Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Chromium trioxide use: Functional chrome plating

ECHA/RAC/SEAC: AFA-O-0000006490-77-02/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

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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11-2120088250-61-0011
11-2120088250-61-0012
11-2120088250-61-0013

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 a simple majority.

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 the risk 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 **seven 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 the 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, Agreed at RAC-27).

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?

Short description of the use

According to the applicant, the use applied for relates to functional chrome plating, which generally involves the use of chromium trioxide in one or more of a series of treatments to deliver a surface coating that can be of unlimited thickness, but is typically between 2µm and 5 mm thick. Functional chrome plating is a wet process within which treatment solutions and rinsate are recirculated in a closed loop with an increased process temperature. The main form of application is by dipping or immersion of parts in an electrolysis 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 6,000 tons/year corresponding to 3000 tons/year as Cr (VI). According to the applicant, the use may be conducted at up to 1,590 sites in the EU.

The applicant presents one exposure scenario (ES) in the Chemical Safety Report (CSR): Functional chrome plating, with one environmental contributing scenario (ECS) and 18 worker contributing scenarios (WCS).

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 this application (up to 1,590 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+ consortium members 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. According to the applicant, many sites only provided static measurement data. 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 ART 1.5 model for WCSs 2-7, 16 and 18. Input parameters for the model were provided in the CSR. OCs and RMMs for each WCS are presented in Table 2. For WCSs 8-15 exposure assessment is based on measured data for Cr(VI) in air from 23 companies performing functional chromium plating. These measurement data, provided by the applicant at the request of RAC, are summarised in the Annex to this opinion (Table A1).

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	Name of the scenario	Duration and frequency of exposure	Concentration of the substance	LEV used	RPE** used + effectiveness	Other RMMs
WCS 1 (PROC 1)	Delivery and storage of raw material	< 8h	Cr(VI) < 50%	no	no	basic general ventilation, closed system
WCS 2 (PROC 8b)	Decanting – liquids	< 60 min	Substantial (10-50% Cr (VI))	no	No	good natural ventilation and enclosure of the material transfer
WCS 3 (PROC 8b)	Decanting and weighing of solids	< 60 min	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)	Mixing liquids	< 15 min	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)	Mixing solids	< 15 min	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)	Re-filling of baths – liquid	< 10 min	Cr(VI) in mixture: Substantial (10-50)	yes	no	good general ventilation
WCS 7 (PROC 8b)	Re-filling of baths – solid	< 10 min	Cr(VI) in mixture: Substantial (10-50%)	yes	Yes, at least half mask with P3 filter, with APF 30*	good general ventilation
WCS 8 (PROC 4)	Functional chrome plating – loading of jigs	< 8h	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation

Contributing scenario	Name of the scenario	Duration and frequency of exposure	Concentration of the substance	LEV used	RPE** used + effectiveness	Other RMMs
WCS 9 (PROC 13)	Functional chrome plating – chemical pre-treatment	< 8h	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)	Functional chrome plating – by dipping and immersion	< 8h	Cr(VI) in mixture: Substantial (10-50%)	yes	no	basic general ventilation
WCS 11 (PROC 13)	Functional chrome plating – rinsing/drying	< 8h	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation
WCS 12 (PROC 13)	Functional chrome plating – chemical post-treatment	< 8h	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)	Functional chrome plating – cleaning and unloading of jigs	< 8h	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation
WCS 14 (PROC 8b)	Functional chrome plating – cleaning of equipment	< 1h	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation
WCS 15 (PROC 8a)	Maintenance of equipment	< 60 min	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation
WCS 16 (PROC 15) :	Laboratory analysis subactivity: Drawing of sample and transfer to laboratory	< 30 min	Cr(VI) in mixture: Substantial (10-50%)	LEV used for sampling	no	good general ventilation

Contributing scenario	Name of the scenario	Duration and frequency of exposure	Concentration of the substance	LEV used	RPE** used + effectiveness	Other RMMs
WCS 16 (PROC 15)	Subactivity: Laboratory analysis	< 60 min	Cr(VI) in mixture: Minor (5-10%)	no	no	basic general ventilation
WCS 17 (PROC 1)	Storage of articles	< 8h	Cr(VI) not detectable in article	no	no	basic general ventilation
WCS 18 (PROC 8b)	Waste management	30 min	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 (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 3 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 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 in case of potential for exposure to chromium trioxide are required for all WCSs except WCS 17 (Storage of articles).

The main activities with potential for exposure to Cr(VI) during functional chrome plating are the sequential process steps involving immersion and rinsing of parts in Cr(VI) containing baths (WCSs 8-15). Although tasks related to functional chromium plating 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 functional 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 for each WCS are presented in Table 3.

Table 3: Worker exposure –inhalation

Contributing scenario	**Route of exposure**	**Method of assessment**	**Exposure value** µg Cr(VI)/m^3	**Exposure value corrected for PPE** µg Cr(VI)/m^3
WCS 1	Inhalation	Qualitative	0	
WCS 2	Inhalation	ART 1.5	0.69	
WCS 3	Inhalation	ART 1.5	1.5	
WCS 4	Inhalation	ART 1.5	0.17	
WCS 5	Inhalation	ART 1.5	0.12	
WCS 6	Inhalation	ART 1.5	1.1	
WCS 7	Inhalation	ART 1.5	0.073	
WCS 8 to WCS 15	Inhalation	Measured data	Combined for WCS 8-15: • arithmetic mean: 1.68* • geometric mean: 0.7 • 90th percentile: 1.42	Combined for WCS 2-8: • arithmetic mean: 1.55 • geometric mean: 0.41 • 90th percentile: 1.42
WCS 16	Inhalation	ART 1.5	0.69	
WCS 17	Inhalation	Qualitative	0	
WCS 18	Inhalation	ART 1.5	0.22	

**Of 23 companies reporting data, the distribution of aggregate inhalation exposure values taken mainly in one year between 2010 and 2013 (1 to 35 measurements each) was as follows: 2 companies > 5; 0 companies 2 to 5, 7 companies 1 to 2; 9 companies 0.5 to 1 and 5 companies <0.5 µg Cr(VI)/m^3.*

The exposure estimate for bath operations (WCS8-15) is derived from the measurement data provided by 23 companies of the consortium from different European countries; Germany, France, The Netherlands, Italy, Spain, Sweden and UK. These data are presented in Table A1 of the Annex to this opinion. The data is based on personal measurements (n=94, 23 companies) conducted in these companies over the period 2010-2013. The plating processes represented by the measured data were mainly open, manual processes with LEV in place, in some cases exposure was controlled by the use of mist suppressant. No further information on OCs or RMMs in place was available. The 90th percentile of these measurements was 1.42 µg Cr(VI)/m^3. In addition, static measurement data are also available from these companies, which the applicant considers support the personal measurement data. However, these data were not made available for RAC, because the applicant felt that preference should be given to personal measurement data.

The effectiveness of respiratory protection was taken into account by the applicant using company-specific information on type of mask and filter used or, if available, the Assigned Protection Factor (APF) provided by the manufacturer of the RPE. In other cases, the 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 could clearly 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. In the case of use 2, this adjustment did not, however, result in any change in the value of the 90th percentile of the exposure data.

To support the reported measurements, data from the literature is also presented (Annex, Table A2a and A2b). RAC notes that although average exposure levels presented in the literature are in the same range as the levels collected by the applicant, also higher exposure levels are 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 in functional chromium plating is 24,6 µg Cr(VI)/m^3.

