20 December 2011

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

	Substance	EC Number
I	Chromium trioxide	215-607-8
II	Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid Dichromic acid Oligomers of chromic acid and dichromic acid	 231-801-5 236-881-5 not yet assigned
III	Sodium dichromate	234-190-3
IV	Potassium dichromate	231-906-6
V	Ammonium dichromate	215-693-7
VI	Potassium chromate	232-140-5
VII	Sodium chromate	231-889-5

This document provides ECHA's responses to comments received during the public consultation on the 3rd draft 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 chromium(VI) 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 seven Chromium 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	**Questioning prioritisation of Chromium (VI) compounds (chromium trioxide versus chromic acids).**	Chromium trioxide (e.g. #1699) • It is difficult to see why the current justification and proportionality of the relevant provisions to handle Chromium trioxide (-solutions) should need further approvals. National and European law already requires aspects of regulatory monitoring and control as well as to the increasing internationalization of requirements. Any additional configurable prioritization and approval of changes will only reproduce the current national requirements. • Furthermore, a separation in chromic acid and chromium trioxide is senseless from the chemical point of view. • Many decades provides a clear understanding of the safety and efficacy and show that on no account an endangering of the end-consumer is realistic.	On the 1st part: see response DD3. Chromic acids are generated from the dissolution of chromium trioxide in water. The European Inventory of Existing Commercial Chemical Substances (EINECS) lists chromium trioxide and chromic acid as separate entries. Therefore, they are regarded as different substances. The two substances 'Chromium trioxide' and 'Acids generated from chromium trioxide and their oligomers' have been included in the Candidate List to complement each other in order to ensure adequate management of the risk regardless of the form in which Chromium trioxide is used / placed on the market. Identification of both substances as SVHC was necessary to avoid a possible evasion of the authorisation requirement for chromium trioxide. (If chromium trioxide was included in Annex XIV but not the chromic acids the authorisation requirement for many uses of chromium trioxide could be evaded by simple replacement of chromium trioxide with chromic acid.) In case of inclusion in Annex XIV, whether a potential user would need to

#	Issue(s) addressed	Comment example(s)	Response
			submit an authorisation application for one or the other substance would depend on the particular case. For example, if a company would start its process/use with Chromium trioxide, then - even if during the process water is added and so actually 'Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid' are generated – the company would need to submit an authorisation application only for Chromium trioxide, assuming that water is added just to bring Chromium trioxide in an applicable form. On the other hand, if a company would start its application/use with 'Acids generated from chromium trioxide and their oligomers' (i.e. Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid,' (i.e. purchase Chromium trioxide in aqueous solution from a supplier), then it would need to apply for use of 'Acids generated from chromium trioxide and their oligomers'. ECHA applied the agreed general prioritisation approach to determine which substances should be recommended to be included in Annex XIV. (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf) The results of the prioritisation including the reasoning why ECHA concluded that chromium trioxide and its solutions should be prioritised can be found in the document linked below. http://echa.europa.eu/documents/10162/17232/prioritisation_results_3rd_rec_en.pdf Note that the agreed prioritisation approach is not intended to assess the risks exerted by particular applications of a substance (e.g. hard chrome plating) 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 our conclusion that some of the uses appear to have a potential for significant worker exposure in combination with a scoring of 3 is correct although exposure to workers may be controlled in many instances. If a substance or a use is not a priori exempted from authorisation in REACH
		6. Resulting requirements: 1. According to the available data there is no basis for an inclusion of the hard chromium plating from Chromium trioxide (-solutions) in Annex XIV of the REACh regulation. 2. In the case of an inclusion it is absolutely necessary to realize a derogation rule for the application of Chromium trioxide (-solutions) for bright chromium plating.	

#	Issue(s) addressed	Comment example(s)	Response
			other (categories of) uses of a substance can only be exempted from the authorisation requirement of the basis of Article 58(2) (for further explanation on the conditions of such exemptions see response DD2).

B – COMMENTS ON ECHA'S PRIORITISATION APPROACH, APPLICATION OF PRIORITISATION CRITERIA AND ASSIGNED SCORES

#	Issue(s) addressed	Comment example(s)	Response
BB1	**Definition of intermediate.**	Chromium trioxide #1457 "The largest part of the registered amount is allocated to uses in the scope of authorisation." Observation: ECHA's interpretation of the concept of 'intermediate' (as given in its June 2010 clarification document) excludes substances used as surface treatments, e.g. Chromium Trioxide used in metal finishing. On that basis, the volumes of Chromium Trioxide used for that purpose fall under the scope of authorisation. However, the conclusion reached in the clarification document cannot be supported. The abovementioned clarification document was reviewed by two independent legal experts, the law firm Field Fisher Waterhouse and Professor Dr. Kristian Fischer, at the request of Industry. In Cefic's position paper of December 2010 (please see link: http://www.cefic.org/Documents/IndustrySupport/Cefic%20concept%20of%20intermediates%20letter%20(2).pdf), 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."	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'.[1]. 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 the actor 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.

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

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		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 AIFM, AIAS, Assogalvanica, VOM BL, VOM NL, Anaz,… and the Institute of Metal Finishing. Within that context, should the literal definition of intermediate under Article 3(15) be applied, the volumes of Chromium Trioxide used in metal finishing would fall outside of authorisation. As a result, the statement made under Point 2.2.1 is without foundation.	
BB2	**Disagreement with prioritisation approach applied.**	Chromium trioxide, #1105 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) Neither chromium trioxide nor chromic acid have 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	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.

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		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 (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 not apply for chromium trioxide 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 not resulting or comparable with	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 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

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		"sources like traffic", "painting with uncontrolled exposure" or (outdoor) "spraying of pesticides". 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 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 chromium trioxide is 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. For the scoring the "number of sites" is multiplied by "Release". Here an inconsistency is present in the evaluation of the use of chromium trioxide in industrial surface treatment: • It is noted that the number of sites of use is unknown, however rated as "high". • It is stated that "Releases and exposure to workers might be controlled in most instances, however some of the uses appear to have a potential for significant worker exposure". Consequently the majority of uses is controlled and should be rated accordingly (score '1'). Assuming that few cases have a potential for high exposure does not justify the classification as "wide-dispersive use", which would base on a high number of point sources with uncontrolled exposure. In addition the approach of ECHA disregards the fact that	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 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 surface treatment consumer exposure to CrVI seems to be no issue but potential exposure of workers to CrVI compounds appears to be, as the use descriptions referring to surface treatment in the registrations and the monitoring results regarding occupational exposure to CrVI compounds cited in the Annex XV dossier for CrO3 indicate. Based on this and in line with the agreed approach some of the uses have a potential for significant[2] 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

[2] 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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		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. Regulatory effectiveness ECHA extends the scoring approach with a verbal-argumentative evaluation. This shall facilitate the determination of the regulatory effectiveness of the authorization process. Considering that there are no existing alternatives for functional chrome plating, there will be no environmental or human health benefit if authorization is required. Unfortunately 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 functional chrome plating without any bureaucratic hurdles. It should be the aim of European authorities that existing technology is optimized at places where the exposition elevated. Please note here that this is only the case for some individual cases. Conclusion It is to note that chromium trioxide in surface treatment applications does neither fulfill the criteria PBT or vPvB properties nor "wide-dispersive use" and regulatory effectiveness is also not present for this case. Consequently neither facts nor the formal process justify a prioritization of chromium trioxide.	combination with a scoring of 3 is in accordance with the agreed approach although exposure to workers may be controlled in many instances.
BB3	**Comments on the rationale of the grouping approach, in particular the possibility to evade the authorisation**	Chromic acid, #1834 We want to draw the attention to the fact that it is against ECHA policy to prioritise substances unless all substances	Thank you for your comment. Grouping of substances for inclusion in Annex XIV in order to avoid evasion of the authorisation requirement for a particular substance (or group of

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	requirement by substituting the substance subject to authorisation with another hazardous substance/s not on the Candidate List.	of the same group are being prioritised at the same time. Therefore, as long as strontium chromate is not even on the candidate list, it is inappropriate for ECHA to recommend other CrVI compounds, and in particular CrO3, for prioritisation for inclusion in Annex XIV.	substances) with substances of similar nature and toxicity (e.g. different salts of CrVI) does not mean, and in terms of regulatory effectiveness does not require to first include all the similar compounds to the Candidate List before it would be meaningful to consider any further risk management measures (e.g. inclusion in Annex XIV) for the individual substances or the entire group. Strontium chromate was included in the Candidate List on 20/06/2011.
BB4	**Defer / delay prioritisation as studies on control of risks are ongoing.**	Sodium dichromate, #1013 Studies are currently ongoing which will indicate whether risks are being effectively controlled using current best practice (for example see http://www.sro.hse.gov.uk – JN4077 – Biological Monitoring in Surface Engineering – Project Number: OH36). These may also indicate whether any remaining risk is due to a lack of application of best practice or whether the best practice guidance is inadequate… It is essential to know whether current controls are adequately addressing the risk or whether additional controls are required. For this reason, it would be prudent to await the outcome of the latest batch of studies into the health effects of chromium (VI) compounds before making a decision on whether sodium dichromate should be added to Annex XIV. If the study recommends that additional equipment is required to achieve optimum control of the risks, this may have an impact on the desire to pursue a potential authorisation request.	Thank you for your comment. The studies you refer to might indeed produce results which could be included in your authorisation application. Especially information on how potential risks are controlled is a compulsory part in every application. Please note that the prioritisation approach which was agreed and applied here to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV 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 conservative approach needs to be taken considering in particular uses or situations in which risks may potentially not be controlled. Therefore, ECHA's conclusion that some of the uses appear to have a potential for significant worker exposure and therefore – in combination with other criteria – qualify for prioritisation and inclusion in Annex XIV was drawn although risks might be adequately controlled in many instances.
BB5	**The information used in support of the prioritisation is not up to date.**	Chromium trioxide, #1088 The baseline data in the Annex XV report overestimates exposure to Chromium compounds; • Our industry is extremely concerned about this proposal for authorization. The baseline data in a 2011	Thank you for your comment. For the purpose of priority setting we have taken all the information that was available to us into account. In particular, this was information from the registration dossiers including 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

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		survey in the Netherlands already demonstrates a reduction in overall use and exposure of hexavalent Chrome compounds compared to the 2001 data used for the Annex XV report.	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.
		Chromic acid, #ATT 1014 By means of a survey by Industox we have obtained a true and accurate insight in the environmental load and occupational exposures related to downstream use of Chromium VI in the (metal) surface treatment and finishing industry in 2011 in the Netherlands. A copy of this report is enclosed. The main conclusions of Industox are: • Data for risk assessment of chromium VI in the Netherlands may deviate substantially - on important issues - from the situation ten years ago. On company level, the use of chromium VI has decreased by 60-90% compared with 10 years ago. • Environmental releases of chromium VI to air and sewage water are 15-20 times lower than estimated by EU-RAR. • The number of exposed workers in the metal treatment industry in the Netherlands is between 250-300. This is substantially lower than ECHA estimates: 44.000 employees in Europe, which would mean that less than 1% of exposed European employees are Dutch, which is hard to imagine considering the market share of Dutch companies. • The survey showed no alternatives for hard chrome plating.	In the case of chromium trioxide/ acids generated from chromium trioxide and oligomers, the prioritisation is based on the available information on current uses and volumes as provided in the registration dossiers and during consultation. See description of the prioritisation approach: http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf . The foreseen future trends can be addressed in the authorisation applications and will be taken into account during the assessment of such applications by the ECHA Committees and in the final decision making by the commission. For further information on the scope and coverage of the prioritisation in the context of ECHA's Recommendation for inclusion of substances in Annex XIV please refer to response BB2. If there is new relevant information available, e.g. changes in tonnage bands or uses, the registration needs to be updated and submitted to the Agency without delay. Generally it is advisable to specify the tonnage per use in the registration dossiers for ECHA to have the best possible base for the prioritisation. This information was not included in the CSRs for all substances.

