Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Chromium trioxide use: Functional chrome plating with decorative character

ECHA/RAC/SEAC: AFA-O-0000006490-77-03/D

Consolidated version

Date: 16 September 2016

Consolidated version of the

Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis

on an Application for Authorisation

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to an application for authorisation for:

Chemical name(s): Chromium trioxide
EC No.: 215-607-8
CAS No.: 1333-82-0

for the following use:

Functional chrome plating with decorative character

Intrinsic property referred to in Annex XIV:

Article 57 (a)(b) of the REACH Regulation

Applicant:

LANXESS Deutschland GmbH in its legal capacity as Only Representative of LANXESS CISA (Pty) Ltd.
Atotech Deutschland GmbH
Aviall Services Inc
BONDEX TRADING LTD in its legal capacity as Only Representative of Aktyubinsk Chromium Chemicals Plant, Kazakhstan
CROMITAL S.P.A. in its legal capacity as Only Representative of Soda Sanayii A.S.
Elementis Chromium LLP in its legal capacity as Only Representative of Elementis Chromium Inc
Enthone GmbH

Reference number:

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11-2120088250-61-0018
11-2120088250-61-0019
11-2120088250-61-0020

Rapporteur, appointed by the RAC: **Tiina Santonen**
Co-rapporteur, appointed by the RAC: **Christine Bjørge**

Rapporteur, appointed by the SEAC: **Simone Fankhauser**
Co-rapporteur, appointed by the SEAC: **Karine Fiore-Tardieu**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On 11 May 2015 LANXESS Deutschland GmbH in its legal capacity as Only Representative of LANXESS CISA (Pty) Ltd., Atotech Deutschland GmbH, Aviall Services Inc, BONDEX TRADING LTD in its legal capacity as Only Representative of Aktyubinsk Chromium Chemicals Plant, Kazakhstan, CROMITAL S.P.A. in its legal capacity as Only Representative of Soda Sanayii A.S., Elementis Chromium LLP in its legal capacity as Only Representative of Elementis Chromium Inc and Enthone GmbH submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **24 July 2015** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **12 August 2015**. Interested parties were invited to submit comments and contributions by **7 October 2015**.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation as well as the responses of the applicant.

The draft opinions of RAC and SEAC take into account the responses of the applicant as well as third parties to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

Due to the need to ensure the efficient use of resources, and in order to synchronise the public consultation with the plenary meetings of the Committees the time limit set in Article 64(1) for the sending of the draft opinions to the applicant has been extended until 30 June 2016.

The draft opinions of RAC and SEAC were sent to the applicant on **21 June 2016**.

The applicant informed on **28 June 2016** that it wished to comment the draft opinions of RAC and SEAC according to Article 64(5) and sent his written argumentation to the Agency on **21 July 2016**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and/or the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **3 June 2016**.

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of RAC was adopted by consensus on **16 September 2016**.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **9 June 2016**.

The draft opinion of SEAC was agreed by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of SEAC was adopted by consensus on **15 September 2016**.

THE OPINION OF RAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

RAC has formulated its opinion on: the risks arising from the use applied for, the appropriateness and effectiveness of therisk management measures described, the assessment of the risks related to the alternatives as documented in the application, the information submitted by interested third parties, as well as other available information.

RAC confirmed that it is not possible to determine a DNEL for the carcinogenic properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that there appear not to be any suitable alternatives that further reduce the risk.

RAC confirmed that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements are expected to improve the situation.

THE OPINION OF SEAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC has formulated its opinion on: the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application, the information submitted by interested third parties, as well as other available information.

SEAC took note of RAC's confirmation that it is not possible to determine a DNEL for the carcinogenic properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant.

SEAC considered that the applicant's assessment of: (a) the potential socio-economic benefits of the use, (b) the potential adverse effects to human health of the use and (c) the comparison of the two is based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the use outweigh the risk to human health, whilst taking account of any uncertainties in the assessment, provided that the suggested conditions and monitoring arrangements are adhered to.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

The suggested conditions and monitoring arrangements are specified in section 9 of the justifications.

REVIEW

Taking into account the information provided in the application for authorisation prepared by the applicant and the comments received on the broad information on use(s) the duration of the review period for the use is recommended to be **four years**.

JUSTIFICATIONS

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property / properties:

- ☒ Carcinogenic (Article 57(a))
- ☒ Mutagenic (Article 57(b))
- ☐ Toxic to reproduction (Article 57(c))
- ☐ Persistent, bioaccumulative and toxic (Article 57(d))
- ☐ Very persistent and very bioaccumulative (Article 57(e))
- ☐ Other properties in accordance with Article 57(f):

2. Is the substance a threshold substance?

- ☐ YES
- ☒ NO

Justification:

Chromium trioxide has a harmonised classification as Carcinogen Cat. 1A H350 and Mutagen Cat. 1B H340 according to CLP. Based on studies which show its genotoxic potential, the Risk Assessment Committee (RAC) has concluded that Chromium trioxide should be considered as non-threshold substance with respect to risk characterisation for carcinogenic effect of hexavalent chromium (reference to the studies examined are included in the RAC document RAC/27/2013/06 Rev. 1).

3. Hazard assessment. Are appropriate reference values used?

Justification:

RAC has established a reference dose response relationship for the carcinogenicity of hexavalent chromium (RAC/27/2013/06 Rev. 1) which was used by the applicant.

The molecular entity that drives the carcinogenicity of chromium trioxide is the Cr(VI) ion, which is released when chromium trioxide solubilises and dissociates.

Chromium (VI) causes lung tumours in humans and animals by the inhalation route and tumours of the gastrointestinal tract in animals by the oral route. These are both local, site-of-contact tumours – there is no evidence that Cr(VI) causes tumours elsewhere in the body.

Dose-response relationships for these endpoints were derived by linear extrapolation. Extrapolating outside the range of observation inevitably introduces uncertainties. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be overestimated.

In the socio-economic analysis (SEA) the remaining human health risks are evaluated based on the dose-response relationship for carcinogenicity of hexavalent chromium (RAC27/2013/06 Rev.1).

Are all appropriate and relevant endpoints addressed in the application?

All endpoints identified in the Annex XIV entry are addressed in the application.

4. Exposure assessment. To what extent is the exposure from the use described?

Description:

Short description of the use

According to the applicant the use applied for relates to functional chrome plating with decorative character which, according to the applicant, generally involves the use chromium trioxide in the electrochemical treatment of metal, plastic or composite surfaces to deposit metallic chromium to achieve an improvement in the surface appearance, level of corrosion protection and to enhance durability. In functional chrome plating with decorative character, chromium trioxide is used to deposit a metallic chromium coating of typically 0.1- 2 µm, or, where increased corrosion resistance is required, a 'micro cracked' chromium deposit of thicknesses typically 0.5 - 2 µm, over a nickel undercoat.

Functional plating with decorative character may include use of chromium trioxide in a series of pre-treatments and surface deposits. It is used widely in automotive, plumbing, household appliances, bathroom, furniture and homeware applications. Functional plating with decorative character includes black chrome plating, provided that there is no residual Cr(VI) on the surface of the article at the detection limit. This has been used, for example, in solar panel manufacture, where deposits are porous and <1 µm thick.

The main form of application is dipping or immersion of parts in a tank or through a series of tanks containing solutions in closed or open systems.

The amount of chromium trioxide involved is stated by the applicant to be 3,000 tons/year corresponding to **1,500 tons/year as Cr(VI)**.

The applicant presents one exposure scenario (ES) in the chemical safety report (CSR): Functional chrome plating with decorative character with one environmental contributing scenario (ECS) and 18 working contributing scenarios (WCS).

It is important to recognise that the final chromium coating does not contain chromium trioxide or any other Cr(VI) substances.

Worker exposure

Exposure estimation methodology:

Introduction: RAC notes the discrepancy in each use applied for, including this one between a) the total number of potential sites which the applicant (organised in the Chromium Trioxide REACH Authorization Consortium - CTAC) considers may be covered by the application (Use 3: up to 1,559 sites as given in the SEA), b) the number of CTAC members (150+) and c) the measured exposure data provided (from 6 to 23 sites for Uses 1 to 5). RAC therefore requested clarification and in response the applicant

provided a description of how they had conducted their supply chain investigation on workplace exposure. The geographical spread of their membership and of those members providing data was also included.

The applicant sent out questionnaires to its 150+ membership in 2013; members who did not respond were reminded formally on several occasions until March 2014. The table below provides a breakdown of the responding companies and their data; even though the total number of sites with personal monitoring data finally used by the applicant is low, RAC considers that understanding the methodology is useful in interpreting the representativeness of the exposure data. Many sites provided only static measurement data according to the applicant. The applicant chose not to use the static data to support their application, thus reducing the dataset significantly. Of the final set of personal measurements, there is a further reduction as some were rejected.

Table 1.

ORIGIN OF THE DATA **USE GROUPS**	**CTAC Companies[1] who were approached for exposure data**	**Sites from which exposure data was collected**	**Sites from which <u>personal</u> monitoring data was used: from Table 2 of the response to the 1st. set of RAC questions. (no. of measurement available / no. used)**	**Geographical location of the sites providing personal monitoring data (in descending order of number of responses)**
Use 1 Formulation	30	15	6 (8/19)	Germany, France, Sweden, Netherlands
Use 2 Functional chrome plating	89	44	23 (96/136)	France, Germany, Spain, UK, Italy, Sweden, Netherlands
Use 3 Functional chrome plating with decorative character	***59***	***34***	***10 (29/40)***	***Germany, France,***
Use 4/5 Surface treatment and other uses (see use description)	110	28[2]	11 (36/40)	France, Germany

[1] Some companies/sites may be in more than one use group

[2] Use 4/5 had the lowest response to the questionnaire in terms of data provided

The applicant describes their experience in approaching DU's, in particular smaller enterprises and the difficulties that they encountered in communicating the need to provide data; this is reflected in the dataset. Significantly, the applicant also reports that when they approached non-CTAC members, even via other industry associations, this yielded no response in terms of exposure data.

The applicant declared in their final response to RAC's questions (Jones Day, 18 April

2016) that they are "*confident that the data presented in the exposure scenarios is representative of European sites*", noting that it "*has been corroborated with findings from recently available public databases*".

Worker Contributing Scenarios: Inhalation exposure has been estimated using the ART 1.5 model for the WCSs 2-7, 16 and 18. Input parameters for the model have been included in the CSR. OCs and RMMs for each WCS are presented in Table 2. For the WCSs 8-15, the exposure assessment is based on the measured data of Cr (VI) concentration in air from 10 individual sites performing functional chromium plating with decorative character. These measurement data, provided by the applicant at the request by RAC, are summarized in annex (Table A1). Only personal measurements have been taken into account in the calculations. The 90th percentile from the measurement data is calculated and used in further analyses.

In the case of WCSs 1 and 17, presenting storage of raw material in sealed containers and storage of chromium plated articles, a qualitative assessment was conducted, from which the applicant concluded that no potential for exposure exists, on the grounds that chromium trioxide is not volatile and hexavalent chromium is not present on the surfaces of treated articles.

As the RAC reference document (RAC27/2013/06 Rev. 1) states that there are no data to indicate that dermal exposure to Cr(VI) compounds presents a potential cancer risk to humans, the applicant has not assessed dermal exposure.

RMMs applied

General overview on the operational conditions and RMMs applied in each contributing scenarios is presented in Table 2.

Table 2: Operational Conditions and Risk Management Measures

Contributing scenario	Duration and frequency of exposure	Name of the scenario	Concentration of the substance	LEV used	RPE** used + effectiveness	Other RMMs
WCS 1 (PROC 1)	< 8h	Delivery and storage of raw material	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation, closed system
WCS 2 (PROC 8b)	< 60 min	Decanting - liquids	Cr(VI) in mixture: Substantial (10-50%)	no	no	good natural ventilation and enclosure of the material transfer
WCS 3 (PROC 8b)	< 60 min	Decanting and weighing of solids	Cr(VI) in mixture: Substantial (10-50%)	no	Yes, at least half mask with P3 filter, APF 30*	good natural ventilation
WCS 4 (PROC 5)	< 60 min	Mixing liquids	Cr(VI) in mixture: Substantial (10-50%)	no	No	good natural ventilation. Physical containment or enclosure of the source of emission.
WCS 5 (PROC 5)	< 60 min	Mixing solids	Cr(VI) in mixture: Substantial (10-50%)	no	Yes, at least half mask with P3 filter, APF 30*	good natural ventilation. Physical containment or enclosure of the source of emission.
WCS 6 (PROC8b)	< 10 min	Re-filling of baths - liquid	Cr(VI) in mixture: Substantial (10-50%)	yes	no	good general ventilation
WCS 7 (PROC 8b)	< 10 min	Re-filling of baths – solid	Cr(VI) in mixture: Substantial (10-50%)	yes	Yes, at least half mask with P3 filter, with APF 30*	good general ventilation

Contributing scenario	Duration and frequency of exposure	Name of the scenario	Concentration of the substance	LEV used	RPE** used + effectiveness	Other RMMs
WCS 8 (PROC 4)	< 8h	Functional chrome plating – loading of jigs	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation
WCS 9 (PROC 13)	< 8h	Functional chrome plating – chemical pre-treatment	Cr(VI) in mixture: Substantial (10-50%)	Yes, if Cr(VI) or other dangerous substances are used in pre-treatment	no	basic general ventilation
WCS 10 (PROC 13)	< 8h	Functional chrome plating – by dipping and immersion	Cr(VI) in mixture: Substantial (10-50%)	yes	no	basic general ventilation
WCS 11 (PROC 13)	< 8h	Functional chrome plating – rinsing/drying	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation
WCS 12 (PROC 13)	< 8h	Functional chrome plating – chemical post-treatment	Cr(VI) in mixture: Substantial (10-50%)	Yes, if Cr(VI) or other dangerous substances are used in post-treatment	no	basic general ventilation
WCS 13 (PROC 4)	< 8h	Functional chrome plating – cleaning and unloading of jigs	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation
WCS 14 (PROC 8b)	< 1h	Functional chrome plating – cleaning of equipment	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation
WCS 15 (PROC 8a)	< 60 min	Maintenance of equipment	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation

Contributing scenario	Duration and frequency of exposure	Name of the scenario	Concentration of the substance	LEV used	RPE** used + effectiveness	Other RMMs
WCS 16 (PROC 15) Subactivity: Drawing of sample and transfere to laboratory	< 30 min	Laboratory analysis (sampling, laboratory analysis)	Cr(VI) in mixture: Substantial (10-50%)	LEV used for sampling	no	good general ventilation
WCS 16 (PROC 15) Subactivity: Laboratory analysis	< 60 min	Laboratory analysis (sampling, laboratory analysis)	Cr(VI) in mixture: Minor (5-10%)	no	no	basic general ventilation
WCS 17 (PROC 1)	< 8h	Storage of articles	Cr(VI) not detectable in article	no	no	basic general ventilation
WCS 18 (PROC 8b)	30 min	Waste management	Cr(VI) in mixture: Substantial (10-50%)	no	During waste transfer activities with potential for exposure to airborne (Cr(VI) at least half-mask with P3 filter with APF 30* is worn	good general ventilation

** according to German BG rule 190*

(Ref: BGR/GUV-R 190 „Benutzung von Atemschutzgeräten", December 2011, http://publikationen.dguv.de/dguv/pdf/10002/r-190.pdf)

*** Respiratory Protective Equipment*

#The applicant has not listed RPE as RMM for WCSs 8-15. However, RAC notes that exposure levels given in table 2a have been adjusted for the use of RPE in those cases in which they have been used. Therefore, RAC considers that RPE shall be used in these tasks as a last resort, if other measures to limit the exposure are not applicable/sufficiently effective.

Other Risk management measures used to control exposure:

Workers involved in these activities receive regular training with regards to chemical risk management and how to properly wear Personal Protective Equipment (PPE). Regular housekeeping and management systems should be in place in order to ensure high standards of operational procedures. Protective clothing, chemical-resistant gloves and goggles are required in case of potential for exposure to chromium trioxide for all WCSs except WCS 17 (Storage of articles).

The main activities with potential for exposure to Cr(VI) during functional chromium plating with decorative character are the sequential process steps of the application in baths (WCSs 8-15). Although tasks related to functional chromium plating with decorative character are by themselves very similar between different sites, the OCs and RMMs differ between the facilities, depending on e.g. building layout, the scale and frequency of plating operations, level of the automation of the process, size of the parts treated etc. According to the applicant, it is therefore not possible to define a single specific set of OCs and RMMs suitable for all sites and situations. RMMs typically used in decorative chrome plating include automation of the process, limiting the quantities of Cr(VI), enclosure of the baths, general ventilation and local exhaust ventilation (with effectiveness adjusted for each specific situation), the use of mist suppressants and the use of Respiratory Protective Equipment (RPE), as well as appropriate work practices and training. RAC agrees that in order to ensure minimisation of the exposure OCs and RMMs have to be adjusted individually for each facility, taking also into account the general principles of the hierarchy of control.

Discussion of the exposure information:

Exposure estimates provided by the applicant for each WCS are presented in Table 3.

Table 3: Worker exposure – inhalation

Contributing scenario	**Method of assessment**	**Exposure value** µg Cr(VI)/m^3	**Exposure value corrected for PPE** µg Cr(VI)/m^3
WCS 1	Quantitative	0	
WCS 2	ART 1.5	0.69	
WCS 3	ART 1.5	1.5	
WCS 4	ART 1.5	0.69	
WCS 5	ART 1.5	0.5	
WCS 6	ART 1.5	1.1	
WCS 7	ART 1.5	0.025	
WCS 8 to WCS 15	measured	Combined for WCS 8-15: • arithmetic mean: 1.15* • geometric mean: 0.72 • 90^{th} percentile: 3.07	Combined for WCS 2-8: • arithmetic mean: 0.81 • geometric mean: 0.27 • 90th percentile: 1.54
WCS 16	ART 1.5	0.69	
WCS 17	Quantitative	0	
WCS 18	Art 1.5	0.22	

**Of 10 companies reporting data, the distribution of aggregated inhalation exposure values taken mainly in one year between 2012 and 2013 (1 to 7 measurements used) was as follows: 2 companies >3; 0 companies 3 to 2; 2 companies 1 to 2; 2 companies 0.5 to 1 and 4 companies <0.5 µg/m³.*

The exposure estimate for bath operations (WCS8-15) is derived from the measurement data provided by 10 companies of the consortium. This data is presented in annex, table A1. The data is based on personal measurements (n=29, 10 companies) during 2012-2013. The plating processes represented by the measured data included both manual and automation processes with LEV in place, in some cases the exposure was controlled by the use of mist suppressant. No further information on OCs or RMMs in place at the measured workplaces was made available. The 90th percentile of these measurements was 3.07 µg Cr(VI) /m^3.

The applicant corrected the exposure estimate of 3.07 µg Cr(VI)/m^3 for the use of respiratory protection (at some locations, for varying periods of time) to derive an exposure level of 1.54 µg Cr(VI)/m^3. According to the applicant's description, in cases where respiratory protection was used during plating processes, the effectiveness of respiratory protection was assessed using the company information on type of mask and filter used. If available, the Assigned Protection Factor (APF) provided by the manufacturer of the RPE was used. In other cases, APF provided by the German BG rule "BGR/GUV-R190" from December 2011 was used. For a minority of measured data, where the duration for which respiratory protection had been used, clearly could be assigned to the measurement results, the applicant adjusted the measured values accordingly. In most of the cases in which the use of RPE was indicated, the specific time period was not identified and the measured values were not adjusted to account for use of respiratory protection in these cases. Exact calculations on adjustement made due to use of RPE were not made available for RAC.

RAC considers that the dataset provided for use 2 (functional chrome plating generally with higher current density, higher formation of hydrogen and higher temperature in the bath under open, manual conditions with LEV at 23 sites) to be a reasonable worst case which adds to the data from Use 3, thus providing a stronger starting point for the evaluation of Use 3 as a whole.

To support the reported measurements, data from the literature is also presented (Annex, Table A2a by the applicant and A2b by RAC). RAC notes that although average exposure levels presented in the literature are in the same range as the levels collected by the applicant, higher exposure levels are also reported.

According to the assessment of measurement data in the MEGA database published in Germany and referenced by the applicant in response to RAC (DGUV-I 213-716: Galvanotechnik und Eloxieren, Oktober 2014; http://publikationen.dguv.de/dguv/pdf/10002/213-716.pdf), the 90th percentile of personal measurements was 2.5 µg Cr(VI)/m^3 and the 90th percentile of stationary measurements was 6.2 µg Cr(VI)/m^3 in decorative chrome plating. Compared to the functional chrome plating, the air levels in decorative plating are often lower. So, in functional chrome plating the 90th percentile of the measurements was 24.6 µg Cr(VI)/m^3. For the loading/unloading of jigs (for chrome plating in general but also relevant to this use) a 90th percentile (personal measurement) of 13.5 µg Cr(VI)/m^3 was calculated.

The assessment mentioned above includes, however, also older data (beginning from 2001) and does not necessarily reflect the current situation properly. This is evidenced by:

- the more recent German BG ETEM report, which shows 95th percentiles of 4.4 µg Cr(VI) /m^3 in personal measurements in 12 job shops (range <0.01-4.8 µg Cr(VI) /m^3);
- HSE data from 14 companies in the UK shows measurement values from <0.1 to 11 µg Cr(VI) /m^3 (10 out of 41 measurements were below 0.1 µg Cr(VI) /m^3). The companies selected represented sites in which highest urinary chromium levels were recorded in preceding biomonitoring analyses.
- an Italian study from 2007 shows values from 0.1 to 3.32 µg Cr(VI) /m^3 (mean 0.65 µg Cr(VI) /m^3) in personal measurements among 20 companies (Annex, tables A2).
- In a French health insurance report with measurements from 2009 -2013 from 14 companies, a 90th percentile of 1.2 µg Cr(VI) /m^3 was reported (Annex, table 2A).
- A recent research report from France (Vincent et al., 2015, see table A3) reports chromium(VI) levels from chrome plating of 0.13 µg Cr(VI) /m^3 (GM), range <0.02-1.71 µg Cr(VI) /m^3 and in hard chrome plating of 0.58 µg Cr(VI) /m^3 (GM), range <0.03-22.81 µg Cr(VI) /m^3, covering ca. 30 sites in total.

RAC notes that extensive data on exposures to Cr(VI), associated with chrome plating and surface treatment, are available in the recent literature, including some independent studies which gives credibility to the applicant's exposure assessment.

In addition to the measured data, the applicant also provided modelled data (ART 1.5) on functional chrome plating which has some relevance for this use. Exposure was modelled for both manual and automatic processes, with covered or uncovered baths and considering both 90 and 99% LEV efficiency. Two different room sizes were included (see the annex, table A4). The exposure modelling estimates varied between 0.27 to 130 µg Cr(VI)/m3. The highest estimate, 130 µg Cr(VI)/m^3, reflected an open, manual system, with 90% LEV efficiency and a room size of 300 m^3. With 99% LEV efficiency the exposure was decreased to 13 µg Cr(VI)/m^3 and further, down to 0.68 µg Cr(VI)/m^3 if the baths are covered. The high exposure level of 130 µg Cr(VI)/m^3 is, however, not supported by the measured data provided either by the applicant or published in the literature. Thus, modelling is likely to overestimate the exposure.

It should be noted that the model did not take into account the use of RPE or mist suppressants. The average efficiency of mist suppressants is 68% according to the study by UK HSL (2014, referenced in applicant's response to the second set of RAC questions). Furthermore, according to the applicant, baths are usually covered or partly covered. Also RPE is used to limit the exposure if other measures are not sufficiently effective. Otherwise, however, the modelling results can be considered to support the measured data.

RAC furthermore notes, that the exposure in decorative chrome plating is in general considered to be lower than in functional chrome plating, because of the lower current density applied, the resulting lower formation of hydrogen and the lower temperature of electrolyte in the bath.

For ancillary activities, like re-adjusting the electrolyte (WCS 6 and 7) and preparatory

steps (WCSs 2-5), sampling (WCS 16) and waste management (WCS 18), exposure estimates have been prepared by modelling using ART 1.5. According to the applicant, each of these sub-scenarios represents on its own a worst-case scenario because the operational conditions (OCs) and RMMs offering the lowest level of protection reported for that one specific activity was used as input parameters, taking into account the various details of the processes carried out and the RMMs applied and reported by different companies.

As a response to RAC questions, the applicant clarified that preparatory steps for the re-adjustment of the electrolyte (WCSs 2-5, decanting, weighing and mixing of either solid or liquid solutions of Cr(VI)) in a manual process are only conducted when small amounts of chromium trioxide are used by companies and that this will not happen on a daily basis (only e.g. 1 or 2 times per month).

The applicant claims that re-adjustment of the electrolyte with aqueous solutions of chromium trioxide is most commonly a fully automated process, and therefore potential for exposure is reduced. According to the RAC's understanding, full automation might not, however, be always the case in particular in smaller operations. Manual re-filling with aqueous solutions of chromium trioxide (represented by WCS 6) is only conducted for adjustments of some type in smaller sized baths and is rarely needed (no frequency given). According to the applicant, manual re-adjustment of the electrolyte with solid chromium trioxide (WCS 7) is more relevant from the exposure potential point of view and is usually conducted by a trained operator, under supervision or by the supervisor.

Sampling (WCS 16, with LEV in place, no RPE) is conducted once per day/shift or per week (and sometimes less often), depending on the process and number of parts being treated. As a general rule sampling once per day or shift is needed in companies with mass production.

