the ROHS Directive does not refer to cobalt or its compounds. The **WEEE Directive 2002/96/EC** aims, as a first priority, at the prevention of waste electrical and electronic equipment, and in addition, the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste. It also seeks to improve the environmental performance of all operators involved in the life cycle of EEE e.g. producers, distributors and consumers and in particular those operators directly involved in the treatment of WEEE. The WEEE Directive requires Member States to take the necessary measures to ensure that producers provide reuse and treatment information for each type of new EEE put on the market. This information shall identify, as far as it is needed by reuse centres, treatment and recycling facilities in order to comply with the WEEE Directive, the different EEE components and materials, as well as the location of dangerous substances and preparations in EEE (as defined by 67/548/EEC and 1999/45/EEC). While the WEEE Directive contributes to environmental protection at the waste life cycle stage of these articles, it does not however set minimum requirements to ensure that the risk is properly controlled from cobalt or its compounds. In relation to **Directive 2010/75/EU (IED**), (which will shortly replace a number of existing Directives including the IPPC Directive), Annex II is an indicative list of the main polluting substances and includes large

#	Group of Exemption request (comment example(s); legislation; use(s); any justification)	Response
		groups of substances. The directive does not specify how to identify polluting substances for which a permit for an installation needs to include an emission limit value. [17] For these reasons the substances for which the minimum requirements set out in the directive apply are not specified in a way that would allow the use of the IED Directive as a reason for exemption under Article 58(2) REACH. It is further noted that pursuant to Article 62(5)(b)(i) REACH an applicant may justify in his authorisation application that emissions from an installation for which an IPPC-permit has been granted do not need to be considered when deciding on an authorisation. This implies that a case specific consideration is needed to judge whether risks arising from IPPC installations are properly controlled. In relation to **Directive 2000/60/EC (WFD**) (and its daughter Directive 2008/105/EC), while these Directives set environmental quality standards for certain substances in the aquatic environment, and a framework for control of emissions, discharges and losses of these substances into the aquatic environment, they do not establish specific emission limits for substances or define risk management measures required. In addition, cobalt and its compounds are not included in the list of priority substances (Annex X), for which EU-wide EQSs are defined. For these reasons the WFD does not appear to be a sufficient justification for exemption under Article 58(2) REACH. It is further noted that pursuant to Article 62(5)(b)(ii) REACH an applicant may justify in his authorisation application that discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive do not need to be considered when deciding on an authorisation. This implies that a case specific consideration is needed to judge whether risks arising from such discharges are properly controlled. **Decision 98/249/EC** approved on behalf of the Community the OSPAR Convention for Protection of the Marine Environment of the North-East Atlantic. This Convention is not applicable to all Member States of the Community. **Directive 96/82/EC (Seveso II)** aims at the prevention of major accident hazards involving dangerous substances and at the limitation of the consequences of such accidents for man and the environment. This Directive only applies to establishments where these substances are present above specified tonnage thresholds. In addition, the focus of the Directive is relatively limited and does not address protection of man via the environment during normal operating conditions. In the absence of such controls, as outlined in the other responses to comments, it does not appear that there is adequate protection of man via the environment from this substance.

[17] The only specific reference to cobalt and its compounds is in Annex VI which sets air emission limit values for waste incineration plants