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 at 12 sites (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 annex, table A4). The exposure modelling estimates varied between 0.27 to 130 µg Cr(VI)/m^3. 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 were covered. The high exposure level of 130 µg Cr(VI)/m^3 is, however, not supported by the measured data either provided 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. Overall, the modelling results can be considered to support the measured data.

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 lowest level of protection through operational conditions (OCs) and RMMs 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 claim 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 the number of parts being treated. As a general rule, sampling once per day or shift is mainly needed in companies with mass production.

It is assumed that the regular maintenance of the baths and related equipment (e.g. LEV, rectifier, pumps, panels etc.) will take 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 represent a worst-case exposure estimate for regular maintenance activities. According to the applicant, if maintenance is needed during the process, often RPE is used. A separate WCS for these situations is not provided. WCS 15 is also said to cover infrequent maintenance activities with longer duration. A separate WCS for these situations is not provided in the case of use 2. 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 up to 4 hours. The exposure estimate (modelled using ART 1.5) for this task is 0.25 µg Cr(VI)/m^3 (the estimate takes the low frequency into account). According to RAC, a separate WCS for infrequent maintenance activities should also have been included in use 2. 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 in the functional chrome plating process 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, according to the applicant, the exposure estimate of 1.42 µg Cr(VI)/m^3 (as 8 h average) applies also to maintenance workers (WCS 15). RAC notes, however, that in small enterprises it is likely that the same workers would be involved in all operations.
- 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 of the supervisor or by the supervisor.
- The most likely combination of tasks for single 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 2 of 1.60 µg Cr(VI)/m^3, under the assumption that these are daily activities.

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	0.073
WCS 8-14 (-15)*	Inhalation	1.42
WCS 16 (sampling		0.11
Total exposure for 8 hours	Inhalation	1.6 ** (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 (WCS 15) 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 2.*

***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 Cr(VI)/m^3, 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 Cr(VI)/m^3.*

Uncertainties related to the exposure assessment:

The number of potential workplaces in the EU performing functional chromium plating is estimated by the applicant to be up to 1,590. The applicant bases the exposure assessment of plating activities on the measured data from 23 companies from seven European countries. However, supporting modelled data was also provided (for this use only). Although in general the most recent literature data supports the applicant's estimate of a maximum individual exposure value of 2 µg Cr(VI)/m^3, 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 2 µg Cr(VI)/m^3.

Lack of detailed description of OCs and RMMs linked to the presented exposure data is a weakness of the assessment. While it is appreciated that it is difficult to define a specific set of OCs and RMMs suitable for all these 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.

Some uncertainties are related to the combined exposure assessment and the frequency of different ancillary activities. In the response to RAC questions the applicant states 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 then this will happen not 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 assuming that this is the case in all sites, the contribution of these tasks to total exposure is low due to low frequency.

There are also some 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 was used as a worst-case estimate. Based on the available data, RAC cannot verify the conservativeness of this assumption, especially in cases in which maintenance is needed during the on-going process. 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 2. 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) Cr(VI)/m^3 (estimate takes low frequency into account). According to RAC, this should also have been included also in use 2.

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 exposure. It should be noted that many other countries 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 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 did not provide an exposure assessment for waste disposal when contracted out to specialised companies. 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

[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)

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 measurement data from 17 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 were 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 17 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 $Clocal_{air, ann}$ (mg Cr(VI)/m^3)	AM (mg Cr(VI)/m^3)	GM (mg Cr(VI)/m^3)	90th percentile (mg Cr(VI)/m^3)
17	2010-2013	4.14×10^{-6}- 2.69×10^{-9}	9.58×10^{-7}	3.83×10^{-7}	2.85×10^{-6}

Note: Regional air concentrations of chromium trioxide, based on modelling with EUSES 2.1.2, are 1.7×10^{-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 2.85×10^{-6} 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

[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)

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 was 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 x 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 A2 in the Annex to this opinion.

The applicant also provided data on the concentration of Cr(VI) in wastewater for 10 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 Cr(VI)/L. The available wastewater monitoring data is included in Table A5 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 x 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 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. One of these three sites was involved in the functional chrome plating.

Alongside this information the applicant also clarified which uses were conducted at each of the 44 sites from which data was provided. Seventeen of the 44 sites (2, 3, 4, 5, 6, 11, 16, 21, 22, 23, 24, 28, 29, 33, 37, 38, 39) were reported to undertake functional chrome plating with five of these sites (5, 6, 11, 16, 39) reporting no emissions to wastewater. Release factors or effluent monitoring information were reported for nine of the 12 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 Table A5 of the Annex to this opinion.
Air	0.001%	Estimated from C_{local}, 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	1.7 x 10^{-15} mg/m^3 (regional exposure) estimated by EUSES 2.1.2. 2.85 x 10^{-6} mg/m^3 (local exposure 90th Percentile)
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 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), and 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 emissions of Cr(VI) to water are "negligible" and that it was therefore appropriate to exclude these releases 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 from 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 nine from a maximum of 1,590 sites across the EU reported to undertake this 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 this route of exposure should be more comprehensively addressed 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 17 companies (representing 11% of CTAC members and approximately 1% of the functional chrome plating industry in the 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 $C_{local\ air,\ ann}$ 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 $PEC_{localair,ann}$ 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*

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 electrolytic plating process is based on measured data from 23 companies (representing less than 2% of companies performing functional chrome plating and 26% of the actual CTAC members reported for Use 2). In addition, literature data on occupational exposure in functional chrome plating is available as well as modelled data provided by the applicant. Although these data generally support the applicant's exposure estimate of 2 µg Cr(VI)/m^3 (that the applicant claims as the maximum individual exposure value), there is also clear evidence of up to an order of magnitude higher exposures.
- For ancillary activities, e.g. decanting and mixing of solids and liquids and maintenance, 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 the general population, the assessment is based on measured data from 17 companies (representing 11% of CTAC members and approximately 1% of the functional chrome plating industry in the 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.

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."

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 using the RAC reference dose-response relationship for the carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1). The applicant has conservatively assumed that all inhaled chromium trioxide particles are in 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 functional 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 functional 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. 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 Cr(VI)/m^3 in functional 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 has been assessed by using modelled data for ancillary activities and by measured data from 23 companies for functional chromium plating operations. A general estimate on 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 some 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 an 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 18). According to this data, only 33% of workers are exposed for 6-8 h/day, 10% are exposed for 3-6 h/day, 9% are exposed for 1-3 h/day and 19% are exposed for less than 1 h/day. In addition, 29% 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). RAC considers that the representativeness of this data across the whole field of industry – about 1,590 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 undertaken using 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 x 10^{-2} per µg Cr(VI)/m^3 for 70 years of exposure (24 h/day, 7 d/week).