It is assumed that the duration of the regular maintenance of the baths and related equipment (e.g. LEV, rectifier, pumps, panels etc.), is 60 minutes every day. According to the applicant, this is a conservative assumption. Regular maintenance is usually conducted when the bath solutions are at ambient temperature and no aerosol formation can be expected. Therefore, the applicant considers that the results of the air measurements conducted during the functional chrome plating process with decorative character represent a worst-case estimate for regular maintenance activities. According to the applicant, if maintenance is needed during the process, often RPE is used. Separate WCS for these situations is not provided. WCS 15 is also said to cover infrequent maintenance activities with longer duration. Separate WCS for those situations is not provided in the case of use 3 either. However, in the case of uses 4/5/6 there is a separate WCS for infrequent maintenance activities (e.g. removal and replacement of filters), which are conducted once per month with a duration of up to 4 hours. The exposure estimate (modelled using ART 1.5) for this task is 0.25 µg Cr(VI)/m^3 (estimate takes the low frequency of task into account). According to RAC, a separate WCS for infrequent maintenance activities should also have been included in use 3. RAC is of the opinion that the exposure estimate in WCS 15 is unlikely to represent these activities properly.

Combined exposure

According to the information provided by the applicant, workers involved in functional chrome plating with decorative character could be exposed through some combinations of tasks (sub-scenarios) performed within a shift. The core activities are the sequential process steps of the application in baths for which potential exposure is estimated using available measurement data. For other activities in this ES, exposure estimates have been prepared by modelling. Summing up exposure estimates across WCS will, according to the applicant, amplify the impact of conservative and worst-case assumptions across activities, resulting in potentially substantial overestimations of potential exposure.

Therefore the applicant has used 2 µg Cr(VI)/m^3 as a reasonable maximum combined individual exposure value. As a response to RAC questions the applicant provided some general information on the tasks which may occur together and contribute to the combined exposure.

According to the applicant:

• Maintenance work (WCS 15) and surface treatment work (WCS 8-14) are tasks conducted by different groups of operators. However, for regular maintenance of the baths and related equipment the applicant assumed that the exposure estimate for the bath activities would represent a worst-case estimate for these regular maintenance activities. Thus, exposure estimate of 1.54 µg Cr(VI)/m^3 (as 8 h average) applies also to maintenance workers (WCS 15). RAC notes, however, based on experience with downstream chromate applications that in small enterprises it is likely that the same workers are involved in all operations/tasks.

• Sampling (sub-activity of WCS 16, exposure estimate 0.11 µg Cr(VI) /m^3) is conducted by laboratory workers - if the company has a laboratory, otherwise it might be conducted by supervisors or by trained operators.

• Re-adjustment of the electrolyte (commonly done with solid chromium trioxide, WCS 7) is usually conducted by a trained operator under supervision or by the supervisor.

• The most likely combination of tasks for individual operators therefore is that the bath operator (WCS 8-14) conducts the sampling (WCS 16, sub activity sampling) and the re-adjustment of the electrolyte with solid chromium trioxide (WCS 7). The combination of these WCSs would result in an exposure estimate for Use 3 of 1.70 µg Cr(VI) Cr(VI)/m^3, under the assumption that these are tasks performed daily.

Table 4: Typical combination of tasks and related combined exposure

Contributing scenario	**Route**	**Exposure value (as 8 h TWA) corrected for PPE** µg Cr(VI)/m^3
WCS 7	Inhalation	0.025
WCS 8-14 (+15*)	Inhalation	1.54
WCS 16 (sampling)		0.11
Total exposure for 8 hours	Inhalation	1.7 ** (applicant's estimate on maximum individual exposure value - 2 µg Cr(VI)/m^3)

**In contrast to the applicant's view, RAC notes that in small companies, maintenance (WCS15)*

may be performed by the same workers as bath operations. However, the applicant's exposure estimate for regular maintenance operations is the same as for bath operations. Infrequent maintenance activities (e.g. removal and replacement of filters) are not assessed separately in the case of use 3.

***RAC notes that if the same worker performs also waste management (WCS 18, transfer of e.g. empty bags to storage area etc), this will, according to ART 1.5 modelling, increase the exposure by 0.22 µg/m³, if it is assumed that it is daily activity. In addition, if the worker performs preparatory steps (WCS 3 and 5, decanting, weighting and mixing of solids) 1-2 times per month, this may increase average daily exposure by ~0.1-0.2 µg/m³.*

Uncertainties related to the exposure assessment:

The number of potential sites in the EU performing functional chromium plating with decorative character is estimated by the applicant to be up to 1,559. The applicant bases the exposure assessment of plating activities in this scenario on measured data from 10 companies in Finland, France and Germany supported by literature data mainly from Western European countries. Although in general the most recent literature data is considered to support the applicant's estimate on a maximum individual exposure value of 2 µg Cr(VI)/m³, both the data available in the literature and the data presented by the applicant (see annex, tables A2 and A3) show variation in exposure levels including also exposure levels up to **an order of magnitude higher** than their proposed limit of 2 µg Cr(VI) /m³.

Lack of detailed descriptions of OCs and RMMs linked to the exposure data presented leads to a significant uncertainty of the applicant's assessment. While it is appreciated that it is difficult to define a specific set of OCs and RMMs suitable for all workplaces, RAC would have expected exposure data clearly linked to specific OCs, RMMs for representative sites with the justification as to how these can represent the whole range of sites.

Further uncertainties are related to the combined exposure assessment and the frequency of different ancillary activities. In the response to RAC questions the applicant stated that preparatory steps for the re-adjustment of the electrolyte (WCS2-5, decanting, weighting and mixing of either solid or liquid solutions of Cr(VI)) in a manual process are only conducted when small amounts of chromium trioxide are used by companies and that this will not happen on a daily basis (only e.g. 1 or 2 times per month). This has not been quantitatively addressed in the application or in WCSs, but accepting that this is the case in all sites, the contribution of these tasks to total exposure would be relatively low due to low frequency.

There are also uncertainties related to the maintenance activities. For the regular maintenance of the baths and related equipment (e.g. LEV, rectifier, pumps, panels etc.), air measurements conducted during the functional chrome plating process were used as a worst-case estimate of exposure. Based on the available data, RAC cannot verify the accuracy of this assumption, especially in cases in which maintenance is needed during the on-going process (as opposed to when it is not operating). In addition, WCS 15 is also said to cover infrequent maintenance activities with longer duration. Separate WCS for these situations is not provided in the case of use 3. However, in the case of uses 4/5/6 there is a separate WCS for infrequent maintenance activities giving an exposure estimate of 0.25 µg Cr(VI)/m³ (estimate takes low frequency into account). According to RAC, this WCS should also have been included in

use 3.

Related to the scenarios involving the use of RPE, the applicant has used assigned protection factor (APF) provided by the German BG rule "BGR/GUV-R190" from December 2011 to account for the effect of RPE on exposures. It should be noted that other countries may use lower APFs for the same type of RPE than Germany. However, in practice, the adequate protection of the RPE is very much dependent on the individual wearer. According to the standard EN 529, RPEs shall be fit tested for each wearer in order to ensure adequate protection. Workers should be adequately trained and supervised for the use and maintenance of the RPE, and their medical fitness should be examined if RPE is used for longer time-periods.

Environmental releases / Indirect exposure to humans via the environment

Summary of applicant's approach to assess environmental releases and indirect exposure to humans via the environment

The applicant considers that measures to prevent or limit the release of Cr(VI) to the environment during functional chrome plating with decorative character are a matter of best practice (as described by BREFs). Whilst emissions to air (via fine dust and particulates) are considered to occur at all use sites, the applicant states that not all sites will necessarily have releases of Cr(VI) to wastewater as both liquid and solid wastes containing Cr(VI) can rather be collected from sites by an external waste management company instead of being discharged in wastewater to the municipal sewer or directly to the environment. The applicant considered that releases to soil, either at a local or regional level, do not occur. RAC notes that the applicant considers that the use is consistent with the environmental release category (ERC) 6b[1]. Whilst the choice of ERC was ultimately not relevant for the exposure assessment described by the applicant RAC notes that according by ECHA guidance on use description (R.12) metals in coatings applied through plating and galvanizing processes activities are intended to be captured by ERC 5[2].

Except in cases involving very low quantities of Cr(VI), air emissions from LEV or extraction systems are treated prior to release to the environment by either filters (e.g. HEPA filter) or wet scrubbers. According to the applicant, a removal efficiency of at least 99% is typical for these techniques, and this efficiency is stated in the exposure scenario for releases to this compartment. Wastes from scrubber systems can be collected by an external waste management company or disposed as wastewater after appropriate on-site treatment.

Emissions to the air compartment are characterised based on a summary of aggregated

[1] In recently revised ECHA guidance on use description (December 2015) ERC 6b refers to "use of reactive processing aid at industrial site (no inclusion into or onto article)". The previous version of R.12 referred to ERC 6b as "Industrial use of reactive processing aids". The default worst-case release factors for environmental compartments for this ERC are unchanged as a result of this revision and are outlined in ECHA guidance on environmental exposure assessment (R.16)

[2] In recently revised ECHA guidance on use description (December 2015) ERC 5 refers to "use at industrial site leading to inclusion into/onto article). The previous version of R.12 referred to ERC 5 as "Industrial inclusion into or onto a matrix". In both new and previous versions of the guidance the scope of the ERC clearly referred to "metals in coatings applied through plating and galvanizing processes". The default worst-case release factors for environmental compartments for this ERC are unchanged as a result of this revision and are outlined in ECHA guidance on environmental exposure assessment (R.16)

measurement data from six EU sites sampled between 2010 and 2013. Individual site measurements were not reported, but details of the calculation of the summary statistics were provided. Where measurements are reported as being below their respective limit of detection, half of the limit of detection was used in the calculation of summary statistics. Similarly, where measurements were reported as total chromium a factor of 0.5 was applied as a worst-case assumption to estimate Cr(VI) emissions. Although the aggregated dataset is characterised in terms of its range, arithmetic mean, geometric mean and 90th percentile, no accompanying contextual information describing the sampling regime at each of these sites is provided in the CSR, i.e. the number of samples taken at each of the sites or details of the sampling or analytical method used (e.g. limit of detection). Equally, the RMMs and OCs in place at each of these sites are not available.

Rather than information on release rates or release factors to the environment from the 6 sites, releases are expressed in the CSR as the concentration of Cr(VI) in air 100 meters from a point source (whilst also taking into account regional background concentrations). However, RAC notes that a release factor to air of 1.0 × 10^{-5} is reported in the succinct summary of risk management measures and operating conditions for the use.

Table 5: Cr(VI) exposure concentrations in air, 100 meters from point source

No of sites	Year	Range $C_{local\ air,\ ann}$ (mg Cr(VI)/m^3)	AM (mg Cr(VI)/m^3)	GM (mg Cr(VI)/m^3)	90th percentile (mg Cr(VI)/m^3)
6	2010-2013	5.08 × 10^{-7}- 3.34 × 10^{-10}	1.52 × 10^{-7}	4.45 × 10^{-8}	3.54 × 10^{-7}

Note: Regional air concentrations of chromium trioxide, based on modelling with EUSES 2.1.2, are 1.7 x 10^{-15} mg/m^3 Cr(VI).

Based on the 90th percentile of these data, the applicant concludes a $PEC_{local,air}$ for use in the assessment of indirect exposure to humans via the environment of 3.54 × 10^{-7} mg/m^3.

Where Cr(VI) is released to wastewater, the applicant considers that treatment (either on-site or off-site) is “generally highly effective”. Wastewater treatment methods can vary between sites, but the most common on-site technique to remove Cr(VI) from wastewaters appear to be via a batch reduction/precipitation process. The applicant states in the CSR that emissions to wastewater are very low and often below limits of detection and can therefore be considered to be negligible. No further data or justification to support this conclusion was initially provided in the applicant’s CSR, but the exposure scenario (and the “succinct summary of operating conditions and risk management measures” intended for enforcement) states that the use should result in “negligible discharge of Cr(VI) in wastewater from the site”. Emissions to water were not incorporated into the applicant’s assessment of indirect exposure to humans via the environment.

At the request of RAC the applicant was invited to elaborate on their description of releases of Cr(VI) to wastewater and the risk management measures in place to

prevent releases. The applicant stated in their answers to the first set of RAC questions that where wastewater is generated the volume is usually limited and the concentration of Cr(VI) in the treated wastewater is low (e.g. less than 50 µg/L). Further, the applicant stated that when wastewater was treated on-site a release fraction to the local municipal wastewater treatment facility in the region of $< 1 \times 10^{-4}$ % was typical.

Since the information on releases received from the applicant in the first set of questions was not supported with either data or reference to other publically available documentation, RAC asked for further information on environmental emissions of Cr(VI) to wastewater in a second round of questions. In response, RAC received summary data for 44 sites involved in chromium trioxide surface treatment activities or formulation of chromium trioxide mixtures, although the exact use of Cr(VI) at each of the sites i.e. formulation or surface treatment was not initially provided. 14 (32%) of the 44 sites reported that they had no wastewater emissions as all wastes were disposed of via some other route i.e. hazardous solid waste. For those sites reporting wastewater emissions, relevant information on annual Cr(VI) releases was received from 13 out of 30 companies. These data are presented in Table A5 in the Annex to this opinion.

The applicant also provided data on the concentration of Cr(VI) in wastewater for 10 sites of the 30 sites that reported wastewater emissions. Due to limited accompanying contextual information on the monitoring data, these data are considered difficult to interpret but in all cases effluent concentrations were <50 µg/L. The available wastewater monitoring data is included in Table A6 in the Annex to this opinion.

For all sites with wastewater emissions, effluents were first subject to on-site treatment before release. In addition, the wastewater from most sites was also subject to further treatment in municipal WWTP before release to surface waters. However, based on the information provided, three sites had direct discharges to surface water after on-site treatment with emission factors greater than (up to two orders of magnitude) the 1×10^{-4} % level claimed by the applicant. Therefore, in a third round of questions, the applicant was specifically requested to undertake an assessment of the indirect impact of the emissions at these sites, and similar emissions at comparable sites, on human health, particularly through the consumption of drinking water to support the applicant's claim that emissions to wastewater were negligible. In response, the applicant responded that data for these sites was either no longer current (as the operating conditions at a site had changed since the measurements were made) or that after further dilution in the receiving environment the Cr(VI) concentration would be far below relevant water quality guidelines (i.e. the WHO/EU guideline for Cr(VI) in drinking water of 50 µg/L and the California Drinking Water Standard of 10 µg/L) and consequently that the risk to human health should be considered to be negligible.

Alongside this information the applicant also clarified which uses were conducted at each of the 44 sites from which data was provided. None of the three sites identified above as having direct emissions to surface water with emission factors greater than 1×10^{-4} % were reported to undertake functional chrome plating with decorative character. Six of the 44 sites (8, 25, 26, 27, 31 and 32) were reported to undertake functional chrome plating with decorative character with one reporting no emissions of Cr(VI) to wastewater (32). Release factors or effluent monitoring information were reported for three of the five sites with wastewater emissions (see Tables A5 and A6 in the Annex to this opinion).

Table 6: Summary of environmental emissions

Release route	Release factor / rate	Release estimation method and details
Water	usually <1 × 10^{-4} % (10^{-6}) and Cr(VI) level in WW <0.05 mg/l	based on the applicant's assessment on good practises. See also Table A5 of the Annex to this opinion.
Air	0.001%	estimated from Clocal, which is based on measured data
Soil	0	no soil releases

Table 7: Summary of indirect exposure to humans via the environment

Protection target	Exposure estimate and details (i.e. methodology and relevant spatial scale)
Man via Environment - Inhalation	3.54 × 10^{-7} mg/m^3 (local exposure 100 m from point source – based on 90^{th} percentile of measured releases) 1.7 × 10^{-15} mg/m^3 (regional exposure) estimated by EUSES 2.1.2.
Man via Environment - Oral	Not considered relevant by the applicant
Man via Environment - Combined	Not considered relevant by the applicant

In summary, the applicant's assessment of exposure via air is based on measured data combined with EUSES modelling. Exposure via air is the only element included in the assessment of indirect exposure to humans via the environment. Exposure via food and drinking water (oral route of exposure) has been waived by the applicant on the basis that emissions are "negligible" or that the transformation of Cr(VI) to Cr(III) will occur sufficiently rapidly in the environment to negate the requirement to undertake an assessment of exposure via the oral route.

RAC evaluation of the applicant's approach to assess environmental releases and indirect exposure to humans via the environment

RAC acknowledges that Cr(VI) will transform rapidly in the environment to Cr(III) under most environmental conditions. This has been previously discussed in the EU RAR for chromate substances (EU RAR 2005). This will reduce the potential for indirect exposure to humans to Cr(VI) via the environment, particularly from the oral route of exposure. Accordingly, the EU RAR only assessed oral exposure to Cr(VI) as result of exposure from drinking water and the consumption of fish, rather than using the standard food basket approach that also includes contributions to oral exposure from the consumption of arable crops (root and leaf), meat and milk. This approach was considered appropriate at the time on the basis that, whilst treatment to remove Cr(VI) from wastewater was considered to be effective, it was not known how comprehensively this treatment was put into practice by users of Cr(VI) in surface treatment. As such, an acknowledged worst-case approach, where treatment was not considered to be in place, was used as the basis for the assessment of indirect exposure to humans via the environment. This assessment concluded that the concern for human

health via indirect exposure was low for all scenarios, although RAC notes that the basis for these conclusions i.e. the underlying dose-response relationship and effects' thresholds for Cr(VI) were different in the EU RAR assessment to those agreed by RAC.

Based on the data provided and analysis undertaken by the applicant, RAC agrees that wastewaters containing Cr(VI) are either not produced or subject to treatment before discharge to either the municipal sewer or the environment. However, based on the information provided by the applicant, RAC does not support the applicant's general conclusion that releases of Cr(VI) to water are "negligible" and that it was therefore appropriate to exclude these emissions from the assessment of indirect exposure to humans via the environment.

RAC notes that these emissions, irrespective of their magnitude, were not incorporated into the applicant's estimates of excess risk for the general population and corresponding impact, upon which a conclusion on negligibility could have been presented more transparently i.e. the relative risks from air and oral exposure could have been apportioned and discussed in a transparent manner. This was despite the fact that a dose-response relationship for the general population for oral exposure was available to the applicant and RAC made repeated requests for the applicant to substantiate their conclusion on the negligibility of wastewater emissions as part of the opinion making process. As part of their response to RAC's questions the applicant notes that concentrations of Cr(VI) in wastewater (and therefore surface waters) are below the WHO/EU drinking water standard for Cr of 50 µg/L. RAC acknowledges that this is relevant information, but notes that WHO drinking water standard for Cr, on which the EU standard is based, is considered to be "provisional" because of uncertainties in the health database. As such, compliance with these standards, whilst reassuring, is also not consistent with a conclusion that emissions are negligible. RAC notes that, using the RAC dose-reference relationship, consumption of 2 L of water containing 50 µg/L Cr(VI) per day results in an intestinal cancer risk of 1.3×10^{-3} in a 60 kg adult.

Equally, the data available on potential emissions to wastewater for this use is limited to three from a maximum of estimated 1,559 sites across the EU reported to undertake the use and no contextual information to assess the representativeness of these sites is available.

The absence of the oral route of exposure in the applicant's assessment of indirect exposure to humans via the environment for this use is considered by RAC to introduce uncertainty to the assessment, particularly on the basis that Cr(VI) is a non-threshold carcinogen and the applicant is responsible for justifying that the benefits of use outweigh the risks. However, given that effective measures to prevent the release of Cr(VI) to the environment appear to be in place and that the conversion of Cr(VI) to Cr(III) in the environment is expected to occur rapidly after release under most environmental conditions this uncertainty is not considered to invalidate the assessment of indirect exposure of humans via the environment undertaken by the applicant, although this route of exposure should be addressed more comprehensively in any review report prepared for this application.

Regarding emissions to air and consequent inhalation exposure of the general population, the assessment is based on measured data from 6 sites (representing 4% of CTAC members and less than 1% of the maximum number of companies performing functional chrome plating with decorative character in EU). However, since no

accompanying contextual information is provided in the CSR, the representativeness of these data is uncertain. In response to a request from RAC the applicant provided additional information from two sites to support the use of the factor of 0.5 to estimate Cr(VI) emissions based on measurements of total chromium. Whilst the data from these two sites supports the use of a factor of 0.5, RAC considers that this factor may not be applicable across all sites / all uses and that measurement data should generally be obtained on the basis of Cr(VI) rather than as total chromium. Notwithstanding these observations, RAC does not find any reason to disagree with the applicant's conclusions that highly effective systems to control air emissions of Cr(VI) are typical across the sites undertaking this use. In addition, RAC considers that reduction of Cr(VI) to Cr(III) in air is likely to further reduce the general population exposure, but that this may not occur so rapidly that emissions to air are not a relevant source of indirect exposure of Cr(VI) to humans via the environment in local scale.

RAC therefore considers that the indirect exposure calculated by the applicant is acceptable for risk characterisation and impact assessment, but contains uncertainties.

Uncertainties related to the environmental releases exposure / assessment of exposure to humans via the environment:

According to the applicant releases to the **wastewater** are negligible. However, on the basis of the data received, releases do occur and RAC considers that these releases should have been more comprehensively addressed in the applicant's exposure assessment. The lack of an assessment of the releases to wastewater thus adds uncertainty.

Although it is acknowledged that release to **air** of Cr(VI) are generally low due to the low volatility of chromium trioxide and modern abatement technology with high efficiency, the estimated $Clocal_{air,\ ann}$ is based on rather limited number of data which RAC was not able to fully evaluate due to the absence of accompanying contextual information. RAC notes that the applicant's use of a 90th percentile value for estimating releases to atmosphere is likely to overestimate the $PEC_{local,air}$ at many of the sites undertaking this use. The $PEC_{local,air}$ values calculated by the applicant based on either the arithmetic or geometric mean, which could be more appropriate for estimating the impacts from a use across multiple sites, are a factor of ~2-3 lower than the 90th percentile. Median exposure values would also have been useful to present.

In addition, RAC notes that the default assumptions in EUSES for local assessment estimate $PEClocal_{air,ann}$ 100m from a point source[3]. This, in general, is likely to overestimate exposure for the majority of the people living in the vicinity of a site (e.g. not everybody that could be affected by a site will live 100 meters from it; some will live further away and be exposed to a lower concentration in air). RAC notes that whilst EUSES is the default assessment tool under REACH Tier I assessments are recognised to have limitations that limit their usefulness within the context of impact assessment (for non-threshold carcinogens)[4].

[3] Using the release data, EUSES estimates a concentration in air 100 m away from a point source.

[4] ECHA R.16 guidance (environmental exposure assessment) states in section R.16.4.3.9, in relation to the use of the EUSES model for assessing indirect exposure to humans via the environment, that *"In light of these limitations, it is clear that a generic indirect exposure estimation, as described by the calculations detailed in Appendix A.16-3.3.9, can only be used for screening purposes to indicate potential problems. The assessment should be seen as a helpful tool for decision making but not as a prediction of the human exposure actually occurring at some place or time."*

Alternative assessment approaches could have been used by the applicant to refine the exposure assessment of the general population, such as modelling approaches that estimate the concentration gradient of Cr(VI) in the atmosphere surrounding a point source, or the use of ambient air monitoring.

Conclusion

- The exposure assessment of functional chrome plating with decorative character is based on measured data from 10 companies (representing less than 1% of companies performing functional chrome plating with decorative character; 17% if the actual CTAC membership reported for Use 3 is considered). In addition, literature data on occupational exposure in functional chrome plating is available. Although these data generally support the applicant's exposure estimate of 2 µg Cr(VI)/m^3 (which the applicant claims as the maximum individual exposure value), there is also clear evidence of exposure up to an order of magnitude higher.
- For ancillary activities, e.g. re-adjusting the electrolyte, sampling or waste management, modelling data is provided and the applicant has not been able to fully assess the combined exposure related to all these tasks. The contribution of these less frequent and shorter duration activities to the total worker's exposure is, however, considered as low.
- The greatest uncertainty arises from the lack of clear link between the OCs, RMMs and exposure values for specific tasks and sites, which could justifiably represent the application. RAC sees this as a substantial weakness of the application, considering that there is a wide variability between the chromium plating sites in relation to e.g. building layout, the scale and frequency of plating operations, level of the automation of the process, use of electrolysis, the size of the parts treated, and the availability of LEV, which affects the exposures and RMMs needed to control the exposure.
- There are uncertainties related to the applicant's claims that wastewater releases are "negligible".
- With respect to emissions to air and inhalation exposure of general population, the assessment of local exposure is based on measured data from six companies (representing 4% of CTAC members and less than 1% of the functional chrome plating with decorative character industry in EU). Therefore, since no accompanying contextual information is provided in the CSR, the representativeness of these data is uncertain. RAC notes that the applicant's approach for assessing general population inhalation exposure is likely to overestimate exposures for the majority of the general population and should be interpreted with caution. Regional exposure of the general population was estimated by the applicant, but is not considered relevant by RAC. Reduction of Cr(VI) to Cr(III) is likely to further reduce the general population exposure.

5. If considered a threshold substance, has adequate control been demonstrated?

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

RAC has concluded that chromium trioxide should be considered as a non-threshold carcinogen with respect to risk characterisation.

6. If adequate control is not demonstrated, are the operational conditions and risk management measures described in the application appropriate and effective in limiting the risk?

☐ YES

☒ NO

Justification:

Workers

The applicant has estimated cancer risk according to the RAC reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1). The applicant has conservatively assumed, that all inhaled chromium trioxide particles are in the respirable range and contribute to the lung cancer risk. Thus, an excess life-time lung cancer risk is 4×10^{-3} per µg of Cr(VI)/m^3.

Evaluation of the Risk Management Measures

This application aims to cover a wide variety of decorative chromium plating sites in the EU. However, the applicant has not been able to provide sufficiently detailed descriptions of OCs and RMMs and their effectiveness applicable to all these sites; operational conditions and risk management measures have been described only at a general level. Although tasks related to decorative chromium plating are by themselves very similar between the different sites performing this use, the exposure (and the required RMMs) will vary, as described in Section 4. According to the applicant, it is therefore not possible to define a single specific set of OCs and RMMs suitable for all sites and situations. The applicant has listed RMMs typically used to decrease the exposure in functional chromium plating with decorative character. These include automation of the process, limiting the quantities of Cr(VI), enclosure of the baths, general ventilation and local exhaust ventilation (with effectiveness adjusted for each specific situation), the use of mist suppressants and the use of RPE.