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		According to the Industox' report, ECHA estimates seem to overrate volume, environmental emissions and the number of exposed workers. The RAR Risk assessment data are ten years old. The Member States committee and the European Commission need an actual and current view to determine if chromium VI must be included in Annex XIV or not. Based on this new information for the Netherlands FME recommends ECHA to carry out further investigation in other Member States. FME also asks ECHA to recalculate, based on the much lower Industox figures for the Netherlands, if chromium VI would still need to be prioritised to be included in Annex XIV. Sodium dichromate, #ATT 711a As a consequence of this measured and factual data, the assessment of the exposure level in the draft recommendation as well as the total and sectorial volumes used are over estimated. Therefore, a lower prioritisation score is applicable and justified. We believe that the updated information (from the CSR) on the measured exposure levels, the analysis of sodium dichromate use for non-intermediate use, brings sufficient proof to indicate a lower prioritisation score. Sodium dichromate, #ATT 520 Ensure Prioritisation that is fact based and therefore, we would like to request the CSR's of these substances being fully recognised and provide additional measured and	

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		factual data that would allow to complement the priority assessment.	
BB6	**Potassium chromate and dichromate do not fulfil prioritisation criteria. Need for regulatory effectiveness should only apply to uses where switch to these compounds was possible.**	Potassium dichromate and Potassium chromate, #669, #1596, #1753 The criteria for prioritization of substances for inclusion into Annex XIV are listed in Art. 58 (3): a) PBT or vPvB properties, or b) wide dispersive use, or c) high volumes. None of these criteria applies to potassium dichromate. As mentioned in the background document, the volume of potassium dichromate manufactured in the EU is quite low and the uses of the substance are not considered as wide dispersive. Nevertheless, we understand the need for the authorisation of potassium dichromate (regulatory effectiveness) to prevent the switch from sodium dichromate, which is fulfilling the criteria of Art. 58 (3), to potassium dichromate for some uses. However, this should not lead to authorization for uses of potassium dichromate 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). Potassium dichromate is an important substance for scientific R&D, which is done in the pharmaceutical industry, in laboratories of waste water treatment plants,	In order to achieve regulatory effectiveness, grouping of substances for inclusion in Annex XIV to REACH is necessary. This can avoid evasion of the authorisation requirement for a particular substance (or group of substances) by substitution with substances of similar nature and toxicity (e.g. different salts of CrVI). Note that inclusion in Annex XIV to REACH is for substances and not for particular uses of the substance. Nevertheless, particular uses are *a priori* exempted from authorisation (see Art. 2 paragraphs 5 and 8, and Art. 56 paragraphs from 3 to 6). Scientific research and development (SRD) is exempted from the authorisation requirement, according to Art. 56(3) REACH. 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) REACH: *"(…) any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year"*. Please, note that • SRD activities can cover analysis for monitoring or quality controls purposes; • Therefore, in principle a substance may be exempted 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 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[3] 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

[3] 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, their 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
		and in routine analytics. It is actually not possible to replace potassium dichromate in these applications.	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 laboratory 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) REACH and no authorisation would be required to continue the use after the sunset date.
BB7	**Description of uses not covered in BD /Information is given on further uses / Further details on uses.**	For example: Potassium dichromate #1787, #656, Sodium dichromate, #619 Use of sodium dichromate in manufacturing of sodium chlorate: The CEFIC Sector Group for Sodium Chlorate was quite surprised to see no reference to this use in the	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 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 chromium(VI) compound 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. Thank you for the provided information, which will be considered for updating the Background Document as necessary. Please note that we had no information on this use as it is not included in the registration(s) submitted for the substance. Note that Art. 22 (1d) requires update of the registration(s) without undue delay in case of new identified uses […] for which the substance is manufactured or imported. Thank you for the provided information, which will be considered for updating the Background Document as necessary. Please note that according to our

#	Issue(s) addressed	Comment example(s)	Response
		report". Chromium trioxide #591 The Annex XV document of chromium trioxide and chromic acid had not taken into account a major industry, the coil coating industry, using the substances in their processes. Therefore, the European Coil Coating Association has prepared an informative report providing essential information of the coil coating process, the use of dichromium tris(chromate), chromium trioxide, and chromic acid in the process, and the safety measures put in place to prevent environmental and personal exposure to the harmful substances. Moreover, data of life-cycle and recycling of the substances and available substances will be provided by a major European coil coater. It will be shown that the substitutes presented in the Annex XV are not relevant or in use today. Please find the report attached.	understanding this use would be covered under metal finishing and surface treatment.

C – COMMENTS ON LATEST APPLICATION DATES, SUNSET DATES AND REVIEW PERIODS

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[4] 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 to 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

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

trichloroethylene will likely be lower than for the five Cobalt and seven Chromium compounds. To get further spreading of the workload, 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.**	All substances.	Thank you for your comment. Please note that setting 'upfront' review periods[5] 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**	Chromic acid, #1099 and	Thank you for your comment.

[5] 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.

#	Issue(s) addressed	Comment example(s)	Response
	because SME's in the field of metal surface treatment may not be able to handle authorisation application processes for cobalt and Chromium (VI) compounds simultaneously at a time.	Chromium trioxide, #1105 Five cobalt salts are present in ECHA's draft recommendation for inclusion on Annex XIV. As these salts and chromium trioxide are used for surface treatment, this sector 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.	Note that in accordance with Art. 62 paragraphs 2 and 3 of REACH, 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 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	**Prolonging application date for SMEs.**	Chromium trioxide, #1105 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. Chromium trioxide, #1004	Thank you for your comment. Note that in accordance with Art. 62 paragraphs 2 and 3 of REACH, 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

#	Issue(s) addressed	Comment example(s)	Response
		High number of SMEs, need for an extension of both dates to be ready for the submission of application for authorisation.	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 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 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.
CC4	**Extension of the deadlines due to the complexity of the supply chain.**	Chromium trioxide, #582 Chromium trioxide is a non threshold carcinogen. Consequently, an application for authorization will need to include a socio-economic analysis(SEA). The supply chains of articles subjected to surface treatment operations involving chromium trioxide are varied and complex. Preparing SEAs will be require a huge amount of	Thank you for your comment. We understand that you request an extension of the latest application dates for chromium trioxide 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

#	Issue(s) addressed	Comment example(s)	Response
		interaction within the supply chains and is expected to take a considerable time. If Chromium Trioxide is to be prioritised for authorization the application and sunset dates should be extended in order to enable robust SEAs to be developed. July 2015 and January 2017 respectively for latest application and sunset dates would provide a minimum realistic time frame in which suitable SEAs could be prepared.	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.
CC5	**Shortening the application date.**	Ammonium dichromate, #543 and Potassium chromate, #551 and Sodium chromate, #553 The timelines foreseen for transitional arrangements should be shortened to an application date of 12 months (sun set date 30 months) after the date of inclusion in Annex XIV.	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 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.
CC6	**Prolong timelines foreseen based on Art. 55 of REACH.**	Chromic acids, #1099 Article 55 (REACH) says that it is the aim to "ensure the good functioning of the internal market" by **progressively**	Thank you for your comment. The Authorisation title has three objectives, which according to Art. 55 are (i) the good functioning of the internal market and (ii) assuring that the risks from substances of very high concern (SVHC) are properly controlled and (iii) that these substances are progressively replaced by suitable alternatives or

#	Issue(s) addressed	Comment example(s)	Response
		replacing SVHC by "suitable alternative substances or technologies where these are economically and technically viable". The regulation specifically 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.	technologies where these are economically and technically viable. This does however not mean that SVHC cannot be subjected to authorisation before suitable alternatives are available or 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 accordance with Art. 62 (4e) and in the substitution plan in accordance with Art. 62(4f) in case alternatives are available). In the process of assessing/granting the authorisation it will then be decided by the European Commission on the basis of the respective analysis by the applicant and the corresponding opinions by the Committees for Socio Economic Assessment and Risk Assessment (SEAC and RAC), which will take into account any relevant information submitted by third parties, whether the applied for authorisation will be granted, which conditions apply and how long the time limited review period will be. By this procedure it is assured that all relevant aspects will be taken into due account to reach both objectives of the authorisation title, namely good functioning of the internal market and proper control of risks and progressive substitution of SVHCs, where possible. This is important information to be included in your 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 authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. Please 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.

#	Issue(s) addressed	Comment example(s)	Response
CC7	**No universal substitute process.**	Ammonium dichromate #1757 Alternative processes a. There are a variety of familiar alternatives for functional chromium plating using hexavalent electrolytes. These alternatives do not include one universal substitute process, capable of replacing hard chromium plating on a one to one basis (For details see attachment). b. If the functional hard chromium plating is to be replaced, it will be necessary to use processes, which do not have the same technical or mechanical properties and, in terms of health, do not offer any improvement in employee protection, because these introduce familiar as well as less well researched safety hazards. Other alternatives, on the other hand, are considered relatively harmless in terms of hazardous substances, however, from a technical vantage point, can only be considered as a substitute for niche applications.	Thank you for your comment. This is important information to be included in your 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.
CC8	**Aerospace industry asking for longest possible timescale to identify, test and qualify alternative**	Sodium chromate, #956, #1224 If ECHA follows previous practice, it is likely that sodium chromate 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	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

#	Issue(s) addressed	Comment example(s)	Response
	substances.	use of sodium chromate 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 sodium chromate. An extension of several years would result in alternatives being developed, industrialisation and then sectoral phase out. Insufficient time could result in manufacturing being moved outside of Europe. Potassium dichromate, #1228 Sodium chromate, #900, #1224 The development of alternative solutions, which do not contain potassium dichromate, has been the subject of Research and Development activities for a number of years, in some cases 20+, and is continuing. It is exceptionally complex. The timescales for such programmes are extensive: typically it is necessary to identify a range of possible alternatives, complete initial screening tests to allow the best contenders to emerge, develop these into commercially viable solutions and then complete the qualification testing demanded by the aerospace industry. Qualification testing has to be completed against either internationally recognised performance standards or internal company standards, in order to satisfy the quality requirements of the industry. The safety critical performance criteria that needs to be met has meant that alternatives have fallen well short. If an alternative is developed it must go through a rigorous program of testing including approvals from EASA (European Aviation Safety Agency) and FAA (Federal Aviation Administration). These are varied depending on the application and will require airworthiness testing. For these reasons, it is essential that prioritisation be deferred for as long as possible, to allow time for alternative solutions to become fully tested and accepted.	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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		Without this delay, it is anticipated that there will be extensive applications for authorisation to continue to use potassium dichromate when it appears on Annex XIV. The level of effort that will be expended in making these applications could be better employed in sorting out the qualification and introduction of alternatives. Similarly, the resources required at ECHA to deal with these applications could be better employed on other topics.	
CC9	**Authorisation not granted.**	Chromic acid, #1834 In case an authorisation which has been applied for in due course is not granted, depending on the timing of the refusal decision, the applicant may not anymore have the possibility to yet go for an alternative to the use of CrVI. Indeed, taking into account the foreseen procedures and consultations, probably about 18 months will be needed before the Commission can decide on an authorisation application. This means that a decision can be expected to be taken at best only a short time before the sunset date and in a number of cases it will probably intervene long after the sunset date. In that case, production will have to be stopped immediately on receipt of the refusal. In the case of our industry, in order to yet change the pre-treatment process from CrVI to a substitute process, the process line has to be modified, and this takes considerable time (cf 'general comments'). We therefore insist that there be a good consultation with the applicant, sufficiently in advance of the issuing of the final decision. That way, as soon as he gets the message that a refusal is likely, the applicant could still take the necessary arrangements to modify the coating line in time.	Thank you for your comment. The Commission is not bound to a particular point in time at which the final decision on granting or refusing an authorisation has to be taken. Nor is there a specific procedure foreseen in case an authorisation is not granted. However, according to Art. 64(1) REACH, ECHA's Committees on Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) have to develop a draft opinion on an application for authorisation within 10 months of receipt. The applicant will receive that draft opinion and will have the possibility to comment if wished so. The applicant will have an indication when receiving the draft opinion if there are factors which might lead to the refusal of the authorisation applied for. The final opinion along with the written comments/argumentation will be sent to the applicant within 15 days after adoption. As it forms the basis for the Commission decision, the final opinion by the Committees will give the applicant valuable information on the possible final outcome. In any case we would encourage you to apply for authorisation as early as possible.
CC10	**Delaying inclusion or extended sunset**	Chromic acid, # ATT 15 and	

#	Issue(s) addressed	Comment example(s)	Response
	periods for chromates due to high complexity of the supply chain (aerospace industry).	Sodium dichromate, # ATT 2 and Potassium dichromate # ATT 1063	Thank you for your comment.
		"While some economies of scale can be achieved by, for example, combining multiple uses into a single dossier, each chromate and its uses would still have to be investigated and justified individually. Many aerospace companies are multinational and each of the resulting legal entities may have to pursue separate authorisation. Studies indicate that the net total just for the aerospace industry could be several thousand for the Chromates that are currently participating in the consultation process.	Please note that in accordance with Article 62 (2) of REACH applications for authorisation can only be made by manufacturers, importers or downstream users of the substance. Other actors in the supply or value chain may however contribute in scientific, practical and financial terms to the development of authorisation applications. High numbers of actors in a supply may in some case indicate high complexity of the supply chain whereas in other cases this may not necessarily be the case, in particular when these high number are the result of extensive parallel structures at the different (vertical) layers.
		Much of the Aerospace industry has highly complex supply chains, with thousands of companies and six or more layers between chemical manufacturer/importer and the manufacturer of the final product. These include parts suppliers, assemblers, processing companies, formulators and distributors in addition to the manufacturers and importers of the substances themselves. This creates substantial complexity in the process of Authorisation, which is expected to take a substantial period of time to accomplish.	
		We understand that the objective of the legislation is to remove hazardous substances from use as soon as is practical, but we must do this by the means that best achieves that result. Large numbers of complex authorisations will place huge financial and resource burdens on industry. Industry will have no choice but to mitigate that cost by then spreading the cost of identifying replacement chemical products over a much longer period. Thus, applying for authorisation could dilute resources currently focused on alternative development and result in a substantial extension of Chromate use well beyond the	Thank you for providing your opinion, In the end it may however be the market forces and the conditions applicable to an authorisation that will govern resource allocation to development and implementation of alternatives.