For a the local population living in the vicinity of chromium plating plants the applicant calculated an excess individual life-time lung cancer risk of $8.27*10^{-5}$. 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 indirectly via the environment

ECS	Inhalation route	
	Exposure level (µg Cr(VI)/m^3)	**Excess risk**
ECS1, local exposure	2.85×10^{-3}	8.27×10^{-5}
ECS1, regional exposure	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 a limited number of data points and does not incorporate any risks via oral exposure. 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 1.3-2 × 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 exposure data clearly linked to specific OCs and RMMs for representative operations, including e.g. automatic versus manual, open versus closed, 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 on 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 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 applicant's exposure assessment (related especially to the representativeness of the presented data) RAC considers that in the human health impact assessment (HHIA) also a 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 included. 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 process of functional chrome plating using chromium trioxide, a surface treatment process that involves depositing a layer of metallic chromium on the surface of a metallic component (e.g. steel, hardened steel, titanium alloys, nickel alloys, copper alloys, aluminium, bronze). For this use, 6 000 tonnes per annum of chromium trioxide are used. The chrome coating provides the component with specific characteristics, such as high mechanical and wear resistance, excellent anticorrosion performance, a low coefficient of friction, adequate layer thickness, anti-stick properties, etc. The applicant describes how the process is specified for particular applications, where this combination of performance characteristics is critical. It is therefore used for technical applications or in specific technical parts that must perform under demanding conditions, e.g. under high temperatures, repetitive wear and mechanical impact. Functional chrome plating using chromium trioxide such as covered by use 2 is applied in different sectors: the aerospace sector, automotive and general engineering (e.g. agricultural machinery, trucks, forklifts), for printing equipment (printing cylinders of rotogravure printing processes), etc. Examples of chromium plated parts within these sectors covered by use 2 are provided by the applicant in table 10 below (taken from the Socio-Economic Analysis for use 1, non-confidential report).

Table 10. Examples of applications and industries in which chromium trioxide formulations are used and such as covered by use 2

Functionalities and applications	**Main industrial sectors**
Electroplating process providing: ➢ Adaptable layer thicknesses of 2 – 5,000 µm ➢ High hardness, a minimum of 700 HV is generally required (exception 1,100 HV in rotogravure printing) ➢ High resistance to wear (e.g. for products exposed to mineral / inorganic material or to fibres) ➢ Corrosion resistance and resistance to chemicals ➢ Low friction and tribologically advantageous ➢ Resistance to temperature ➢ Anti-adhesive ➢ Machinable and repair possible	➢ Aerospace and defence (e.g. jet turbine engine parts, landing gears) ➢ Steel industry, manufacturing of steel (e.g. moulds and rollers) ➢ Printing industry (e.g. printing cylinders) ➢ General Engineering (e.g. paper manufacturing and processing, machinery, tools and machine parts - plated or re-plated-, and hydraulics) ➢ Automotive (e.g. shock-absorbers, piston rods in cars) ➢ Other uses (e.g. sugar sieves, textile manufacturing and concrete pumps, oil

The applicant describes how they carried out an extensive literature survey and a consultation of the companies of concern to identify and assess potential alternatives to chromium trioxide in functional chrome plating. All in all, 18 potential alternatives were identified. The applicant classified those into 3 categories (see also Appendix 1 – Masterlist of alternatives):

- **Category 1:** 8 alternatives that are considered promising, where considerable R&D efforts have already been carried out within the different industry sectors, these are: *electroless nickel plating, nickel electroplating, case hardening (carburizing, carbonitriding, cyaniding, nitriding, boronizing), thin and thick chemical vapour deposition (CVD), nanocrystalline cobalt phosphorus alloy coating, high velocity thermal process, trivalent hard chromium, physical vapour deposition (PVD)*
- **Category 2:** 4 alternatives with clear technical limitations, which may only be suitable for a limited number of applications but not as a general alternative, these are: *plasma spraying, general laser and weld coating technology, stainless steel, thermal spray coatings, mineral acids (for pre-treatment)*

- **Category 3:** 6 alternatives have been screened out at an early stage of the analysis and are not applicable for the use applied for, such as *ion implantation, iron-phosphor coating, plastic coating, chromium III ionic liquids, cobalt-tin plating, zinc-based materials*

6 out of these 18 substances could be excluded from further assessment based on the fact that they are not applicable for the uses covered by this application for authorisation, i.e. these are classified as category 3 alternatives. The remaining 12 alternatives (processes as well as substances) are in the focus of ongoing R&D programs. These 12 alternatives were further assessed by the applicant with the conclusion, that 8 out of the 12 have been identified as promising alternatives, i.e. they are classified as category 1 alternatives and are further evaluated in the application. The remaining 4 alternatives showed clear technical limitations. According to the applicant, they may only be suitable for a limited number of applications, but not as a general alternative (category 2) for the use applied for.

The applicant concludes that none of the alternatives is technically feasible for key applications within the use applied for. During the last 30 years, intensive research was carried out in order to identify and develop viable alternatives to chromium trioxide in functional chrome plating. The applicant describes how challenging and complex it is to replace chromium trioxide based plating in applications that demand superior performance (technical characteristics needed, such as wear and corrosion resistance, hardness, layer thickness, coefficient of friction, etc.). Several potential alternatives (those classified into category 1) are under intense investigation across industry sectors, some are qualified for specific applications but none of them is able to meet all the performance requirements of functional chrome plating with chromium trioxide. The review period requested for this use (12 years) coincides with best case (optimistic) estimates by all industry sectors (aerospace, automotive and general engineering, steel, metal precision parts, manufacture of printing equipment) of the required time to industrialise alternatives to chromium trioxide for functional chrome plating for key applications.

Technical feasibility

Chromium trioxide in functional chrome plating delivers specific technical characteristics which are key requirements in different steps of the surface treatment process (pre-treatment and main coating process). Functional chrome plating can be applied on a variety of surfaces including steels, stainless steels, nickel based alloys, copper alloys, aluminium alloys, titanium alloys, etc. The key functionalities for functional chrome plating were identified by the applicant during the consultation process he carried out. They take into account the whole surface treatment process but the most important key functionalities of the high-quality final product are related to the chromium trioxide based electroplating step, which results in a high-end wear resistance and hardness of the coating. The key functionalities of chromium trioxide based surface treatment are wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, effect on surface morphology. The sector specific key functionalities of metallic chrome coatings are summarised by the applicant in table 11 (taken from Analysis of Alternatives, non-confidential report).

Table 11. Sector specific key functionalities of metallic chrome coatings

Quantifiable key functionality	Aerospace	Automotive and General engineering	Steel	Metal precision parts	Manufacture of printing equipment
Wear resistance	Not generally defined	< 5-10 mg /10,000 U	< 10 mg/ 10,000 U	Not quantitatively measured	Not quantitatively measured
Hardness	700-900 HV	850-1,200 HV	850-1,000 HV	1,100 HV	1,000-1,400 HV
Layer thickness	> 100 µm	20-50 µm	Depends on application	15µm	5-25 µm
Corrosion resistance*	SST: > 750 h	SST: 100–500 h	Depends on application	Not quantitatively measured	Not quantitatively measured
Coefficient of friction	< 0.2	< 0.1	Not generally defined	< 0.2	Not quantitatively measured

*There are different standardised SST tests available which vary between sectors, applications and substrates. An important quality criterion is given by the hours to resist certain test conditions. In addition, the results of corrosion resistance tests are evaluated using a rating scale between 10 and 1 (10 representing the best rating and no corrosion). The required minimum rating also varies between the different industrial sectors; thus comparability of sectors is limited: a rating of 10 after a 100 h SST test may be comparable to a rating of 4 after 500 h.

As stated above, the applicant identified 8 alternatives which are considered as promising candidates to replace functional chrome plating with chromium trioxide in the future (category 1 alternatives). At present, these alternatives still show technical deficiencies, which are summarised by the applicant in table 12 (taken from Analysis of Alternatives, non-confidential report).