According to the applicant, it would be possible to develop a recommendation on control hierarchy and associated practical RMM guidance along the lines of UK COSHH Essentials (www.hse.gov.uk/coshh/essentials) to be implemented in order to reach exposure levels below 2 µg/m^3 in decorative chrome plating. The guidance will be provided to Downstream Users attached to SDS. The applicant is developing such an approach but it is not available yet for review by RAC. RAC acknowledges the

applicant's intentions and reminds that according to REACH such "guidance" in the form of exposure scenarios is mandatory.

Risk characterisation

Occupational exposure in functional chromium plating with decorative character has been assessed by using modelled data for ancillary activities and by measured data from 10 companies for chromium plating (bath) operations. A general estimate on a maximum individual exposure level of 2 µg Cr(VI) /m^3 has been derived on the basis of information on the most probable combinations of WCSs and expert judgement by the applicant. The exposure assessment includes uncertainties related especially to the representativeness of the exposure estimates across the wide-range of companies in the EU and the assessment of combined exposure. However, the available data (provided by the applicant and the literature data, see annex, table A2) shows that using appropriate RMMs (which have to be adjusted on a case-by-case basis for each chromium plating facility) it is possible to reach combined, shift-long exposure levels well below 2 µg Cr(VI) /m^3 in chromium plating.

However, taking these uncertainties and the broad scope of the use into account, RAC consider that the exposure level of 2 µg Cr(VI) /m^3 calculated by the applicant as a 8 h maximum combined individual exposure value, resulting in excess risk of 8×10^{-3} is an appropriate starting point for socio-economic analysis by SEAC. RAC takes note of the applicant's response that this would set a "baseline reference value or *conditio sine qua*" and implicitly already constitutes a condition in case the authorisation is granted. It should be noted that this value is proposed by the applicant and should not be seen as an endorsement by RAC as a safe or acceptable level for this non-threshold substance.

In the CSR, the applicant has not considered the duration and frequency of exposure of different occupational groups. However, in SEA the applicant presents data collected from the CTAC members describing average exposure times of potentially exposed workers (SEA, Annex B, table 17). According to this data, only 15% of workers are exposed for 6-8 h/day, 6% are exposed for 3-6 h/d, 8% are exposed for 1-3 h/day and 44% are exposed for less than 1 h/d. In addition, 27% of workers are exposed only infrequently (e.g. once a week, month, year). This data has been used to correct exposure times for human health impact assessment (HHIA) in SEA. RAC considers that the representativeness of this data across the whole field of industry – about 1550 sites - is uncertain. Therefore RAC is bringing this uncertainty to SEAC's attention and notes that a HHIA using also the worst case approach, which assumes that all regularly exposed workers are exposed up to 8 h per day and infrequently exposed workers are exposed on average up to 1 h/d, should be performed. This sensitivity analysis would address some of the uncertainties related to the applicant's risk calculations for workers.

Table 8: Excess risk estimates for 40 years exposure for workers

WCS	Inhalation route	
	Adjusted exposure (µg Cr(VI)/m^3)	**Excess risk**
Total	2	8×10^{-3}

Indirect exposure to humans (general population) via the environment

The applicant has estimated excess cancer risks based on inhalation exposure of the general population. Risk characterisation has been made according to the RAC reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1). The applicant has conservatively assumed that all inhaled chromium trioxide particles are in the respirable range and contribute to the lung cancer risk. Thus, an excess life-time lung cancer risk is 2.9×10^{-2} per µg Cr(VI)/m^3 for 70 years of exposure (24 h/day, 7 d/week).

For a local population living in the vicinity of chromium plating plants the applicant calculated an individual excess life-time lung cancer risk of 1.03×10^{-5}. The applicant has also calculated the excess individual risk related to regional exposure (4.93×10^{-14} for 70 years of exposure, 24 h/day, 7 d/week). However, as Cr(VI) is effectively reduced to Cr(III) in the environment, RAC agrees with the conclusions of the previous EU RAR for chromate substances that regional exposure may not be very relevant.

Table 9: Excess risk estimates for 70 years exposure for man exposed via the environment

ECS	Inhalation route	
	Exposure level (µg Cr(VI)/m^3)	**Excess risk**
ECS1, local	3.54×10^{-4}	1.03×10^{-5}
ECS, regional	Not relevant	

This estimate does not take into account further conversion of Cr(VI) to Cr(III) in the atmosphere. On the other hand, the exposure estimate is based on limited number of data points. RAC also notes that the applicant assumed that all environmental exposure was associated with particles within the respirable size range. This assumption could have led to an overestimate of risk as only respirable particles are associated with life-time lung cancer risk. Inhalable particles are associated with the dose-response relationship for intestinal cancer, which is approximately an order of magnitude less sensitive than the dose-response for lung cancer. The relative proportion of particles in the respirable and inhalable size ranges in the atmosphere was not discussed by the applicant.

Risks from oral exposure via food or water were not considered by the applicant. After a request from RAC, the applicant calculated Cr(VI) concentrations in the environment for two sites that had direct emissions to surface water (sites 18 and 33 performing chromium surface treatments, see the Annex to this opinion). Based on these concentrations RAC calculated excess risks of $1.3\text{-}2 \times 10^{-8}$. RAC considers these risks

are low but, as discussed in section 4, does not fully support the applicant's conclusion, based on the information provided, that risks via wastewater can simply be considered to be negligible.

Conclusion

RAC concludes that:

- There is a wide variety of chromium plating sites (varying depending on e.g. building layout, the scale and frequency of plating operations, level of the automation of the process, size of the parts treated etc.) resulting in variation in exposure levels and RMMs applied. While it is appreciated that it is difficult to define a single, specific set of OCs and RMMs suitable for all these workplaces, RAC would have expected to receive at least exposure data clearly linked to specific OCs and RMMs and for representative operations, including e.g. automatic versus manual, open versus closed systems, with a justification as to how these can represent the applicant's claims. Taking these uncertainties into account, RAC considers that the RMMs and OCs described in the application are not appropriate and effective in limiting the risk to workers.
- RAC proposes to use the applicant's estimate of a maximum combined exposure level for 8 hours of 2 µg Cr(VI) /m^3, resulting in an excess life-time lung cancer risk for workers of 8 × 10^{-3} as the basis of further analyses by SEAC. It should be noted that this value is proposed by the applicant in the CSR and its use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC as a safe or acceptable level for this non-threshold substance.
- According to the data on exposure times (presented in the SEA), the duration and frequency of exposure of some worker groups in chromium plating may be limited. However, because of the uncertainties in the applicant's exposure assessment (related especially the lack of detail with which to assess the representativeness of the data presented) RAC considers that in human health impact assessment (HHIA) also a worst case approach should be applied, which assumes that all regularly exposed workers are exposed up to 8 h per day and infrequently exposed workers are exposed on average up to 1 h/d. This sensitivity analysis would address some of the uncertainties related to the risk calculations for workers.
- There is an uncertainty related to the oral exposure of general population via the drinking water due to the applicant's assessment of the releases to the wastewater, which is not fully supported by RAC.
- For the local general population inhalation exposure, the exposure estimate is based on limited number of data points without contextual data. As described in section 4, highly effective RMMs to control air emissions are typical for the industry.
- RAC considers that the applicant's estimate of general population risk at the local scale is sufficient for further analysis by SEAC, but notes that the applicant's approach is based on several assumptions that are likely to significantly overestimate risks to the majority of the population. The possible transformation of Cr(VI) to Cr(III) in the atmosphere is also not considered. Regional exposure, which was estimated by the applicant, is not considered to be relevant by RAC due to transformation of Cr(VI) to Cr(III) that will occur

rapidly under most environmental conditions.

7. Justification of the suitability and availability of alternatives

7.1 To what extent is the technical and economic feasibility of alternatives described and compared with the Annex XIV substance?

Description:

Summary of the analysis of alternatives undertaken by the applicant

The applicant describes the use of chromium trioxide electrolyte utilised in functional plating of articles with decorative character, which is a surface treatment process that involves depositing a thin coating of metallic chrome from the chromium trioxide electrolyte on the surface of a plastic or metallic component following product specific under plates. The coating provides the article with a resistant, durable and safe finish, normally with a bright or matt silvery (occasionally black) appearance. The process is used by different industry sectors (such as automotive, consumer goods, cosmetic, electrical devices, furniture, general engineering, lamps & light fittings, locks & fittings, sanitary, store construction, tools, wheels & castors and white goods, etc.) in order to meet strict performance criteria necessary for regulatory compliance, public safety and to satisfy customer expectations. For the use 3 applied for, 3,000 tonnes per annum of chromium trioxide are used. Examples of chromium plated parts and articles within these sectors covered by use 3 are provided by the applicant (in the Socio-Economic Analysis, non-confidential report) in table 10 below.

Table 10. Examples of applications and industries in which chromium trioxide formulations are used such as covered by use 3

Functionalities and applications	Main industrial sectors
➢ Corrosion resistance. Used on plastics and metals (applied on the top of another coating, such as Ni, preventing the corrosion of bright surfaces generated by bright (nickel) undercoats) ➢ Decorative character, e.g. bright, reliable and/or consistent surface appearance, colour stability, wear resistance, and anti-adhesive	➢ Automotive (e.g. chrome plated plastic parts in vehicles) ➢ Sanitary (e.g. chrome plated sanitary fittings like taps, showers, handles, valves in bathrooms and kitchens) ➢ White goods (e.g. household appliances like washing machine rings, coffee machines) ➢ Medical articles for hospitals ➢ Cosmetics (e.g. cosmetic fragrance caps) ➢ Furniture and lighting ➢ Black chroming (e.g. spacecraft components, electronics, optics and lasers and solar panels)

The applicant describes how they carried out an extensive literature survey and a consultation of the companies of concern in order to identify and assess potential alternatives to chromium trioxide in functional chrome plating with decorative character. All in all, 31 potential alternatives were identified. The applicant classified

those into 3 categories (see also Appendix 1 – Masterlist of alternatives):

- **Category 1:** 4 alternatives that are considered promising, where considerable R&D efforts have already been carried out within the different industry sectors, these are: *mineral acid based solutions & potassium permanganate based solution (both only for the pre-treatment stage for plastic substrates), trivalent chromium plating, PVD (physical vapour deposition: lacquer + PVD + lacquer and PVD metal)*
- **Category 2:** 9 alternatives with clear technical limitations, which may only be suitable for a limited number of applications but not as a general alternative (see Appendix 1, Masterlist of alternatives)
- **Category 3:** 18 alternatives have been screened out at an early stage of the analysis and are not applicable for the use applied for (see Appendix 1, Masterlist of alternatives)

18 out of these 31 substances could be excluded for any further assessment based on the lack of performance, i.e. these are classified as category 3 alternatives (the reasoning for their exclusion is listed in the Masterlist of alternatives, Appendix 1). The remaining 13 alternatives (processes as well as substances) are in the focus of ongoing R&D programs, where much effort is currently put into research on alternatives for the etching (which is a pre-treatment process, not a stand-alone process) as well as for the electroplating with chromium trioxide. The unique functionalities of chromium trioxide make it an ideal and not easy to replace substance where superior requirements and demanding conditions (aesthetics/colour, corrosion and chemical resistance, abrasion resistance, etc.) need to be fulfilled. These 13 alternatives (category 1 and 2) were further assessed by the applicant, who clarifies that category 2 alternatives may only be suitable for limited number of applications, but not as a general alternative for the use applied for.

The applicant concludes that currently none of the alternatives is technically feasible for key applications within the use applied for. Functional chrome plating with decorative character has unique technical functions that offer substantial advantages compared to potential alternatives. Amongst others, these include corrosion resistance, chemical resistance, wear resistance/abrasion resistance, excellent health and environmental safety for finished articles (no nickel leaching), adhesion between coating and substrate, sunlight resistance/UV resistance, temperature/heat resistance, conservation of the aesthetic coating. The process itself is complex and involves numerous steps, such as etching of plastics as pre-treatment (interlinked with the main process, therefore separation is not possible without modifying/impairing the overall process or the performance of the final product) and several underplating steps followed by the chrome electroplating process (which is the main process). The review period requested for this use (7 years) coincides with best case (optimistic) estimates by all industry sectors (automotive, sanitary, white goods, cosmetics, general engineering, furniture, etc.) of the required time to industrialise alternatives to chromium trioxide for functional chrome plating for key applications.

Technical feasibility

Using chromium trioxide has, according to the applicant, multifunctional positive effects based on the characteristics of the Cr(VI) compound. Especially beneficial are its excellent corrosion protection and chemical resistance to nearly all substrates in a wide

range of environments, wear and abrasion properties and a high aesthetic surface with mirror-like reflection. Chromium trioxide is used for a large variety of applications in a number of different sectors (see above), which rely on the use of different kinds of metal substrates (such as brass, zinc, magnesium, aluminium, steel, etc.) and plastic substrates (such as acrylonitrile-butadiene-styrene, polypropylene, etc.). The plating process consists of several steps, which are depicted in Figure 1 (taken from the Analysis of Alternatives, non-confidential report).

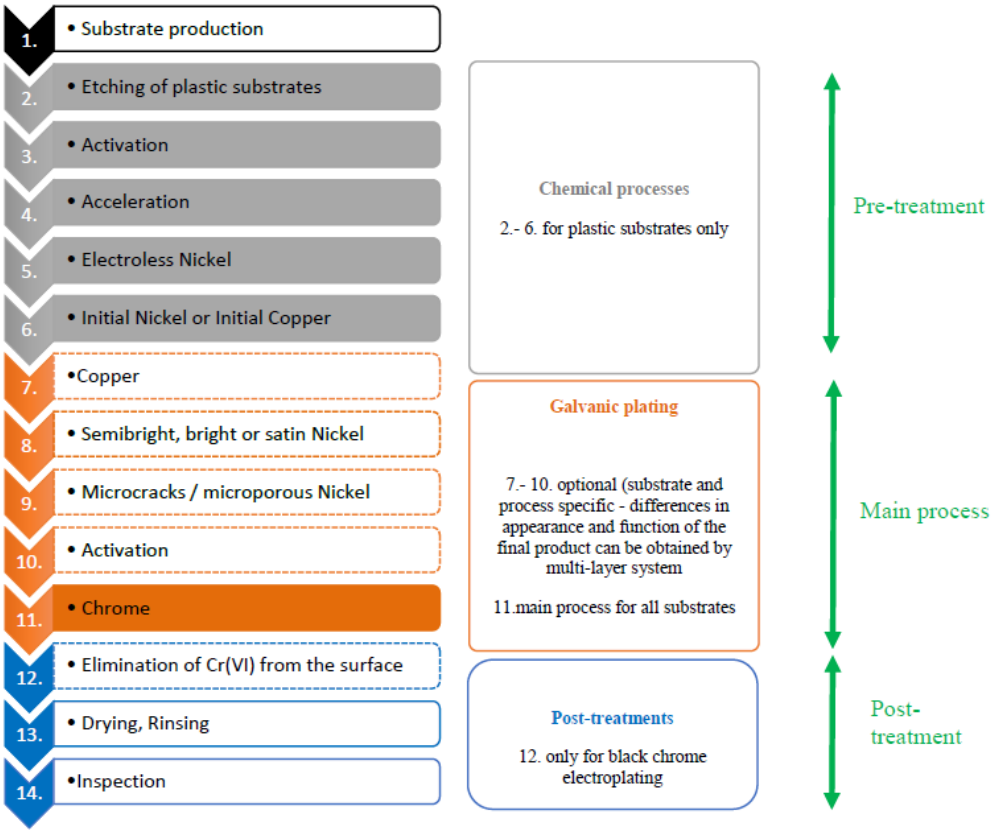

Figure 1. Flow chart for the plating process

The key functionalities for chromium trioxide were identified by the applicant during the consultation process he carried out. They take into account the whole surface treatment process and are, amongst others, corrosion resistance, chemical resistance, wear/abrasion resistance, prevention of nickel leaching, adhesion between coating and substrate, hardness, sunlight/UV resistance, temperature/heat resistance and aesthetics. The key process functionalities of chromium trioxide in the pre-treatment of plastics are described in Table 11 (from Analysis of Alternatives, non-confidential report).

Table 11. Key process functionalities of chromium trioxide based etching pre-treatment of plastics

Process	Key Process Functionality
Etching of plastics	Removal of residuals from the surface
	Long-time bath stability
	Simple bath maintenance
	Simple analytical method for process control
	Rack with treated parts also usable with subsequent process step
	Etch rate: removal of butadiene-1,3
	Surface roughness: cavern depth & amount of caverns

The sector-specific key functionalities of chromium trioxide based electroplating are depicted in a non-exhaustive list which is attached to this opinion in Appendix 2.

As stated above, the applicant identified 2 potential alternatives for chromium trioxide based electroplating and 2 potential alternatives for the pre-treatment stage which are considered to be promising future substitutes (category 1 alternatives). Several others are classified as category 2 alternatives, which means that they show clear technical limitations and may only be suitable for a limited number of applications but not as a general alternative to chromium trioxide. Tables 12 and 13 below (taken from Analysis of Alternatives, non-confidential report) give an overview of these potential alternatives.

Table 12. List of plating alternatives categorised

Category	Alternative	Part of Process Chain
Category 1 alternatives	Trivalent chromium plating	Bright/matt plating Black
	PVD based processes: Lacquer + PVD + Lacquer and PVD metal	Bright/matt plating Black chrome plating
Category 2 alternatives	Satin & black anodized aluminium	Bright/matt plating Black chrome plating
	Chromium free electroplating: multi-component coating systems (Cu, Sn, Zn, Ni, Co), gold and platinum electroplating, zinc electroplating	Bright/matt plating Black chrome plating (Zn electroplating)
	Wet lacquering	Bright/matt plating Black chrome plating
	CVD: Chemical Vapour Deposition	Bright/matt plating
	DLC: Diamond Like Carbon	Bright/matt plating

	Electroless Nickel plating	Bright/matt plating Black
	Powder Coating (Pulverlack)	Bright/matt plating Black
	Stainless steel (alternative substrate)	Not only plating process, but overall process chain would be replaced

Table 13. List of etching pre-treatment alternatives categorised

Category	Alternative	Part of Process Chain
Category 1 alternatives	Mineral acid based etching	Etching of plastics
	Potassium permanganate based etching solution	Etching of plastics
Category 2 alternatives	Polyamide	Alternative substrate / etching of plastics

The applicant assessed each of these potential alternatives against the criteria mentioned above. In addition, a specific assessment for the sectors concerned (specific requirements in sectors such as sanitary, automotive, cosmetics, white goods, furniture, general engineering, etc.) was carried out. Even though these alternatives are the most promising ones currently, they are claimed to still show either technical deficiencies, or have economical disadvantages. However, the applicant states that some of these may already be used in certain industry sectors for special applications or special parts but they cannot be used as a general alternative of a process step in chromium trioxide based electroplating process chains. Further specification of what is meant by “certain industry sectors” or “special applications/parts” is not available in the application and couldn’t be clarified for SEAC during the opinion-making process. Based on experience and with reference to the actual status of R&D programs, alternatives are not foreseen to be industrialised before 7 years after the sunset date. This statement is claimed to be valid for all industry sectors affected for the use of chromium trioxide for functional chrome plating with decorative character for key applications.

One of the specific sectors covered in the scope of the application is the **cosmetics sector.** Functional chrome plating with decorative character is applied also for products such as perfume caps, lipstick caps, jar caps, nail files, nail scissors, etc. Within this sector, one of the main criteria for claiming technical infeasibility of alternatives is the aesthetic criteria. The applicant claims that there are several reasons why substitution is not feasible for the cosmetics sector right now:

- high quality standards set by luxury cosmetic companies (high quality is necessary to justify the price of the consumer product and to maintain the reputation of the luxury brand)
- non-acceptability by consumers: however this argument was not substantiated by any supportive information
- technical requirements partly again referring to aesthetics (coating to remain intact, even though the product is carried in a hand bag over a certain period of time), and partly referring to avoidance of “negative impacts” of the packaging

item on the actual product, but it was impossible for SEAC to scrutinise this argument due to the lack of substantiated data present in the application for authorisation

Furthermore, the applicant notes that the cosmetics sector accounts for only 2% of the annual tonnage stated in the application for authorisation. SEAC notes that this still amounts to the use of 60 tonnes of chromium trioxide per year, which is not negligible.

In the public consultation, comments were submitted claiming alternative technologies being already feasible, e.g. embedded PVD for design parts (ePD). The applicant informed SEAC that this alternative is recognised by industry as a promising coating technology that is likely to be established for some decorative coating applications in the automotive and sanitary sector. However, the applicant argues that this technology could only be applied for a small percentage of the applications. According to information provided by the applicant, ePD is:

- applied as a **parallel technology** to functional chrome plating with decorative character for parts **which have not been functional chrome plated before**
- (partially) **already implemented as a substitute** to functional chrome plating with decorative character
- considered **being an alternative** to functional chrome plating with decorative character **in the future** (within the 7 years review period requested). The applicant however claims that ePD would be a potential future alternative only in max. 1%-10% of the applications within use 3
- **not considered being an alternative** to functional chrome plating with decorative character before the sunset date (and not within the 7 years review period requested) for the other 90%-99% of the applications within use 3

The applicant outlined several reasons for why ePD is a potential future alternative in 1-10% of the uses. These include that ePD cannot be applied on metals, that it does not provide satisfying resistance under mechanical or chemical stress and that it cannot be applied on all geometries with satisfying results (e.g. no sharp edges are possible).

Economic feasibility

Economic feasibility aspects have been provided for category 1 (those being considered promising being a substitute in the future) as well as category 2 (clear technical limitations, only suitable for a limited number of applications but not as a general substitute) alternatives. The applicant states that due to the fact that all of the above mentioned category 1 and 2 alternatives show significant technical failures, no detailed quantitative analysis of the economic feasibility was performed. Only rough estimates and broad considerations about potential impacts on certain sectors (e.g. automotive) or information that alternative processes are completely different from the conventional electroplating process are given. Generally, the applicant concludes that the overall costs of alternatives (due to investment, process rearrangement etc.) are expected/reported by industry sectors to be higher than those for functional chrome plating with decorative character. According to the applicant, a more detailed assessment of economic feasibility can only be provided in the review report if the technical issues have been solved. Specific cost proposals can then be developed for article parts, that can be treated alternatively (chromium trioxide-free) but the economic feasibility will strongly depend on the percentage of those parts that can be

covered by the alternative in question. On SEAC's request, the applicant provided additional information about the costs expected from the use of Cr (III). However, this information remains unsubstantiated and does not allow for verification.

Table 14 below summarises the information provided by the applicant on economic feasibility of the alternatives – category 1 & 2.

Table 14. Summary of the information provided by the applicant on economic feasibility of the alternatives

Alternative	Economic feasibility considerations
Category 1	
Mineral acid (etching pre-treatment only)	• No indication that this alternative would not be economically feasible • However, new investment needed for installation of additional bath equipment for rinsing processes
Potassium permanganate (etching pre-treatment only)	• Higher maintenance and disposal costs
Trivalent chromium plating (Cr(III))	• Operational costs up to 30% higher • Cr(III) is more expensive • Less air pollution treatment measures needed and reduced costs for handling and disposal of hazardous waste • Installation of additional baths per company: €0.8-3 million • R&D costs per company for the further development or adaptation of Cr(III) solutions to meet the minimum requirements for specific applications: >€0.15 million • Reduced energy costs
PVD (physical vapour deposition: lacquer + PVD + lacquer and PVD metal)	• Operational costs for lacquer + PVD systems are up to 150% higher and for PVD metal up to 50% higher • High maintenance costs • High investment cost: new line about €1 million, resulting in investment costs (only for the PVD coating) of at least €2 million
Category 2	
Satin & black anodized aluminium	• Costs from constructing a completely new process line comprising new bath equipment, new technical installations and new energy supply • Costs of chemicals are 2-3 times higher • Up to 20% higher energy cost
Chromium-free electroplating: zinc electroplating, multi-component coating system of copper, tin, zinc, nickel cobalt; gold and platinum	• Multi-component coating systems: higher costs (chemicals and analytical effort) • Black passivated zinc coatings: lower installation and process costs • Gold and platinum electroplating: more expensive noble

electroplating	metals
Wet lacquering	• Operational costs at least 30% higher due to increased demand on maintenance of the process equipment • Higher energy costs for UV radiation
CVD	• At least twice higher costs (investment costs, etc.)
DLC	• Costs up to 150% higher
Electroless nickel plating	• Higher costs (energy, higher thickness, etc.) • Electroless nickel plating with incorporated PFTE particles (store construction sector): 4-5 times higher costs
Powder coating	• Up to 30% higher operational costs • High investment costs
Stainless steel	• 30% - 40% higher production costs due to the higher technical effort required and that the additional cost of an adequate post-treatment passivation is necessary
Polyamide (etching pre-treatment only)	• Redesign and rebuild cost

Conclusion

The applicant has made an extensive assessment of alternatives, especially when it comes to the aspect of technical feasibility. All in all, 31 potential alternatives were identified, screened and classified into the above listed 3 categories (see also Appendix 1 – Masterlist of alternatives). This categorisation gives a good overview of why certain alternatives were considered further and why others have been excluded from any further assessment. For those alternatives considered as promising future substitutes (category 1 alternatives) or for those which may only be a substitute for a limited number of applications (category 2 alternatives), a description of the substance ID & properties and the process was provided. Furthermore, general as well as sector specific assessments were provided for concluding on technical feasibility followed by a brief discussion about the availability of the techniques.

Only a very brief discussion, containing mainly qualitative and broad considerations on economic feasibility was provided, such that no assessment was performed allowing a comparison of the alternatives or any evaluation of the economic feasibility. The applicant states that this is due to the fact that none of the alternatives are currently regarded feasible from a technical point of view. According to the applicant, a more detailed assessment of economic feasibility can only be provided in the review report if the technical issues have been solved, as the costs will strongly depend on the percentage of parts that can be covered by the alternative in question. However, the lack of a detailed assessment on economic feasibility does not allow SEAC to conclude on this aspect.