#	Issue(s) addressed	Comment example(s)	Response
		Sunset Date. Authorisation could therefore delay the replacement of these substances by several years." Possible Solutions: *1. Delay of inclusion (preferred)* "ECHA and the EC may feel that this approach would allow industry to slow down the replacement process. ASD *[i.e. European Aerospace &Defence Association submitting the comment]* does not believe that this is the case. The entry of Chromates onto the Candidate List has, by itself, put pressure on industry to replace them. Once a substance is on the Candidate List, the associated reporting requirements of Article 33 and Article 7 are invoked. There is some expectation for downstream users and end users to do what they can to obtain and manage the required information even though their suppliers, in turn, have their own obligations to provide Article 33 Declarations. These are expensive and resource-intensive processes, to the extent that many companies have a policy of starting the replacement process where possible as soon as the substance is added to the Candidate List rather than waiting until it is in Annex XIV. In combination with pressure from outside the EU, and especially from the USA, means that in the case of Chromates, the aerospace industry is anxious to replace these substances as soon as possible." *2. Extended sunset period* "As an alternate to delaying the entry of chromates into Annex XIV, a sunset period that is longer than the current maximum of four years could also be applied. The problem	As already explained in the report on the results of the prioritisation (http://echa.europa.eu/documents/10162/17232/prioritisation_results_3rd_rec_en.pdf) there appear to be no reasons that in technical terms (i.e. regulatory effectiveness) would suggest to refrain from recommending this substance group for inclusion in Annex XIV. Lack of alternatives as well as established safety requirements or performance standards, if addressed in the authorisation application, 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. Those factors may impact the decision on granting the authorisation and the conditions applicable to the authorisation, such as e.g. the length of the review period of the authorisation.

#	Issue(s) addressed	Comment example(s)	Response
		with this approach, though, is that once implemented it has no flexibility. By delaying entry into Annex XIV, ECHA can monitor the replacement process and time that entry to match the actual progress that has been made by industry. Extending the sunset period does not allow this. Although this solution solves the conflicts that have been discussed herein, and hence is acceptable to the aerospace industry, it also imposes other complications that delaying entry in Annex XIV does not have. Industry will only want to start the process of applying for authorisation once it knows for certain that it cannot qualify a replacement chemical product in time. Given that an application must be submitted at least 18 months prior to the Sunset Date, and it takes at years to prepare the application, these periods must be added to the amount of time by which the Sunset Date is extended. Thus if it is believed that a replacement substance will be available by 2017, then the Sunset Date would need to be a minimum of 30 months later than this to allow any authorisation application resulting from failing to qualify the replacement, to be prepared and processed. To set a date that is any earlier could result in companies having to prepare authorisation applications anyway just in case qualification of the replacement fails. Companies will not be able to take the risk of a replacement's qualification failing and then finding themselves unable to use either the original substance or a replacement. It is recognised that some other industries may be able to react to less demanding technical requirements faster than the aerospace industry and thus not need extended Sunset Dates. ECHA and the EC may thus be concerned that these industries would be allowed to continue using hazardous substances when it is not necessary. ASD does not recommend adopting split Sunset Dates, since this creates	As already explained above, the time needed to replace Annex XIV substances in certain uses is an important factor which should be reflected in the authorisation application and consequently will be taken into account in opinion forming and final decision making on granting of the authorisation. Please note that authorisation shall, apart from promoting substitution, ensure that risks from substances of very high concern are properly controlled. Disregarding this latter aspect could mean to neglect occupational health and safety aspects. Note further that Article 61 (2) stipulates that authorisations may be reviewed at any time if new information on possible substitutes becomes available.

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		supply chain uncertainty, for which an extended sunset period is necessary to manage and control due to the complexity of the Aerospace and Defence supply chain."	
CC11	**Extension of deadlines to allow for formation of consortia.**	Potassium dichromate #1228, Potassium chromate #1596, Sodium chromate #1224, Sodium dichromate #1370: An additional reason for deferring the prioritisation of potassium dichromate is the need to allow sufficient time for the formation of suitable consortia, involving actors from all parties concerned in the supply chain. These are essential if comprehensive applications are to be made for Authorisation. Given the complex nature of an application for Authorisation, and the likely need for negotiations involving value of existing background data and intellectual property rights, an extended period of time is required to allow consortia to be formed.	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 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. 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.
CC12	**Request for later application and sunset date.**	Sodium dichromate, #711 regarding use in Electrolytic Tin Plating (ETP) and Electrolytic Chromium Coated Steel (ECCS) for steel packaging: The sector launched a substitution plan and advanced well	We acknowledge the efforts by your sector to find and implement suitable alternatives to the use of sodium dichromate. Documentation of these measures will be crucial for a potential application for authorisation. The rest of this application could thus mainly focus on demonstration of proper control of risks arising from your uses of sodium

#	Issue(s) addressed	Comment example(s)	Response
		with it …. Indeed requiring authorisation within the timeframe 2012-2016 would divert resources and attention of the sector to the authorisation application while we feel this time and efforts should at this stage be best spend on the further finalisation of the substitution plan…. In our opinion this option is more effective and leads to a quicker substitution of sodium dichromate and is consequently a better balance between industry efforts and regulators administrative ruling to achieve the common goal of a safe manufacturing and use of ETP and ECCS.	dichromate until the substitution process for this substance is finalised. Please note that authorisation shall, apart from promoting substitution, ensure that risks from substances of very high concern are properly controlled.
CC13	**Prolong AD as DU needs to see if their supplier will apply for authorisation.**	Chromic acid, # ATT 1170 and Sodium dichromate, #ATT 1772 "Our own supplier isn't able to tell us what he's going to do. During this wait, we are resourceless: as downstream-users we are not prepared to gather technical, administrative and financial means for completing an authorization file according to the ECHA's dates."	Thank you for your comment. Generally we advice downstream users to aim for a good communication within the supply chain to identify and agree on the most appropriate actor to apply for authorisation for certain use and how the different actors can best contribute to this work. In addition you might be able to get support from industry associations of your market sector. Please refer also to the Guidance on preparation of an application for authorisation, especially Appendix 2 on applications by several legal entities (http://www.echa.europa.eu/documents/10162/17229/authorisation_application_en.pdf).
CC14	**Prolonging the deadlines/granting exemption referring to Art. 1 of REACH.**	Chromic acid, # ATT 1507 "Authorisation can nearly be regarded as ban".	Thank you for your comment. Note that authorisation is not comparable to a ban or restriction of a substance but rather to a licensing system. Recognised substances of very high concern may be granted an authorisation if the applicant can show proper control of

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		A rushed interdiction does not conform to enhancing competitiveness as stated in Art. 1 of REACH. It would rather limit competitiveness in European companies. Foreign companies not liable to REACH have clear advantages.	risks arising from the uses applied for or if there is no suitable alternative available to the substance and the socio economic benefits of a use outweigh the associated risks for health and environment. Increased competitiveness of the European industry may be achieved by the requirement to develop suitable alternatives and to substitute substances of very high concern by alternative substances or technologies where these are economically and technically viable. Eventually, the authorisation requirement will result in reduction of the use of hazardous substances at workplaces and in products containing less hazardous substances and exerting lower associated risks.
CC17	**Later application dates because organisation of AfA for many small scale DU.**	Sodium dichromate, #1132, #1232 One additional point needs to be considered: the tonnage of sodium dichromate which is used by the Aerospace & Defence Industry (total, including all its supply-chain) is very low (greatly below 1t/year for each entity, and an estimate of < 20t/year for all our industry), so low that the consortium in charge of sodium dichromate registration dossier did not present a dossier for surface treatment. Our industry has been obliged to negotiate directly with its suppliers so that a registration dossier is deposited. A consequence of this situation is that no upstream supplier will push the Authorisation process, and our industry, as downstream user will have to establish a consortium, together with its surface treatment suppliers (>500), in order to prepare applications for authorisation. In particular we expect a very long and complex convergence process on substitution readiness assessment, amplified by the great number of actors, with different level of stakes. The vast majority of our companies have not presented any registration dossiers and we therefore have not the same experience as the chemical industry has gained	See response CC3.

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		during the registration phase.	
CC18	**Deferring prioritisation/exemption based on existing licenses, permits**	Chromium trioxide, #1435 It is important for contractual reasons between authorisation stakeholders and practical risk control reasons that prioritisation of the substances wait until ongoing studies are complete. Where a site's use of chromic acid is regulated and therefore by definition is well controlled, the risk to the worker, public and to the environment is minimised. Where permits and licenses have been granted, we ask that consideration be given to exempt the use from REACH authorisation. Consequently please consider deferring prioritisation until there is a clear agreed exposure level that needs to be met by authorisation applicants, in order to be successful.	Thank you for your comment. During development of the recommendation to include a substance in Annex XIV ECHA considered a range of criteria, including the overall potential for exposure of human beings arising from the uses of a substance (see response BB2 for more details). For chromium trioxide a high priority for inclusion in Annex XIV has been determined on the basis of the agreed prioritisation approach. Uses which are not exempted generically from authorisation (see response S24 for more information) can only be exempted from the authorisation requirement on the basis of existing Community Legislation imposing minimum requirements relating to proper control of risks from the uses of the substance for human health or the environment (Article 58 (2); see table E for further details and an assessment of the relevant Community Legislation).
CC19	**Extension of the deadlines due to comparison with other substances proposed to authorisation**	Chromium trioxide, #1004 Dates which are proposed are very small compared to other susbtances proposed to authorisation. We need an extension of the deadlines (30 months instead of 18 months as mentioned in the recommendation). The reasons mentioned in the attachment are: - the particular economic situation connected at the supply chain - no consumers exposed - very occasionally few employees exposed - R&D programs and qualifications running for some surface treatment - Exemption for automatic process or for enclosed process using chromium six	Thank you for providing this information. However, your letter doesn't appear to provide tangible data on the basis of which the appropriate lengths of deadlines for latest application dates or sunset dates could be determined.

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		- Better consideration with technical and economical technics limits of substitutes which are mentioned in the Annex XV's file. - Better consideration of the existing legal and regulatory framework regarding the impact on workers and on environment Conclusion: To conclude the lack of alternatives to chromium trioxide will increase outsourcing and lead to the closure of European surface treatment installations. Activities will be relocated in developing countries where workers and environment are not protected by regulations as high as the European regulations. Moreover this relocation will cause massive importations of new products as well as numerous round trips for maintenance of parts, which is contrary to the EU ambitions in reducing the Co2 emissions.	