Table 12. Technical deficiencies of category 1 alternatives by sector

	Alternative	Aerospace	Automotive & General engineering	Steel industry	Metal precision parts	Manufacture of printing equipment
1	**Electroless nickel plating**	- corrosion resistance - hardness - layer thickness - process conditions	- corrosion resistance - hardness - wear resistance - friction	- hardness - layer thickness - wear resistance - coefficient of friction	- hardness - corrosion resistance - endurance	- anti-adhesion - hardness
2	**Nickel and nickel alloy electroplating**	- hardness - coefficient of friction - wear resistance - microstructure	- hardness - wear resistance - microstructure	- hardness - coefficient of friction - morphology - wear resistance	- wear resistance - hardness - corrosion resistance - plating bath conditions	- anti-adhesion - wear resistance - hardness
3	**Case hardening**	- corrosion resistance - coefficient of friction/ lubricity - process temperature - hardness (depends on substrate)	- corrosion resistance - rebuilding of parts - coefficient of friction - anti-stick properties - hardness (depends on substrate)	- corrosion resistance - rebuilding of parts - hardness (depends on substrate)	- corrosion resistance - rebuilding of parts - hardness (depends on substrate)	- hardness - rebuilding of parts
4	**(Thin) CVD**	- corrosion resistance - process temperature - layer thickness - Large geometries	- size limitations - process temperature - corrosion resistance	- size limitations - process temperature - process time	- layer constitution - suitability for the sectors' products	- size limitations - process time - process temperature
	Thick CVD (aerospace)	- process temperature - size limitation				
5	**Nanocrystalline cobalt phosphorus alloy coating**	- hardness - layer thickness	- hardness	- uniformity - hardness - adhesion (for Ni-W-Plating)	- corrosion resistance - hardness	- anti-adhesion - hardness - wear resistance
6	**High velocity thermal processes**	- geometry - wear resistance (depends on the coating, loads, wear	- brittleness - geometry - process temperature	- brittleness - reproduction of surface	- process temperature - surface conditions	- homogenous surface/ porosity - constant thickness

		mechanisms and the counterparts) - corrosion resistance (depends on the coating) - hardness (depends on coating)				
7	**Trivalent functional hard chromium**	- microstructure - process maturity - layer thickness	- hardness - wear resistance - layer thickness - endurance - microstructure	- roughness/ microstructure - hardness - adhesive strength to substrate - layer thickness - corrosion resistance	-microdistribution - layer thickness - hardness	- scale up - stable process conditions
8	**PVD**	- corrosion resistance - layer thickness - wear resistance - longevity/ fatigue - coefficient of friction (depends on process)	- process temperature - layer thickness - corrosion resistance - geometry - rebuilding of parts	- brittleness - geometry - internal stress - layer thickness - rebuilding of parts	- layer constitution - geometry - brittleness - internal stress	- wear resistance - geometry - process temperature

The applicant assessed each of these 8 alternatives against the above mentioned technical criteria (such as hardness, wear resistance, coefficient of friction, etc.). In addition, a specific assessment for the sectors concerned (specific requirements in the aerospace sector, in the automotive and general engineering sector, for steel, metal precision parts, etc.) was carried out. The applicant's overall conclusion is that the analyses show that currently there are no technically feasible alternatives to functional chrome plating with chromium trioxide for key applications. Several potential alternatives are subject to ongoing R&D, but these do not yet support the necessary combination of key functionalities in order to be considered technically feasible. Based on experience and with reference to the actual status of R&D programs, alternatives are not foreseen to be commercially available for key applications and pre-treatment before 12 years after the sunset date.

In the public consultation, comments supporting the conclusion of the applicant on technical feasibility were submitted. But comments were also submitted by third parties claiming alternatives being feasible and available (e.g. nitrocarburizing (gas or liquid)). These technologies were already part of the applicant's assessment, i.e. no complete new technology was introduced by third parties during the public consultation. The issue was discussed further between the applicant, third parties and RAC & SEAC rapporteurs. 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 (based on technicalities). This explanation shows that the alternatives claimed feasible by third parties are:

- applied as a **parallel technology** to hard chrome plating for parts **which have not been functional chrome plated before**
- (partially) **already implemented as a substitute** to functional chrome plating (components with lower technical requirements, **not being part of the scope of the application**)
- considered **being an alternative** to functional chrome plating **in the future** (within the 12 years review period requested). The applicant however claims that nitrocarburizing would be a potential future alternative only in max. 5% of the applications within use 2
- **not considered being an alternative** to functional chrome plating before the sunset date (and not within the 12 years review period requested) for the other 95% of the applications within use 2

Additionally, the applicant provided examples for the above listed 4 categories together with specific feedback and a clarification regarding why they do not consider these alternatives suitable. However, due to the broad scope of this use applied for and the fact that numerous applications are covered by the use, SEAC recognises this list of examples of articles/application areas as not being an exhaustive one.

Economic feasibility

Economic feasibility aspects have only been provided for category 1 alternatives (those considered promising of being a substitute in the future). The applicant states that due to the fact that all of the above mentioned category 1 alternatives show significant technical failures, no quantitative analysis of the economic feasibility was performed. Only a very rough estimate and broad considerations about whether costs are expected to be higher/lower is included in the application for authorisation. 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. Generally, the applicant concludes that the overall costs for alternatives (due to investment, process costs, etc.) are expected/reported by industry sectors to be higher than those for functional chrome plating with chromium trioxide. Table 13 summarises the information on economic feasibility.

Table 13. Summary of the information provided by the applicant on economic feasibility of the alternatives

Alternative	Economic feasibility considerations
Electroless nickel plating	• Ni is generally more expensive • Ni baths maintenance costs are 7 times higher • Electricity costs are 10 times lower
Nickel electroplating	• Ni reactants are more expensive • Electricity costs are 4 times lower

	• Other costs (investments, etc.) are between 2 and 8 times higher • Particularly significant cost for printing sector
Case hardening (carburizing, carbonitriding, cyaniding, nitriding, boronizing)	• Cost factor is about 3 times higher
Thin and thick chemical vapour deposition (CVD)	• CVD processes include relatively high costs because it is a complex technology that requires a vacuum chamber. The costs for the equipment are indicated to be $1-2 million for the coating system, with additional costs for pre- and post-treatment • Aerospace sector: a general economic assessment is not possible because the process costs depend on nature of component (batch process), energy consumption and chamber size. Costs for thick coatings may be competitive for parts with complicated geometry for which thermal spray coatings would be unsuitable • General engineering sector: costs are 3 times higher for the thin CVD process. Costs are even higher for thick CVD due to longer deposition times • Steel industry also reports higher costs related to higher energy consumption that is required to heat up work rolls (substrate) • Printing industry: stated that vacuum chambers that are large enough for the several meters long rotogravure equipment lead to high production and investment costs. The price per preparation of the cylinder surface was roughly estimated to be 16 – 80 times higher compared to functional chrome plating
Nanocrystalline cobald phosphorus alloy coating	• Relative process costs of nano Co-P plating are reported to be slightly (1.3 times) higher
High velocity thermal process (HVOF)	• The implementation of high velocity processes requires complex machines and infrastructure equipment. The installation costs for completely new plant and machine lines comprise €75,000-200,000 for equipment, €75,000 for the robot and€ 200,000 for the room, that is in total €350,000 to 475,000 • Overall, the cost factor of HVOF is 5.4 times higher • The general engineering sector states that although production costs of HVOF plating are “several times higher” • The aerospace industry expects that the production costs for HVOF are significantly higher which is due to higher equipment costs increased by set-up costs for each part, and higher costs for post-treatment (grinding and polishing). Divergence of costs are expected to be even higher for complex parts