7.2 Are the alternatives technically and economically feasible before the sunset date?

☐ YES

☒ NO

Justification:

Applicant's conclusion on technical feasibility: the applicant concludes that currently there are no technically feasible alternatives to chromium trioxide used for functional chrome plating with decorative character for key applications. Based on experience and with reference to the status of R&D programs, alternatives are not foreseen to be commercially available before 7 years after the sunset date. The applicant's reasoning for this conclusion is given in section 7.1 above.

Applicant's conclusion on economic feasibility: the applicant states that because all of the shortlisted alternatives (category 1+2 alternatives) fail significantly when it comes to technical aspects and because costs cannot be known until the technical issues are solved and it is clear what article parts can be covered by the alternative, no detailed quantitative analysis of the economic feasibility was conducted. Economic feasibility is discussed very briefly, mainly qualitatively and only in broad terms without further substantiation. However, it is reported that the overall costs for alternatives are expected/reported by industry to be higher than those for functional chrome plating with decorative character.

Conclusion

SEAC's conclusion on economic feasibility: as stated in section 7.1 above, SEAC cannot conclude on the economic feasibility of alternatives due to the fact that no such assessment was performed by the applicant allowing a comparison of the alternatives on this aspect or any evaluation of the economic feasibility. Economic feasibility is discussed in the application for authorisation very briefly, mainly qualitatively and only in broad terms. For assessing the economic feasibility of alternatives in general, not only production costs, once the technical issues are solved, could be taken into account but also the costs of developing and transitioning to achieve technical feasibility can be considered. These costs were, however, not considered by the applicant. The applicant concludes that the overall costs for alternatives are expected/reported by industry to be higher but due to the lack of a detailed assessment, SEAC cannot conclude on the economic feasibility of alternatives.

SEAC's conclusion on technical feasibility: as stated in section 7.1. above, the applicant has made an extensive assessment of alternatives, especially when it comes to the aspect of technical feasibility. All in all, 31 potential alternatives were identified, screened and classified into the above listed 3 categories (see also Appendix 1 – Masterlist of alternatives). In SEAC's view, this categorisation gives a good overview about why certain alternatives were considered further and why others have been excluded from any further assessment.

During the public consultation, comments were submitted supporting the conclusion of the applicant on technical feasibility. For this use, supportive comments were even

submitted by sectors that were not specifically dealt with within the application. For example a downstream user from the dental and surgical industry claimed that also for this sector, currently no alternative substance and/or process fulfils the technical characteristics needed. Comments were also submitted by third parties claiming alternatives being feasible and available. These alternative technologies were already part of the applicant's assessment, and hence no completely new technology was introduced during the public consultation. The suitability of alternatives was discussed further between the applicant, third parties and RAC & SEAC rapporteurs. Furthermore, the applicant provided additional information, at SEAC's request, clarifying why the alternatives claimed feasible by third parties are overall not suitable substitutes to chromium trioxide-based functional chrome plating with decorative character (based on technicalities,). SEAC takes note of the applicant's claims on this aspect.

Nevertheless, due to the extremely broad scope of this application for authorisation and especially of the precise applications covered by this use applied for, SEAC cannot exclude that there are indeed applications where substitution is already feasible or will become so in the short term. In fact, it is not clear to SEAC when alternatives will eventually become available for specific uses. For example, SEAC finds it difficult to conclude on the technical feasibility of alternatives within the cosmetics sector as it challenges the applicant's argumentation that the criteria outlined by the applicant do indeed refer to technical characteristics. The applicant claims that alternatives would lead to non-acceptability by consumers, but did not provide any supporting evidence. This aspect further adds to the uncertainties present in the application for authorisation. The applicant himself states that "*However, some of these possible alternatives may already be used in certain industry sectors for special applications / special parts but not as a general alternative of a process step in chromium trioxide based electroplating process chains".* Ideally, SEAC would have been provided with an exhaustive list of all the applications/components covered by the use applied for in order to judge about the actual feasibility/infeasibility and to ensure that substitution takes place where already feasible. However, SEAC recognises that this is hardly possible for applications for authorisation covering such a broad scope and hence such a high number of products. The applicant provided a list containing an overview of sectors concerned, respective article examples and whether or not alternative technologies claimed feasible by third parties can be applied or not. Due to the broad scope of the use applied for and the fact that applications are numerous, this list cannot be considered exhaustive. According to the applicant, applications where substitution is already possible are not covered by the use applied for anyhow. The applicant does, however, not specify such applications or their related technical requirements. SEAC finds the applicant's approach to resolve this issue not fully appropriate and emphasises the need for the applicant to demonstrate more concretely that substitution has taken place where indeed already feasible. This could have been achieved by undertaking a more precise and use-specific assessment of alternatives. Generally, it should be made clear by the applicant which technical applications are covered by the use applied for and which are not.

However, based on the available information, SEAC agrees to the applicant's conclusion that *overall,* technically feasible alternatives for chromium trioxide-based functional chrome plating with decorative character do not seem to exist before the sunset date. The uncertainties pointed out above are taken into account by SEAC in the recommendation for the review period and the condition for the review report.

7.3 To what extent are the risks of alternatives described and compared with the Annex XIV substance?

Description:

The applicant has considered 13 different alternatives for the purpose of Functional Chrome Plating with decorative character with chromium trioxide for a number of different sectors, such as but not limited to automotive, consumer goods, cosmetics, electrical devices, furniture, general engineering, lamps & light fittings, locks & fittings, sanitary, store construction, tools, wheels & castors and white goods. However, the analysis of alternatives shows that there are no technical feasible alternatives to functional chrome plating with chromium trioxide for key applications. Several potential alternatives are subject to ongoing R&D, but do not currently support the necessary combination of key functionalities to be considered as technically feasible alternatives. Therefore, a detailed risk assessment of the alternatives to facilitate a comparison with chromium trioxide has not been conducted. The only information provided by the applicant was the hazard classification and labelling of the alternatives and these were compared to the classification of chromium trioxide to indicate less or more severe toxicity of the alternatives.

During the trialogue meeting with the applicant, ECHA and the rapporteurs, information was given by third parties on alternative techniques to functional chrome plating with decorative character. These included Embedded Physical Vapour Deposition (PVD that give plastic material a metallic look and is used in a wide range of products including automotive interior and exterior design, consumer electronic and sanitary and household design.

The applicant responded that wherever it was possible to use alternatives, the hard chrome plating was already replaced by alternatives, however, where the alternatives could be implemented was not covered in this application for authorisation.

- Alternative 1: Trivalent chromium plating

In general, trivalent chrome electroplating processes are considered as less hazardous than hexavalent chromium electroplating due to the significantly lower toxicity profile of the trivalent chromium. For example Cr(III) chloride has mainly irritant properties and it has been classified as Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Acute Tox 4. However, the bath chemistry typically comprises also a high concentration of boric acid, which is a SVHC substance classified as Repr. 1B for fertility and development and included in the REACH candidate list and currently in the 6th recommendation for inclusion in Annex XIV. The transition from chromium trioxide electroplating to trivalent chromium therefore needs careful consideration as to whether it constitutes a shift to less hazardous substances.

- Alternative 2: PVD based processes – lacquer + PVD + lacquer and PVD metal

Based on the available information on the substances used within this alternative, titanium nitride would be the worst case with a classification as Flam. Sol. 2, Skin Irrit. 2 and Eye Irrit. 2 As such, transition from chromium trioxide – which is a non-threshold carcinogen – to one of these substances would constitute a shift to less hazardous substances.

- Alternative 3: Satin and black anodized aluminium

Based on the available information on the substances used within this alternative, cobalt di(acetate) would be the worst case with a classification as Muta.2, Carc. 1B, Repr. 1B. Skin Sens.1, Resp. Sens 1, Aquatic Acute 1 and Aquatic Chronic 1. Cobalt di(acetate) is a SVHC and included on the Candidate list according to REACH Annex XV. The use of cobalt di(acetate) instead of chromium trioxide is therefore not a significant improvement regarding the reduction of overall risk.

- Alternative 4: Chromium free electroplating (zinc electroplating, multi-component coating system of copper, tin, zinc, nickel, cobalt; gold and platinum electroplating)
- Based on the available information on the substances used within this alternative, nickel sulphate would be the worst case with a classification Muta. 2, Carc. 1A, Repr. 1B, Acute Tox. 4, Skin Irrit. 2, Skin Sens. 1, Resp. Sens. 1, STOT RE 1, Aquatic Acute 1 and Aquatic Chronic 1. Nickel sulphate is not yet included on the Candidate list or the Authorisation list according to REACH Annex XIV, nor included in the Community Rolling Action Plan (CoRAP), indicating substances for evaluation by the EU Member States in the next three years. Transition from chromium trioxide – which is a non-threshold carcinogen – to the above mentioned alternative containing nickel sulphate in particular would clearly not constitute a shift to less hazardous substances.Alternative 5: Wet lacquering/colour painting
- Based on the available information on the substances used within this alternative, polyurethane 4-methyl-m-phenylene diisocyanate would be the worst case with a classification as Carc.2, Skin irrit. 2, Skin Sens. 1, Eye Irrit. 2, Acute Tox. 2, Resp. Sens.1, STOT SE 3 and Aquatic chronic 3. A second worst case process uses titanium dioxide as a colouring pigment, classified as Carc.2 and Acute Tox. 4. Both substances are classified as carcinogenic but yet not further evaluated under REACH. Considering the classification of the diisocyanate, a transition from chromium trioxide to a ‘suspected human carcinogen’ with respiratory sensitizer properties is unlikely to constitute a shift to less hazardous substances. Alternative 6: Chemical vapour deposition

Based on the available information on the substances used within this alternative, titanium nitride would be the worst case with a classification as Flam. Sol. 2, Skin Irrit. 2 and Eye Irrit. 2. As such, transition from chromium trioxide to one of these substances would constitute a shift to less hazardous substances.

- Alternative 7: Diamond like carbon

Based on the available information on the substances used within this alternative, graphite would be the worst case with a classification as Eye Irrit. 2 and STOT SE 2. As such, transition from chromium trioxide - which is a non-threshold carcinogen - to one of these substances would constitute a shift to less hazardous substances.

- Alternative 8: Electroless nickel plating

Based on the available information on the substances used within these two alternatives nickel sulphate constitutes the toxicological worst case scenario and is classified as Skin Irrit. 2, Skin Sens. 1, Resp. Sens. 1, Muta. 2, Carc. 1A, Repr. 1B, STOT RE 1, Aquatic Acute 1, Aquatic Chronic 1. As such, transition from chromium trioxide – which is a non-threshold carcinogen – to the above mentioned alternative

would clearly not constitute a shift to less hazardous substances.

- Alternative 9: Powder coating

Powder coating is considered to use only ingredients less hazardous than Cr(VI) components and therefore, the transition from chromium trioxide to powder coatings would constitute a shift to less hazardous substances. Nevertheless, it has to be considered that the application of powder coatings may generate an explosive atmosphere and special explosion prevention measures may become necessary. In case of transition, any replacement will need to be carefully evaluated on a case by case basis.

- Alternative 10: Stainless steel

Stainless steel is a term that defines a diverse family of alloys, containing iron and a minimum of 10.5% of chromium or in some cases nickel (≥ 8%) and/or molybdenum. Nickel is the only substance of major importance in regard to the hazard classification of stainless steel in solid form. Although, stainless steels are generally considered non-hazardous to human health and the environment, stainless steels containing more than 10% nickel are classified as STOT RE 1, with 1-10% as STOT RE 2, and with less than 1% nickel they are not classified. Furthermore, stainless steel containing more than 1% of nickel is classified as carcinogen category 2 when classified as a simple mixture. However, no carcinogenic effects resulting from exposure to stainless steels have been reported, either in epidemiological studies or in tests with animals. Since the exact composition of a possible alternative substance is not known, an assessment regarding the overall risk to human health and the environment is not possible. However, transition from chromium trioxide, which is a non-threshold carcinogen, to stainless steel would constitute a shift to a less hazardous substance.

- Alternative 11: Mineral acid based etching solution

Based on the available information on the substances used within this alternative, nitric acid would be the worst case with a classification as Ox. Liq. 3, Skin Corr. 1A, Met. Corr. 1, Skin Irrit. 2, Eye Dam. 1, STOT SE 3. As such, transition from chromium trioxide - which is a non-threshold carcinogen - to one of these substances would constitute a shift to less hazardous substances.

- Alternative 12: Potassium permanganate based etching solution

Based on the available information on the substances used within this alternative, potassium permanganate would be the worst case with a classification as Oxid Solid 2, Acute Tox. 4, Aquatic Acute 1 and Aquatic Chronic 1. As such, transition from chromium trioxide - which is a non-threshold carcinogen - to one of these substances would constitute a shift to less hazardous substances.

- Alternative 13: Polyamide (alternative substrate)

The polyamide products/substrates (polymers) do not have any kind of hazard classification and labelling. However, based on the available information on the substances used within this alternative, using polyhexamethylene adipamide would be the worst case with a classification as Skin Irrit. 2, Eye Irrit. 2 and Aquatic Chronic 4. As such, transition from chromium trioxide - which is a non-threshold carcinogen - to one of these substances would also constitute a shift to less hazardous substances.

7.4 Would the available information on alternatives appear to suggest that substitution with alternatives would lead to overall reduction of risk?

☐ YES

☐ NO

☒ NOT APPLICABLE

Justification:

Taking into consideration 13 alternatives for chromium trioxide presented in the non-use scenario, the applicant informed, that the most promising alternatives across all sectors are trivalent chromium electroplating and a combination of lacquer + PVD + lacquer. Transition from chromium trioxide – which is a non-threshold carcinogen – to one of these alternatives would constitute a shift to less hazardous substances.

Conclusion

The most promising alternatives are considered by the applicant to be trivalent chromium electroplating and a combination of lacquer + PVD + lacquer. Transition from chromium trioxide – which is a non-threshold carcinogen – to one of these alternatives could constitute a shift to less hazardous substances. However, RAC notes that, some of the alternatives and additives involved may be subject to further regulatory scrutiny and must be carefully evaluated on a case by case basis.

7.5 If alternatives are suitable (i.e. technically, economically feasible and lead to overall reduction of risk), are they available before the sunset date?

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

Not relevant as alternatives are not currently suitable. However, SEAC notes that the applicant argues that none of the potential alternative technologies, as of today, have the production capacity to replace the market for electroplated parts.

8. For non-threshold substances, or if adequate control was not demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ YES

☐ NO

☐ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:

Additional statistical cancer cases

The estimated number of additional statistical cancer cases has been calculated using the excess risk value presented in section 6 and the estimation of the number of exposed people provided by the applicant. Furthermore, the differences in the duration of the exposure of workers have been taken into account following the approach used by the applicant in the SEA.

SEAC notes that these calculations are based on the estimation of exposed populations and duration of exposure as provided by the applicant. Even if it is not possible to confirm the exact numbers of workers exposed, nor the allocation of workers between the groups with different exposure durations, SEAC agrees that the approach can be used to quantify the estimated statistical cancer cases. However, due to these exposure durations being uncertain and difficult to verify and in order to test the robustness of the cost-benefit ratio, SEAC additionally calculated the estimated statistical cancer cases with different (worst case) assumptions, i.e. with only two different values for the duration of exposure (see Table 15 below). It is noted that the exposure durations should be considered as part of the CSR, and that it is unclear how the durations have been considered already when deriving the estimates for the combined exposure.

RAC concludes that the regional scale assessment of man via environment may not be very relevant, and there is no need to estimate the additional statistical cancer cases from this exposure route. For SEAC, the regional assessment is therefore not regarded as relevant for assessing the human health impacts.

Furthermore, the applicant derived non-fatal cancer cases using the survival rate based on average mortality rates for lung cancer in the EU-27, namely 82.8% for both sexes. This gives less than 5 additional non-fatal cancer cases following the applicant's approach and less than 3 following SEAC's alternative approach per year.

Table 15. Estimated additional statistical fatal cancer cases, based on the applicant's assumptions (review period applied for and 1 year of exposure)

	Exposure duration per day (h)	Exposure 8h adjusted TWA (µg/m³)	Excess lung cancer risk	Number of exposed people	Estimated statistical fatal cancer cases (years of exposure)	
					7 y	1 y
Workers – Combination of WCS	<1	0.25	0.001	27,168	4.75	0.70
	1-3	0.75	0.003	4,767	2.50	0.36
	4-6	1.5	0.006	3,703	3.89	0.56
	6-8	2	0.008	9,534	13.35	1.91
	Not regularly exposed	0.25	0.001	16,708	2.92	0.42
Workers total				61,880	27.42	3.91
	Exposure 24h (µg/m³)				**7 y**	**1 y**
Man via environment - Local	3.54×10^{-4}		1.03×10^{-5}	10,000 × 1,559 sites = 15,590,000	16.06	2.29
Man via environment - Regional	Not relevant					
Total					**43.47**	**6.21**

Table 16. Estimated additional statistical fatal cancer cases, based on SEAC's alternative (worst case) approach (review period applied for and 1 year of exposure)

	Exposure duration per day (h)	Exposure 8h adjusted TWA (µg/m³)	Excess lung cancer risk	Number of exposed people	Estimated statistical fatal cancer cases (years of exposure)	
					7 y	1 y
	Up to 8	2	0.008	45,172	63.24	9.03
	Not regularly exposed	0.25	0.001	16,708	2.92	0.42
Workers total				61,880	66.16	9.45
	Exposure 24h (µg/m³)				**7 y**	**1 y**
Man via environment - Local	3.54×10^{-4}		1.03×10^{-5}	10,000 × 1,559 sites = 15,590,000	16.06	2.29
Man via environment - Regional	Not relevant					
Total					**82.22**	**11.75**

The estimated additional statistical fatal cancer cases reported in Tables 15 and 16 are one element of the calculations used to value, in monetary terms, the human health impacts of granting an authorisation. These impacts can then be measured against the expected economic benefits of granting an authorisation. As methodologies used by the applicant (particularly the generic exposure assessment for the general population using the EUSES model) focus on individuals or locations with a high potential for exposure, the overall number of cases is likely to have been significantly overestimated. In the absence of more refined estimates, RAC and SEAC have based their opinion on the assessment presented by the applicant. However, the health impacts should not be seen as equivalent to the human health impact that will occur if an authorisation for this use is granted. As such, the re-use of these estimates outside of this socio-economic analysis is advised against.

Costs of continued use (HH)

The applicant's assessment:

For calculating the costs of the continued use of chromium trioxide, **excess lung cancer risks for workers** and the **general population exposed via the environment** were assessed. The applicant used the reference dose-response relationship (DRR) confirmed by RAC for the carcinogenicity of chromium trioxide. An extrapolation of the workers and population exposed was performed to consider all health impacts related to this use. The basis for the extrapolation was data gathered from CTAC use group 3 members that was extrapolated first to cover consortium members that did not provide information and second to the whole plating industry covered by this use. In this extrapolation companies were divided into two groups based on their size. It was assumed that the average number of exposed workers and the respective distribution regarding exposure times is equal to the data provided by members. According to the applicant it has substantially overestimated the health impacts.

- **Health impacts for workers**: according to the exposure scenario (available through the CSR) and in accordance with the ECHA paper, only lung cancer is considered in this assessment. The share of particles that enter the gastro-intestinal tract is assumed to be zero. For the calculation of health impacts related to lung cancer, the Excess Lifetime Risk (ELR) is calculated based on the DRR as agreed by RAC (4.00×10^{-3} per µg Cr(VI)m³). This ELR refers to a working lifetime exposure with continued working-daily exposure. In order to use this ELR within this application for authorisation, it was adapted by the applicant to the review period applied for (7 years) and the actual hours of potential exposure per day. Furthermore, average mortality rates for lung cancer in the EU-27 were taken into account, namely 82.8% for both sexes. In order to evaluate the additional cancer cases in monetary terms, monetary values as suggested by the ECHA 2011 guidance on socio-economic analysis in applications for authorisation were used by the applicant: a Willingness to Pay (WTP) to avoid a cancer case of €400,000 per non-fatal case and €1,052,000 (lower bound based on the median value) or €2,258,000 (upper bound based on the mean value) per fatal cancer case (VSL). As the WTP values are based on a 2003 study, the applicant adjusted them to the year of the sunset date by using GDP deflator indexes. Based on these assumptions (upper bounds have been

used by the applicant), the health impacts for workers were monetised (price adjusted) and sum up to an amount of €79 million.

- **Health impacts man via the environment**: the applicant's assessment was performed on two spatial scales: locally in the vicinity of point sources of release to the environment, and regionally for a larger area. For the local assessment, an assumption of 10,000 people working and living in the near neighbourhood at any one site has been taken (15,590,000 as a whole) and the DRR as confirmed by RAC has been used (2.9×10^{-2} per µg Cr(VI)m³). For the regional assessment, following a worst-case approach, the population of the EEA was taken as a basis, i.e. 512,888,463 people and the DRR as confirmed by RAC has also been used (2.9×10^{-2} per µg Cr(VI)m³). These figures are claimed by the applicant to be conservative and to highly overestimate the occurring impacts. Respectively, the Predicted environmental concentrations (PECs) local and regional have been used. Again, the assessment was adapted to the time frame of 7 years (requested review period). Based on these assumptions (upper bounds have been used by the applicant), the health impacts for man via the environment sum up to €46 million.

SEAC's view:

In general, SEAC agrees to the approach taken by the applicant. The methodologies used are regarded as being appropriate for assessing the human health impacts due the exposure to chromium trioxide. Upon request, the applicant provided the calculation spreadsheets, in order for SEAC to be able to verify the calculations made. The economic concepts were applied correctly. However, several assumptions taken within the human health impact assessment have underlying uncertainties, such as the different exposure durations for workers. It is not possible, either for RAC, or for SEAC to verify the exact number of workers exposed/the allocation of workers between the different exposure duration groups as set up by the applicant. SEAC therefore set up an additional (worst case) scenario with only two different exposure duration groups, as depicted in Table 16 above. For the calculation of human health impacts for workers, using sensitivity values for VSL, this results in monetised impacts of €191 million instead of €79 million as calculated by the applicant. For the health impacts related to man via the environment, RAC concluded that the applicant's assessment related to the regional exposure of the EEA population is not relevant as chromium(VI) is effectively reduced to chromium(III) in the environment (conclusion within the EU RAR). For SEAC, the regional assessment is therefore not regarded as being relevant for assessing the human health impacts man via environment regional.

The following two scenarios have been taken forward for concluding on the cost-benefit ratio:

Scenario 1: the applicant's approach (5 different exposure duration groups, see Table 15 above) which results in total human health impacts in the amount of €60.8 million – 125.4 million.

Table 17. Human health impacts according to the applicant's approach

Monetised health impacts, workers	€38.4 million - €79.2 million
Monetised health impacts, man via environment (local)	€22.4 million - €46.2 million
Total:	€60.8 million – €125.4 million

Scenario 2: SEAC's alternative (worst case) approach (2 different exposure duration groups, see Table 16 above), which results in total human health impacts in the amount of €115.2 million – €237.6 million.

Table 18. Human health impacts according to SEAC's approach

Monetised health impacts, workers	€92.7 million - €191.2 million
Monetised health impacts, man via environment (local)	€22.5 million - €46.4 million
Total:	€115.2 million – €237.6 million

The applicant's estimate of exposure, which is used for the exposure assessment of the general population, was based on a modelled concentration located 100 m from a point source, which is consistent with the default assumptions used in the EUSES model for local scale assessments. RAC considers that the default assumptions used for the local scale exposure assessment in EUSES are conservative and are likely to overestimate the risks and consequently the estimated number of statistical cancer cases for the general population. In addition, SEAC notes that the way the RAC dose-response functions are applied assumes that the effects (in terms of disease burden/number of cases) occur without delay (i.e. at the beginning of the exposure period). However, any such effects would occur over time as a result of prolonged exposure and hence, the latency around exposures and effects is not accounted for. As knowledge of the time profile of excess incidence along with appropriate discounting is lacking, the values presented here are potentially overestimated. Furthermore, the dose-response relationships for these endpoints were derived by linear extrapolation. Extrapolating outside the range of observation inevitably introduces uncertainties. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be overestimated. Despite this potential overestimation, SEAC takes note of the estimated statistical cancer cases for this use applied for. As can be seen from Table 14 and 15 above, considering a 7 years exposure for workers and humans via the environment, the figures range between 43 and 82 statistical fatal cancer cases. These should be considered in the context of the wide scope of the application covering 61,880 workers and 15.6 million of the general population.

