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On behalf of its member companies, the European Committee for Surface Treatments ("CETS"), an international federation of national associations engaged in the supply of technology, chemicals, and paint products to the surface treatment industry¹, wishes to bring forward the following comments/objections to the prioritisation of the substance Chromium Trioxide in Annex XIV to REACH.

Before proceeding, it should be noted that Chromium Trioxide has since decades been safely used mainly in metal finishing (e.g. decorative plating) as an intermediate. Historically, it was part of the third priority list of existing substances under the legal framework of <u>Regulation</u> (EC) n. 793/93. For each substance on a Priority List, a Member State would volunteer to act as Rapporteur, undertaking an in-depth risk assessment and recommending a strategy to limit risks of exposure to the substance, if necessary.

In the case of Chromium trioxide, the abovementioned process resulted in the Commission recommendation of 30 May 2008, which concluded (along with the accompanying communication²) that <u>restrictions were not required</u>. 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."³

More recently, Chromium trioxide was identified as a Substance of Very High Concern ("SVHC") under REACH and subsequently included in the candidate list for authorisation on 15 December 2010. These developments did not stem from any new information following

³ Commission Recommendation of 30 May 2008 on risk reduction measures for the substances chromium trioxide, ammonium dichromate and potassium dichromate (notified under document number C(2008) 2326). OJ L 158, 18.6.2008.

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¹ See full list of members on <u>http://www.cets-surface.eu/cets-members/index.html</u>, which effectively includes the entire metal plating Industry.

 ² Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: chromium trioxide, ammonium dichromate, potassium dichromate. (2008/C 152/01)



from the Commission recommendation of 2008, but the substance's classification as a carcinogen and mutagen⁴. This approach is thus wholly inconsistent.

Furthermore, the inclusion of Chromium Trioxide in Annex XIV to REACH would be scientifically and legally flawed because, first, Chromium Trioxide is not subject to authorisation as it is used by the plating industry as an <u>intermediate</u>; second, the Annex XV dossier prepared by Germany which serves as the basis for such inclusion contains a series of <u>scientific inaccuracies</u>; third, the use of Chromium Trioxide is already regulated and adequately controlled by relevant <u>workers protection legislation</u> applicable in the European Union, as a result of which any further measure would be unnecessary and <u>disproportionate</u>; fourth, there are <u>no suitable alternatives</u> on the European market and a restriction of Chromium Trioxide would entail severe consequences.

Overall Comment

At the outset, the first stage of the authorisation process, as described in Article 59 of Regulation 1907/2006, only requires the examination of the intrinsic properties of the substance in order to determine whether it meets the criteria for identification as a substance of very high concern, as set out in Article 57 to REACH. As a result, there is no need at that stage to look at the uses of that substance. Once a substance has been included in the Candidate List it may be considered for inclusion in Annex XIV. This will take into account, amongst other things, the uses of that substance. As stated by ECHA (and supported by the General Court, in Case T-1/10 R), "not all substances in the Candidate List will be automatically considered for inclusion in Annex XIV REACH."

To put it differently, there is no legal obligation that a substance included in the Candidate List should be included (or even considered for inclusion) in Annex XIV. The contrary would result in disproportionate measures being taken, as is the possibility in the case at hand. Indeed, <u>a decision to include Chromium Trioxide would not only be unjustified, but would have significant implications to the Industry as a whole.</u>

As Chromium Trioxide is mainly used as an isolated intermediate, the application of the authorisation procedure becomes largely redundant. This also has implications on the volumes that can be taken into consideration for prioritisation. If for whatever reason the

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It is worthwhile noting that inclusion in the candidate list alone imposes additional regulatory measures in the form of information and communication obligations.



metal plating industry's interpretation of that concept is not accepted (an interpretation which is fully supported by all of industry and is based upon the literal wording of REACH), this still does not detract from the fact that Chromium Trioxide has already been subjected to an in-depth assessment, as mentioned above, which concluded that the existing legislative framework for workers protection was sufficient. Therefore, Chromium Trioxide should not be prioritised for inclusion in Annex XIV. This finding is further supported by the procedural irregularities of the review program, i.e. that the Annex XV dossier prepared by Germany (the basis of the present authorisation procedure) is flawed (see the comment below on Point 2.2.2.2 of the ECHA background document).

Should Chromium Trioxide be prioritised for Annex XIV inclusion, it is imperative that the application and sunset dates be extended. As a non-threshold carcinogen, an application for authorization for Chromium Trioxide will need to include a socio-economic analysis. Given the complexity of the supply chains of articles subject to this category of surface treatment, additional time is needed. In that respect, the following dates should apply: application date (date for submitting applications for authorisation): July 2015 ; and sunset date: January 2017.

I. Observations on ECHA's background document

Observations on document developed in the context of ECHA's third Recommendation for the inclusion of Substances in Annex XIV.

Point 2.2.1 Volume(s), imports/exports

<u>"The largest part of the registered amount is allocated to uses in the scope of authorisation."</u>

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, 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."⁵

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 2.2.2.1 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).

⁵ Cefic paper of December 2010 (please see link: <u>http://www.cefic.org/Documents/IndustrySupport/Cefic%20concept%20of%20intermediates%20letter</u> <u>%20(2).pdf</u>)



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, we refer to the investigation carried out by Regione Lombardia 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."⁶

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.

⁶ Decreto Regione Lombardia No 3357 of April 13, 2011 Vademecum for the improvement of safety and health of workers employed in electroplating activities.



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 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.
- 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 inhalable 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 nonexhaustive 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 2.5 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 uses appear to have a potential for 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 <u>restrictions were not</u> <u>required</u>. 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. Suggestions/Requests

Alternative to Annex XIV inclusion

If additional risk management measures are needed, we believe that the strategy for limiting risks as described in the Communication from the Commission⁷ is a far more proportionate means of resolving any alleged outstanding issues.

This document makes reference to, by way of example, the establishment at European Union level of occupational exposure limit values for chromium (VI) compounds, as well as biological limit values.

Should Chromium Trioxide be included in Annex XIV

Should Chromium Trioxide be prioritised for Annex XIV inclusion, it is imperative that the application and sunset dates be extended. As a non-threshold carcinogen, an application for authorization for Chromium Trioxide will need to include a socio-economic analysis. Given the complexity of the supply chains of articles subject to surface treatment, additional time is needed.

In that respect, the following dates should apply: application date (date for submitting applications for authorisation): July 2015 ; and sunset date: January 2017.

A failure to grant additional time would have the practical effect of transforming the Annex XIV listing into an outright ban.

⁷ See footnote 2.



III. 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 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.

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