Trivalent hard chromium	• All in all, similar costs (equivalent costs for chemicals, lower electricity costs, lower waste treatment and ventilation costs, higher production costs)
Physical vapour deposition (PVD)	• The installation costs for a completely new plant and machine lines are estimated to be about $ 1-3 million for the coating system, with additional costs for cleaning lines • Overall, the cost factor of PVD is 3.4 times higher

Conclusion

The applicant has made an extensive assessment of alternatives, especially when it comes to the aspect of technical feasibility. All in all, 18 potential alternatives were identified, assessed and classified into the above listed 3 categories (see also Appendix 1 – Masterlist of alternatives). This categorisation gives a good overview about why certain alternatives were considered further and why others have been excluded from any further assessment. For those alternatives considered promising to be a substitute in the future (category 1 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.

A very brief discussion, mainly qualitative, and broad considerations on economic feasibility were provided. No assessment was performed allowing e.g. 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 thorough assessment on economic feasibility makes it impossible for 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 functional chrome plating with chromium trioxide 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 12 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 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 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.

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, 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, 18 potential alternatives were identified, assessed and classified into the above listed 3 categories (see also Appendix 1 – Masterlist of alternatives). This categorisation gives a good overview about why certain alternatives were considered further and why others have been excluded from any further assessment. The alternatives mentioned in the comments submitted during the public consultation were already discussed by the applicant in his assessment.

Nevertheless, due to the extremely broad scope of this use applied for, SEAC cannot exclude that there are indeed a limited number of applications where substitution is already feasible or will become so at short-term. In fact, it is not clear to SEAC when alternatives will eventually become available for specific applications. Ideally, SEAC would have been provided with an exhaustive list of all the applications/components covered by use 2 in order to judge the actual feasibility/infeasibility of alternatives 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 numerous applications are covered by this use, this list cannot be considered exhaustive. 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 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 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 12 different alternatives to chromium trioxide used for the purpose of functional chrome plating in a number of sectors, such as aerospace, automotive & general engineering, steel, metal precision parts and manufacture of printing equipment. Pre-treatment using chromium trioxide has been assessed separately. However, the analysis of alternatives shows that there are no technically feasible alternatives to functional chrome plating with chromium trioxide for key applications (before the sunset date). Several potential alternatives are subject to ongoing R&D, but do not currently support the necessary combination of key functionalities to be considered technically feasible alternatives. Therefore, a detailed risk assessment of the alternatives to facilitate a comparison with chromium trioxide has not been conducted, the only hazard information provided by the applicant was the 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.

- Alternative 1: Electroless nickel plating
- Alternative 2: Nickel and nickel alloy electroplating

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 3: Case hardening: carburizing, carbonitriding, cyaniding, nitriding, boronizing

Based on the available information on the substances used within this alternative, sodium cyanide, is classified as Acute Tox. 2, Acute Tox. 1, Eye Dam. 1, Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1. Furthermore, carbon monoxide is classified as Press. Gas, Flam. Gas 1, Acute Tox. 3, Repr. 1A, STOT RE 1. As such, transition from chromium trioxide – which is a non-threshold carcinogen – to one of the above mentioned alternatives would constitute a shift to less hazardous substances. However, some of the proposed alternative substances are also under observation regarding their toxicity. Therefore, each replacement has to be carefully evaluated on a case by case basis.

- Alternative 4: Chemical vapour deposition (CVD)

Based on the available information on the substances used within this alternative, aluminium oxide, as the toxicological worst case, is classified as STOT SE 3, Acute Tox. 4. Although RAC notes that aluminium has a long biological half-life in humans and there are concerns on the effects of cumulative aluminium exposure on the central nervous system

(Vesa Riihimäki and Antero Aitio: Occupational exposure to aluminium and its biomonitoring in perspective; In: Critical Reviews in Toxicology; 42(10): 827-853; 2012), a transition from chromium trioxide to one of these substances would constitute a shift to less hazardous substances.

- Alternative 5: Nano-crystalline cobalt phosphorus coating

Based on the available information on the substances used within this alternative, cobalt dichloride, as a worst case, is classified as Acute Tox. 4, Skin Sens. 1, Resp. Sens. 1, Muta. 2, Carc. 1B, Repr. 1B, Aquatic Acute 1, Aquatic Chronic 1. While this substance is currently not included in the candidate list, other cobalt compounds are on the REACH candidate list for substances of very high concern. As such, transition from chromium trioxide to one of these substances would not constitute a shift to significantly less hazardous substances.

- Alternative 6: High velocity thermal process

Various different powder materials are used for high velocity processes, for which data on some substances is regarded as confidential business information by the applicant. As an example, the hazard profile from an often-used coating material (WC-12Co,) is classified according to the suppliers SDS as Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Carc. 2. As such, transition from chromium trioxide – which is a non-threshold carcinogen – to WC-12Co may not constitute a shift to a significantly less hazardous substances.

- Alternative 7: Trivalent chrome 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 needs careful consideration as to whether it constitutes a shift to less hazardous substances.

- Alternative 8: Physical vapour deposition (PVD)

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 9: Plasma spraying
- Alternative 10: General laser and weld coating technology

See alternative 6 for information.

- Alternative 11: Stainless steel and high speed steel (HSS)

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, according to the CLP criteria, 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, chromium oxide surface of the stainless steel limits the release of constituent metals from the stainless steel matrix and no carcinogenic effects resulting from exposure to stainless steels have been reported, either in epidemiological studies or in tests with animals. Since the exact process of stainless steel coating and exact composition of the alternative substance is not known, an assessment regarding the overall risk to human health and the environment is not possible. The transition from chromium trioxide plating to the use of stainless steel may result in lowering of the overall risk although it should be noted that the production process of stainless steel includes steps resulting in the exposure of workers and MvE to hexavalent chromium and nickel.

- Alternative 12:Thermal spray coating

See alternative 6 for information

During the trialogue meeting with the applicant, ECHA and the Committees rapporteurs, information was given by third parties on alternative techniques to functional chrome plating. These included Pulsed Plasma diffusion (PPD), IONIT OX processes and liquid nitrocarburizing (CLIN – Cold Liquid Carbon Nitriding). PPD was presented as an innovative technology that includes a combination of hydrogen, nitrogen and electricity to produce an environmentally friendly and cost-effective alternative to hard chrome plating. The IONIT OX process combines thermochemical processing, gas nitrocarburising, plasma activation and oxidation and uses ammonia and carbon dioxide process gases with a controlled chemical decomposition for formation of nitrides and carbonitrides. The third party informed that these were proven alternatives to hard chrome plating. CLIN is based on the chemical reaction between diffused nitrogen into the surface of the ferrous metal and the carbon from appropriate sources and gives from 0 to 40 µm thin compound layer.

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

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:

Based on the limited hazard assessment of alternatives a transition from chromium trioxide to some of the 12 substances included in the assessment would for a limited number of alternatives (alternatives 4, 7, 8 and 11) constitute a shift to less hazardous substances.