Benefits of continued use (cost of non-use scenario)

The applicant's assessment:

For calculating the benefits of the continued use of chromium trioxide the applicant took into account two cost factors: **social impacts (job losses)** and **economic impacts (lost purchasing volumes)**, whereas social impacts account for around 90 % of the estimated total costs. Assessments are based on feedback received by companies. The applicant claims that the assessment of the costs of the non-use scenario leads to a clear underestimation of impacts as the assessments have been performed using an "underestimation approach", i.e. lower values have been used as input factors. The applicant described the efforts they had made to collect additional information and explained the reasons why specific information requests from SEAC could not be provided e.g. due to not being able to disclose certain kind of company specific information (compliance with EU competition law), due to other confidentiality aspects within the consortium and due to the fact that specific type of information is claimed to be currently not available (e.g. costs of applying alternative substances and/or technologies). In order to back up the assessments made, the applicant provided case studies during the opinion-making process of RAC and SEAC, on SEAC request, which should give a further indication about the magnitude of effects of not granting an authorisation:

- The **non-use scenarios:** the non-use scenarios were, in the words of the applicant, developed by independent consultants who are experienced in the process of developing such scenarios for EU regulatory purposes and are based on feedback by consortium members, a series of bilateral discussions as well as site visits and meetings with companies. Due to the extremely broad scope of the use applied for as well as highly complex, integrated and inter-dependent supply chains, the applicant states that a detailed description of all non-use scenarios would not be feasible. Therefore, consolidated non-use scenarios have been developed, which are claimed to be representative for the responses of the affected industry sectors. The reaction of affected sectors due to not granting an authorisation would be a **partial** or a **complete shutdown of production facilities**, a **relocation of production facilities to non-EEA countries** as well as **a transfer of production processes/production volume to non-EEA facilities and re-import of plated parts** with chromium trioxide**;** respectively **import of complete products** into the EEA and **subcontracting to non-EEA suppliers.** This means that e.g. plating facilities are expected to shut down their activities related to chrome plating as chromium trioxide is necessary for the pre-treatment process of some substrates (etching of the surface) and the plating process itself. Those companies that offer other surface treatment/other business activities also reported that they would partially or totally (depending on the share of chrome plating of their total business) shut down their facilities or seek to apply non-mature technologies. As those technologies are unlikely to fulfil the customers' requirements at present, it is very likely that customers will look for other sources (non-EEA suppliers) of chromium surface treatment to cover their demand. Those who are able to relocate to a non-EEA country are expected to do so, but especially for SMEs, which represent the majority of job-platers in the EEA, this is not a feasible option. The consequence for actors further down the supply chain, such as article manufacturers and assemblers of

chrome-plated components that operate in-house, is that they are expected to either shut down their facilities and subcontract these operations to companies outside the EEA or relocate the respective business lines to non-EEA territory. For application areas, where transport over long distances (to galvanic baths in non-EEA countries) isn't possible (such as tapware blanks or plastic parts, having highly sensitive surfaces) further sub-assembly steps are likely to be relocated as well. This means that even larger parts of businesses will be migrated to non-EEA countries. During discussions with RAC and SEAC rapporteurs, representatives of companies explained that once a production/business line is located outside the EEA, it will probably not be relocated to the EEA once alternatives to chromium trioxide are available. The applicant states that, as a final consequence, the entire European supply chain from the plating shops upwards will move to non-EEA countries and also subsequent parts of the supply chain may relocate over time. With a shift of production/business lines to non-EEA countries, the applicant expects furthermore a leakage of know-how/technology in the EEA.

In addition to the above, the applicant provided information on specific challenges (the need for compliance with other regulations, rigorous testing and validation procedures, etc.) and consequences of the non-use scenario, esp. for the automotive and the sanitary sectors in order to justify the requested review period of 7 years.

- **Social impacts (job losses)**: the applicant assessed the impact of loss of earnings related to job losses following a production stop or relocation of business outside the EEA. SEAC was informed that other further social impacts may occur due to a non-authorisation, such as foregone productivity of the workers, secondary and tertiary job losses, additional costs for the society due to unemployment and impacts of loss of purchasing power, but these impacts have not been considered or quantified in the cost-benefit analysis. Data gathering was performed through sending questionnaires to member companies of the consortium. These companies were asked how many jobs related to the use of chromium trioxide would be lost as a consequence of their individual non-use scenarios. In addition, companies were asked to classify the jobs that would be lost according to their education levels (low skilled/high skilled/academic). In case this was not possible for companies, impacts of job losses were calculated for the lowest education level (low skilled) only. For the calculation of social impacts the applicant furthermore assumed that workers that lose their job due to a closure or relocation will either remain unemployed for the entire duration of the requested review period (7 years) or will replace another unemployed person in case of re-employment. Compared to the number of sites taken into account in the human health impacts assessment, the lower bound of the number of sites has been used by the applicant to estimate the job losses (i.e. 809 sites doing functional plating with decorative character). The present value of the total social impacts for a period of 7 years (requested review period) sum up to €9,585 million, reflecting a loss of 46,700 jobs.

- **Economic impacts**: the applicant's assessment of economic impacts is based on lost purchasing volumes. No extrapolation was performed for this assessment, i.e. only data was used that was directly reported by companies of the consortium. These impacts have been calculated as the present value of future expenses for raw materials and energy in the year of the sunset date and sum up to €1,537 million, which means a loss to the EEA society in 2017 in the case of non-authorisation.

  During opinion development, SEAC requested the applicant to provide additional information on economic impacts of the non-use scenario. The applicant provided additional information on expected negative economic impacts for job platers. According to the applicant, job platers have an estimated turnover of €80,000 per employee and year and an assumed profit margin of 10%. Using this information as a benchmark for **expected profit losses** due to a non-use of chromium trioxide for functional chrome plating with decorative character, the shut-down of facilities employing 46,700 people would result in profit losses of €373 million per year.

- **Impacts in the supply chain**: During the opinion-making process the applicant provided case studies on SEAC's request showing the impacts on downstream users within different sectors in order to complete the assessment of social and economic impacts as described above. For two sectors, profit losses and the value added foregone was estimated, as described below and summarised in Table 10.

  For the impacts on the **sanitary sector**, the applicant estimates (based on consultations with industry experts) that around 67,000 employees and 1,400 companies are involved in the manufacture of sanitary taps and valves in the EU. Based on data on production values from Germany, Italy and the United Kingdom, as well as an assumed profit margin of 10-12%, the applicant concludes that those three national markets alone generate more than €0.6-0.7 billion profits annually.

  For the impacts on the **automotive sector**, the applicant states that non-authorisation will result in interruption of the supply chain until the demand can be satisfied by non-EEA production. The consequence is expected to be a 90% loss of the European vehicle production during the first month after the sunset date, 80% loss during the second month and full production after 10 months. Overall, the applicant claims that this would result in a loss of production of 6.3 million vehicles due to interruption of the supply chain. Based on an average EBIT[5] of €1,000 per manufactured car, the overall EBIT loss would be €6.3 billion. Assuming that the value added of the automotive industry is directly correlated with its production output, the applicant claims that a non-granted authorisation would result in a loss of value added of €46.3 billion.

[5] EBIT = Earnings before interest and taxes

Table 19. Summary of the case studies performed for use 3, functional chrome plating with decorative character

Case study	Economic impact [€ billion per year] (see Annex SEA 1 for detail)	Metrix
Sanitary sector	0.6-0.7	Profit loss
Automotive sector (OEMs and suppliers)	46.3	Value added foregone

On SEAC's request, the applicant provided an overview of the share of different affected sectors within the use applied for. Although the applicant stated that this overview is given by industry experts and gives therefore a valid estimation, the percentages mentioned should be understood as an indication only, as not all manufacturers and/or importers and formulators were able to identify the end-uses of their raw materials or as job platers might do chrome plating for different end-uses. Additionally, variations in market shares and stock building might further distort this classification.

Table 20. Overview of the market shares of different sectors in the supply chain

Sector	Share
Automotive	71.2 %
Construction	0.4 %
Consumer and white goods	6.9 %
Cosmetics	2.2 %
Furniture	1.7 %
Medical	2.0 %
Sanitary	15.2 %
Others / unassigned	0.4 %
Total	100%

- **Sensitivity analysis:**
  In order to account for uncertainties for the calculation of job losses, the applicant performed a sensitivity analysis which covers 24 different scenarios, including:

  -> all job losses considered for the **length of the review period**, lower bound/upper bound
  -> all job losses considered for **1 year only**, lower bound/upper bound
  -> **70%** of job losses considered for **1 year only**, the remaining **30%** considered for the **length of the review period**, lower bound/upper bound.

  The above 6 scenarios were combined with a sensitivity check for the human

health impacts (using the central and sensitive Value of Statistical Life respectively) and for the number of sites using chromium trioxide for functional chrome plating with decorative character in the EEA (2 further scenarios, number of sites low/high). The outcome of the analysis shows that in each of the 24 developed scenarios the benefits of granting an authorisation outweigh the risks of continued use of chromium trioxide. Additional information on economic impacts for different affected sectors, such as profit and revenue losses, value added foregone, etc., which was provided on the request of SEAC, is not included in this assessment.

SEAC's view:

SEAC regards the applicant's approach for assessing the economic impacts of not granting an authorisation and the welfare loss to society respectively not being fully appropriate. Furthermore, the data gathering and the calculations performed by the applicant lack clarity and transparency, e.g. when it comes to the representativeness of data used or the impacts on certain sectors affected. For example, the applicant explains that only between roughly a third and half of the companies consulted (among the CTAC member companies) responded to their questionnaires. SEAC understands that the assessment of both costs and benefits is specifically difficult for upstream applications covering such a broad scope, different and complex supply chains, a huge number of affected people (human health impacts) and companies (economic impacts) but even more a transparent and clear approach is needed in order for SEAC to properly verify the calculations and outcome of the assessment.

- The **non-use scenario(s):** SEAC agrees that the extremely broad scope of the use applied for as well as highly complex, integrated and inter-dependent supply chains make the description of the non-use scenario difficult. SEAC acknowledges that for such broad upstream applications, the detailed description of all possible non-use scenarios is a challenging task. However, SEAC determined deficiencies with the applicant's approach: the use applied for within this application for authorisation is extremely broad. It covers multiple industry sectors and a huge number of actors down each supply chain. SEAC has reservations about the conclusion of the applicant that the main consequence for all involved actors would be a shut down or relocation of business outside the EEA, as this claim wasn't substantiated by any supporting evidence. SEAC agrees that this could be the case for many of the job platers, however, for some actors in the supply chain it might easily be possible to import treated products from outside the EEA, whilst for others, this might not be a viable solution at all. In SEAC's view, a better description of how actors in different sectors/supply chains might be affected would have been needed together with a description of the respective economic consequences expected, e.g. the expected profit losses to actors in different levels of the supply chain (suppliers of raw materials, job platers, article manufactures, any other relevant actor). Furthermore, it would have been relevant for SEAC to know whether the non-use scenario would also result in new business opportunities for other companies in the EU. Even though the case studies provided during the opinion-making process on request of SEAC help to better understand possible consequences within different sectors, the overall information at hand is not detailed,

substantiated and verifiable enough to allow (a) robust non-use scenario(s) to be defined for the broad use applied for, which is one of the main reasons that causes uncertainties within this application for authorisation.

- The assessment of **job losses (social impacts)** and **lost purchasing volumes (economic impacts)**: SEAC does not agree that the approach taken by the applicant is fully appropriate in order to assess the negative economic consequences and the welfare loss to society due to the substance being no longer available for the use applied for:

    - Instead of assessing job losses as the main negative (economic) impact of not granting an authorisation, other relevant economic impacts to society or loss of profits could have been assessed.
    - The costs related to lost purchasing volumes are not elaborated and are not justified as representing losses in terms of a net economic welfare analysis. As such, they would merely represent cost savings, rather than losses.
    - Although SEAC certainly notes the dimension of the unemployment effects due to a non-authorisation, it is not clear, or demonstrated otherwise by the applicant, that the effects arising from unemployment due to a closure or relocation of a company have merely distributional consequences at the societal level. Moreover, the assumptions taken by the applicant (workers that lose their job due to a closure or relocation will either remain unemployed for the entire duration of the requested review period (7 years) or will replace another unemployed person in case of re-employment) are regarded by SEAC being highly unrealistic and do not fit with the applicant's argument of having taken an "underestimation approach" for calculating the costs of the non-use scenario.

- The assessment of job losses and lost purchasing volumes was supplemented by information on **profit losses to job platers**, as well as **supply chain impacts,** on the request of SEAC. SEAC takes note of the possible profit losses of €373 million per year for job platers. However it notes that they do not reflect the net changes in profit in the EU over time as the resources may be used to generate profits in other companies. Furthermore, even though this supplementary cost information on profit losses and supply chain impacts cannot be thoroughly verified by SEAC, as little to no information about assumptions taken and methodologies used is available, it gives an indication of the dimension of the expected negative economic impacts and supports the overall conclusion of the applicant that the economic effects of not granting an authorisation in the supply chain are significant.

- The applicant provided a **sensitivity analysis** for the calculation of social costs (job losses) in order to test the robustness of the cost-benefit ratio. SEAC notes that the sensitivity analysis includes the estimated lost purchasing volumes which are in SEAC's view not an appropriate parameter to measure net welfare impacts. Furthermore, the additional information on profit and revenue losses, value added foregone, etc., which was provided as part of the case studies for

different sectors on request of SEAC, is not included in this sensitivity check. Including these impacts would strengthen the argument of the applicant, that the socio-economic benefits of continued use of chromium trioxide outweigh the risks. Despite of the deficiencies, this sensitivity check supports the overall conclusion that there are net benefits from granting the authorisation.

Conclusion on benefits and costs

SEAC does not regard the applicant's approach for assessing the negative economic impacts of not granting an authorisation and the welfare loss to society respectively as fully appropriate, which gives rise to uncertainty. Nevertheless, SEAC considers that the following information provided by the applicant is sufficient to conclude that the benefits of continued would be significant and will allow a comparison with the health impacts:

- Information on possible profit losses of job platers (provided by the applicant during the opinion making process, used as a benchmark for expected profit losses for the use applied for) of €373 million per year
- The social cost of job losses of €1,470 million based on the assumption of a 1 year unemployment period and lost salaries as presented in the sensitivity analysis (NPV)
- Significant supply chain impacts for affected end-user sectors, such as automotive and sanitary industries.

The dimension of the supply chain impacts depends on the responses of different industrial sectors if authorisation is not granted. Due to the lack of information on assumptions taken and methodologies used in the estimation of the supply chain impacts, as well as the uncertainties in the non-use scenarios for different actors in the supply chain, SEAC cannot confirm any of these monetary estimates provided by the applicant. However, SEAC agrees that the negative economic effects of not granting an authorisation in the supply chains are significant. SEAC notes that even if there is less uncertainty in the non-use scenario for the job platers, SEAC cannot confirm that all of them would shut-down if the authorisation is not granted. Additionally, SEAC takes note that the possible profit losses do not reflect the net changes in profit in the EU over time as the resources may be used to generate profits in other companies.

Regarding the human health impact assessment, SEAC agrees to the applicant's approach although the assumptions taken are uncertain, e.g. the exact number of sites covered by the application for authorisation, the number of workers exposed and the allocation of workers between different exposure durations. In order to test the robustness of the cost-benefit ratio, SEAC set up an additional (worst case) scenario, which considers some of the respective uncertainties present in the applicant's approach. The human health impacts of these two scenarios range from €61 to €238 million for the seven years review period requested. Furthermore it has to be noted that the way the RAC dose-response functions are used assumes that the effects (in terms of disease burden/number of cases) occur immediately (i.e. at the beginning of the exposure period). However, the effects are occurring over time as a result of prolonged exposure and hence one need to account for the latency around exposures and effects. This requires knowledge of the time profile of excess incidence along with appropriate discounting to be undertaken. Given the lack of such information, the values presented here are potentially overestimated.

For drawing a conclusion on whether the benefits of continued use of chromium trioxide have been adequately shown to exceed the risks, SEAC takes note of the following impacts:

- Monetised health impacts range between €60.8 and €237.6 million, calculated over 7 years (potential overestimation)
- Possible profit losses of €373 million per year based on information submitted by the applicant on turnover/profits of job platers
- Expected social costs of €1,470.6 million due to job losses (workers (lower bound of potentially affected workers) assumed being unemployed for 1 year) based on salary costs
- Expected significant negative impacts in the supply chain for different affected industries, such as automotive and sanitary goods

In SEAC's view the above values and information allow a comparison of the expected benefits of continued use of chromium trioxide to the expected risks to human health. For human health impacts, the related uncertainties are reflected in the lower and upper bound for the Value of a Statistical Life and are considered through the additionally set-up (worst case) scenario by SEAC. Moreover, these effects have not been discounted. For the social cost of job losses, the lowest value as calculated by the applicant was chosen (job losses considered for one year of unemployment only, based on salary costs, lower bound of potentially affected workers). The above values for economic and social impacts assume a complete shut-down of all plating sites covered by this use. In case of a partial shut-down only, this would reduce both, profit losses and social costs of job losses. Furthermore and as already mentioned above, SEAC notes that the resources may be used to generate profits in other companies.

It should be noted that the above estimates on the economic impacts do not give an overall monetised picture of the expected negative economic consequences of not granting an authorisation, but depict only some of the expected effects. In particular, they do not contain quantified supply chain impacts for different affected end-user sectors (as mentioned above), which are considered to be significant but for which no substantiated monetised figure is available to SEAC. Although SEAC regards the applicant's approach to assess the negative economic consequences of a non-use scenario as not being fully appropriate and although this approach gives rise to uncertainty, it is obvious from the information given that already expected profit losses (based on information from the applicant on profits of job platers) or social cost of job losses (lower bound of affected workers, assuming 1 year of unemployment only) alone would outweigh the monetised human health impacts, which are regarded as being an overestimation.

Therefore, SEAC supports the conclusion of the applicant's assessment, that the benefits of continued use outweigh the risks to human health.

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation:

Exposure scenarios

RAC takes note of the applicant's intention to develop a detailed set of Risk Management Measures (RMM) guidance documents to be provided in support of their Downstream Users (DUs) by the sunset date for chromium trioxide.

Supply chain communication is considered to be a prerequisite to achieve the objective of reducing exposure to workers and humans via the environment. Recognising the applicant's obligation to include representative exposure scenarios (ES) in their Chemical Safety Report (CSR) as defined in Annex I sections 0.7 and 0.8 of REACH for the different types of processes and individual tasks, specific ESs shall be developed for typical decorative chrome plating operations, including e.g. automatic versus manual, open versus closed systems. These shall describe typical Operational Conditions (OCs) and RMMs (including also organizational measures) to control workers' exposure to the substance as well as emissions to the environment together with resulting exposure levels and shall be provided to downstream users. The hierarchy of control principles according to Chemical Agent Directive (98/24/EC) and Carcinogens and Mutagens Directive (2004/37/EC) including any relevant subsequent amendments shall be followed in the selection of RMMs described in ESs. These ES shall be developed and made available to Downstream Users of this application and for the inspection of the enforcement authorities, **without delay and at the latest 3 months after the applicant has been informed that an authorisation is granted for this use**.

RAC notes that based on their assessment, maximum individual exposure values for workers (as provided in chapter 10 of the CSR) and release values for the environment (see table 6) were proposed by the applicant, with the intention that these are adhered to. It is inappropriate for RAC to endorse any specific exposure value for a non-threshold substance. However, RAC recognises the applicant's commitment to support the downstream users in the progressive reduction of exposures and releases to as low a level as technically and practically possible. This progressive reduction, evidenced by systematically decreasing exposure and release levels, shall therefore be demonstrated.

Validation of Exposure Scenarios

Such ESs shall be validated and verified by the applicant through an analysis of tasks as well as through representative programmes of occupational exposure and environmental release measurements relating to all processes described in this use applied for.

Downstream User Monitoring

Workers

The downstream users covered by this application and where relevant the applicant shall implement at least annual programmes of occupational exposure measurements relating to the use of the substance described in this application. These monitoring programmes are needed to demonstrate that OCs and RMMs are appropriate and effective in limiting the exposure. Monitoring programmes shall be based on relevant standard methodologies or protocols and be representative of (i) the range of tasks undertaken where exposure to the substance is possible (i.e. the programme shall

include both process and maintenance workers), (ii) the operational conditions and risk management measures typical for these tasks and (iii) the number of workers that are potentially exposed.

The reports presenting the results of the monitoring and of the review of the RMMs and OCs shall be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted. Detailed summaries of the results with the necessary contextual information shall be included in any subsequent authorisation review report submitted.

Environment

Emissions of Cr(VI) to wastewater and air from local exhaust ventilation shall be measured at individual sites. Measurements should be representative for the operational conditions and risk management measures typical for the industry and should be undertaken according to standard sampling and analytical methods, where appropriate. The results of monitoring programmes shall be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted.

Continuation of monitoring requirements

The information gathered in the monitoring programmes shall be used by the applicant and the downstream users covered by the application to review the risk management measures and operational conditions as indicated above.

Whilst monitoring programmes are essential for the development and verification of ES by the applicant, it is not the intention that all DUs of this application should continue monitoring programmes for the duration of the validity of the authorisation granted.

Where, following the implementation of the OCs and RMMs of the ESs, the DU can clearly demonstrate that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible, and where it is demonstrated the OCs and RMMs function appropriately, the monitoring requested for this authorisation may be discontinued.

Where the monitoring programme has already been discontinued in accordance with the above, any subsequent change in OCs or RMMs that may affect the exposure at a downstream user's site shall be documented. The downstream user shall assess the impact of such change to worker exposure and consider whether further monitoring needs to be undertaken to demonstrate that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible in the changed worker setting.

Review reports

In any subsequent review report, in order to facilitate the assessment of the exposures resulting from the use, the applicant shall provide the exposure scenarios for typical, representative plating plants, listing OCs and RMMs together with resulting exposure levels. A justification as to why the selected scenarios are indeed representative for the use shall be provided along with a justification that the OCs & RMMs follow the

hierarchy of control principles and are appropriate and effective in limiting the risks. Furthermore, more detailed task descriptions shall be provided with a discussion and justification regarding the choice of OCs & RMMs.

The assessment of indirect exposure and risk to humans via the environment should be refined beyond the default assumptions outlined in ECHA guidance and the EUSES model with specific data appropriate to a more refined analysis. All reasonably foreseeable routes of exposure to humans via the environment shall be included in the assessment (i.e. the oral route of exposure should be fully assessed).

Justification:

The level of detail in the applicant's exposure scenario (ES) presented in the CSR could be significantly improved with due consideration of Annex I section 0.7 of REACH. While Section 0.8 indicates that an ES may cover a wide range of processes, the level of detail is dependent on the use, the hazardous properties and the amount of information available. In the view of RAC, such information is available, and bearing in mind the intent of the REACH regulation and the hazard of a non-threshold carcinogen such as Cr(VI), the general nature of current ESs (lacking clear information on the linkage between OCs and RMMs and exposure levels) is a significant source of uncertainty in this application.

The applicant's assessment of the exposure, risk and impacts for humans via the environment is based on a series of default assumptions that are likely to result in a significant overestimate of health impacts. This introduces considerable uncertainty to the applicant's assessment, which should be addressed in any review report.

Description of conditions and monitoring arrangements for review reports by SEAC:

In case the applicant submits a review report, a more detailed assessment of the uses applied for or a more specific (narrow) scope of the use applied for is required.

Justification:
SEAC notes that the wide scope of the use applied for (Functional Chrome Plating with decorative character) includes technical applications for which suitable alternatives may already be available and implemented or will become so in short term. The related assessment performed by the applicant is too general to exclude these from the scope of the authorisation.

10. Proposed review period:

☐ Normal (7 years)

☐ Long (12 years)

☒ Short (4 years)

☐ Other:

Justification:

In identifying the review period SEAC took note of the following considerations:

RAC's advice:

Considering that

- there are uncertainties in the exposure assessment, which may result in underestimation of risk to workers;
- RMMs and OCs are not described in sufficient detail to allow the Committee to fully evaluate whether they are appropriate and effective in limiting the risk to workers;
- RAC confirmed that there are risk-control concerns, i.e., operational conditions and risk management measures described in the application do not limit the risk;

Therefore strict additional conditions and monitoring arrangements are proposed.

RAC gave no advice on the length of the review period.

Other socio-economic considerations

In addition to RAC's advice as stated above, SEAC takes note of the following information for the recommendation of the review period:

- **Alternatives:** The applicant performed its assessment based on a 7 years review period, due to feedback from industry on (best/optimistic) estimates of the schedule required to implement alternatives to chromium trioxide mixtures used in functional chrome plating with decorative character. Additionally, the specifications of the automotive sector and the sanitary sector as well as special requirements within other applications (e.g. the cosmetics sector) are explained. Furthermore this period reflects the normal review period of ECHA. According to the applicant, the requested 7 years form the minimum period required for industry to substitute. SEAC agrees to the applicant's conclusion that currently, there doesn't seem to exist an *overall* technically feasible alternative for chromium trioxide-based functional chrome plating with decorative character for key applications. However, due to the broad scope of the use applied for, SEAC cannot exclude that it may cover applications where substitution is already feasible or will become so at short-term, which gives rise to uncertainty. In SEAC's view the applicant failed to provide supporting evidence for the technical infeasibility of alternatives for some of the application areas within sectors covered by this use applied for (e.g. within the white goods sector, furniture or other sectors covering products, such as locks and fittings, lamps and light fittings). SEAC specifically challenges the appropriateness of the argumentation used for claiming alternatives technically infeasible within the cosmetics sector, where the applicant claims that alternatives would lead to non-acceptability by consumers but did not provide evidence supporting this claim. This further adds to the uncertainties present in the use applied for.

- **Benefits of continued use:** Social impacts, i.e. job losses, are the main impacts that have been assessed by the applicant for the non-use scenario and economic impacts are only briefly assessed, weakly justified and only based on purchasing volumes lost. Although SEAC certainly notes the importance of unemployment effects, those are often regarded as having rather a distributional character and are not necessarily appropriate for assessing the welfare loss to

society. During the opinion making process the applicant complemented its assessment with case studies and information on expected negative economic impacts in the supply chains, which give an indication on profit losses, revenue losses, value added foregone and loss in turnover for different affected sectors. Unfortunately, these assessments could not be verified adequately by SEAC due to little information about methodologies used and assumptions taken. In other words, the way the economic impacts have been assessed by the applicant gives rise to uncertainty about the actual consequences of the non-use scenario. Nevertheless, SEAC considers that the provided information is sufficient to conclude that the benefits of continued use are significant and allow a comparison with the health impacts.

- **Risks of continued use / impacts to human health:** According to the assessment of the applicant and as confirmed by the additional (worst case) scenario that was set up by RAC and SEAC, significant impacts to human health (workers, man via the environment) are expected from the continued use of chromium trioxide in functional chrome plating with decorative character. Whilst SEAC agrees to the approach taken and the methodology used by the applicant in the assessment of impacts to human health, the assumptions taken are uncertain, e.g. related to the number of sites covered by the application for authorisation, the number of workers affected, the duration of exposure, the set-up of the exposure scenarios as such, etc. However, due to the nature of RAC's dose response functions, i.e. assuming that the effects occur at the beginning of the exposure period, the values estimated within the human health impact assessment are potentially overestimated as these effects have not been adjusted for the latency related to exposures, and associated discounting undertaken. The (worst case) scenario set up by RAC and SEAC provides an additional margin of safety for the assessment of human health impacts. Nevertheless, SEAC takes note of the potentially overestimated statistical fatal cancer cases for this use applied for, ranging from 43 to 82 considering a 7 years (review period requested by the applicant) exposure for workers and man via the environment.