D – COMMENTS ON USES / REQUESTS FOR EXEMPTIONS:

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DD1	**Socioeconomic benefits of a use, no Alternatives on a use, Impact of ceasing a use.**	Chromium trioxide (e.g. # 756) To clarify specific points of discussion and make the arguments more understandable the study attached "Report on inclusion of chromium trioxide (CrO3) in Annex XIV" was carried out. For detailed arguments, evidences and citation please see the study attached. The results are summarized below. 1. Occupational safety a. The quality of the data of the Annex XV dossier published for consultation referring to the risks for lung cancer is not reproducible and unclear (For details see attachment, Chapter 3). b. No risk in application of Chromium trioxide (-solutions) for the end-consumer or industrial client since only pure Chromium metal is deposited on the substrate and there is no hexavalent chromium on top of the plated parts. c. Safe handling of the solutions to minimize the risk for the co-workers nearly to Zero for dermal or respiratory tract absorption (as evidenced by of regular medical visits and vaccination of the co-workers involved). 2. Occupational diseases Of the 193 confirmed cases of occupational disease in the period from 2001 to 2010, only 14 cases or 7.25% were caused by the effects of chromium and its compounds in the plating plant. According to the estimate made by the author in the annex XV report, approximately 440,000 employees work in the surface treatment industry in Europe. Of these approximately one-tenth work with chromium (VI);	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.

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		amounting to approx. 44,000 employees in the EU. In Germany, the metal refining industry employees approximately 45,000 people. Assuming that in Germany approx. one-tenth also work with chromium (VI), this means 4,500 employees for Germany. Above we have shown, that the cases of lung cancer involving workers working with chromium in plating plants averaged 1.4 cases per year during the last 10 years. For the 4,500 employees working with chromium (VI) this means the risk of contracting lung cancer is 0.00031 or 3.1 out of 10,000. By comparison the risk for the entire German population, of dying of lung cancer was 5.2 out of 10,000 in 2009. (For details see attachment, chapter 5). 3. Alternative processes a. There are a variety of familiar alternatives for functional chromium plating using hexavalent electrolytes. These alternatives do not include one universal substitute process, capable of replacing hard chromium plating on a one to one basis (For details see attachment, chapter 6.2, 6.3 and 6.4). b. If the functional hard chromium plating is to be replaced, it will be necessary to use processes, which do not have the same technical or mechanical properties and, in terms of health, do not offer any improvement in employee protection, because these introduce familiar as well as less well researched safety hazards. Other alternatives, on the other hand, are considered relatively harmless in terms of hazardous substances, however, from a technical vantage point, can only be considered as a substitute for niche applications. 4. Overall implications: a. The application of hard chromium plating in shows a high socio-economic benefits due to the functional properties in a wide range of products (For details see attachment, chapter 6.1). 5. Summarized comments: • It is difficult to see why the current justification	

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		and proportionality of the relevant provisions to handle Chromium trioxide (-solutions) should need further approvals. National and European law already requires aspects of regulatory monitoring and control as well as to the increasing internationalization of requirements. Any additional configurable prioritization and approval of changes will only reproduce the current national requirements. • Furthermore, a separation in chromic acid and chromium trioxide is senseless from the chemical point of view. • Many decades provides a clear understanding of the safety and efficacy and show that on no account an endangering of the end-consumer is realistic. 6. Resulting requirements: 1. According to the available data there is no basis for an inclusion of the hard chromium plating from Chromium trioxide (-solutions) in Annex XIV of the REACh regulation. 2. In the case of an inclusion it is absolutely necessary to realize a derogation rule for the application of Chromium trioxide (-solutions) for hard chromium plating. 3. If an inclusion in Annex IV will take place and no derogation rule can be realized it is necessary to guarantee adequate periods for the application of Chromium trioxide (-solutions). Other Comments: 1.) No risk for the final consumer: Metallic chromium is free of the chromium (VI) species, is not carcinogenic and has been classified by the International Agency for Research on Cancer (IARC) as not classifiable in Group 31. Impairments to health resulting from metallic chromium and its	

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		alloys (e.g. ferrochromium) are unknown2. Thus hard chromium plating does not pose any risk whatsoever for final consumers. On the contrary, hard chromium plating has been in use in the foodstuffs industry for decades. Hard chromium plating is affected by this classification in precisely the same manner as decorative chromium plating, because chromium is deposited from electrolytes containing chromium (VI), not because it poses any threat to final consumers. 2.) No risk for people working at the hard-chrome-equipments: Skin contact is possible as a matter of principle during all types of disassembly work, when working on the baths and when replenishing chromium trioxide. However, work instructions as well as personal protective equipment have been issued for all such working areas, which when observed and used are capable of preventing skin contact. In the improbable event of skin contact (accident) emergency action is required to quickly remove the chromium from the skin and reduce the chromium (VI) still present, to decrease the hazard of absorption into the body and minimize any resulting toxic or carcinogenic effects. At last we refer to the "Report on inclusion of chromium((CrO3)in Annex XIV" / Fraunhofer IPA, dated 02th september 2011 (see upload attachment).	
DD3	**Request to exempt chromium trioxide and chromic acid (chromosulfuric**	Chromic acid, #1667 No risks for humans, environment or society due to very	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

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	acid, i.e. H2SO4 + CrO3) from authorisation for (hard) chrome plating on the basis of Art. 58(2) and restrictive national regulations.	restrictive national law (+ list of national regulations) and control of compliance (also in Chromic acid, #1043: reference to UK safety instructions by HSE) Chromic acid, #833, #850 In Deutschland werden die Aspekte zusätzlich zu den EU-Regelungen [*mentioned in exemptions section below*] im Rahmen der Verordnungen erweitert bzw. umgesetzt: • Chemikaliengesetz • Gefahrstoffverordnung • Bundesimmissionsschutzgesetz • Arbeitsstättenverordnung • Verordnung zur arbeitsmedizinischen Vorsorge • Arbeitsschutzgesetz • Kreislaufwirtschafts- und Abfallgesetz • Wasserhaushaltsgesetz o Abwasserverordnungen o Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen • TRwS	the use of the substance, the risk is properly controlled'. 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 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; 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[6] 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 EU legislation is relevant in the context to be

[6] 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.

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		• Berufsgenossenschaftliche Vorschriften Die Aspekte eines sicheren Umgangs werden wesentlich im Rahmen der Bundes-Immissions-Schutz-Verordnungen (12. BimSchV) und der Störfallverordnung (StöfallV), §§ 8 und 9, geregelt. Die sichere Handhabung von Chromsäure (-lösungen) in den Betrieben ist durch die anhängende Studie mit der Auswertung der Messergebnisse aus den letzten 10 Jahren belegt. (→ exemption for galvanic surface treatment) in English: In Germany/Austria, the additional regulations manage the handling of the aspects: - ASchG (ArbeitnehmerInnenschutzgesetz) - GKV (Grenzwerteverordnung) - ChemG (Chemikaliengesetz) - AStV (Arbeitsstättenverordnung) - VGÜ (Gesundheitsüberwachung am Arbeitsplatz) - AWG 2002 (Abfallwirtschaftsgesetz) - Wasserrechtsgesetz - DOK-VO (Sicherheits-und Gesundheitsschutzdokumente) - Kenn-Vo (Kennzeichnungsverordnung - Vexat (Verordnung explosionsfähiger Atmosphären) - MuSchG (Mutterschutzgesetz)	assessed (no national legislation). (ii) Minimum requirements for controlling risks to human health and the environment need to be imposed in a way that they cover the life cycle stages resulting from the uses in question. (iii) There need to be binding and enforceable minimum requirements in place for the substance(s) used. In conclusion, - national legislation provides no basis for an exemption in accordance with Article 58(2); - in addition, as regards points (ii) and (iii) above, there is apparently no consistent framework of EU legislation in place that would apply to the uses of chromium trioxide and chromic acid in galvanic surface treatment in a lifecycle perspective. In particular, existing EU legislation does not appear to set out minimum requirements addressing the control of cancer risks arising from occupational {and/or professional} uses of the mentioned CrVI-substances. Decisive is that at least a part of the life-cycle, namely the cancer risk arising from occupational and professional exposure to the CrVI-substances, is not properly controlled by existing EU legislation. (For further details on the assessment of existing EU legislation see table E.)

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		- KJBG (Kinder- und Jugendbeschäftigungsgesetz) - GewO (Gewerbeordnung) • A safe handling of Chromium trioxide (-solutions) taking place in the companies is substantiated in the attached study documenting the measurement results over the last 10 years. Ammonium dichromate, #1736 ADC is a cmr-substance. In Germany use of cmr-substances is regulated by "Gefahrstoff-Verordnung" (Issue 28.07.2011, §10) . Application of ADC as used at MICROMETAL is not forbidden in Germany.	
DD4	**Exemptions for R&D.**	Chromic acid, #863 and Chromium trioxide, #659 Chromic acid and chromium trioxide are used in laboratory preparations, referenced in the NF A 05-150 and ASTM E 407, and in several reference books in metallography (references 1-3) - Chromic acid electrolyte NF E3 - ASTM 83 - Poulton 2 - Frinkeldey - Preparation to remove oxide from breaks for aluminum - Sargent	The use of chromium compounds in laboratory preparations referred to in your comment 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). Such provision 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

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		Reference 1: Metals Handbook Vol 8 Structures and Phases Diagrams 8th Edition – American Metals Society – 1973 – Library of Congress Card Number 27-12046 Référence 2: DeFerri Metalographia – 1966 – D/1966/0170/2 Reference 3 :Atlas Métallographique – CTIF – Edition Technique de l'Industrie de la Fonderie They are also used for the determination of COD (chemical oxygen demand) AFNOR : NFT 90101 There is no alternative test method, an exemption should be granted for these uses. Ammonium dichromate, #982 Laboratory measurment for quality reasons and/or monitoring of release require uses of such substances. Ammonium dichromate, #1844 Used in laboratories in small quantities. Sodium dichromate, #1773, #1795	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[7] 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 laboratory 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.

[7] 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.

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		Description of use in diagnostic tests.	
DD5	**Exemption for precursor uses to SRD.**	Example: filling into packages, preparation of formulations described in standards or Pharmacopoeias like e.g. DIN, EN, ISO, ASTM, Reag. Ph. Eur and ACS, till the use as calibration standard for ICP and AAS. - to be used before R&D applications. (obligation by government to use such standards, small amounts, well-trained IND and PROF users). The substance will only be supplied in packages used in laboratories, e.g. small bottles. Cobalt diacetate is used in the laboratory by industrial and professional users that are well-trained. The volume needed for one analysis is minimal. The exemption is required e.g. to secure routine analytics done in laboratories. **Production of test cuvettes for analysing COD (chemical oxigen demand) in WWTP.** Potassium dichromate is a compound that is required for the analysis of COD (chemical oxygen demand, determination of oxidisable fractions). In a sulphuric acid solution, the organic substances in water reduce the dichromate ion (Cr2O72-) to Cr3+ ions. For laboratory and field analyses, cuvette tests exist in which the reagents are provided and ready for use. In many countries, these cuvette tests have been accepted as an alternative to the norm methods. Many laboratories have been accredited for the implementation of this method. The advantage of the cuvette test is that the risk of contamination by the noxious substances, and thus also with the potassium dichromate, is low for the user. It is effectively a closed system, since the user only has to add the water sample once. After this, the cuvette remains sealed for the rest of the analysis procedure (decomposition, evaluation). Accordingly, the risk of	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). 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.

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		coming into contact with the reagent is very low. As the equipment producer, we assume responsibility for disposal of the cuvettes after they have been used. The used tests are collected from all over Europe and returned to the HACH LANGE environment centre, where they are processed in accordance with the applicable regulations. The metal components, silver and mercury, are separated by electrolysis. The residual dichromates are reduced to trivalent chromium in acid and then enter the resource recycling cycle. In 2009, the method was recognised with awards including the German Sustainability Award. We would like to invite you to visit our environment centre and see it for yourselves. Compared with the conventional reference procedures, the cuvette test needs 90% less pollutants, and a correspondingly smaller quantity of potassium dichromate. There are currently no procedures for determining oxidisable substances except determination by potassium dichromate. The entire waste water treatment programme is controlled on the basis of COD. COD determination is the central, indispensable component of waste water treatment throughout Europe. For the reasons outlined above, it is not possible to issue a blanket prohibition of the use of potassium dichromate while there are no legal alternatives. Therefore, it is essential to exempt the use of potassium dichromate for "analysis purposes" respective "laboratory uses" from the requirement for approval, or it should be classified as an approved use. The scoring approach of the Potassium dichromate gives a low priority for the inclusion in Annex XIV. The reason to prevent a replacement from other hexavalent chromium compounds with Potassium dichromate, leads serious problems in the analytical sector.	
DD6	**PPORD exemption.**	Chromic acid, #1099 and Chromium trioxide, #1105	Thank you for your comment.