Conclusion

RAC therefore concludes that, as some of the alternative substances are subject to further regulatory scrutiny due to possible concern over their risk to human health and the environment, any replacement 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.

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 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 being 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 per year following the applicant's approach and SEAC's alternative approach.

Table 14. 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)	
					12 y	**1 y**
Workers – Combination of WCS	<1	0.25	0.001	4,392	1.32	0.10
	1-3	0.75	0.003	2,062	1.86	0.16
	4-6	1.5	0.006	2,289	4.12	0.34
	6-8	2	0.008	7,608	18.26	1.52
	Not regularly exposed	0.25	0.001	6,577	1.97	0.16
Workers total				22,928	27.53	2.29
	Exposure 24h (µg/m³)				**12 y**	**1 y**
Man via environment - Local	2.85×10^{-6}		8.27×10^{-5}	10,000 x 1,590 sites = 15,900,000	225.42	18.78
Man via environment - Regional	Not relevant					
Total					**252.94**	**21.08**

Table 15. 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)	
					12 y	**1 y**
	Up to 8	2	0.008	16,351	39.24	3.27
	Not regularly exposed	0.25	0.001	6,577	1.97	0.165
Workers total				22,928	41.22	3.43
	Exposure 24h (µg/m³)				**12 y**	**1 y**
Man via environment - Local	2.85×10^{-3}		8.27×10^{-5}	10,000 x 1,590 sites = 15,900,000	225.42	18.78
Man via environment - Regional	Not relevant					
Total					**266.63**	**22.22**

The estimated additional statistical fatal cancer cases reported in Tables 14 and 15 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 the 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 2 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 the members. According to the applicant this approach has substantially overestimated the health impacts. Most of the cancer cases (more than 90% for use 2) are related to the exposure of the population via the environment.

- **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)m^3). 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 (12 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 €80 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 (15,900,000 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 12 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 €651 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. At 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 exact number of sites and workers affected, the different exposure durations for workers, etc. 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 15 above. For the calculation of human health impacts for workers, using sensitivity values for VSL, this results in monetised impacts of €119 million instead of €80 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.

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 14) which results in human health impacts in the amount of €354.3 million – 730.8 million.

Table 16. Human health impacts according to the applicant's approach

Monetised health impacts, workers	€38.6 million - €79.6 million
Monetised health impacts, man via environment (local)	€315.7 million - €651.2 million
Total:	€354.3 million – €730.8 million

Scenario 2: SEAC's alternative (worst case) approach (2 different exposure duration groups, see table 15), which results in human health impacts in the amount of €373.7 million – €770.7 million.

Table 17. Human health impacts according to SEAC's approach

Monetised health impacts, workers	€57.8 million - €119.1 million
Monetised health impacts, man via environment (local)	€315.9 million - €651.6 million
Total:	€373.7 million – €770.7 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 100m 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 12 years exposure for workers and humans via the environment, the figures range between 253 and 267 statistical fatal cancer cases. These should be considered in the context of the wide scope of the application, covering 22,928 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 more than 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. Furthermore, the applicant described the efforts they had made to collect additional information and explained briefly 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) and due to other confidentiality aspects within the consortium. 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 shutdown** or a **complete shutdown of production facilities**, a **relocation of production facilities to non-EEA countries** as well as **subcontracting to non-EEA suppliers.** This means e.g. that job platers and in-house platers won't be able to carry out their business any more. They are expected to shut down their production lines in the EEA and cease the delivery of chrome plated parts. 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. They are expected to shut down their business activities. The consequence for actors further down the supply chain, such as article manufacturers, assemblers and end-user companies of functional chrome treated parts and components, is that they fulfil their demand for chrome plating services at non-EEA suppliers. They will possibly also relocate parts of their assembly lines to non-EEA countries. For some industry sectors, such as the printing industry, a non-authorisation is claimed to have devastating effects, as e.g. European rotogravure printers will have to shut down their production completely. Due to price and time pressure, highly skilled workers being required in production, transport difficulties, etc. relocation of the functional chrome plating of printing cylinders is not regarded as being an option for this sector. According to the applicant the supply chain will change from the use scenario illustrated in Picture 1 to the non-use scenario illustrated in Picture 2.