#	Group of Exemption request (comment example(s); legislation; use(s); any justification)	Response
EE10	**Co(II) carbonate, #1199;** The **discharge of liquid waste via water treatment installation** is covered by the Directive **2000/60/EC Water Framework Directive** and **Directive 2008/105/EC**.Cobalt and corresponding compounds are not listed in Annex X (list of priority substances in the field of water policy). The **discharging of chemical waste** is covered by the Waste Framework Directive (**2006/12/EC, revised by 2008/98/EC**)	In relation to **Directive 2000/60/EC (WFD**) (and its daughter **Directive 2008/105/EC**), while these Directives set environmental quality standards for certain substances in the aquatic environment, and a framework for control of emissions, discharges and losses of these substances into the aquatic environment, they do not establish specific emission limits for substances or define risk management measures required. In addition, cobalt and its compounds are not included in the list of priority substances (Annex X), for which EU-wide EQSs are defined. For these reasons the WFD does not appear to be sufficient as a reason for exemption under Article 58(2) REACH. It is further noted that pursuant to Article 62(5)(b)(ii) REACH an applicant may justify in his authorisation application that discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive do not need to be considered when deciding on an authorisation. This implies that a case specific consideration is needed to judge whether risks arising from such discharges are properly controlled. The **Waste Framework Directive (2008/98/EC)** aims at, *inter alia*, protecting the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste (including hazardous waste). Wastes classified as hazardous are considered to display one or more of the properties listed in Annex III of the Directive - which includes CMR properties. Wastes classified as hazardous feature on the list established by Commission Decision 2000/532/EC. Spent catalysts containing dangerous transition metals or dangerous transition metal compounds – including cobalt – are listed as hazardous waste and need to be treated accordingly. The Waste Framework Directive in general contributes to environmental protection at the waste life cycle stage. The spent catalysts are specifically listed as hazardous waste and therefore there appears to be minimum requirements related to the waste stage of this use. However, as outlined in the responses to other comments, there does not appear to be sufficient protection of man via the environment at other life cycle stages of this specific use.
EE11	**Cobalt diacetate, #744; IED Directive.** "**Automated processes and enclosed systems in surface treatment** should be exempted, as well as **activities covered by the IED directive**."	In relation to **Directive 2010/75/EU (IED**), (which will shortly replace a number of existing Directives including the IPPC Directive), Annex II is an indicative list of the main polluting substances and includes large groups of substances. The directive does not specify how to identify polluting substances for which a permit for an installation needs to include an emission limit value.[18] For these reasons the substances for which the minimum requirements set out in the directive apply are not specified in a way that would allow the use of the IED Directive as a reason for exemption under Article 58(2) REACH. It is further noted that pursuant to Article 62(5)(b)(i) REACH an applicant may justify in his authorisation application that emissions from an installation for which an IPPC-permit has been granted do not need to be considered when deciding on an authorisation. This implies that a case specific consideration is needed to judge whether risks arising from IPPC installations are

[18] The only specific reference to cobalt and its compounds is in Annex VI which sets air emission limit values for waste incineration plants

#	Group of Exemption request (comment example(s); legislation; use(s); any justification)	Response
		properly controlled.
Other legislation		
EE12	**Cobalt dichloride, #1516;** If products are manufactured by Genetically Modified Microorganisms (GMMs), which is often the case in the biotech industry, the products are manufactured complying with **Directive 2009/41/EC which lays down common measures for the contained use of GMMs.**	**Directive 2009/41/EC** lays down measures for the contained use of GMMs with a view to protecting human health and the environment. However, the Directive does not specifically aim to control the risks arising from the use of cobalt dichloride or other non-GMM substances.
EE13	**Cobalt diacetate, #586; Regulation 2011/10/EU** on plastic materials and articles intended to come into contact with food – CoAc is listed as a specific additive for food contact plastics. There is no consumer or worker exposure to CoAc in any downstream product of PTA, IPA or DMT manufacture. This legislation in combination with some of the above, relevant for **uses as catalyst / production of PET**.	Cobalt diacetate is used as a catalyst in manufacture of terephthalic acid (PTA), isophthalic acid (IPA) and dimethylterephthalate (DMT). PTA, etc are monomers for subsequent manufacture of polymers e.g. PET. The residual levels of cobalt in the PTA, IPA & DMT products are <1ppm as cobalt. The metal is present as cobalt terephthalate which is bound into the subsequently manufactured PET resin in a non soluble form. Resulting polymers are used in food contact plastics and therefore must comply with the migration requirements of **Regulation 2011/10/EU** on plastic materials and articles intended to come into contact with food. In principle, there should be no consumer or worker exposure to cobalt acetate in the downstream product of PTA, IPA or DMT manufacture. Cobalt diacetate is not specifically identified as a named substance in **Council Regulation 2011/10/EU**. However, cobalt salts are ***authorised*** to be used intentionally in the manufacture of plastics provided specific conditions apply. The conditions concern the migration level of cobalt from plastic layer to contact food. The conditions on cobalt salts are noted in respect of **Regulation 2011/10/EU.** However, the Regulation does not specifically aim to control the risks arising from the use of cobalt acetate (or cobalt salts) as a catalyst or in the production of PET and does not specify minimum requirements to control such risks in these upstream processes.
EE14	**Cobalt dichloride, #1085;** Specific exemption for **use in vitro diagnostic assays and in medical devices**: The use for the substance in medical device is regulated by **Council Directive 90/385/EEC and Directive 98/79/EC for in**	It is noted that the comment does not appear to include a request for exemption for uses but rather a statement that no authorisation application is needed for these uses. We wish here also to refer to recital 18 of Commission Regulation (EU) No 143/2011 of 17 February 2011, amending Annex XIV to REACH for the first time (please see also our response to issue DD7).