- **Risk / benefit ratio:** With the information (both, quantitatively and qualitatively) available in the application, provided during the opinion making process by the applicant and submitted during the public consultation, SEAC agrees to the applicant's conclusion that the benefits of the continued use of chromium trioxide for functional chrome plating with decorative character outweigh the risks to human health. Although the applicant's approach of assessing the benefits of continued use of chromium trioxide as well as assessing the risks to human health gives rise to uncertainty, in SEAC's view, this conclusion is valid and is further substantiated by the additional (worst case) scenario for assessing the impacts to human health, as set up by RAC and SEAC.

Although some of the requirements for recommending a normal review period[6], such as requested by the applicant, could be regarded as being fulfilled for some of the industrial sectors and applications covered by this use (e.g. certification & qualification

[6] See also: https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf

schemes in the automotive sector), SEAC notes that this is not the case for the full scope of this use applied for and for all sectors and applications covered respectively. SEAC has reservations about the appropriateness of the applicant's approach. The deficiencies present in the application lead to substantial uncertainty on the actual consequences for the different actors in the supply chain and the actual negative economic impacts of not granting an authorisation. However, it is clear from the information given in the authorisation application and case studies that not granting an authorisation for functional chrome plating with decorative character would lead to negative economic impacts for many different sectors in the EEA and to social costs related to unemployment. Overall a net benefit from granting the authorisation is expected.

In conclusion, taking into account

- the applicant's argumentation regarding the time required to industrialise alternatives put forward to justify the requested review period of 7 years,
- the expected negative economic consequences down the supply chain,
- the expected social costs due to unemployment,
- the expected human health impacts,
- the substantial uncertainties arising from the applicant's approach (due to the broad scope, the lack of supporting evidence for claiming alternatives technically infeasible for some of the application areas within sectors covered by this use applied for and the lack of an appropriate assessment of economic costs of a non-use),
- that the requirements for a normal review period have not been met,
- RAC gave no advice on the length of the review period,

SEAC recommends a short (4 year) review period.

11. Did the Applicant provide comments to the draft final opinion?

☒ YES

☐ NO

11a. Action/s taken resulting from the analysis of the Applicant's comments:

☒ YES

☐ NO

☐ NOT APPLICABLE

Justification:

The final opinion was modified to better describe the purpose and nature of quantifying the estimated statistical cancer cases. Some editing was done also to clarify for example the proposed conditions and the reasons for uncertainty in the applicant's assessments.

The responses of RAC and SEAC to the Applicant's comments on the draft opinions are available in the Support document.

ANNEX

Table A1. Calculations based on aggregated company/site data Use 3

Company	Result (µg/m3) *	No of measurements available	No of measurements finally used for the calculation of result	Period	LEV	Process type	Mist suppressant used
X1	1.00	4	2	2013	yes	automatic	yes
X2	0.23	3	3	2012	yes	automatic	yes
X3	0.38	1	1	2012	yes	manual/ automatic	yes
X4	3.70	1	1	2012	yes	automatic	no
X5	1.30	1	1	2013	yes	manual	nr
X6	0.55	3	3	2012	yes	manual	nr
X7	3.00	2	2	2012	yes	automatic	yes
X8	0.38	4	4	2013	yes	automatic	yes
X9	0.81	5	5	2013	yes	manual	nr
X10	0.18	16	7	2013	yes	automatic	yes
Total		40	29				

* Not adjusted for use of respiratory protection

Arithmetic Mean 1.15
Geometric Mean 0.72
90th Percentile 3.07

This specific data on use 3 comes from CTAC companies in France or in Germany

Table A2a. Background literature data provided by applicant

Overview of published measurement data			no of samples		results of sampling (µg/Cr(VI)/m³)							
reference	period	no of companies	personal	static	personal		static		average personal	average static	90th (95th) percentile	
					min	max	min	max			personal	static
Italian authority report Lombardy	2003-2004	14	44 workers		0,01	37,7	0,01	14,7	2	2		
Italian authority report Piedmont	2007	20	42	49	0,10	3,32	0,10	7,81	0,65	2		
French health insurance report Ile de France	before 2010	9	60	34	0,05-23				1			
French health insurance report Pays de la Loire	2009-2013	14	37		0,02	3,12			0,5		1,2	
German BG ETEM report: gravure printing	2012	14	27	71	0,01-2,1						(0,3)	(0,4)
German BG ETEM report: job shops	2012	12			<0,01-4,8						(4,4)	(4,6)
CTAC Sub Use 2**	2000-2013	23	110	>400					1,68		1,42 (4,7)	
CTAC Sub Use 3**	1999-2013	23	40	>80					0,88		3,07	
CTAC Use 4/5/6**	1999-2013		40						1,16		2,94	
CTAC Use 6**	2007+ 2013-2014	7	54		0,02	2,24					1,45	

**Summary values reflect aggregated values by companies (Tables in ANNEX 1), most between 2010-2013, without RPE. The CTAC data from uses 2-6 comes from the following countries: France, Spain, The Netherlands, Slovakia, Sweden, UK.

Table A2b Additional background literature data collected by RAC

Overview of published measurement data			**no of samples**		**results of sampling (µg/Cr(VI)/m³)**							
reference	**period**	**no of companies**	**personal**	**static**	**personal**		**static**		**average personal**	**average static**	**90th (95th) percentile**	
					min	**max**	**min**	**max**			**personal**	**static**
HSE 2013 : Exposure to hexavalent chromium, nickel and cadmium compounds in the electroplating industry	2008-2009	14	41		<0,1	11						
German MEGA database*: Functional chrome plating	2001-2011	66	145						2,6**		24,6	
German MEGA database*: Decorative chrome plating	2001-2011	40	46						-		2,50	
German MEGA database*: Chromating/Passivation	2001-2011	10	18						-		6,76	
German MEGA database*: Loading and unloading jigs	2001-2011	29	44						-		13,5	

*report DGUV 213-716, 2014

** 50th percentile

Table A3: Occupational Exposure to Chrome VI Compounds in French Companies: Results of a National Campaign to Measure Exposure (2010–2013)*

Levels of Cr VI exposure for the different activity sectors

Activity sector	*N*	Mean (µg/m³)	GM (µg/m³)	GSD	Range (µg/m³)	% of results >1 µg/m³
Hard chrome plating	97	1.60	0.58	4.22	<0.03–22.81	33
Chrome plating	90	0.28	0.13	3.46	< 0.02–1.71	1.1

Levels of Cr VI exposure for the different types of task performed

Type of task	*N*	Mean (µg/m³)	GM (µg/m³)	Range (µg/m³)	% of results >1 µg/m³
Use of electroplating systems	184	0.94	0.28	<0.02–22.81	19.6

* Vincent R, Gillet M, Goutet P, Guichard C, Hédouin-Langlet C, Frocaut AM, Lambert P, Leray F, Mardelle P, Dorotte M, Rousset D. Occupational exposure to chrome VI compounds in French companies: results of a national campaign to measure exposure (2010-2013). Ann Occup Hyg. 2015 Jan;59(1):41-51.

Table A4: Modelled data on fuctional chrome plating provided by the applicant

Results of Modelling

The results of the modelling are provided in the table below.

ART Models for different plating situations							
No.	**Title**	**Exposure Duration (h)**		**Bath covered?**	**Room size (at least)**	**Result in µg/m³ (90th Percentile)**	
		In breathing zone	**Outside breathing zone**			**Efficiency LEV 90%**	**Efficiency LEV 99%**
1	Manual, open	2	6	No	300m³	130	13
2	Manual, covered	2	6	Yes, LLC†	300m³	6.8	0.68
3	Automatic, open	0.5	7.5	No	1000m³	36	3.6
4	Automatic open	0	8	No	1000m³	27	2.7
5	Automatic, covered	0.5	7.5	Yes, LLC†	1000m³	3.6	0.36
6	Automatic, covered	0	8	Yes, LLC†	1000m³	2.7	0.27
† Low level containment							

Table A5: Data from the applicant on release of Cr(VI) to the aquatic environment. Since also the data from uses 3-6 were considered as useful for the assessment of releases from functional chrome plating, also these are included in the table. Specific use is mentioned in the last column.

Site	Cr(VI) released per site per annum (grams)	Annual tonnage chromium trioxide	Emission factor (%) discharged from site	Use
31	0.9	38	$2.37 \times 10^{-6**}$	3
7	<1	45	$6.67 \times 10^{-6**}$	1,4,5
38	1.2	40	$3.00 \times 10^{-6**}$	2
37	1.65	42	$3.93 \times 10^{-6**}$	2
3	2	30	$6.67 \times 10^{-6**}$	2
2	4	36.2	$1.10 \times 10^{-5**}$	2
19	5	0.15	$3.33 \times 10^{-3**}$	4
18	11	2.05	5.37×10^{-4}	4,5
17	31.7	0.16	$1.98 \times 10^{-2**}$	4,5
4	50	15	$3.33 \times 10^{4**}$	2
15	152#	16.36	9.29×10^{-4}	4
25	175.5	15	$1.17 \times 10^{-3**}$	3
33	314##	4	7.85×10^{-3}	2,6
Median*	**5**		**3.33×10^{-4}**	
90th Percentile*	**258.6**		**1.50×10^{-2}**	

**Calculated by ECHA*

***discharge subject to further treatment in municipal wastewater treatment plant prior to discharge to surface water, which will reduce the emission factor to surface water*

#according to the applicant this value is no longer relevant (since the end of 2015) due to improvements to the RMMs at the site

##according to the applicant this value was incorrect and the annual release of Cr(VI) to water over the last two years was 49 – 150g

Table A6: Wastewater monitoring data. Since also the data from uses 3-6 were considered as useful for the assessment of releases from functional chrome plating, also these are included in the table. Specific use is mentioned in the last column.

Site	Cr(VI) concentration in wastewater (µg/L	Notes/contextual information	Use
7	<10	2014/2015	1,4,5
8	<100		3
22	6.2	October 2015	2
23	<50	June 2015	2
24	2.9 – 9.9	N=6	2
34	<30	Annual average from daily measurements	1
37	30	Average of 100 samples	2
38	20	Average of 100 samples	2
41	<20	November 2015	NA
42	11		NA
Median*	15		
90th Percentile*	50		

**Calculated by ECHA (censored values treated as ½ LOD)*

NA-data not available

In a third round of questions from RAC the applicant was asked to undertake an assessment of the indirect impact of the emissions of the three sites that discharged measurable quantities of Cr(VI) directly to surface water (site 15, 18 and 33). Further the applicant was asked if the discharge to surface water would lead to an implication for human health from exposure to Cr(VI) via drinking water. The applicant responded that at site 15 the information given was no longer applicable since the Cr(VI) release to wastewater reflected the situation to the end of June 2015. After June 2015 the amount of Cr(VI) release to wastewater was reduced significantly since one production line accounting for 99% of chromium trioxide release has been removed and it was expected that the release to the aquatic environment will be much lower. However, recent monitoring data is not yet available. Furthermore, further improvements at this site will be made in 2016 with closed wastewater treatment system and the solid waste will be treated as hazardous waste with zero release to wastewater.

As regards site 18 the applicant informed that the 11g of Cr(VI) discharged to wastewater per year resulted in 7.5 x 10^{-8} mg/L of Cr(VI) in surface water based on a river flow at 4.62 m^3/s and amount of wastewater of 1,907 m^3/year, and further that it is expected that Cr(VI) will be transformed to Cr(III), therefore, the risk of human exposure to Cr(VI) from drinking water is considered negligible from this site.

As regards site 33 the applicant informed that the data was incorrect and that the annual release of Cr(VI) to water over the last two years was 49 – 150g and not 314 g as informed

by the applicant in the second round of questions from RAC. This resulted in a Cr(VI) release to wastewater between 0.1 and 0.5 µg/l. The applicant informed further that this level of discharge to water resulted in 5 x 10^{-8} mg/L of Cr(VI) in surface water when the treated wastewater was discharged to a canal with an average outflow to the sea of 100 m^3/s. The applicant informed that it is further expected that Cr(VI) will be transformed to Cr(III), therefore, the risk of human exposure to Cr(VI) from drinking water is considered negligible from this site.

Appendix 1. Masterlist of alternatives with classification into categories 1 – 3 and short summary of the reason for classification of alternatives into category 3

Nr.	Alternative Substance / Alternative Process	Category	Screened out because
Pre-treatment: Etching of plastics			
1	Mineral acid based solutions	1	
2	Potassium permanganate based solution	1	
3	Catalysed plastic (noble metal)	3	Not industrially feasible for high volume production, worse process
4	Conductive paint	3	Not industrially feasible for high volume production
5	Gaseous etching / gas etching	3	Not industrially feasible for high volume production – limitation due to the use of gastight containers
6	Ionic liquids	3	- very early R&D stage (literature research), more R&D necessary - technically not feasible: dissolution of different kind of plastic substrates
7	Laser activated embedded metal particles / etching on catalysed plastic (LPKF)	3	- technically not feasible: process engineering not equivalent, only a few exemplary parts have been tested resulting in insufficient adherence, not applicable for large parts - Not industrially feasible for high volume production
8	Mechanical methods: Mechanical Sanding / shot blasting / media blasting /	3	- not for complex geometries and not for inner diameters
9	Plasma etching	3	- Technically not sufficient, earliest R&D stage, difficult and complex technique, not for high volume throughput of parts
10	Heat treatments: Heat gun	3	-- Not suitable for plastic substrates - possible over-heating and damaging of the substrate
11	Polyamide	2	
Chromium trioxide based electroplating			
12	Satin & black anodized aluminium	2	

13	Chromium free electroplating: Chromium free electroplating: • multi-layer electroplating system of copper, tin, zinc; nickel, cobalt • gold and platinum electroplating • zinc electroplating	2	
14	Wet lacquering	2	
15	CVD (Chemical vapour deposition)	2	
16	DLC (Diamond Like Carbon)	2	
17	Nanocrystalline coating (process: HVOF, Thermal spray processes)	3	- Not seen as alternative for decorative applications - Temperature far too high (600 °C) for application on plastic parts. Layer thickness too high, no optical performance (aesthetics not sufficient)
18	Electroless Nickel plating	2	
19	Palladium/Nickel/Tin-Copper + PVD	3	- Not a stand-alone alternative, only describing an alternative multi-layer system with additional PVD - Palladium (or palladium/platinum) only as final coating instead of Metallic chrome coating from chromium trioxide - only niche application due to high costs of the final coating and the two process steps including PVD - hardness and corrosion resistance lower as Metallic chrome coating from chromium trioxide
20	Powder Coating (Pulverlack),	2	
21	Ormocere layers (Polymere)	3	• very early R&D level (research at universities / institutes), • layers are transparent
22	Stainless steel	2	
23	Trivalent chromium plating	1	
24	PVD (Physical vapour deposition): Lacquer + PVD + Lacqer and PVD	1	

25	Case hardening: Carburising, CarboNitriding, Cyaniding, Nitriding, Boronising	3	- No alternative for decorative application, these are surface treatments without any decorative aspect (high performance coatings for abrasive wear) - process is higher than ABS melting temperature – not applicable on plastic substrates - colour change due to sun and weathering
26	Hot Stamping	3	- very narrow process window concerning geometry and adhesion, even worse with additional protecting clear coat, - New parts need to be developed, optic needs to be changed, use of actual plastics raw parts not possible - Hardness and scratch resistance much worse compared to metallic chrome coatings from chromium trioxide - colour change due to sun and weathering
27	IMD (Inmould Decoration)/ IML (Inmould Layer) foil	3	- Hardness and scratch resistance much worse compared to metallic chrome coatings from a chromium trioxide New parts need to be developed, optic needs to be changed, use of actual plastics raw parts not possible, very early R&D stage - - yellowish, clouding process marks
28	Aluminium (plus preprocessing) plus clear coat (floating process)	3	- no alternative: optics not comparable, not for complex geometries, reproducibility and availability not sufficient, risk of filiform corrosion of exterior automotive parts
29	Tin-Cobalt / Nickel-Cobalt-Tin plating	3	- This is an alternative multi-layer electroplating system comprising a cobalt layer and cobalt is classified as SVHC substance
30	Aluminium coating on copper plating , followed by anodization	3	- Process is too high for plastic substrates, technically not feasible, - economically not feasible due to the numerous process steps of high costs

31	Copper plating	3	Not sufficient as stand-alone coating, aesthetic not comparable to metallic chrome coatings from a chromium trioxide electrolyte

Appendix 2. Key functionalities of chromium trioxide based electroplating per sector

(The table is non-exhaustive and its intention is not to cover all electroplating process relevant functionalities, but those which are helpful to evaluate potential alternatives and alternative coatings).

Key Functio-nality	Auto-motive exterior	Auto-motive interior	Cosmetic sector	Furniture	General Engineer-ring	Sanitary sector	Store Construct.	White Goods sector	Others (exemplarily)
Corrosion resistance	- 480 h NSST EN ISO 9227 (up to 1000 h) - up to 96 h CASS EN ISO 9227 - Numer- ous tests acc. to OEM specific a- tions such as for example Florida or Kalahari simula-tion	- 240 h NSST EN ISO 9227 - 24 h CASS EN ISO 9227	24 h SST ASTM B117	- 600 h SST EN ISO 9227 - 3 cycles (each 24 h EN ISO 6270-2 plus 1 cycle (24 h in EN ISO 9227.	*	- 300 h (> 500 h to 1000 h) EN ISO 9227 4 to 24 h CASS EN ISO 9227 - 3 cycles in Kesterni c h Test EN ISO 6988 / DIN 5001 8	*	240 h in NSST EN ISO 9227	- 96 h NSST EN ISO 9227 (wheels & castors)
Chemical resistance (resistance against cleaning agents)	No visual degrad a- tion of the coating after testing with differen t chemic als	No visual degrada-tion of the coating after testing with different chemical s	No visual degrad a- tion of the coating after testing with differe nt chemic al s	*	*	No visual degrad a- tion of the coating after testing with differen t chemic als	*	No visual degradatio n of the coating after testing with different chemicals Condensati on water test to DIN ISO 6270	No visual degradation of the coating after testing with different chemicals

Wear resistance / abrasion resistance (scratch resistance)	- Taber abrasion: 80% remain- ing gloss after 20 double strokes EN 2813 - car wash resistance ISO 20566	Taber abrasion: 10,000 hubs - further tests acc. to OEM specifications, for example Abrex or Martindale	No defects after tests on "Consumer's handbag behave-iour"	*	*	Taber abrasion: no visually detect-able damages	25000 double strokes in abrasion testing	Taber abrasion: no visually detectable damages after 500 double strokes	
Ni leaching (not toxic)	0.5 µg/cm² per week (BedGgstV)	0.5 µg/cm² per week (BedGgstV)	0.5 µg/cm² per week (BedGgstV)	0.5 µg/cm² per week (BedGgstV)	0.5 µg/cm² per week (BedGgstV)	0.5 µg/cm² per week (BedGgstV) long-term Nickel release test (EN 16058	0.5 µg/cm² per week (Bedgst V)	0.5 µg/cm² per week (BedGgst V)	0.5 µg/cm² per week (BedGgstV)
Adhesion	GT0 to GT1 (after temper a- ture cycle test) in cross-cut test EN ISO 2409 Peel resistance : > 3.5 N/cm to 9 N/cm (ABS: 7 N/cm)	GT0 to GT1 (after tempera- ture cycle test) in Cross-cut test EN ISO 2409 Peel resistance: > 3.5 N/cm to 9 N/cm (ABS: 7 N/cm)	Cross-cut test EN ISO 2409: GT0			Cross-cut test EN ISO 2409 (GT0 to GT1 (after tempera- ture cycle test)			Cross-cut test EN ISO 2409 (GT0) (electrical devices)

Sunlight resistance (UV exposure)	- 3200 h Florida simulation	- 10 exposure cycles according to ISO 75202	Simula- tion of 6 month exposure to artificial light in stores	*	*	Company specific sun tests	*	Suntest with a 1,500 W xenon lamp and 765 W/m²radiated power	
Temperature change resistance / heat resistance	OEM specification	OEM specification	*	*	Temper a- ture resistance > 750°C	5 cycles in temper a- ture cycle test according to EN 248	*	-3 cycles in temperature cycle test (each 80°C for 19 h, cooling period, -20°C for 4 h) -1 cycle in temperature shock	-3 cycles in temperature cycle test EN ISO 2409 (each 80°C for 19 h, cooling period, -20°C for 4 h) (electrical devices)
Electrical conductivi ty	Not appli c- able	Not applicable	Not applicabl e	Not applicable	High electrical conductiv ity of the surface	Not appli c- able	Not applicable	Not applicable	Not applicable
Reflection behaviour / absorption capability	Not appli c- able	Not applicable	Not appli c- able	Not applicable	The surface shall absorb and not reflect direct incident light and heat (low reflection behave- iour)	Not appli c- able	Not applicable	Not applicable	Not applicable

Aesthetics	- Surface has to be free of any kind of defects such as pores, cracks and blistering - Colour testing according to EN ISO 11664 - Finish quality (bright or matt) can be tested acc. to primordial pattern	- Surface has to be free of any kind of defects such as pores, cracks and blistering - Colour testing according to EN ISO 11664 - Finish quality (bright or matt) can be tested acc. to primordial pattern	Surface has to be free of any kind of defects such as pores, cracks and blistering after tests on "Consumer's handbag behaviour"	Surface has to be free of any kind of defects such as pores, cracks and blistering	Surface has to be free of any kind of defects such as pores, cracks and blistering	Surface has to be free of any kind of defects such as pores, cracks and blistering	Surface has to be free of any kind of defects such as pores, cracks and blistering	Surface has to be free of any kind of defects such as pores, cracks and blistering Brightness measuring	Surface has to be free of any kind of defects such as pores, cracks and blistering

** no specific quantitative values on this parameter, as other parameters are more relevant for the applications of the sector*

Support document

Applicants' comments and RAC and SEAC response to comments on the Draft Opinions on the Uses 1 to 6 of the application for authorisation

Substance name: Chromium trioxide
EC number: 215-607-8
CAS number: 1333-82-0
Submission number: JV555362-13
Applicants:
LANXESS Deutschland GmbH in its legal capacity as Only Representative of LANXESS CISA (Pty) Ltd.
Atotech Deutschland GmbH
Aviall Services Inc
BONDEX TRADING LTD in its legal capacity as Only Representative of Aktyubinsk Chromium Chemicals Plant, Kazakhstan
CROMITAL S.P.A. in its legal capacity as Only Representative of Soda Sanayii A.S.
Elementis Chromium LLP in its legal capacity as Only Representative of Elementis Chromium Inc
Enthone GmbH

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I. Context of the AfA – Legitimate Expectations – Good Administrative Practice

The applicants recognise that there are several challenging aspects to the AfA, not least the technical complexity of surface treatment chemistry and processes, the sheer number of industries which rely on chromium trioxide surface treatment or plating, the complexity of the supply chain and the various end uses (articles), and the associated assessment of alternatives. Additionally, of course the CTACSub application is the first substantial upstream AfA, meaning there is as yet limited relevant precedent in relation to several important aspects, and there was no specific guidance available at the time of development and submission of the AfA. Indeed, this is still the case.

As previously presented and known to the Committees, the CTACSub application itself was developed with close regard to all available relevant legislation and guidance at the time of submission and was found compliant by ECHA. It was discussed (including the definition of use applied for) in several pre-filing meetings with ECHA including a PSIS. The applicants had on these occasions presented their approach and definitions of use applied for. The applicants had also pointed out that a definition of use applied for per end use article would not only lead to a multiplication of uses all requiring individual AoA etc., although the critical parameters for the different uses are largely similar, but would also be practically impossible in the specific case because the plating and surface treatment industry is characterized to a significant extent by SMEs which simultaneously treat and plate parts for various customers from different use sectors, all requiring similar or largely similar technical functionalities (so- called job platers).

What's more, the AfA was finalised and submitted prior to the development of any substantial opinions by RAC and SEAC in relation to other authorisations, let alone so-called upstream applications. In this context, it should also be acknowledged that there is no specific guidance published relating to the approach for an upstream application. Also, no FAQs have been published to address the specific issues that have arisen in the upstream applications submitted to date (e.g. how to submit confidential data in case of a joint application). The applicants therefore suggest that this and any application should be assessed with clear respect to the guidance available and applicable at the time of preparation and submission. While thinking in the Committees regarding data requirements and the methods appropriate for both upstream applications and applications in general appears to have evolved in recent months, as evidenced in opinions published in recent months, this is not captured in the current guidance and was not available to CTACSub at the time the AfA was prepared and submitted.

Accepting this, the applicants also submit that technical approaches or methodologies meeting the requirements of the published guidance should be treated with equivalent merit.

Response of RAC and SEAC
Under the principle of legitimate expectations, rules of law must be clear and precise and their application must be foreseeable by those subject to them. In particular, an EU body might give precise assurances that it will act in a certain way and on which a person could legitimately rely. Under the principle of good administration, an EU body should act diligently and reasonably by avoiding, for example, unclear, inaccurate and imprecise communication. In applications for authorisation, the conformity check conducted at the beginning of the AfA review is limited in scope and does not exclude a subsequent opinion that such AfA leaves significant uncertainty justifying a short review period. The current draft opinions do not contradict the outcome of this conformity check, as these opinions support granting an authorisation, but merely conclude that the wide uncertainties raised by this AfA would justify a short review period. There has not been any assurance given to CTAC that its AfA did not raise any significant uncertainty and that a regular review period could be granted. There have been several informal and formal interactions between ECHA (including the rapporteurs) and the applicants e.g. to reduce any uncertainty. These discussions cannot prejudge the content of the opinions which may indeed evolve until the adoption of the final versions, in particular for complex issues such as this AfA. In relation to the guidance available to the applicant, ECHA notes that there were several guidance documents available at the time of preparing the application, including Guidance on the preparation of an application for authorisation, Guidance on how to develop the description of uses in the context of authorisation, Guidance on the preparation of socio-economic analysis as part of an application for authorisation, Guidance on information requirements and chemical safety assessment, and Guidance on occupational exposure estimation (https://echa.europa.eu/guidance-documents/guidance-on-reach).