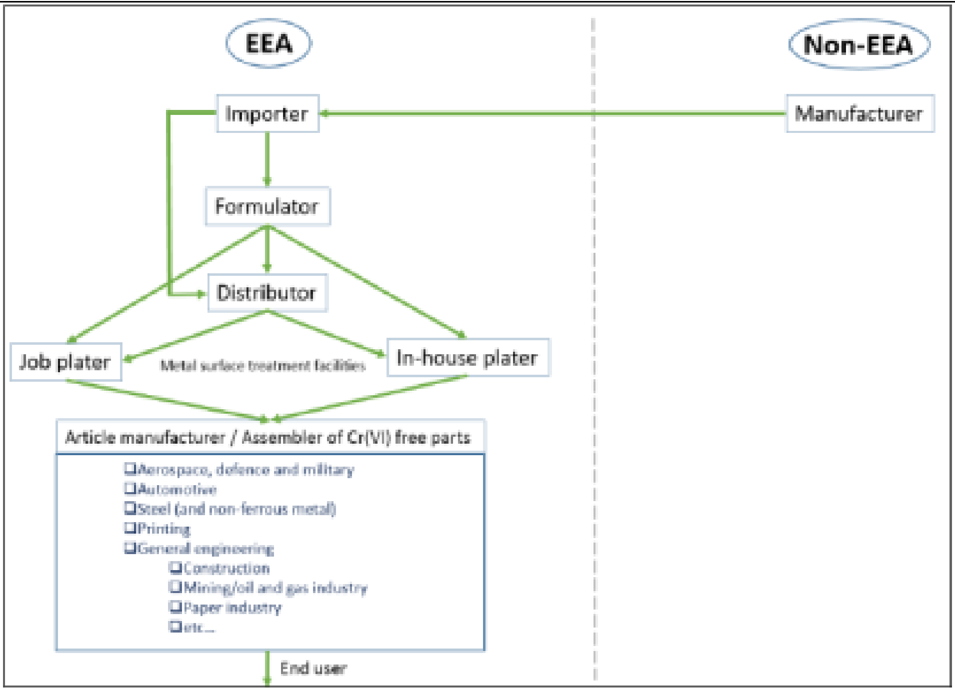

Figure 1. Generalised supply chain in the use scenario

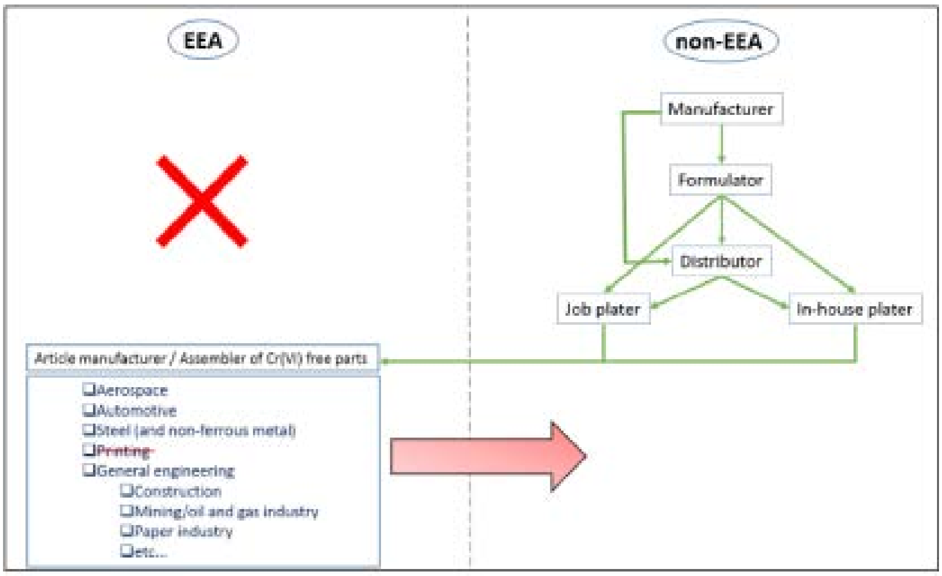

Figure 2. Generalised supply chain in the non-use scenario

Furthermore, the applicant provides information on sector-specific challenges (qualification, certification, industrialisation of alternatives) and consequences of the non-use scenario, esp. for the justification of the requested 12 years review period for the following sectors: aerospace industry, automotive industry, steel (and non-ferrous metal) industry, manufacture of printing equipment, metal precision parts and functional chrome plating for general engineering applications.

- **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 to 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 (12 years) or will replace another unemployed person in case of re-employment. The present value of the total social impacts for a period of 12 years (requested review period) sum up to €7,939 million, reflecting a loss of 23,205 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. The calculations are based on purchase losses of companies that carry out surface treatment to their European suppliers. 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 €649 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, the shut-down of facilities employing 23,205 people would result in profit losses of €186 million per year.

- **Impacts in the supply chain**: During the opinion-making process, on request of SEAC, the applicant provided case studies showing the impacts on downstream users within different sectors in order to complete the assessment of social and economic impacts as described above. For several sectors, profit losses, revenue losses, loss in turnover and/or the value added foregone was estimated, as described below and summarised in table 16.

  The applicant states that the annual turnover for the **European Aviation, Space and Defence** industries is €197 billion. According to the applicant a minimum of 50% of the turnover would be lost if authorisation is not granted. This is claimed to be a very low estimate as the substance is needed for thousands of components which will lead to substantial consequences not only for new products, but also for refurbishment and repair in the aftermarket. The turnover is assumed to be lost for a minimum of 12 months which results in €99 billion. Furthermore, assuming an average profit of 10% of turnover, the profit loss as a result of not granting the authorisation is estimated at €9.9 billion per year.

Airlines and flight operators rely on daily maintenance, repair and overhaul (MRO) activities in order to maintain the permission to fly and to fulfil the required safety aspects. Based on expert consultations, every day about 5,000 aircraft inspections take place, and 6,100 engine parts and 2,500 aircraft components are overhauled in Europe. In the applicant's view a conservative assumption that 20% of these parts rely on chromium trioxide would mean that 1,700 parts a day depend on the authorisation of chromium trioxide. Airplanes would need to stay grounded in case daily MRO activities can't be performed any longer. The applicant quotes a study published by IATA[5] of the impact of Eyjafjallajokull's volcanic ash plume in 2010[6], which states that at the peak, airlines lost US$400 million revenues a day, as aircraft had to stay grounded (claimed by the applicant to be the same situation in case chromium trioxide cannot be used anymore) and more than 1.2 million passengers were affected every day. European airlines represent approximately 70% of lost revenues. At the peak of the ash plume 75% of the European airline operations had been down. The applicant concludes that a non-granted authorisation would affect 100% of the European airline operations, therefore a daily loss of approximately US$375 million revenues for European airlines can be estimated. This is equivalent to €280 million per day or €102 billion per year.

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[7] 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 billion.

The applicant gives similar information also for other affected sectors. The results are summarised in table 18 below.

[5] International Air Transport Association

[6] https://www.iata.org/whatwedo/Documents/economics/Volcanic-Ash-Plume-May2010.pdf

[7] EBIT = Earnings before interest and taxes

Table 18. Summary of the case studies performed for use 2, functional chrome plating

Case study	Economic impact [€ billion] (see Annex SEA 1 for detail)	Metric
Aviation, space and defence industry	9.9	Profit loss (per year)
Airlines	102	Revenue loss (per year)
Automotive sector (OEMs and suppliers)	46.3	Value added foregone (per year)
Hydraulic cylinders	0.72	Value added foregone (per year)
Gravure printing industry	5-18	Value added foregone (per year)
Steel	7.5	Profit loss (per year)
Genaral engineering	46.2	Turnover loss (2 months)

On SEAC's request, the applicant provided an overview of the share of different affected sectors within the use applied for (see table 19). Although the applicant states 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 job platers might do chrome plating for different end-uses. Additionally variations in market shares and stock building might further distort this classification.

Table 19. Overview of the market shares of different sectors in the supply chain

Sector	**Share**
Military and aerospace	2.8 %
Automotive	35.1%
Mining/oil gas industry	3.3%
Printing Industry	11.5%
Energy	0.1%
Sanitary	0.1%
Furniture	0.3%
General engineering	10.6%
Food industry	0.5%
Steel industry	2.3%
Textile	0.7%
Others/ unassigned*	7.4%
Hydraulics	25.1%
Medical and pharma	0.2%
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:

  -> 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 lack clarity and transparency, e.g. when it comes to the representativeness of data used (the applicant explains that e.g. only between roughly a third and half of the CTAC member companies consulted 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, a large amount of different sectors, 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. E.g. for some actors 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 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, and any other relevant actor). Furthermore, it would have been interesting 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 the 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 (12 years) or will replace another unemployed person in case of re-employment) are regarded by SEAC as 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 €186 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. Even though the supplementary 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 costs and benefits

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 use 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 €186 million per year
- The social cost of job losses of €753 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 sectors such as the aviation, space and defence industry, airlines, the automotive sector, the hydraulic cylinder sector, the gravure printing industry, the steel industry and general engineering.

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 duration groups. 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 €354.5 to €770.7 million for the 12 years review period requested for. 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 €354.5 and €770.7 million, calculated over 12 years (potential overestimation)
- Possible profit losses of €186 million per year based on information submitted by the applicant on turnover/profits of job platers
- Expected social costs of €753 million due to job losses (lower bound of potentially affected workers assumed to be unemployed for 1 year) based on salary costs
- Expected significant negative impacts in the supply chain for different affected industries, such as aviation, space and defence, airlines, automotive, hydraulic cylinders, gravure printing, steel and general engineering

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 the expected profit losses (based on information from the applicant on profits of job platers) or the 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

<u>Description for additional conditions and monitoring arrangements for the authorisation</u>:

Exposure scenarios

RAC takes note of the applicant's proposal 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 objectives 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 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 to 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 the 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 and be available to national enforcement authorities. 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).

Updated, representative exposure scenarios, supported by measurement data, presented in a review report may remove the current need for monitoring requested for this authorisation.

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 ES (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) 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 (…. _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 considers that the review period should be no longer than seven years.