#	Group of Exemption request (comment example(s); legislation; use(s); any justification)	Response
	vitro diagnostic medical devices. According to Article 60(2) the Commission should not consider the risks to human health, when granting authorisations, with the use of substances covered by the above directives. Therefore an application for authorisation is not needed.	**Council Directive 90/385/EEC** deals with an 'active implantable medical device' (AIMD) meaning any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure; 'active' in that the medical device relies for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity, and, as a medical device, does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. Medical devices can administer or incorporate substances (if defined as medicinal products) An Essential Requirement of the device is that its use does not compromise the clinical condition or the safety of patients. It must not present any risk to the persons implanting them or, where applicable, to other persons. The Directive (a product safety directive), deals with design (essential requirements) and conformity assessment of devices manufactured & supplied to the EU. **Council Directive 98/79/EC on i**n vitro diagnostic medical devices sets out a framework for the design (essential requirements) and conformity assessment of devices manufactured & supplied to the EU. This includes reagents and reagent products.

CONCLUSION

On the basis of the criteria and approach set out in the introduction, ECHA has made the following observations on the argumentation brought forward by commenting parties in relation to exemption requests under Article 58(2) REACH:

- existing EU legislation aimed at protection of workers against risks to their health (including Directives 98/24/EC and 2004/37/EC) currently do not impose binding minimum requirements for controlling risks to workers health during the use phase or throughout the life cycle of the cobalt (II) compounds proposed for Annex XIV.

- In addition, in terms of protection of humans via the environment, the risks from the proposed Annex XIV substances do not appear to be sufficiently controlled at EU level. While there is EU legislation in place which addresses particular life cycle stages (such as waste) or, in certain cases, the control of accidents, there does not appear to be sufficient protection of man via the environment at other life cycle stages which are considered to fall within the scope of authorisation.

These conclusions have been reached based on an analysis of each piece of legislation separately and collectively.

GLOSSARY

CAD	Council Directive 98/24/EC of 7 Aprl 1998 on the protection of workers from the risks related tchemical agents at work
CMD	Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
GMM	Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms.
IED	Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control).
IPPC	Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control.
ROHS	Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
Seveso II	Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances
WEEE	Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)
WFD	Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy
Waste FD	Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives
CAD	Council Directive 98/24/EC of 7 Aprl 1998 on the protection of workers from the risks related tchemical agents at work
CMD	Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

F – Miscellaneous

#	Issue(s) addressed	Comment example(s)	Response
FF1	**Market share away from European manufacturers**	Cobalt(II) carbonate, #641 The cobalt industry is small but significant in value terms for Europe. Cobalt carbonate, as are the other cobalt compounds subject to this review, is a critical raw material that is the starting point for a range of downstream industries that are crucial to many other EU initiatives, such as clean air and energy and resource efficiency, to say nothing about the economic added value for the European economy. Catalysts produced from these substances are essential to the economy of European chemical manufacturing industry, enabling reactions to take place at low temperatures, low pressures, with wider benefits for energy and resource efficiency. Desulphurized fossil fuels are just one of the resulting products that are vital to Europe's efforts to improve the health of the population by producing clean air. All engineering companies in Europe rely on cutting tools that have employed the use of one or more of these compounds at an early stage of their manufacture. Modern electronic devices such as computers, mobile phones, and hybrid cars use rechargeable batteries, the latest generations of which use components which used at least one of these cobalt compounds at an early stage in their manufacture. Meanwhile, Cobalt has been designated a 'critical raw material' by the European Commission. There has been no impact assessment for the effect on industry or these other cornerstone EC policies as part of this Prioritisation. These products are so fundamental to our daily lives that they will continue to be produced. These downstream products will still be imported into Europe, regardless of whether any of the five cobalt substances are placed in Annex XIV or not, as they	Thank you for your comment. Please note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives. As the cobalt(II) substances included in the draft recommendation are carcinogenic and toxic for reproduction, there is a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses. An authorisation requirement for the cobalt(II) salts will accordingly ensure that the health of workers in the EU involved in the uses of the mentioned Cobalt salts is protected. Authorisation does not ban or restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are properly controlled or that there are no alternatives available and the socio-economic benefits are outweighing the risks arising from the uses. Information and concerns brought forward in your comments can be included in the application, should you decide to apply for authorisation of your uses of the substance or if your supplier applies for you. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the

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		do not contain any of the five cobalt compounds. ***However, Annex XIV listing will create uncertainty as to the ability of European industry to produce these products in future, and downstream users will need to develop new non-European sources to protect their supply chain, taking market share away from European manufacturers.*** The small tonnage of uses within scope will not justify companies applying for Authorisation. Only European Industry will be adversely impacted. We believe that these decisions should not be taken lightly as their economic impact on Europe can be profound. If necessary, more time should be taken to improve the quality of the data used to make the Prioritisation determination for these substances, particularly at this time of economic hardship across Europe.	authorisation, such as e.g. the length of the time limited review period of the authorisation.