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		Chromium compounds: The product and process oriented research and development (PPORD) should be clearly exempted from the authorization process. Please note the following reasons: a. Development of alternative technologies has to use chromium trioxide. In a first step alternative technologies base on improvements of existing technologies. This assures the smooth and progressive transition. 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 should result in optimized processes reducing the risks for human health and the environment. Furthermore new risk mitigation measures can only be developed based on PPORD with chromium trioxide. 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.	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.
DD7	**Use in pharmaceuticals.**	Chromium (VI) compounds: Use in pharmaceuticals	According to Art. 2 (5) (a) of the REACH Regulation, the provisions of Titles VII (Authorisation) shall not apply to the extend that a substance is used "in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. It is important to note that this exemption applies only to substances which are covered by the relevant authorisations for medicinal products, such as active substances for use as starting materials within the meaning of the medicinal products legislation. If the substance falls within this definition, *e.g.,* because it is covered by a manufacturing authorisation, it is exempt from the

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			authorisation requirement.
DD8	**Exemption for hard chrome plating based on no availability of alternatives.**	Chromic acid, #787, #ATT 1774 "Is substitution an option? First we wish to remind the reader that to be suitable an alternative must be: • available • technically and economically feasible for the use • reduce the overall risk. For many years, research has been conducted on potential ways of substituting hexavalent chromium in various processes, precisely because of the known toxicity of this substance. One of the processes for which substitution has been extensively researched is hard chrome plating and, as of today, no real substitution has been found." (→ Request to exempt hard chrome plating) "Claims about the possibility of replacing hard chrome plating by plasma coatings can be in some cases acceptable but in most cases are incorrect and even dangerous. The Copterline accident in August 2005 is a dramatic reminder of that reality. On 10th August 2005 a Copterline helicopter (Sikorsky S-76) en route to Helsinki, Finland crashed into the sea near Tallinn, Estonia few minutes after taking off. There were 14 people on board, all of whom were killed. The cause of the accident was the failure of the power flying control system. Plasma coating on the pistons of the power flying control system had flaked off and blocked the return valve, causing the aircraft to lose its	Thank you for your comment. The Authorisation title, *inter alia*, has the objective (Art. 55) to progressively replace SVHC by suitable alternatives or technologies where these are economically and technically viable. This does however not mean that SVHC 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 accordance with Art. 62 (4e)). 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.. Also information regarding research and development that the applicant considers relevant should be included in the assessment of alternatives as part of the application for authorisation.

#	Issue(s) addressed	Comment example(s)	Response
		manoeuvrability. Piston is just an example of the numerous parts for which hard chrome plating has been used successfully and safely for decades, until substitution came into the picture."	
DD9	**Exemption based on PPORD/SRD.**	Chromium trioxide, # 845 Description of essential use of Chromium trioxide (CAS number 1333-82-0) for the application of an exemption from authorisation to product and process orientated research and development (PPORD) of failure analysis of new semiconductor manufacturing processes and products Background Crystal defects in all their appearances and forms play an important role in semiconductor device manufacturing, as they negatively impact yield and quality in the sense of semiconductor device (microchip) performance and reliability. All major semiconductor companies have so-called "failure analysis" (FA) process development labs, where the potential impact of crystal defects during processing on device yield and performance is quantitatively determined. Typically, process induced crystal defects are analyzed by means of preferential etch (where crystal defects are selectively etched or decorated) followed by some form of microscopy (DICM, SEM, TEM) to inspect and identify the defect(s) in question. Use of chromium trioxide in dedicated etchants is essential: Chromium trioxide (CrO3) is part of specific liquid etch mixtures that are used for this kind of process orientated defect analysis . These liquid etchant mixtures are commonly known as Sirtl etch, Wright etch and Secco etch, named after their inventors. All these etchants are based on Fluoric acid (HF) and CrO3. The use of chromium trioxide in these etches is essential,	From the use description provided, it appears that chromium trioxide is used for quality control purposes in the production of semiconductor devices. This fact is relevant when considering whether the described use would fulfil the definition of PPORD in Article 3(22). However, ECHA has considered that it is not appropriate to recommend an exemption for PPORD for this use as there is not enough certainty whether this use actually fulfils the criteria for PPORD. Nonetheless, according to your description, chromium trioxide is used as indicator in an etchant mixture (analytical agent) for analysis of production process induced crystal defects in semiconductor devices. This fact appears to be relevant when considering whether the described use would fulfil the definition of scientific research and development (SRD) 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 covers analysis for e.g. monitoring and quality control purposes, as long as the chemical substances used for this analysis are used under controlled conditions and in a volume of less than one tonne per year. We would suggest that you examine whether the use of chromium trioxide for the detection of production process induced crystal defects in semiconductor devices can be regarded as SRD in accordance with the definition set out in Article 3(23). If you conclude that this is the case, this use 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. See response DD4 for further details on preconditions to benefit from the exemption of SRD from authorisation.

#	Issue(s) addressed	Comment example(s)	Response
		where a specific and high selectivity is required (e.g. when more crystal defects play a role or if the crystal defects are unknown). To make process induced crystal defects visible by microscopy it is necessary to de-construct a device by using an etchant which is able to selectively and reliably highlight these defects in a qualitative and quantitative way while minimizing ambiguity from the potential of artifact generation. [References] Availability of Substitutes for Chromium trioxide: No CrO3-free etchants exist for high selectivity process applications. Some CrO3-free etchants exist however these are only useful for other applications. Where high selectivity is required (e.g. for qualification and development of new processes and products and for detailed process analysis of crystal defects) the use of CrO3-based etchants is essential as only it has the property required to selectively etch and there are no adequate substitutes . Characteristics of CrO3 use in the semiconductor industry Amount of substance used: The typical use of chromium trioxide by an average device manufacturer company for device failure analysis process development purposes ranges from a few grams to a few hundred grams per year per company. The European manufacturing semiconductor industry on a worst case scenario would use less than 2kg per year. Technical conditions and measures to prevent release at process level: Handling of chromium trioxide is done in an exhausted chemical hood. Worker exposure scenario: • Exposure to solid CrO3: The dedicated mixtures are generally prepared in the lab	

#	Issue(s) addressed	Comment example(s)	Response
		at a frequency of once in 1-3 years and a handling duration in a fume cupboard of less than 5 minutes. Because of the short exposure period with no visible dust formation, dust sampling and analysis cannot be performed. • Exposure to liquid etch mixture containing CrO3: At a maximum the FA expert performs 15-30 minutes of etching per week with an exposure frequency of only a few times per week, depending on the number of samples to be analyzed. Organizational measures to prevent / limit releases, dispersion and exposure: • Laboratory personnel are trained about the risks to safely handle CrO3. • Lab personnel wear adequate personal protective equipment. • Used chromium trioxide containing etchant is collected and disposed of as hazardous waste. Thus, any potential human exposure via inhalation is typically below the detection limit. No dermal exposure occurs due to chemical resistant protective gloves that are worn during handling the substance. Synopsis The use of CrO3-based etchants for semiconductor device failure analysis process development is essential for development of new manufacturing processes for the semiconductor industry. The minimal amount of the substance used in the European semiconductor industry, proper waste disposal and negligible worker exposure qualifies this use for an exemption from authorisation as outlined in Reach article 56 (3) for the use of the substance for product and process orientated research and development. References	

#	Issue(s) addressed	Comment example(s)	Response
		[1] Defect etching in silicon. Based on various original papers http://www.tf.uni-kiel.de/matwis/amat/def_en/kap_6/advanced/t6_1_2.html [2] Wet-Chemical Etching and Cleaning of Silicon, Virginia Semiconductor Inc. January 2003 Section: G Silicon Defect Delineation Etches.	
DD10	**Exemption for the use of chromium trioxide as precursor for the polymerization of ethylene and alpha olefins.**	Chromium trioxide, # 769 Comments on a use of chromium trioxide as precursor for the polymerisation of specific HDPE grades *Volumes produced* Less than 10 sites using CrO3 for HDPE production have been identified in EU. Most sites have a production / consumption of CrO3 of less than 1 ton/year, a few less than 2 tons/year. None above 2 tons/year. *Manufacture and releases from manufacture* Cr III is supplied to the plant, supported on a silica carrier. This material, inactive and essentially not harmful (except for dust) at this stage, is discharged into a fluidized bed reactor (called activator) where it is submitted to an oxidation in company proprietary conditions (generally batch process). The activator is equipped with thorough filtering systems. During that operation, the Cr III base component is brought to Cr VI valence state (CrO3). This is the active species for the polymerization of ethylene. The activated batch is conveyed with non dispersive means into a storage tank, which in turn will, at the proper moment in the production wheel, be fed into the polymerization reactor through metering systems that do not allow release	Thank you for your comment. 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'. 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 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; 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[8] for the control of

[8] 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.

#	Issue(s) addressed	Comment example(s)	Response
		to the environment. The release to the environment from manufacture and subsequent use is estimated to be max 0.1%. *Uses and releases from uses* The Cr VI precursor is fed in a polymerization reactor. During that reaction, the Cr VI species is reduced to the Cr III valence state (arguably Cr II first and then Cr III is subsequent reactions). Hogan et al, Appl. Polym. Symp. !§, 49-60 (1981) There is no measurable CrO3 left in the polymer, and even if there is some, it is embedded in the bulk of the polymer and will not migrate. Release of CrO3 from polymerization and use of polymer is not possible. Geographical distribution A few sites in Belgium, in Spain, in Sweden and in the Netherlands. *Availability of information on alternatives* This type of polymerization chemistry yields polyethylene grades with unique macromolecular structures (long chain branching and molecular weight distributions) that make them the preferred choice in many applications. This uniqueness has not been reproduced with other precursors in spite of intensive research over the last 5 decades. {Replacement entails deep modification of the polymerization process, retooling of the customers processing machines, redesign of the end use articles, …} Existing specific Community Legislation relevant for possible exemption Chromium oxide residues are allowed in plastics materials intended for food contact applications: • Chapter I par 2.4 of the Dutch Food and	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 EU legislation is relevant in the context to be assessed (no national legislation). (ii) Minimum requirements for controlling risks to human health and the environment need to be imposed in a way that they cover the life cycle stages resulting from the uses in question. (iii) There need to be binding and enforceable minimum requirements in place for the substance(s) used. In conclusion, as regards points (ii) and (iii) above, there is apparently no consistent framework of EU legislation in place that would apply to the uses of chromium trioxide as precursor for the polymerization of ethylene and alpha olefins. In particular, existing EU legislation does not appear to set out minimum requirements addressing the control of cancer risks arising from occupational {and/or professional} uses of the substances Decisive is that at least a part of the life-cycle, namely the cancer risk arising from occupational and professional exposure to the CrVI-substances, is not properly controlled by existing EU legislation. (For further details on the assessment of existing EU legislation see table E.)

- 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
		Packaging Utensils (Warenwet), where chromium oxide is allowed with a specific migration limit of 0,1 mg/kg food (expressed as chromium) (Supplement 34) • Recommendation (Empfehlung) III (Polyethylene) of the German Kunstoffe in Lebensmittelverkehr: Recommendations of the Bundesinstitut fur Riscobewertung (BfR)(former BgVV), Status March 2011, where oxides of chromium are allowed in the final food contact article up to a concentration of 10 ppm (expressed as chromium). http://bfr.zadi.de/kse/faces/DBEmpfehlung_en.jsp?filter=clear *Prioritisation* Chromium trioxide used in HDPE production is used in low volumes. The uses falling under authorisation are expected to take place at a very limited number of sites and no exposure of workers may occur with no release to the workplace. This use is therefore not wide-dispersive. On the basis of the prioritisation criteria this use of chromium trioxide does not get high priority for inclusion in Annex XIV. The scoring approach applied to the use of chromium trioxide in HDPE does not get a high priority score for inclusion in Annex XIV. An exemption of authorisation is therefore required for this use. *Conclusion* Polymerization of ethylene and alpha olefins with CrO3 precursors should be exempt from authorization because the way the substance is used implies that: • workers are not effectively exposed, • there is practically no release to the environment, • there is no release in the use phase,	Process descriptions, information on risk management measures, releases and on the low level of risk associated to a use as well as on the availability and suitability of alternatives or the (adverse) impacts of ceasing a use are important. Information regarding these topics should be provided as part of the application for 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. With regard to your statements about the priority for inclusion in Annex XIV of the described use please note that this priority is determined per substance and not per individual use because inclusion in Annex XIV is per substance and not per use (for further details on priority setting please refer to table B and in particular to response BB2).