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 12 years review period, due to feedback from industry on estimates of the schedule required to industrialise alternatives to chromium trioxide mixtures used in functional chrome plating. Additionally, specifications of affected sectors, e.g. the aviation (legislative requirements) and automotive sector (certification schemes) are explained. The 12 years review period reflects the standard long review period of ECHA. However, the applicant in principle requests a longer review period than 12 years. SEAC agrees to the applicant's conclusion that currently, an *overall* technically feasible alternative for chromium trioxide-based functional chrome plating for key applications doesn't seem to exist. 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

- **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 will 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 continued use of chromium trioxide in functional chrome plating. 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. regarding 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 253 to 267 considering a 12 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 continued use of chromium trioxide for functional chrome plating 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 criteria for recommending a long review period[8], 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 schemes as well as legislative requirements within different industries, the unlikeliness that alternatives will overall become available in the short run, etc.), 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 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 would lead to significant 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 12 years,
- the expected negative economic consequences down the supply chain,
- the expected social costs due to unemployment,
- the expected human health impacts,

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

- the uncertainties arising from the applicant's approach (due to the broad scope and the lack of an appropriate assessment of economic costs of a non-use),
- that the criteria for a long review period have not been met,
- RAC advices to SEAC a review period no longer than 7 years,

SEAC recommends a normal (7 years) 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.

ANNEXES

Table A1. Calculations based on aggregated company/site data Use 2

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
A	0.55	1	1	2013	yes	manual	no
B	0.82	6	2	2010-2011	yes	manual	yes
C	0.50	1	1	2012	yes	manual	yes
D	0.40	8	2	2012	yes	manual	partially
E	1.00	1	1	2012	yes	manual	nr
F	0.07	35	9	2013	yes	manual	nr
G	0.27	5	5	2013	yes	manual	no
H	17.50	4	2	2013	yes	manual	no
I	1.22	1	1	2012	yes	manual	no
J	0.69	2	2	2013	yes	manual	partially
K	0.70	4	4	2011-2013	yes	manual	no
L	0.43	2	2	2012	yes	manual	no
M	1.10	3	1	2013	yes	manual	yes
N	0.09	2	2	2012	yes	manual	nr
O	1.43	36	36	2000-2013	yes	manual	yes
P	5.10	2	2	2011-2012	yes	manual	nr
Q	0.63	6	6	2013	yes	manual/automatic	no
R	0.95	5	5	2012	yes	manual	no
S	0.60	6	4	2011	yes	manual	no
T	1.23	3	3	2012	yes	manual	nr
U	0.70	1	1	2012	yes	manual	yes
V	1.40	1	1	2013	yes	manual	yes
X	1.29	1	1	2013	yes	manual	no
Total		136	94				

*Not adjusted for use of respiratory protection

This specific data on use 2 comes from CTAC companies in France, Germany, The Netherlands, Spain, Italy, Sweden and UK.

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)
CTAB Sub Use 2**	2000-2013	23	110	>400					1,68		1,42 (4,7)	
CTAB Sub Use 3**	1999-2013	23	40	>80					0,88		3,07	
CTAB Use 4/5/6**	1999-2013		40						1,16		2,94	
CTAB 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 following countries: France, Germany, Italy, 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 functional 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	2.37×10^{-6}**	3
7	<1	45	6.67×10^{-6}**	1,4,5
38	1.2	40	3.00×10^{-6}**	2
37	1.65	42	3.93×10^{-6}**	2
3	2	30	6.67×10^{-6}**	2
2	4	36.2	1.10×10^{-5}**	2
19	5	0.15	3.33×10^{-3}**	4
18	11	2.05	5.37×10^{-4}	4,5
17	31.7	0.16	1.98×10^{-2}**	4,5
4	50	15	3.33×10^{4}**	2
15	152#	16.36	9.29×10^{-4}	4
25	175.5	15	1.17×10^{-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 waste water treatment plant prior to discharge to surface water, which will further 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 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 waste water (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 314g 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 $5x10^{-8}$ 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 (selection process)

Section	Alternative Substance / Alternative Process	Category	Screened out because
7.1	**Electroless nickel plating** /nickel-tungsten, nickel-boron, nickel diamond composite, nickel-phosphorous, nickel-polytetrafluoretyhlene; Ni-SiC /NiP-PTFE	1	
7.2	**Nickel & nickel alloy electroplating** /ickel-tungsten-boron, nickel-tungsten- silicon-carbide, tin-nickel, nickel-iron- cobalt, nickel-tungsten-cobalt, nickel tungsten, Fe-Ni-Cr /disperse nickel electroplating in bath containing a.o. $NiSO_4$, MoO_3 and SiC	1	
7.3	**Case hardening** (carburizing, carbo nitriding, cyaniding, boronizing, nitriding) /plasma diffusion: plasma nitriding, nitrocarburizing, low pressure nitiriding /explosive hardening	1	
7.4	**CVD (thin & thick)** /Chemical Vapour Deposition (CVD): TiN, WC, ZrN /Plasma enhanced Chemical Vapour Deposition Coating (PECVD)	1	
7.5	**(Nano) Co-P plating** /cobalt electrolysis /(Nano) Co-P plating	1	

7.6	**High velocity thermal processes** /HVOF CrC-NiCr, WC-Co, WC-Co-Cr, Co-Cr-Mo, Mo /HVAF /detonation spraying /CoCrMo commercially available product (by HVOF or plasma)	1	
7.7	**Cr(III) based processes**	1	
7.8	**PVD** /Physical Vapour Deposition (PVD) techniques: Cr, CrC, CrN, MoS2, SiC, TiAlN, TiN, WC-C:H, ZrN, Zr oxides, organic zirconates	1	
Section	**Alternative Substance / Alternative Process**	**Category**	**Screened out because**
	/DLC (PVD technique)		
7.9	**Plasma spraying**	2	
7.10	**Weld and Laser processes** weld coatings /electro spark alloying (tungsten carbids, Co-based alloys) /explosive bonding /plasma powder welding torch laser alloying and laser cladding (NiC)	2	
7.11	**Stainless steel & HSS**	2	
7.12	**Thermal spray processes** /arc Spraying /cold gas spraying /flame spray coating -wire flame spraying -powder flame spraying /molybdenum thermal sprayed coatings	2	

-	**Ion Implantation**	3	Ion implantation is not working as stand-alone replacement for functional chrome plating as no additional layer is applied and the surface is not rebuilt to its original layer thickness and rebuilding parts can thus not be reworked. In addition, the process has to be conducted under vacuum conditions which is not feasible for large parts.
-	**Iron-phosphor coating**	3	Salt spray tests for iron phosphor coatings showed decomposition of the layer leading to severe substrate corrosion.
-	**Plastic coating**	3	Plastic coating was mentioned as alternative to copper coating with functional chrome plating in gravure printing. Early R&D coating tests showed insufficient performance for hardness. This significantly reduces the maximum amount of copies to 200,000. Furthermore, plastic coatings cannot be engraved with the traditional method using diamonds and existing alternative engraving methods are not compatible. Plastic coatings do not withstand shape cutting as the material is too brittle.
-	**Chromium III ionic liquids**	3	R&D ongoing regarding alternative for decorative applications but not for functional chrome plating.
-	**Cobalt-tin plating**	3	Cobalt-tin plating is mainly used for decorative applications and not for functional chrome plating.
-	**Zinc-based materials** (zinc, zinc-tin, zinc-aluminium, zinc-nickel based passivation, non-electrolytic zinc plating)	3	Zinc is a “soft” metallic material with hardness values below 450 HV and therefore not a metallic chrome coating alternative. Zinc-based coating materials show insufficient performance in corrosion and wear resistance, and the coefficient of friction.