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II. General comment on upstream applications and uncertainty – Legitimate Expectations, Good Administrative Practice, Equal Treatment, Proportionality Uncertainties cannot be avoided in any application for authorisation. This is why the guidance explicitly requires an uncertainty analysis. In upstream applications there is increased potential for uncertainty. The uncertainty is 'systemic'. SEAC itself acknowledges the problems of uncertainty such as broad uses across several industry sectors and inevitable variations in operating conditions between facilities in the draft opinion[1]. At the same time there is no explicit guidance to applicants on how to deal with uncertainty and to which level uncertainty is acceptable because it would be upstream systemic. How specific should scenarios be? Is it possible to work with representative data from facilities and articles? How is representativeness and reliability established? Can applicants exclude older or unreliable data in order to better represent the use applied for?

Leaving aside the unavailability of detailed guidance on upstream applications, from a practical point of view, however, it is evident that for the upstream application to work as a concept, it must be possible not only to tolerate but to deal pragmatically with uncertainty. The corollary of not doing so is that the terms of an upstream application will always be less favourable than that which can be achieved by a downstream application, conferring commercial disadvantage to those reliant on upstream authorization. These of course contain a high proportion of SMEs who cannot financially afford, handle the complexities or manage the language burden of a downstream application. These SMEs are at a clear disadvantage to larger companies who have the resources to submit individual, bespoke applications with specific technical and financial data and can therefore apparently realise longer review periods with, consequently, an improved commercial position in terms of, for example, securing long term contracts for supplying their products or external investment.

This is particularly evident in the CTACSub case, where some individual downstream users, the data of which are included in the CTACSub data set, decided to file simultaneous DU applications gaining support by the Committees for long review period recommendations, whereas the same or similar applications included in CTACSub's upstream application with the same data are faced with short draft review period recommendations. The market impact of such outcome is dramatic though because the companies in the scope of the CTACSub application, in case of shorter review periods are faced with uncertainty and are squeezed out of the market. Moreover, the majority of the SMEs currently act as toll manufacturers or suppliers (Job Platers) for larger companies that have or will file individual DU applications, destroying their SME business model. Larger manufacturing companies themselves will not invest in surface treatment due to lack of investment security. Without SME Job Platers, these companies will move from the EU over time to gain access to surface treatment.

Leaving aside the market implications and the question of equal treatment of same or similar situations, it should be emphasized again that the upstream application approach from a policy perspective provides many advantages and should therefore be the favoured approach to REACH authorization rather than to become a last resort vehicle for the unhappy few who cannot afford or do not have in-house resource or know-how to file their DU AfA. Upstream AfAs reduce administrative and financial burdens for the authorities and industry; they inherently are better designed and adequately flexible to ensure fair competition and a level playing field (all companies in the same situation obtain the same review periods, OEMs can contract different DUs ensuring flexibility of supply). Through the setting of appropriate conditions, certainty can be achieved without compromising safety.

A pragmatic approach to addressing uncertainty might involve various qualitative and/or quantitative approaches (e.g. contextual information, sensitivity analysis) or the Committees could engage independent experts or hear expert witnesses to corroborate the facts in the AfA. In the case of the CTACSub application, failing explicit guidance and instruments, the applicants' approach was to err on the side of caution by making conservative assumptions that would avoid criticism that the assessment under-represented risks or over-represented health impacts and was therefore not robust. At the same time, the applicants provided available contextual information and sensitivity analysis to demonstrate that the conclusions were highly conservative. The public consultation provides further checks on the availability of alternatives; the response to the public consultation for the CTACSub AfA was overwhelmingly supportive in this regard. A

couple of companies claimed alternatives were available, however no evidence could be provided to substantiate this and CTAC members disagreed with the claims, showing the 'alternative' technologies in question are in fact used in the manufacture of products with lower performance criteria and cannot be considered drop-in replacements. However, in spite of this very conservative approach and validation of the AoA through the public consultation, and even though SEAC concludes that the uncertainties in the CTACSub application are tolerable and RAC and SEAC reconcile in the draft opinions that the uncertainties are not considered to change the risk characterisation, the RAC and SEAC nevertheless consider the uncertainty as that significant as to propose both conditions and shorter than applied for review periods for all uses, which we perceive as an excessive "double penalty".

Given the uncertainty analysis conducted by the applicants themselves and their conservative approach, the applicants suggest that any remaining perceived uncertainty should be tackled with the least restrictive measure achieving the same aim, which is the imposition of suitable conditions rather than also a reduction of review periods.

Workable conditions rather than the shortening of the review period are the proportionate (least restrictive and suitable) instrument to deal with systemic uncertainty. Such conditions are equally suitable to achieving the same aim (protection of workers and phase out of uses in cases alternatives are deemed available) whilst maintaining business and work places in the EU. The adoption of an overall short review period would create additional cost, lead to uncertainty, supply chain restrictions and less competition in the market, unemployment and relocation. We suggest, in particular that the Committees should not consider a short review period as a positive license to continue to operate. Rather the opposite is true. A short review period is perceived as an invitation to re-location and shut-down in the EU. This is particularly the case in relation to the use of chromium trioxide in surface treatment where the substance is, to all intents and purposes, an intermediate not present on the finished article; products surface treated with chromium trioxide can be imported without restriction or risk to health and will therefore remain on the EU market in absence of technically and economically feasible alternatives.

1) For example on page 39 the draft opinion on Use 3 notes that "Ideally, SEAC would have been provided with an exhaustive list of all the applications/components covered by the use applied for in order to judge about the actual feasibility/infeasibility and to ensure that substitution takes place where already feasible. However, SEAC recognises that this is hardly possible with applications for authorisation covering such a high number of products". On page 29 the draft opinion on Use 3 states ". It is appreciated that it is difficult to define a single, specific set of OCs and RMMs suitable for all these workplaces."

Response of RAC and SEAC

Uncertainty/upstream applications: SEAC agrees that uncertainties cannot be totally avoided in applications for authorisations. SEAC acknowledged this in its draft opinions but, additionally, highlighted the fact that some of the uncertainties present within this AfA are not due to the nature of applications for authorisations themselves, but rather to the approach chosen by the applicant (e.g. the broad scope, the approach for assessing economic impacts, etc.). The committees informed the applicant about these uncertainties already during the opinion-development stage.

The applicant points out that there is no explicit guidance on how to deal with uncertainty and to which level uncertainty is acceptable because it is systemic in upstream applications.

Guidance on how to deal with uncertainty in an application for authorisation is available on ECHA's website, e.g. within the "Guidance on the preparation of socio-economic analysis as part of an application for authorisation" (http://www.echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf).

Moreover, during the opinion development process of RAC and SEAC, there was continuous exchange between ECHA, RAC/SEAC and the applicant, in which the applicant was informed about the concerns of RAC/SEAC and about present uncertainties and which kind of information is deemed necessary in order to reduce these concerns and uncertainties. In this case, the communication with the applicant was specifically intensive. Therefore, we do not agree to the applicant's claim that there was not enough guidance available on how to deal with uncertainties. In fact, RAC and SEAC pointed out many times the shortcomings of the AfA. We would like to emphasise, again, that the concerns RAC and SEAC raised in their opinion are due to the way the applicant approached its assessment, and do not relate to the nature of upstream applications themselves.

The applicant claims, that due to missing guidance and instruments (see our response to this claim above) it was decided to make conservative assumptions. The scientific committees already pointed out in their opinions that some of the assumptions made cannot be regarded as conservative, e.g. assumptions taken in the socio-economic assessment about unemployment.

Double penalty: we do not agree to the applicant's view that the conditions imposed and the recommendation for shortening the review periods are a kind of double penalty. RAC and SEAC followed the provisions of the legal text and the specific principles of the committees (e.g. for conditions as pointed out in Article 60 of the REACH regulation and for the review period as laid down in the document "Setting the review period when RAC and SEAC give opinions on an application for authorisation", https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf) when formulating their opinions. The latter document clearly points out that 7 years is regarded as the normal review period and in addition to recommending a short review period, additional conditions (and possible monitoring arrangements) could be recommended by the committees.

Short review periods: the principles for recommending short review periods for applications for authorisation are set out in the document "Setting the review period when RAC and SEAC give opinions on an application for authorisation" (https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf). Within this document, it is clearly stated which criteria lead SEAC to recommend a short review period, e.g. significant technical or scientific uncertainty related to the impacts of authorisation, the analysis of alternatives is not thorough enough in demonstrating that no suitable alternatives will become available during the normal period, etc. RAC and SEAC clearly followed these principles, when formulating their opinions.

Under the principle of equal treatment, comparable situations must not be treated differently and different situations must not be treated in the same way unless such treatment is objectively justified. Breach of the principle of equal treatment as a result of different treatment presumes that the situations concerned are comparable, having regard to all the elements which characterise them. CTAC and downstream users who have submitted an individual AfA may have submitted the same data, but there may be objective reasons to treat them differently. In the case of CTAC, the AfA/ES covers several applications, some with significant uncertainties in terms of OC/RMM and suitability of

alternatives with the risk of lower protection for human health and the environment if the review period and the authorisation conditions were set based on the safest and clearest application. Therefore, it is not clear that the draft opinions would violate the principle of equal treatment.

Independent experts or witnesses: It is up to CTAC to demonstrate their case and bring the evidence for this, not up to RAC/SEAC to engage independent experts and witnesses for that purpose.

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III. General Comments on Review Period, Good Administrative Practice

The applicants requested a review period of 12 years for Uses 2 and 4, but note that maximum review periods of 7 years are recommended by RAC due to uncertainty in relation to workers and environmental exposure and despite abundant evidence that no alternatives are available. Such concerns can be easily captured by the requirement to provide exposure information during the initial review term. We suggest that the conditions to address RAC's concerns on uncertainty on exposure / emissions be worded with the following aims:

(i) The provision of workers exposure monitoring data is based on new Exposure Scenarios that the applicants will develop based on the Good Practice Sheets they have suggested to develop.

(ii) As these Good Practices will have to be implemented – where not already done so – in the course of 2016/2017, exposure monitoring[2] should start in 2018 to establish a baseline.

(iii) To demonstrate the applicant's commitment to this process, we suggest that an interim report could be submitted to the Commission setting out the baseline exposure data against which continuous improvement will be demonstrated thereafter. This could be done for example four years after the sunset date for all Uses if the applied for review periods were maintained for all Uses.

With such conditions in place, the applicants submit that long (12 year) review periods for Use 2 and 4, in line with those requested and consistent with the clear results of the analysis of alternatives are sustainable. The approach is further discussed below at Section V.

Response of RAC and SEAC

It should be noted that the review period for Uses 2 and 4 was not only shortened because of the concerns by RAC but rather because SEAC considered that the criteria for a long review period were not met.

RAC especially recommended that appropriate exposure scenarios shall be developed and validated with measured data. RAC cannot comment on the benefits of "Good Practice Sheets" as they are not available yet. RAC notes that bullet point (iii) is addressed to the European Commission.

SEAC does not agree that the results of the AoA of Uses 2 and 4 of this AfA are clear, as suggested by the applicant in their comments. SEAC stressed in its opinion that due to the very broad scope of the use applied for, SEAC cannot exclude that there are indeed a limited number of applications where substitution is already feasible or will become so within the short-term. The applicant tried to solve this issue through stating that those applications where alternatives are already feasible and available are not covered by the AfA. Such an approach is not considered to be appropriate by SEAC. For the detailed argumentation given by SEAC, please consult the opinion text on Uses 2 and 4, chapter 7.2. SEAC's conclusion is based on the legal text, where in Article 60(4) of the REACH regulation it is stated that an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and **if there are no suitable alternative substances or technologies.** As recognised also by the applicant, there might be niche applications where substitution will become feasible in the short term. Therefore, SEAC can by no means agree to the applicants' claim that the AoA for Uses 2 and 4 show clear results.

Under the proportionality principle, legal acts must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.

In this case, it is unclear whether and to what extent the conditions (interim report after four years, etc.) proposed by CTAC would be less onerous: CTAC suggest that some sort of review of the interim report by the EU authorities (and review of measurement campaigns by enforcement authorities) would, in any case, be warranted. Further, the measures proposed by CTAC entail significant uncertainties: what would be the quality of (1) new ES to be developed by 2023, (2) Good Practices and (3) the proposed interim report? Finally, the elements in support of CTAC (risk of delocalisation) are not fully substantiated.

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As regards Uses 3 and 5, the applicants requested a review period of 7 years while SEAC has recommended a review period of 4 years. SEAC sets out that uncertainties in the application (potential technical availability of alternatives for certain end use articles) steer it to recommend a lower review period. In particular while on the one hand it finds in general technical alternatives are not available for Cr(VI), it cites "the substantial uncertainties arising from the applicant's approach (due to the broad scope, the lack of supporting evidence for claiming alternatives technically infeasible for some of the application areas within sectors covered by this use applied for and the lack of an appropriate assessment of economic costs of a non-use[3])" as reasoning for a short review period. In other words for Uses 3 and 5, the review periods suggested are caused by the 'extremely broad'[4] use applied for which would not exclude that for single applications, technical and economic alternatives would be available.

The applicants respectfully submit that this assessment is incomplete and should be corrected for two reasons: (1) as the applicants had argued in their AfA[5], many, in particular small and medium sized, companies that use chromium trioxide are so-called job platers plating for various customers from different article sectors. For them, any alternative accepted by an individual customer is not economically viable as long as not all customers accept this alternative, as no second plating line can be installed for individual applications. In Use 3 this is in particular true for furniture, white goods, and cosmetics, but also for automotive applications. Further discussion on economic feasibility is provided at Annex A. (2) Even in case trivalent chrome can be used for plating in some applications (e.g. some shorter life time sanitary applications, some automotive applications with lower functional requirements, some architectural or furniture applications with lower functional requirements), the pre-treatment (etching) of plastic substrates[6] is always conducted with chromium trioxide and cannot be conducted with another pre-treatment chemical (which therefore in itself justifies the requested seven year review period. In addition, again in the case of SMEs, even if final plating could be converted to trivalent chrome, as long as no second plating line can be installed for permit or economic reasons, the use of chromium trioxide for final plating must continue[7]. Finally, again, it has to be noted that the outcome of the public consultation did not identify available alternatives; alternatives for a limited number of products with lower performance criteria in the automotive and tool production industry were claimed. However, the applicants could confirm these products are outside the scope of the application. No information regarding alternatives or potential alternatives for any sector or product was received to challenge the findings of the AoA. Taking this together with current R&D outlook, the applicants underline their position that a 7 year review period is appropriate for uses 3 and 5.

If SEAC nevertheless maintains that, despite the job shop plater situation working for multiple end user industries and the lack of any alternative for etching of plastics, alternatives for certain end use article sectors for Uses 3 and 5 could be available within a shorter timeframe, then proportionality principle considerations would suggest that this should not lead to a shortening of the review period of the entire use applied for (this is more restrictive than necessary), but only for those end use sectors where SEAC considers that alternatives are technically and economically available (exclusion list). Hence, in such case, we suggest that it would be appropriate for SEAC to point out in its opinions those sectors in which alternatives will be available in 4 years, which would then allow the European Commission to take this into account in its final decision making process and allow the European Commission to consider and adopt a shorter review period for those niche sectors, if justified, and/or set a condition whereby the applicants would have to set out in their safety data sheets that chromium trioxide should not be used for certain end uses after a certain period of time. Alternatively, SEAC could set out in its opinions a positive list of sectors for which it considers that there is no uncertainty in relation to the non-availability of alternatives, which again would allow the European Commission to adopt a differentiated approach on review periods in its decision.

[2] Applicants offer to prepare a protocol to support consistency in monitoring and further harmonisation in exposure data

[3] The applicants do not agree with SEAC's finding that there is a lack of an appropriate assessment of economic costs of a non-use, as discussed in detail at Annex A

[4] P. 39 draft Opinion Use 3.

[5] AoA Use 3. P. 10: „Several consortium members are job platers, applying the functional chrome plating with decorative character for a variety of customers in different sectors."

[6] AoA Use 3, P. 16: "In contrast, the etching pre-treatment of plastic substrates as described below is necessarily performed in a chromium trioxide containing etching bath."

[7] AoA Use 3 p. 17: „Etching is generally performed in a single process line together with the main treatment."

Response of RAC and SEAC

In relation to the reason for the review period for Uses 3 and 5, it is the applicant's responsibility to define the scope of an AfA and the uses applied for. As explained in the SEAC opinion text, there are **several reasons** for recommending a short review period for Uses 3 and 5, not only the broad scope, such as pointed out by the applicant in its comments. For SEAC's full argumentation, please consult the opinion text. The criteria for SEAC's conclusion are laid down in the document "Setting the review period when RAC and SEAC give opinions on an application for authorisation" (https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf). The applicant again uses the argument that those applications, where substitution is already possible, are not covered by the scope of this AfA. This approach is not regarded as appropriate, as already stressed in the SEAC opinion.

In their comments on the draft opinion, the applicants explain that many companies, in particular small and medium sized companies that use chromium trioxide are so-called job platers who plate for various customers from different sectors. The applicant explains that for those companies, an alternative is economically viable only if all of his customers accept this alternative as otherwise no second plating line could be installed for individual applications by only a few customers. Whilst this claim is not substantiated by supporting evidence, SEAC finds this argument to be logical. However, as SEAC agrees to the applicant's conclusion that no overall technically feasible alternatives for chromium trioxide-based functional chrome plating seem to exist before the sunset date, alternatives are not regarded as suitable by SEAC anyhow. The short review periods recommended by SEAC for Uses 3 and 5 are mainly due to the broad scope of the uses applied for and the way the economic impacts have been assessed by the applicant, which both give rise to uncertainty.

The applicant also states that pre-treatment (etching) of plastic substrates is always conducted with chromium trioxide and cannot be conducted with another pre-treatment chemical. In Use 3, two Category 1 alternatives for the etching of plastics have been identified (mineral acid based etching and potassium permanganate based etching). Whilst the first one is disregarded completely by the applicant (no further R&D to be performed), the latter one is undergoing further R&D. However, similar to the alternatives for plating, even these most promising alternatives are still claimed to have deficiencies and further R&D is required to make them feasible. Furthermore, Use 3 also covers the electrochemical treatment of metal and composite surfaces.

Referring to proportionality principle considerations, the applicant suggests in his comments that SEAC should recommend different review periods for different end-use sectors and/or to set out in its opinions a positive list of sectors for which no to little uncertainty is present. SEAC considers this as a shift of tasks within the authorisation

scheme, as these activities are according to the legal text the applicant's duty and not within SEAC's remit. SEAC's task is to evaluate the overall use(s) applied for, the data submitted and analysis made by the applicant. Apart from the fact that it is not SEAC's task to identify the sectors in question, the applicant didn't provide the necessary data in order for SEAC to perform such an assessment, either in the original AfA, or during the opinion development process and/or the commenting phase.

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Comment received

IV. Other Comments on Individual Uses

In addition to the discussions above, certain other relevant discussions are relevant.

In regard to Use 4, SEAC notes concerns regarding the broad use and the possibility that it may include applications where substitution is already feasible or will become so at short-term as well as the diversity of the operational conditions and risk management measures (as discussed at Section V). Applicants have described that hundreds of thousands of part designs are affected for each surface treatment, and that an early substitution will only be potentially feasible for a small fraction, and even then following extensive qualification of the alternative by each OEM on a part-by-part basis with respect to its performance in respect of all critical key functionalities. This situation will not change in future; applicants agree with SEAC that due to the number of parts covered an exhaustive list (positive and/or negative) of all the applications/components covered by Use 4 is not feasible in any case. Taking this together, the applicants are of the opinion that it is not proportionate to shorten the review period to reflect the shortest possible substitution time. Considering also the measures proposed in this document to address RAC's concerns regarding the operational conditions and risk management measures, applicants believe a long review period is justified. A statement from ASD is provided at Annex B.

Response of RAC and SEAC

Please see our responses to your comments regarding the recommendation of short review periods together with operational conditions and monitoring arrangements above. These are valid for this comment on the SEAC opinion on Use 4 as well (comment II, "double penalty").

SEAC's concern with regards to the broad scope of Use 4 is explained in detail in the SEAC opinion text. The applicant was informed during the opinion development process about this concern. SEAC's acknowledgement that an exhaustive list of all applications/components covered is not feasible in this case is not an admission of the applicant's approach, but rather the conclusion that due to the way the scope was defined this is not regarded as a viable way forward. Nevertheless, SEAC emphasises that it is the applicant's duty to clearly describe what is within the scope of the AfA and what is not and to demonstrate that technical applications for which suitable alternatives are available (or becoming available in short term) are not covered by the use applied for. This aspect is unclear within this AfA and raises concern, as it increases uncertainty.

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In regard to Use 5, the AfA also covers ECCS. As set out in the AfA, the steel packaging industry has undertaken extensive research over many years towards the identification of feasible substitutes for the chromates. For the manufacture of ECCS, the results of research and development work as highlighted in the TRL and MRL timeline submitted show that it is not yet possible to switch to an alternative that can guarantee equivalent technical and economic performance. There is a clear intention of the user sector to proceed with the evaluation and implementation of relevant alternatives, but the replacement of ECCS will require extensive research work. Based on the experience in finding and qualifying an alternative for tinplate - as detailed in the tinplate Analysis of Alternatives and in the information shared in 2015 by APEAL and APEAL members to the applicant - and pre-shortening this timeframe in an ambitious manner, APEAL members estimated in the AoA to CTAC that a new R&D campaign to identify a suitable alternative and the subsequent qualification process by the can-makers would require 12 years before it can produce successful results. APEAL members agreed to shorten this review period requested of 12 years to 7 years in order to account for the versatility of the various uses grouped together. Shortening this review period further leads to such a short review period that it loses all connections with a realistic substitution dynamics for the steel packaging sector and this particular application, as highlighted in the information submitted by APEAL members. Should ECCS have been presented as a standalone Application for Authorisation, APEAL members would have requested a 12 year review period?

Response of RAC and SEAC

Please see our responses to your comments on recommending shortening of the review periods in the SEAC opinion text and above. SEAC cannot recommend individual review periods for all the technical applications covered by the use. However, it cannot be excluded that there are technical applications for which a review period longer than 4 years could be justified.

In general, SEAC would like to emphasise that the principles/criteria for recommending short, normal or long review periods are laid down in in the document “Setting the review period when RAC and SEAC give opinions on an application for authorisation” (https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf).

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Comment received

In regard to Use 6, APEAL members were surprised at the conditions attached to the draft opinion, especially those relating to environment releases. The application for authorisation was openly submitted as a "bridging" application for Use 6, i.e. for a chromium trioxide use that is in fading out mode. The current draft opinion suggests certain conditions that may not realistically be met or proven (due to detection and quantification limits) given existing facilities, noting at the same time that many releases from ETP processes are part of compound releases[8], meaning operators would need to invest substantially (e.g. separating effluent streams, with implications for substantial investment relating to treatment and monitoring) to demonstrate compliance. Significant investment or improvement of performance in this area is not to be expected prior to substitution, especially in the context that the concerned operations are directing their investments towards the implementation of the alternative to chromates. Furthermore the basis for the emission factor for release to air is unclear. APEAL members' focus is and should be to succeed in the short term substitution to an alternative and this does not seem to be reflected in certain conditions presented in the current draft opinion.

[8] I.e. Emissions from several sources at these integrated steel processing facilities are combined and released via one point. There is typically not monitoring of individual effluent streams.

Response of RAC and SEAC

There is a typing error in the emission factor to air - the correct number is 1.0×10^{-5}, which was based on the information provided by the applicants in their succinct summary of OCs and RMMs for Use 6.

It should be noted that the assessment of releases to air is based only on limited number of data from 6 sites shared across Uses 4, 5 and 6. Also, the conclusion of the negligibility of the waste water releases was not fully substantiated with the data. Therefore, RAC considers that there are uncertainties in the assessment of environmental releases and risks to humans via indirect exposure. However, RAC recognises that this is a bridging application and the intention is to substitute chromium trioxide in this use within next four years. Therefore, RAC has amended these conditions to better reflect the situation and specify that these requirements (for additional data on releases) apply only in the event that a review report is submitted for the use (i.e. in case substitution will not occur within the predicted time frame).

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Comment received

V. Comments on Conditions

Validation of Exposure Scenarios, Downstream User Monitoring (Workers, Environment)

RAC wants to link submitted exposure data to a defined set of OC and RMM and show how these represent the whole range of sites. Applicants have previously explained the associated challenges, but nevertheless would like to be supportive of this request. Having considered the request in detail, applicants are of the view that, to deliver this, a distinction

on the level of uncertainty associated with individual tasks and thus the consequences for conditions is necessary for practical reasons and consistent with RAC's aims.

In the case of the bath operations (Uses 2, 3, 4 and 5), the RAC's concern relates to the level of detail in the description of OCs and RMMs for each measurement. This can be addressed in the review reports and by annual measurement campaigns available to the local enforcement authorities. In order to agree typical "representative" applications against which best practices are elaborated, the applicants had suggested (as is recognized by RAC/SEAC and set out at Section III herein) a detailed set of OC and RMM guidance documents (Good Practice Sheets or Task Sheets). Once these representative applications have been implemented/recognised at site level, measurement campaigns as set out in the draft Opinions could be started. Once these measurements have been conducted, detailed ES can be elaborated and a baseline for continuous improvement can be set. The applicants therefore suggest a step-wise approach: (1) task sheets latest by sunset date; (2) implementation of task sheets at site level (2017/2018); (3) annual measurement campaigns starting 2018; (4) development of detailed Exposure Scenarios on the basis of the structure of the matrix of the task sheets by 2023. The applicants respectfully submit that it would not be useful to submit detailed ES before the Task Sheets will have been implemented and first measurements on the basis of this new structure will have been collected, as such early ES (by the sunset date) would not correspond to the implemented Task Sheets which should form the basis for any future measurement campaigns.