#	Issue(s) addressed	Comment example(s)	Response
		• there is no exposure of the consumers This is valid for industrial use but the same applies to R&D sites, where polymerisation process is identical, the quantities used are even smaller and the frequency of use lower.	

E. EXEMPTION REQUESTS WITH REFERENCE TO EXISTING COMMUNITY LEGISLATION

INTRODUCTION

According to Article 58(2) 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'.*

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 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[9] 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 chromium (VI) compounds proposed for Annex XIV were identified as Substances of Very High Concern (SVHC) and added to the Candidate List due to their carcinogenic and/or mutagenic and/or toxic for reproduction properties. Therefore, in the following it is

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[9] 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, ECHA has 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, ECHA has 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 seven Chromium compounds on their own or in mixtures is prohibited by Annex XVII to the REACH Regulation (entries 28, 29 and 30). Available information does not indicate exposure of consumers to these seven specific Chromium 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.

#	**Exemption requests** (substance; legislation; use(s); any justification; submitter)	**Response**
Human health-based legislation		
EE1	**Chromium trioxide, #953** Opinion prepared by Field Fisher Waterhouse on behalf of ECMA. Background information on the relevant Community legislation: According to Article 58.2 of REACH, uses or categories of uses may be exempted from the authorisation requirement if the risk is properly controlled, on the basis of existing EU legislation imposing minimum requirements for the protection of human health or the environment. On the basis of Article 58.2 of the REACH Regulation, we submit that the uses of the chromium trioxide used as active catalyst substance should be exempted from authorisation because these uses are covered by existing EU legislation, and in particular Directive 98/24 on the protection of the health and safety of workers from the risks related to chemical agents at work and Directive 2004/37 on the protection of workers from the risks	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.

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	related to exposure to carcinogens or mutagens at work, which impose minimum requirements that ensure the risks are properly controlled. Directive 98/24, Directive 2004/37 and Directive 2008/1/EC (IPPC) are existing EU legislation that properly control the risks to human health and/or the environment from the uses of chromium trioxide as described above and this legislation imposes minimum requirements for the control of risks of the use. Indeed, Directive 98/24 is a Directive based on Article 118a of the EC Treaty, which provided for the adoption of minimum requirements in order to guarantee a better level of protection for the safety and health of workers and which allowed Member States to apply stricter (but not less stringent) requirements under certain conditions. Directive 2004/37 was adopted on the basis of former Article 137(2) of the Treaty on the European Communities, now Article 153 of Treaty on the Functioning of the European Union), which also enabled the adoption of "minimum requirements". Both Directive 98/24 and Directive 2004/37, therefore, lay down "minimum requirements" within the meaning of Article 58(2) of the REACH Regulation. Both Directives seek to protect workers from risks posed during exposure to products containing chromium trioxide. Elements in support of the exemption of uses of chromium trioxide as active catalyst substance from the authorization requirement, under Article 58.2 of REACH: The fact that risks posed by the use of chromium trioxide as active catalyst substance are properly controlled by Directive 98/24 and Directive 2004/37 has been formally acknowledged and confirmed by the European Commission. Specifically, chromium trioxide was subject to a risk assessment organized under the previously applicable Regulation 793/93. As a result of the risk assessment, the European Commission adopted its Communication on the results of the risk evaluation and the risk reduction strategies (2008/C 152/01, O.J. C152/1, 18.6.2008) and its Recommendation on risk reduction measures (2008/455/EC, O.J. L 158/65, 18.6.2008). The use of chromium trioxide as active catalyst substance has been	The risk evaluation and risk reduction strategies identified in the Commission Communication 2008/C 152/01 and Recommendation 2008/455/EC have acknowledged the significant risks posed by chromium trioxide to human health and environment. In consequence, it is recommended that employers using chromium (VI) compounds for use in the manufacture of pigments and dyes, the formulation of metal treatment products, electrolytic metal plating, and as mordants in wool dyeing take note of any sector specific guidance developed at national level, based on the practical, non-binding guidance available from the Commission, as provided for in Article 12(2) of Council Directive 98/24/EC (CAD). Both Directives (CMD and CAD) 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 **chromium trioxide** from authorisation in accordance with Article 58(2) of the REACH Regulation. The comments on a potential, future revision to the CMD and the on going discussion on the establishment of an occupational exposure limit at European level are noted. However, at this time the status of this limit, indicative or binding, is not yet concluded and the measure is not yet in place. The conditions on chromium salts are noted in respect of food contact applications. **Council Regulation** 2**011/10/EU** does not specifically aim to control the risks arising from the use of chromium trioxide as a catalyst or in the production of plastics for food contact applications and does not specify minimum requirements to control such risks in these upstream processes.

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	assessed during the risk assessment in so far as it triggered exposure of workers to chromium trioxide. The European Commission concluded, in this respect, that "the legislation for workers' protection currently in force at Community level, particularly Directive 2004/37/EC of the European Parliament and Council (the Carcinogens and Mutagens Directive), is generally considered to give an adequate framework to limit the risks of substances to the extent needed and shall apply". Within this framework, the Commission recommended that a Community-level occupational exposure limit (OEL) and a Community-level biological limit value be established. Implementing such a limit would be effective in limiting the risk to workers. The EU Commission is pressing ahead with the potential revision of the carcinogens and mutagens directive (2004/37/EC) (in 2013) and the inclusion of an Occupational Exposure Limit (OEL) for hexavalent chromium compounds is being proposed (for Annex III of the directive). The inclusion of this OEL at a community level would certainly limit and control any risk to workers. Overall this shows that the European Commission considers the current workers protection legislation, and specifically Directive 2004/37, as providing adequate control for the use of the chromium trioxide as active catalyst substance. As a result, these uses should be exempt from the authorization requirement in accordance with Article 58.2 of the REACH Regulation. Additionally there are German and Dutch legislation regulating the content of catalysts residues in HDPE used for food contact applications. Chromium oxide (referring to all forms of oxides) is allowed in plastics for food contact applications according to:	
Environment-based legislation		
EE2	**Chromic acid, #1480** Chromium surfaces are now free of hexavalent chrome after the coating process. Efforts are thus focussed on chromium trioxide in the	Both **Directive 2002/95/EC** (Directive 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; RoHS), which is to be repealed on 3 Jan 2013 by **Directive**

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	electrochemical process and are not motivated by demands for a chromium(VI)-free surface. **ELV, RoHS and WEEE directives** do not apply to electroplated chromium surfaces. Electrochemically deposited chromium coatings are accepted as being non-hazardous in contact with food.	**2011/65/EU,** and **Directive 2000/53/EC** (Directive of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles; ELV) set a maximum concentration value of 0,1 % by weight in homogeneous materials for amongst others hexavalent chromium. These limits are in place mainly to prevent heavy metals such as hexavalent chromium entering the waste stream and to avoid subsequent releases to the environment when waste is incinerated or landfilled. It could be argued that for the articles covered by these Directives, the requirements set out in the Directives related to hexavalent chromium could be seen as "minimum requirements for controlling risks to human health and the environment" resulting from the waste phase of the articles specified in the directives. However, while the RoHS and ELV Directives contribute to human health and environmental protection at the waste life cycle stage, 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 which are considered to fall within the scope of authorisation.
EE3	**Chromic acid, #1688** Apply exemption for all **rotogravure printers** and companies which prepare print-ready gravure cylinders to use chromium trioxide. This may also be possible in advance according to Art 58(2) of REACH: chromium trioxide is subject to the restrictions of the strict safety standards according to the **Seveso directives and for carcinogenic substances** in general.	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. Chromium trioxide is listed as a Seveso substance under categories 1 (very toxic), 2 (toxic), 3 (oxidising) and 9i (R50). However, 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.
EE4	**Chromic acid, #1194** (Exemption for Chromic acids) … for surface treatment activities regulated by the **IED Directive 2010/75/UE** and the best available	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

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	techniques. **In attachment #ATT 3** Most of the installations using chromium trioxide are regulated by the european **IED directive** and apply the best available techniques. The BREF regarding Surface Treatment of Metals and Plastics recommends ventilation, air extractors and indicates emission limit values in water and air. We consider this directive as the legal basis of exemptions possibilities. **Chromic acid, #823** We have already authorisation by DREAL to work. [i.e. That are the inspectors in France.]	identify polluting substances for which a permit for an installation needs to include an emission limit value. [10] 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.
EE5	**Chromic acid, #850** In der EU sind die Belange zur Sicherung von Mensch und Umwelt beim Gebrauch von Chromsäure (-lösungen) ebenfalls bestens geschützt durch: • EG 1907/2006 (REACH-Verordnung) • EG/1272/2008 (GHS-Verordnung) • 2002/95/EG (ROHS) • 2002/96/EG (WEEE) • 196/82/EG (Seveso-II-RL) • 2010/75/EU (IVU) • 2000/60/EG (WRR)	The **RoHS Directive 2002/95/EC**, which is to be repealed on 3 Jan 2013 by **Directive 2011/65/EU,** restricts the levels of Chromium VI 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. The RoHS Directive sets a maximum concentration value of 0,1 % by weight in homogeneous materials for hexavalent chromium. This limit is in place mainly to prevent hexavalent chromium entering the waste stream and to avoid subsequent releases to the environment when waste is incinerated or landfilled. It could be argued that for the articles covered by this Directive, the requirements set out in the Directive related to hexavalent chromium could be seen as "minimum requirements for controlling risks to human health and the environment" resulting from the waste phase of the articles .

[10] The only specific references to chromium and its compounds are in Annex I where facilities engaged in production of chromic acids on an industrial scale are listed as requiring a permit; and in Annex VI which sets air and wastewater emission limit values for chromium and its compounds in waste incineration plants

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	• 98/249/EG (Request for a general exemption of galvanic surface treatment using chromic acids)	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 RoHS and WEEE Directives contribute to human health and environmental protection at the waste life cycle stage of these articles, 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 which are considered to fall within the scope of authorisation. 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. However, 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. 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.[11] For these reasons the substances for which the minimum requirements set out in

[11] The only specific references to chromium and its compounds are in Annex I where facilities engaged in production of chromic acids on an industrial scale are listed as requiring a permit; and in Annex VI which sets air and wastewater emission limit values for chromium and its compounds in waste incineration plants.

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
		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). It is further noted that pursuant to Article 62(5)(b)(i) 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, chromium (VI) 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.
EE6	**Chromic acid, #1834** Exemption for use in conversion layer on aluminium before powder coating asked for as it falls "under the scope of the Industrial Emissions Directive (former IPPC Directive). Permitting sets strict limits to emission levels to air, water, exposure to workers etc"	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. [12] 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

[12] The only specific references to chromium and its compounds are in Annex I where facilities engaged in production of chromic acids on an industrial scale are listed as requiring a permit; and in Annex VI which sets air and wastewater emission limit values for chromium and its compounds in waste incineration plants

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
		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.
EE7	**Chromic acid, #662** Exemption for use in labs to determine COD in waste water. They refer to various EU legislation re. waste water management but supposingly that is not really an issue to be checked.	The use of chromium trioxide for laboratory use may fall under the exemption from the authorisation requirement in accordance with Article 56(3) REACH. We would suggest that you examine whether the mentioned use of your substance can be regarded as fulfilling the requirement of Article 56(3). If you conclude that your use of the mentioned substance fulfils the above requirement, the use can benefit from the exemption from authorisation as set out in Article 56(3) and no authorisation would be required to continue the use after the sunset date.
EE8	**Chromic acid, # 1703** Parts of aircraft equipment (and also some medical, nuclear, defence shipping and rail applications) have safety critical requirements set by regulating authorities, e.g. European Aviation Safety Agency or European Space Agency. The regulators specify usually performance requirements rather the specific substances. Such industry needs chromic acid. (general exemption asked)	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 outlineds earlier in this Table apply. The reference to safety critical requirements under other legislation can be reflected in the application for authorisation and will be taken into account by the Risk Assessment and Socio-economic Ananlysis Committees when evaluating such applications and by the Commission when taking the final decision on the authorisation.
EE9	**Sodium chromate, # 874** The use of Sodium Chromate as anti-corrosion inhibitor in absorption refrigerators should be exempt from inclusion in Annex XIV and hence REACH Authorization requirement. Dometic takes this position on the grounds that for this specific use of sodium chromate: 1) human and environmental health risks are adequately controlled by existing EU legislation – article 4(2)(a)of Directive 2000/53/EC on End-of Life Vehicles and article 4(1) of Directive 2002/95/EC restricting the use of hazardous substances in electrical and electronic equipment (RoHS); and 2) currently no commercially viable alternatives to the aforementioned use of sodium chromate are available.	Both **Directive 2002/95/EC** (Directive 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; RoHS), which is to be repealed on 3 Jan 2013 by **Directive 2011/65/EU,** and **Directive 2000/53/EC** (Directive of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles; ELV) set a maximum concentration value of 0,1 % by weight in homogeneous materials for amongst others hexavalent chromium. These limits are in place mainly to prevent heavy metals such as hexavalent chromium entering the waste stream and to avoid subsequent releases to the environment when waste is incinerated or landfilled. In relation to the 2011 RoHS Directive certain applications are exempted from restriction

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
		including "hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution". In relation to the ELV Directive (and Commission Directive 2011/37/EU amending Annex II of the ELV Directive) certain materials and components are exempt from the above limits. This includes the use of hexavalent chromium "as an anti-corrosion agent of the carbon steel cooling system in absorption refrigerators in motor-caravans up to 0,.75 % by weight in the cooling solution except where the use of other cooling technologies is practicable (i.e. available on the market for the application in motor caravans) and does not lead to negative environmental, health and/or consumer safety impacts". It could be argued that for the articles covered (and exempted) by these Directives, the requirements set out in the Directives related to hexavalent chromium could be seen as "minimum requirements for controlling risks to human health and the environment" resulting from the waste phase of the articles. However, while the RoHS and ELV Directives contribute to human health and environmental protection at the waste life cycle stage, 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 which are considered to fall within the scope of authorisation.
EE10	**Chromic acid, #ATT 17** "The relationship between Seveso Directive, IED and permits/authorization and all substances that they regulate, and REACH, should be clarified and published as a matter of priority, as it again, it affects the validity of arguments and risk controls that need to be included in authorisation dossiers. **Chromic acids, #ATT 17**	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. [13] 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

[13] The only specific references to chromium and its compounds are in Annex I where facilities engaged in production of chromic acids on an industrial scale are listed as requiring a permit; and in Annex VI which sets air and wastewater emission limit values for chromium and its compounds in waste incineration plants

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	As it is not possible to effectively commence work on authorisation dossiers without this clarity, we would ask that prioritisation of this be deferred until the agreed legislative position on this has been made clear."	whether risks arising from IPPC installations are properly controlled. 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. However, 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.
EE11	**Chromic acid, #ATT 17 [*referring to CAD and CMD*]:** Competent authorities and industries respondents to permits/authorization believe that covered sites have a recognisably higher safety in comparison with other sites. Sites using chromium compounds are monitored for emissions. Releases are monitored and controlled via all kind of directives. Best available techniques to control risks are mandated. Where there are breaches and releases occur, regulatory authorities are able to take strong action, just as is in the case with REACH.	
EE12	**Chromic acids, #ATT 1029** The use of chromium trioxide / chromic acid in the surface engineering sector is already subject to many pieces of both EU and individual Member State legislation, for example: 1 - Directive 2010/75/EU on Industrial Emissions (integrated pollution prevention & control) 2 - Directive 96/82/EU on the control of major accident hazards involving dangerous substances	In relation to **Directive 2010/75/EUC (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. [14] 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

[14] The only specific references to chromium and its compounds are in Annex I where facilities engaged in production of chromic acids on an industrial scale are listed as requiring a permit; and in Annex VI which sets air and wastewater emission limit values for chromium and its compounds in waste incineration plants

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	3 – Directive 98/249/EU on the convention for protection of the marine environment of the north-east Atlantic 4 – Directive 2000/60/EU on establishing a Framework for Community action in the field of water policy 5 – Directive 2002/96/EU on waste electrical and electronic equipment 6 – Directive 2002/95/EU on the restriction of hazardous substances 7 – Directive 200//112/EU on classification, labelling and packaging of substances and mixtures	whether risks arising from IPPC installations are properly controlled. 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. However, 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. 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, chromium (VI) compounds are not included in the list of priority substances (Annex X), for which Community 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. 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

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
		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). The **RoHS Directive 2002/95/EC** (Directive 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; RoHS), which is to be repealed on 3 Jan 2013 by **Directive 2011/65/EU,** set a maximum concentration value of 0,1 % by weight in homogeneous materials for amongst others hexavalent chromium. These limits are in place mainly to prevent heavy metals such as hexavalent chromium entering the waste stream and to avoid subsequent releases to the environment when waste is incinerated or landfilled. It could be argued that for the articles covered by the RoHS Directive, the requirements set out in the Directive related to hexavalent chromium could be seen as "minimum requirements for controlling risks to human health and the environment" resulting from the waste phase of the articles . While the RoHS and WEEE Directives contribute to human health and environmental protection at the waste life cycle stage of these articles, 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 which are considered to fall within the scope of authorisation.
EE13	**Sodium dichromate, #1132** It is important to note that the RoHS regulation allows exemption for chromium (VI) compounds that are to be used in transport applications. Other regulations applied to the aerospace industry detail corrosion	**Directive 2002/95/EC** (Directive 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; **RoHS**), which is to be repealed on 3 Jan 2013 by **Directive 2011/65/EU**, set a maximum concentration value of 0,1 % by weight in homogeneous materials for amongst others hexavalent chromium. This limit is in place mainly to prevent heavy metals such as hexavalent chromium entering the waste stream and to avoid subsequent releases to the environment when waste is incinerated or landfilled.

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	performance requirements for corrosion protection.	The RoHS Directive does not apply to 'means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved'. It could be argued that for the articles covered (and exempted) by this Directive, the requirements set out in the Directive related to hexavalent chromium could be seen as "minimum requirements for controlling risks to human health and the environment" resulting from the waste phase of the articles. However, while the RoHS Directive contributes to environmental protection at the waste life cycle stage, as outlined in the other responses to comments, 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. The reference to performance requirements under other legislation can be reflected in the application for authorisation and will be taken into account by the Risk Assessment and Socio-economic Analysis Committees when evaluating such applications and by the Committee when taking the final decision on the authorisation.
Other legislation		
EE8	**Chromic acid, # 1703** Parts of aircraft equipment (and also some medical, nuclear, defence shipping and rail applications) have safety critical requirements set by regulating authorities, e.g. European Aviation Safety Agency or European Space Agency. The regulators specify usually performance requirements rather the specific substances. Such industry needs chromic acid. (general exemption asked)	The reference to safety critical requirements under other legislation can be reflected in the application for authorisation and will be taken into account by the Risk Assessment and Socio-economic Analysis Committees when evaluating such applications and by the Commission when taking the final decision on the authorisation.
EE14	**Chromium trioxide, #658**	The use of chromium trioxide in wood preservation referred to in your comment may fall under the exemption from the authorisation requirement in accordance with Article 56(4)(b) REACH,

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	Use that should be excempted from the authorisation process: Use of chromium trioxide in wood preservation: Chromium trioxide is used as fixative in wood preservatives which are biocidal products, product type 8. Reasons: Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market imposes comprehensive requirements relating to the protection of human health or the environment for the use of wood preservatives (product type 8), the risk of wood presevatives is properly controlled. In Article 5 of the directive the conditions for an authorization of a biocidal product are stated: … Article 5 (Directive 98/8/EC) Conditions for issue of an authorisation 1. Member States shall authorise a biocidal product only if (a) the active substance(s) included therein are listed in Annex I or IA and any requirements laid down in these Annexes are fulfilled; (b) it is established, in the light of current scientific and technical knowledge, and is shown from appraisal of the dossier provided for in Article 8, according to the common principles for the evaluation of dossiers as laid down in Annex VI, that, when used as authorised and having regard to: — all normal conditions under which the biocidal product may be used, — how the material treated with it may be used, — the consequences from use and disposal, the biocidal product: (i) is sufficiently effective, (ii) has no unacceptable effects on the target organisms, such as	i.e. regarding uses of substances in biocidal products within the scope of Directive 98/8/EC. We would suggest that you examine whether the mentioned uses of your substance can be regarded as fulfilling the requirement of Article 56(4)(b). If you conclude that your uses of the mentioned substance fulfil the above requirement, the uses can benefit from the exemption from authorisation as set out in Article 56(4)(b) and no authorisation would be required to continue the use after the sunset date.

#	Exemption requests (substance; legislation; use(s); any justification; submitter)	Response
	unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates, (iii) has no unacceptable effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. through drinking water, food or feed, indoor air or consequences in the place of work) or on surface water and groundwater, (iv) has no unacceptable effect itself, or as a result of its residues, on the environment having particular regard to the following considerations: — its fate and distribution in the environment; particularly contamination of surface waters (including estuarian and seawater), groundwater and drinking water, — its impact on non-target organisms; ….	

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 chromium (VI) 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.
ELV	Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles.
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.

F – MISCELLANEOUS

#	Issue(s) addressed	Comment example(s)	Response
FF1	**Comments on alternative risk management options.**	Chromic acid, #1834 Re. use in conversion layer for aluminium before powder coating: - study by IOM recommended Community-wide OEL value - risk controlled (RAR) Suggest Restrictions under REACH (as for CrVI in cement) if further regulatory measures are needed.	Thank you for your comment. Information on a low level of risks exerted by particular uses should be part of the applications for authorisation to be submitted to ECHA (Art. 62(4) (d) – Chemical Safety Report). 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. Please note that in the process of assessing whether a substance on the Candidate List has priority for inclusion in Annex XIV and therefore should be recommended for inclusion in this annex we are not in the position to assess alternative regulatory risk management options for particular uses.
FF2	**Comparison of the authorisation process to a ban.**	Chromic acid, #ATT 1836 and Sodium dichromate, #ATT 1837 Hard chromating is a key surface treatment for the mechanical and metal working industries in Europe. We are worried about the consequences that a general ban of this use will have on our operations whenever our service or part suppliers will not obtain or request an Authorization. Beyond the loss of economic activity throughout the European industry, should we be forced to source those parts or services from outside the EEA, such a ban will have other detrimental effects on our organisation: longer logistical chains, higher inventories of capital-intensive spare parts.	Thank you for your comment. Note that authorisation is not comparable to a ban or restriction of a substance but rather to a licensing system. Recognised substances of very high concern maybe granted an authorisation if the applicant can show proper control of risks arising from the applied for uses or if there is no suitable alternative available to the substance available and the socio economic benefits of a use outweigh the associated risks for health and environment It may indeed happen that a manufacturer/importer decides to not apply for authorisation of uses he currently supplies for. In such case the downstream user has the possibility to look for another supplier willing to apply for the DU's uses or to develop his own application for his use(s) (and those of his DUs, if relevant). In the latter case it is advisable to inform the supplier and – if relevant - the downstream user(s) of the intention to make an application for authorisation. Generally we strongly advocate for a good communication within the supply chain to identify and agree on the most