For spraying and machining applications (Use 4 and 5) RAC's concern relates to a lack of measurement data (whereas modelled data has been provided, in accordance with existing guidance). In order to attend this concern rapidly, the applicants suggest that a condition be proposed according to which measurement campaigns are conducted and results submitted to ECHA by the Sunset Date and before implementation of the Task Sheets. Thereafter, the stepwise approach for all other applications suggested above may be followed.

The applicants respectfully request that the conditions should be rephrased accordingly.

<u>Limited power of Applicants to enforce conditions in the supply chain</u>

The applicants are supportive of the requirement to monitor worker exposure and environmental releases and to validate Exposure Scenarios but note that this will need to be carried out by downstream users. Applicants can communicate requirements and support the development of methods and protocols to support consistent approaches (see the Task Sheets). Similarly, the applicants are willing to use the information gathered in the monitoring programmes to review and improve the risk management measures and operational conditions.

However, in each case, applicants are not in a position to demand such information through the supply chain, as this would lead to transparency of markets and potential release of sensitive confidential business information. The conditions should be worded accordingly. The applicants consider and are currently exploring whether – as long as the ECHA DU notification portal will not include a reporting mechanism for exposure data - to organize a third party depository of measurement information that would contract directly with the downstream users for them to deposit their measurement information.

Review Reports

The conditions stipulate the provision of specific information to be included within a review report. This includes: more detailed exposure scenarios for typical, representative plating plants, listing OCs and RMMs together with resulting exposure levels and a justification as to why the selected scenarios are indeed representative for the use; assessment of exposure through all relevant routes of exposure of man via the environment; a more detailed assessment of the uses applied for or a more specific (narrow) scope of the use applied.

Such conditions require extensive work in and across currently inhomogeneous supply chains. As discussed above, the timeframe for providing the information requested is envisaged to be 2023; a shorter review period would result in a reduced, less consistent and less robust data set.

Response of RAC and SEAC

The applicant has proposed to develop a detailed set of Risk Management Measures (RMM) guidance documents to be provided in support of their Downstream Users (DUs) by the sunset date for chromium trioxide. Under REACH, risk management guidance distributed in the supply chain to downstream users is called an exposure scenario. It is a legal obligation of manufacturers/importer of chemicals to provide such exposure scenarios for their downstream users. Therefore, those good practise sheets prepared by the applicant by the sunset date should fulfil the requirements of REACH exposure scenarios for communication in the supply chain.

RAC welcomes the applicant's stepwise approach for the collection of new exposure data and further refining exposure scenarios on the basis of new data collected after the sunset date, and expects to see the results of this work presented in review report. However, in the case of Uses 3 and 5 the schedule should be refined to fit within the review period of 4 years recommended by SEAC. In any case, it is the applicants' legal obligation under REACH to have exposure scenarios and the conditions given for a review report are related to the refinement of the current scenarios in order to improve their quality in due consideration to Annex I section 0.7 of REACH.

The applicants suggest an additional condition related to submitting of further data on exposure in spraying and machining operations by the sunset date. Since the review period was shortened mainly because of the SEAC related concerns, this additional condition would not affect the length of the recommended review period. In addition, it would require some additional review of the data by ECHA/RAC, for which there is no provision in the legislation.

RAC recognises the problems associated with the potential release of confidential business information. RAC finds the applicant's proposal for a third party depository for measurement data as an interesting idea to overcome this problem. RAC notes that CTAC itself proposes certain additional authorisation conditions that might require a similar treatment of confidential business information (e.g., measurement campaigns whose results are submitted to ECHA by the Sunset Date).

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Comment received
Additional Conditions As noted in [these comments] and previous submissions, the applicants welcome conditions to reduce perceived uncertainty associated with the authorisation in order to achieve review periods in line with that requested and reflecting the AoA. Specifically, this relates to conditions as necessary to differentiate on review periods and so ensure proportionality between applicants and uses in terms of review periods. Applicants also reiterate that they have invited conditions relating to worker exposure levels. The draft opinion recognises the applicants' intention to set a "baseline reference value or conditio sine qua". This would implicitly or explicitly constitute a condition in case the authorisation is granted. To elaborate, the applicants are confident that an upper-bound exposure level that can be achieved through implementation of good practice. Such a 'bright line' sets a clear expectation for exposure across industry, addressing the requirements for authorisation that exposure be minimised and the economic impacts of an authorisation outweigh the health impacts, while foreseeing continuous improvement in exposure. The applicants remain supportive of conditions referring to such an exposure level in order to address residual concerns by RAC regarding uncertainty relating to exposure by clearly identifying to downstream users exposure levels that are expected to be achieved. The applicants note that substantially higher occupational exposure levels are under consideration by the Commission, and such a condition would provide an additional layer of protection of worker health[9]. RAC notes it is inappropriate to endorse any specific exposure value for a non-threshold substance; however in the applicants' view a condition that requires progressive reduction of exposures and releases to as low a level as technically and practically possible within the boundaries of good practice can be provided without any such endorsement. Indeed RAC can emphasise that this is not a safe exposure level. As RAC considers that the exposure level of 2 µg Cr(VI) /m^3 as an 8 hour maximum combined individual exposure value is an appropriate starting point for the SEA, there is no technical reason to resist such a limit for surface treatment activities. This in place, residual uncertainty relates not to the requirements for worker exposure, but to the extent to which individual companies comply, as is the case for any authorisation, and can only be addressed through enforcement. [9] Given the obligation for downstream users to comply with the Exposure Scenarios and the parallel requirement to comply with European health and safety legislation that mandates, amongst other clear provisions, reduction in exposure to Cr(VI), the CTACSub application supports clear expectations for worker exposure at any facility. Facilities that rely on the authorisation may make improvements before the sunset date to comply with the Exposure Scenarios and any associated conditions. A 'bright line' would be helpful in that regard.
Response of RAC and SEAC
RAC's approach to dealing with the risk assessment of non-threshold carcinogens is through the use of dose-response data to estimate unit cancer risks. At no point has RAC been

tasked with evaluating 'practical thresholds' or to pronounce on the acceptability of any such limits. Therefore, RAC clearly does not endorse exposures of 2 µg/m^3 Cr(VI) as proposed by the applicants as being safe. RAC does however recognise the efforts of the applicants in seeking to reduce worker exposure to Cr(VI) through the various uses in its application for authorisation.

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21/07/2016		10

Comment received

VI. Presentation of the Opinion

The applicants strongly object to the presentation of cancer cases in the draft opinion.

The presentation of cancer cases resulting from exposure to man via the environment is not appropriate because the scale of conservatism in the assessment is so high that the final numbers are completely misleading.

The exposure assessment prepared by the applicants involves very conservative methods and assumptions for man via the environment, as explained in the application and subsequent responses to questions from RAC. This explanation is set out again below but for the avoidance of any doubt involved massive over-estimation of exposure levels and population exposed. The aim of the risk assessment was to demonstrate that the economic impacts of an authorised use outweigh the health impacts. As such, the exposure estimates generated in the assessment are not appropriate for use in this manner. The applicants have emphasised that levels of exposure to Cr(VI) in the environment are likely to be very low, if not negligible, in practice. Furthermore, at such low levels, there is no evidence that health effects will occur (i.e. the health effects could realistically be nil).

The presentation the cancer cases does not include any of the contextual information set out above, such that these numbers can (and likely will) be wrongly used. The applicants have already seen evidence of this in the public domain (1452 fatal cancer cases in the preliminary draft opinions rounded up to 1500 for reporting purposes)[10] [Annex C][11]. In fact it is highly likely that such numbers will continue to be exploited and miscommunicated to vilify the chromium industry. Furthermore the information, released with ECHA's endorsement, may be taken out of context to support legal action.

In the case of an upstream authorisation where it is necessary to make more assumptions to interpolate and extrapolate data, the conservatism in the assessment will be substantially greater than for a downstream application which can rely on site specific data. The publication of cancer cases allows for comparative judgments between applications for any substance that are ill-founded, technically incorrect and which will discriminate against upstream applications.

In terms of context, it is not only the conservative nature of the assessment that is relevant. There is also at present no link to the scale of the application, inviting misguided statements regarding the health impact of authorisation. Indeed even RAC refers to the [substantial health risk], whereas the health risk is very low when releases and exposure are minimised in accordance with good practice, as prescribed in the Exposure Scenarios.

A distinction has to be made between the calculation of cancer cases for the purpose of weighing economic impacts and health impacts using the dose-response relationship and monetised approach requested by ECHA and a precise and accurate assessment of likely cancer cases and the impact of making any such information publicly available with insufficient information on its provenance and guidance on its use.

In the applicants' opinion, the presentation of "estimated statistical fatal cancer cases" should not be included in the draft opinion at all. Failing agreement on that, at the very least, the opinion should be amended in such a way that the context and limitations of the estimates, as described above, are fully and clearly indicated.

Appropriate disclaimers could read 'The estimated fatal cancer cases are calculated to provide a worst case perspective of risks to health using conservative assumptions that are likely to substantially over-estimate the results by many orders of magnitude. The estimates below are not intended to provide a realistic or accurate assessment of health effects to workers or the public. `

[10] http://chemsec.org/we-can-look-into-the-future-this-is-how-we-do-it/

[11] With regard to this example, it should also be clearly stated that the total number of cancer cases (across all 6 uses) according to SEAC's calculations in the draft opinion itself is 500. This takes into account additional worst case assumptions on top of those conservative assumptions already made by the applicant. It also relates to the longer requested review period rather than the review period recommended in the draft opinion. SEAC's worst case would be <300 based on the shorter review periods, indicating a further lack of relation between the estimates and the outcome of draft opinion).

Response of RAC and SEAC

The human health impact assessment including the quantification of cancer cases is expected to part of the application for authorisation when relevant. RAC and SEAC are aware of the challenges in communicating the assessments and their results in the opinion documents. Some amendments have been made to the presentation of these cancer cases in the final opinion to better describe the purpose of the quantification.

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Comment received

Annex A

Detailed Comments

<u>All Uses: CSR, specifically MvE</u>

Despite a conservative approach and submission of over 40 case studies showing that release to water is negligible, and despite the challenges of an upstream application, the wording in the draft option is rather negative on this, stating e.g. that release to water were not incorporated into the applicants estimates of excess risk for the general population even though RAC ultimately acknowledges that exposure to MvE it is unlikely to result in a

significant under-estimation of the risk[12]. The applicants point out again that the assumptions made in the assessment of exposure to man via the environment are highly conservative. Furthermore, and notwithstanding our comments on Use 6 at Section IV, the applicants have invited a condition to restrict emissions to water in order to address concerns around releases to water.

[12] RAC notes that the indirect exposure calculated by the applicant is acceptable for risk characterisation and impact assessment but contains uncertainties.

Response of RAC and SEAC

RAC agrees that, overall, risks related to wastewater releases are likely to be small. However, RAC does not consider that the applicant's approach was conservative in this regard.

RAC does not consider that the case studies provided by the applicant showed that the releases to water of Cr(VI) were negligible; they rather showed the extent that releases did occur. RAC considers that the applicant should not have disregarded these releases in their assessment and that their significance should have been properly assessed.

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All Uses: AoA, specifically economic feasibility of alternatives

In the draft opinions (e.g. Use 5 P. 48) it is stated that "SEAC cannot conclude on the economic feasibility of alternatives due to the fact that no such assessment was performed by the applicant allowing a comparison of the alternatives on this aspect or any evaluation of economic feasibility".

According to the ECHA guidance document[13], the key criteria for the economic feasibility of an alternative is "whether the net present value of the revenues minus costs is positive." In other words, the issue is that using the alternative should result in generating gross profit". Looking further into the detail of the guidance document it is clear that the necessary cost analysis can only be conducted on a company specific basis, i.e. this is not in any case possible for an upstream application

This being so, the applicants elected to gather sector-specific data regarding the cost differences between the use of CrO3 and the respective potential alternative. The applicant collected the data from individual companies per Use and presented an average figure in the respective sections of the AoA to provide SEAC with a reasonable overview. The aim was to assess whether economic issues would be a hurdle for the affected companies to move to the potential alternative or whether possible additional costs would be in an acceptable range (in which case technical issues would be the predominant hurdle to overcome for companies to move to the potential alternative substance/technology).

For Use 2 SEAC provided in Table 13 of the Draft opinion the outcome of the applicants' assessment regarding the economic feasibility. It should be noted that none of these

potential alternatives were claimed infeasible for economic reasons. The hurdle to move to an alternative for Use 2 is clearly the technical deficiencies of the potential alternatives which have been described in detail in the AoA.

For Use 3 SEAC provided in Table 14 of the draft opinion the outcome of the applicants' assessment regarding the economic feasibility. Quantitative economic information was provided for the most promising alternatives in category 1 - Cr(III) and PVD - as far as available. The issue with new PVD technologies, as is the case for the ePD advertised by Oerlikon, is that although several CTAC members have asked Oerlikon for a concrete price offer to assess the economic feasibility, Oerlikon did not provide the requested offer to the applicants – even not until today - although it had been requested several times. This made it very difficult for the applicants to elaborate the economic feasibility for this potential alternative and necessitates questions regarding the motivation and/or ability of Oerlikon to commercialize their product.

For the category 2 and 3 potential alternatives – which have been screened out from the beginning or have clear technical limitations - only limited economic information was available to the applicants as no experience with serial production exists.

For Use 4 SEAC provided in Table 12 of the draft opinion the outcome of the applicants' assessment regarding the economic feasibility. For all potential alternatives it was stated by the applicant that economic issues are not the hurdle to change to the alternatives. For example, the AoA stated "No indication that these alternatives are not economic feasible", "in general economic feasible", "in general less costly". The technical deficiencies in combination with the outstanding qualification and certification requirements mean these cannot be considered potential alternatives. Therefore a clear statement on the economic feasibility has been provided by the applicant.

For Use 5 SEAC provided in Table 15 of the Draft opinion the outcome of the applicants' assessment regarding the economic feasibility. For all category 1 alternatives it was stated by the applicant, that economic issues are not the hurdle to change to the alternatives. For example, the AoA stated "No indication that these alternatives are not economic feasible", "Indication that these alternatives are in general economic feasible". For the category 2 and 3 alternatives - which have been screened out from the beginning or have clear technical limitations - only limited economic information was available to the applicants as no experience with serial production for the respective industry sectors exists.

In the Draft Opinions SEAC suggests in its conclusion on economic feasibility that the costs of developing an alternative could have been submitted to provide more clarity on the economic feasibility of the alternatives. During the preparation of the application, CTAC members discussed this. However, it was finally agreed not to proceed this way. R&D costs are mainly generated at OEM level and at the companies offering these alternative substances (formulators) or the respective technology provider, but financial impact of implementing the alternative substance / technology would be realised at the level of the job plater who would need to implement the alternatives at manufacturing sites. Providing R&D costs therefore would be misleading in terms of the overall economic feasibility of alternatives as R&D costs occur at a different level of the supply chain than the application of the surface treatment.

For Use 4 R&D projects from OEMs like Airbus and Boeing are described in detail in the AoA and the associated costs are in a range of many millions of Euro. However, this figure again relates only to R&D and does not provide any insight on whether the job platers supplying

the OEMs would be financially able to implement the alternative (also considering points made elsewhere about the implications for capital and operational expenditure of having to support numerous different alternative technologies supported by different companies). For this reason the R&D costs were not provided as part of the economic feasibility assessment.

Regarding Use 3, for example, R&D projects from the plastic plater group as suppliers for the automotive industry are described in detail in the AoA. The associated costs were mainly generated at the companies who offer the alternatives (e.g. Oerlikon) as they provided the coated samples which were then tested at OEMs' or applicants' sites. If these development costs would have been presented in the AoA they would not have given further insight whether the plastic platers would be financially able to implement the alternative. For this reason the R&D costs have not been provided as part of the economic feasibility assessment.

[13] https://www.echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf

Response of RAC and SEAC

As explained in detail in the draft opinions, in the assessment of economic feasibility of alternatives, not only production costs or R&D costs, but the overall costs of developing and transitioning to achieve technical feasibility could be considered. It is up to the applicant to decide on an approach, SEAC only highlighted in its opinions what an applicant might wish to consider. For most uses, the applicant makes rather general statements, such as "the alternative is generally more expensive", "electricity costs are 10 times lower", "other costs (investments, etc.) are between 2 and 8 times higher", etc. With such general statements the evaluation of the economic feasibility is not possible for SEAC. However, as SEAC agrees to the applicant's conclusion that an overall technically feasible alternative does not seem to exist before the sunset date (for details see SEAC's conclusion on each of the uses applied for in the opinion text), alternatives are not regarded as being currently (or by the sun-set date) suitable by SEAC anyhow. Further information on economic feasibility could have been provided in support for longer review periods.

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21/07/2016		13

Comment received

Use 4: AoA

In the following, statements from the Draft Opinion for Use 4 are highlighted in bold. The applicants comment are provided in normal font.

Page 44: *"However, SEAC notes that the use applied for in fact covers many specific technical applications e.g. pre-treatment, passivation processes, chemical conversion coating, chromic acid anodising including associated CrO_3 processes, sacrificial and diffusion coatings for corrosion protection, etc. which are all covered by the generic use name 'surface treatment'. The analysis of alternatives provided by the applicant does not fully differentiate between the*

various technical applications and process steps which is considered by SEAC a clear shortcoming of the analysis." and

Page 46: "Generally, it should be made clear by the applicant which technical applications are covered by the use applied for and which are not. This information allowing differentiation across technical applications was not provided by the applicant and is considered a shortcoming of the analysis."

The applicant does not agree with these statements, as the term "surface treatment" used in the use description is clearly defined in the AfA. Furthermore, the applicant made clear which technical applications are covered by the use applied for:

- Table 4 on page 14 lists all surface treatments concerned within this AfA;
- Chapters 3.2.1- 3.3.1.4 provided descriptions on all surface treatments affected;
- Key functionalities are clearly described and quantified (if applicable) for every surface treatment in table 5 (page 25);
- The assessment of alternatives is performed for every surface treatment separately, as shown in

  Table 7 (page 43, AoA) and in Table 11 on page 41 in this draft opinion.

In summary, the AoA differentiated between the surface treatments covered in the dossier and carried out a separate evaluation of the alternatives.

Page 46: ***"Nevertheless, due to the broadly defined scope of the use applied for, SEAC cannot exclude that there are indeed "surface treatment" uses or process steps using chromium trioxide, where substitution is already feasible or will become so in the short-term."***

As clearly said in the AoA, for applications that are in scope of this AfA, sector-wide substitution is not expected within the timeframe of the applied for review period. The AoA recognises that, in principle, recertification of the design may occur within review period. Indeed the aerospace industry has a substantial and widely-stated commitment to the replacement of hexavalent chromium, which requires significant investment at individual company and sector level, and some success would be expected as a result. However, it has to be emphasised that this is the exception, not the rule. The opportunity to substitute relates to individual components with generally lower performance specifications and, even here, successful substitution can take several years. It is wholly disproportionate to focus on these few opportunities for successful substitution following significant investment versus the massive challenge to substitute Cr(VI) across the aerospace industry.

Page 46: ***"Furthermore, it is not clear to SEAC when alternatives will eventually become available for specific applications within this use. Ideally, SEAC should have been provided with an exhaustive list of all the applications/components covered by use 4 in order to judge about the actual feasibility/infeasibility and to ensure that substitution takes place where already possible."***

The applicants consider that it would be neither practically possible nor helpful to SEAC to provide an exhaustive list of all the applications/components covered by use 4 for the following reasons:

- Production of aircraft or spacecraft alone requires a huge amount of parts, many of which have critical performance and safety requirements. An aircraft is composed of between 0.4 million and

  6 million parts, depending on its size. This AfA covers a multitude of parts used within the aerospace industry e.g. 280,000+ part designs for chromic acid anodizing and sealing after anodizing, 137,000+ part designs for chromate conversion coatings.

- Each component has unique performance specifications, considering a range of parameters including but not limited to size, shape and functionality.

- Each OEM has a unique set of performance requirements, including its own requirement for certification and qualification.

Key challenges in preparing the AoA for the CTACSub AfA were to identify and summarize key functionalities and corresponding requirements across this multitude of parts and OEMs and then to present a representative feasibility assessment of potential alternatives in non-specialist terminology. In practice, performance requirements for current surface treatments are set out in detailed specifications by individual OEM. These are company- and product-specific and cannot be read-across companies or products.

To restate the requirements for substitution, the AoA has been conducted on the basis of the listed set of key functionalities (see pg. 12 of the Draft Opinion). A product for which the whole set of critical key functionalities is not relevant is not within the scope of the AfA, although recognising that the relative importance these parameters varies between applications and products.

Any potential alternative technology or substance will have to be assessed against its performance for all critical key functionalities. As explained in the AoA and subsequent responses to questions from SEAC, the representative set of quantified key functionalities serves as an example specification for aerospace applications within the scope of the AfA. This set serves as the base for a first level screening. However, the relevant decision on the feasibility of any potential alternative needs to be made on a case by case basis. This requires significant investment and resource per component-application combination. Due to the multitude of parts and individual specifications involved it is not practicable to carry out a comprehensive second level screening within the AoA or to compile an exhaustive list for this AfA.

The representative requirements for the key functionalities were chosen to help in conveying the bigger picture. Most of the potential alternatives are eliminated at a first screen against these criteria. None of the potential alternatives tested is currently able to fulfil the specific needs of the aerospace sector for applications that are in the scope of this AfA against the quantifiable requirements, as reflected in the overall low maturity of most candidate alternatives as described in the AoA. Even where testing on the first screening level is successfully completed, extensive further testing over many years is required to develop and implement the potential alternative on the individual specification level. Still at this stage, severe failures can occur when testing under conditions more relevant to in-service and design aspects is carried out.

Most importantly, public safety is paramount and the aerospace sector has set its performance standards and specifications for chromate replacements to reflect equivalency

to chromate performance in order to maintain the industry's very high and long-standing safety record.

Page 46: "According to the applicant, applications where substitution is already possible are not covered by the application anyhow. The applicant does, however, not specify such applications or their related technical requirements. SEAC finds the applicant's approach to resolve this issue not fully appropriate and emphasises the need to ensure that substitution takes place where indeed already feasible. This could have been achieved by undertaking a more precise and use-specific assessment of alternatives.

Page 65: "According to the applicant, the requested 12 years coincide with estimates by the aerospace industry of the schedule required to industrialise alternatives to chromium trioxide. However, due to the way the scope of the use applied for was specified, SEAC cannot exclude that it may cover applications where substitution is already feasible or will become so at short- term."

As already emphasized, the AfA is an upstream application covering uses of a substance that is very widely used in the EU at hundreds of sites for aerospace applications.

Based on this upstream supply chain, covering a multitude of companies and parts and the requirements of the certification and qualification process, it is obvious that the developmental status of alternatives will vary throughout the sector. It has been explained that substitution will only occur or could be expected to occur within the review period applied for in the case of a few components in specific applications for individual OEMs. The applicant wants to reemphasise that, depending on the particular surface treatment, at least 137,000+ part designs are affected, and that an earlier substitution can only be expected for a tiny percentage of this.

Response of RAC and SEAC

SEAC notes that the applicant provided in his AoA for Use 4 a table that gave an overview of surface treatment processes indicating the most important application methods, the purpose and example products. The applicant informed SEAC that this is not an exhaustive list. Furthermore, SEAC notes that the applicant described key functionalities for different surface treatment steps. Due to this assessment, SEAC stresses in its opinion that overall the applicant's AoA is regarded as extensive, especially when it comes to the aspect of technical feasibility. This is highlighted in SEAC's conclusion in chapter 7.1 of the SEAC opinion. However, SEAC needs to evaluate the availability and suitability of alternative substances and/or technologies **related to the use applied for**, which is defined by the applicant as the use of Chromium trioxide in **surface treatment** for applications in the aeronautics and aerospace industries, unrelated to functional chrome plating or functional chrome plating with decorative character. As already pointed out above (and in the SEAC opinion text), the defined scope within this AfA is broad also for Use 4. This raises uncertainties. In addition to the uncertainties present in the assessment of alternatives, also the assessment of impacts (human health impacts, economic impacts, etc.) is surrounded by uncertainties. This was highlighted by the committees throughout the whole opinion-development process. SEAC in detail explained its reasons for recommending a normal review period for Use 4 in Chapter 10 of its opinion text as we do not see the criteria for recommending a long review period being fulfilled.

Date	CTAC	Comment number
21/07/2016		14

Comment received

Annex B: ADS comment

Short review cycles are damaging to business certainty affecting business decisions, such as whether to invest, or where to invest. This point is crucial for chemicals where alternatives cannot be substituted in all applications for the foreseeable future. The length of the review period should be driven by the availability of alternatives, and not be a penalty for the difficulties of data gathering which arise from the complex downstream supply chain.

Instead, Exposure Scenarios in the chemical safety report, combined with the downstream user obligations in REACH Articles 37(5) and 66, is therefore the primary, and most effective, control for chemical safety under an Authorisation.

Response of RAC and SEAC

Currently, there are 3 standard periods for RAC and SEAC when recommending the review period: a short review period of 4 years, a normal review period of 7 years and a long review period of 12 years. From the starting point of the normal review period, there are specific criteria laid down in the paper “Setting the review period when RAC and SEAC give opinions on an application for authorisation” (https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf), which the committees apply when recommending review periods. For all 6 Uses covered by this AfA, Section 10 of the opinion text explains in detail why specific review periods are recommended by the scientific committees. The final decision is taken by the European Commission in comitology procedure.

SEAC agrees that the suitability of the alternatives is one of the main aspects to consider when recommending review periods. The possibility of alternatives becoming suitable for certain uses covered by the AfA is considered in Section 10 of the opinion text.