#	Issue(s) addressed	Comment example(s)	Response
			appropriate actor to apply for authorisation for certain use and how the different actors can best contribute to this work. In addition you might be able to get support from industry associations of your market sector within the whole supply chain.)
FF3	**Lack of documentation in the description of alternatives.**	Sodium dichromate, #1135 In the annex XV dossier some alternatives are described but these are in our view not well documented. Important elements which are lacking are amongst others: - The economic feasibility of the substitution linked to the factor that imported articles with chrome plating will remain a fact after the sunset date, - The technological challenge including the economic costs for re-designing products as well as production facilities given that complete new installation have to be put in place for the alternatives, - The technical properties of the substitution including long term behavior and certification. In different current markets, such as automotive, off-road vehicles, aeronautic applications, … with strong, long term quality guarantees, security issues and very stringent certification obligations. This increases the technical challenges of any substitution program.	Thank you for your comment. Main purpose of an Annex XV dossier is to provide information on the SVHC properties of the substance concerned in accordance with Article 57 of REACH in order to facilitate the identification as substance of very high concern. The information on alternatives given in the second part of the Annex XV report is not intended to serve as an extensive analysis of alternatives but to support steps of the authorisation procedure potentially following inclusion in the Candidate List, in particular the assessment of time requirements for developing an analysis of alternatives in the context of an authorisation application An analysis of alternatives is required later in the process as part of the application for authorisation. It should – amongst other issues - cover also the technical and economic feasibility of substitution including e.g. the transferral costs to the alternatives (like costs for equipment, training, potential down-time, regulatory costs), costs due to market changes or costs due to re-design of products. Please refer to the Guidance on preparation of an application for authorisation for further information (http://www.echa.europa.eu/documents/10162/17229/authorisation_application_en.pdf).
FF4	**Observations on ECHA's background document.**	Chromium trioxide # 1457 Observations on document developed in the context of ECHA's third Recommendation for the inclusion of	Thank you for your comments and the information provided

#	Issue(s) addressed	Comment example(s)	Response
		Substances in Annex XIV. Point 2.2.1 Volume(s), imports/exports "The largest part of the registered amount is allocated to uses in the scope of authorisation." Observation: ECHA's interpretation of the concept of 'intermediate' (as given in its June 2010 clarification document) excludes substances used as surface treatments, e.g. Chromium Trioxide used in metal finishing. On that basis, the volumes of Chromium Trioxide used for that purpose fall under the scope of authorisation. However, the conclusion reached in the clarification document cannot be supported. The abovementioned clarification document was reviewed by two independent legal experts, the law firm Field Fisher Waterhouse and Professor Dr. Kristian Fischer, at the request of Industry. In Cefic's position paper of December 2010 (please see link: http://www.cefic.org/Documents/IndustrySupport/Cefic%20concept%20of%20intermediates%20letter%20(2).pdf), 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 AIFM, AIAS, Assogalvanica, VOM BL, VOM NL, Anaz,… and the Institute of Metal Finishing. Within that context, should the literal definition of intermediate under Article 3(15) be applied, the volumes of Chromium Trioxide used in metal finishing would fall outside of authorisation. As a result, the statement made under Point 2.2.1 is without foundation.	Point 2.2.1 and 2.2.2.2 See response BB1. In addition, it is stressed that the assessment whether a use should be considered as use of the substance as intermediate has been done only for prioritisation purpose and it does not conclude or define the status of the use under the REACH Regulation. In general, in the 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.

#	Issue(s) addressed	Comment example(s)	Response
		Point 2.2.2.1 Manufacture and releases from manufacture "No information is available on the manufacture of chromium trioxide itself". Observation: Information is available. ECHA has simply failed to take into consideration a number of studies that were performed under EU programs with public funding , which involved the participation of a number of interested parties (for further information see our observation on point 4 below). Point 2.2.2.2 Uses and releases from users. "falling under authorisation are…metal finishing" Please see observation in Point 2.2.1 "Recent exposure information reported in the annex XV dossier presented by Germany…" Observation: We wish to stress the fact that Germany's dossier is not representative of worker exposure in Europe. It is our understanding that the information derived therein came mainly from data collected from a limited number of industrial sites in Germany that were not complying with exposure reduction measures. An accurate assessment should be based on an examination of multiple sites throughout the European Union. Moreover, as stated in page 19 of the Annex XV dossier for chromium trioxide, "in Germany the occupational exposure limit, which was based on the technical feasibility was withdrawn in 2006." Therefore, the fact that an added safety requirement has been removed should also lead to the conclusion that it is misrepresentative as a European standard. Indeed, point 3.3.4 of ECHA's guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern states that, "certain types of information, including exposure-related information, are needed for the later process used to prioritise the substances for inclusion on Annex XIV, once the dossier has been accepted." This point goes on to make reference to 'available' information on exposures. In this connection,	Point 2.2.2.1: For the purpose of priority setting we have taken all the information that was available to us into account. In particular, this was information from the registration dossiers including CSRs, the Annex XV reports and from the comments received during public consultation on the SVHC identification of the substances. In addition, comments by industry associations that have been submitted during MSC discussion of the prioritisation have been carefully considered. Point 2.2.2.2: The conclusion reported in the ECHA's background document regarding uses and releases from uses is not only based on the exposure information reported in the Annex XV dossier prepared by Germany but also on all the other available information (e.g. information in CSRs). The exposure information available only supports the fact that there might be some exposure to workers even though for some applications and installations the risks associated to the use of chromium VI compounds is nowadays reduced.

#	Issue(s) addressed	Comment example(s)	Response
		we refer to the investigation carried out by Regione Lombardia (see Decreto Regione Lombardia No 3357 of April 13, 2011 Vademecum for the improvement of safety and health of workers employed in electroplating activities) in the highly industrialised zone of Como in Italy that states that, "the risk for workers is at present greatly reduced in comparison with previous years" and that, "levels of exposure (of workers) to chromium hexavalent are not different from those found in the population." Notwithstanding the above, it should not be forgotten that Chromium Trioxide has already undergone rigorous assessment and consideration at the European Union level under Regulation 793/93. The conclusion reached in the Commission's recommendation of 30 May 2008 was that the existing legislative framework was sufficient. The only outstanding action suggested in the risk reduction strategy was to establish at Union level occupational exposure limit values for Chromium hexavalent ("CrVI") compounds. If indeed needed, this would be a far better solution when compared to Annex XIV listing. Point 2.3 Availability of information on alternatives Observation: We stress that the alleged alternatives to Chromium plating are not suitable. This conclusion is partly made by the background dossier itself. HVOF is not able to give a useful thickness to coating in the majority of items. Moreover, when spraying Chromium compounds at high temperatures, Cr III oxidizes to Cr VI (similar to when welding stainless steel). This means an increase of risk for the worker. Vacuum coatings and nanotechnology may be applied only on small size products with very high added value. This is because the creation of the vacuum requires a high energy consumption. At present, the risk linked to nanotechnology is under investigation. This is because nanoparticles have such a small size that they can cross the cellular membrane; therefore, the health hazard may be dramatically high.	

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		Zinc based alternatives and nickel based alternatives are not actual alternatives. Indeed, zinc and nickel treatments are complementary to chromium plating or processes addressed to other characteristics. Part modification cannot be considered as an alternative. Below we shall briefly comment on two of the suggestions given in the Annex XV dossier: - the use of plastic instead of metal: Plastic also needs to be plated (for certain uses) and it does not have the structural properties needed for a number of products. In addition, plastic is not as recycled as metals. Therefore, plastic instead of metals translates to a greater environmental impact. - the use of stainless steel instead of iron: We stress that stainless steel contains roughly 10% chromium metal. Welding of stainless steel will expose millions of workers to a great health risk because Cr metal is transformed by welding in hexavalent Chromium in the inhalble gases. Point 2.4 Existing specific Community legislation relevant for possible exemption Observation: In the "Environmental Risk Reduction Strategy and Analysis of Advantages and Drawbacks for Hexavalent Chromium" (RRS) final report of October 2005, there is a non-exhaustive list of existing controls on emissions and exposure to Hexavalent Chromium. In this connection, we believe that existing EU-wide measures, International measures and National measures represent a legislative framework that is capable of assuring that risks deriving from the use of Chromium Trioxide are adequately controlled. Indeed, as previously stated, such a conclusion has already been drawn by the Commission in its 2008 recommendation. To that end, we stress, in particular, the importance of Directives 96/61/EC and 2008/01/EC on integrated pollution prevention and control, and Directives 96/82/EC and 2003/105/EC on the control of major-hazards involving dangerous substances.	Point 2.3: (DD1) 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

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		Point 2.5 Any other relevant information (e.g. for priority setting) The inherent properties score for Chromium Trioxide is 1. Practically speaking, this means that there are other substances which are stronger candidates for Annex XIV inclusion. Such a finding is further supported by the outcome of the in-depth assessment that was undertaken on Chromium Trioxide under Regulation 793/93, where the Commission in its recommendation effectively stated that restrictions are unnecessary. Point 3.1 Prioritisation: Verbal argumentative approach High Volumes allocated to uses in the scope of authorisation We reiterate our observation made to point 2.2.1. of the Background Document, Chromium Trioxide used in electroplating should be considered as an intermediate. High Number of sites This is an exaggeration, as only 2.5 % of metal working companies in the EU are metal finishing installations using Chromium Compounds. With respect to exposure to workers, we refer to our observation on point 2.2.2.2 of the Background Document. Point 3.1 Prioritisation: Scoring approach High Volumes allocated to uses in the scope of authorisation We request that the volume be reviewed, as Chromium Trioxide used in electroplating should be considered as an intermediate. High Number of sites As stated above, only 2.5 % of metal working companies in the EU are metal finishing installations using Chromium Compounds. Therefore, a Score of 1 should be given. "Some of the the uses appear to have a potential for	inclusion Annex XIV. Point 2.4: See section E of this RCOM for further information on the basis for requesting an exemption with reference to existing community legislation (article 58(2) of REACH) and assessment of the requests made.

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		significant work exposure. Score 3". We reiterate our observation on point 2.2.2.2 of the Background Document. As a consequence, we suggest that a score of 1 be given. Point 4. References A number of important documents are missing. This includes, by way of example, the Commission recommendation of 30 May 2008 which concluded that restrictions were not required. Instead, it stated that, "the legislation for workers protection currently in force at community level is generally considered to give an adequate framework to limit the risks of the substances to the extent needed and shall apply." It is also worthwhile mentioning the earlier document "Environmental Risk Reduction Strategy and Analysis of Advantages and Drawbacks for Hexavalent Chromium" (RRS) made Under Framework Contract: CPEC 24 of October 2005. Lacking this report, the reader misses an important document where, after considering effectiveness, practicality, economic impact and monitorability, it is stated that (paragraph 4.2. of the Executive summary): "marketing and use restrictions would be inappropriate and disproportionate measures for risk reduction. The risks have been clearly overestimated in the RAR and in the majority of Member States measures are already in place which reduce unacceptable risks, if not eliminate them. Techniques and technologies currently available are able to ensure adequate control of risks." II. Conclusions • Chromium Trioxide is mainly used for metal finishing; therefore, its principal use is that of an intermediate. As a result, a significant proportion of volumes used fall outside the scope of the authorisation procedure. • Chromium Trioxide has already been subject to an in-depth assessment within the framework of Regulation 793/93. The conclusions of that assessment as given in the	Point 2.5 In ECHA's document describing the agreed prioritisation approach (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf), 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 like Chromium trioxide. However 2 other criteria have to be taken into account when prioritising, namely 'volume' and 'wide dispersive use' as the prioritisation is intended to consider the potential risks arising from the uses of a substance and not only its intrinsic properties. Regarding the reference to the outcome of the assessment under the ESR programme see EE1. Point 3.1: See response given to point 2.2.1 and 2.2.2.2 Regarding the number of sites please note that the number of sites do not refer only to metal finishing installations but to all uses identified for chromium trioxide.

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		Commission's subsequent recommendation and communication were that restrictions were not required. Instead, "the legislation for workers protection currently in force at community level is generally considered to give an adequate framework to limit the risks of the substances to the extent needed and shall apply." • The Annex XV dossier prepared by Germany is flawed with respect to the exposure data relied upon therein. • The alleged alternatives to Chromium plating identified by Germany are not suitable. • The Annex XV dossier prepared by Germany fails to mention a significant amount of literature, which supports the view that prioritisation of Chromium Trioxide is unwarranted. • Inclusion in Annex XIV can only be subject to extended application and sunset dates. A failure to do so would mean an outright ban on Chromium Trioxide being used for metal finishing/electroplating.	Point 4: As mentioned before we have taken all the information that was available to us into account. In particular, information from the registration dossiers including CSRs, the Annex XV reports and from the comments received during public consultation on the SVHC identification of the substances. It should be noted that some of those references are compilation of several references (e.g. the Annex XV report) where the reference you mentioned is included.