Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Chromium trioxide use: Surface treatment (except passivation of tin-plated steel (ETP)) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering (unrelated to Functional chrome plating or Functional chrome plating with decorative character)

ECHA/RAC/SEAC: AFA-O-0000006490-77-05/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:

Surface treatment (except passivation of tin-plated steel (ETP)) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering (unrelated to Functional chrome plating or Functional chrome plating with decorative character)

Intrinsic property referred to in Annex XIV:

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

Applicant:

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

Reference number:

11-2120088250-61-0028
11-2120088250-61-0029
11-2120088250-61-0030
11-2120088250-61-0031
11-2120088250-61-0032
11-2120088250-61-0033
11-2120088250-61-0034

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

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

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

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

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

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

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

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

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

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

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

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

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

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

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

The draft opinion of SEAC was agreed by consensus.

The opinion of SEAC

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

THE OPINION OF RAC

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

RAC has formulated its opinion on: the risks arising from the use applied for, the appropriateness and effectiveness of 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 **four years**.

JUSTIFICATIONS

The justifications for the opinion are as follows:

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

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

2. Is the substance a threshold substance?

- ☐ YES
- ☒ NO

Justification:

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

3. Hazard assessment. Are appropriate reference values used?

Justification:

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

The molecular entity that drives the carcinogenicity of Chromium trioxide is the Cr(VI) ion, which is released when the substances solubilise and dissociate.

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 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 an overestimate.

In the socio-economic analysis (SEA) the remaining human health risks are evaluated based on the dose-response relationship for carcinogenicity of hexavalent chromium

(RAC27/2013/06 Rev.1).

Are all appropriate and relevant endpoints addressed in the application?

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

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

Description:

Short description of the use

According to the applicant, the use applied for relates to the surface treatment (except ETP) for applications in various industry sectors: architectural, automotive, metal manufacturing and finishing, and general engineering. The application includes, among other, processes that convert the surface of an active metal by delivering a barrier film that provides various critical functions, including protecting the metal from corrosion, providing resistance to wear by increase of the hardness of the surface or an adhesive base for subsequent painting or bonding, or a chemical polish, and/or colouring the metal. The processing surface can also be a plastic that needs to be activated. The application includes a variety of processes like etching, pickling, passivation, chemical conversion coating, grain-oriented electrical steel insulation, electrolytic chrome oriented steel, chromatic anodising, sacrificial coating, diffusion coating and paint for corrosion protection.

The main form of application is dipping or immersion of parts in a tank, or through a series of tanks, containing solutions in closed or open systems. However, the solution containing Cr(VI) additionally is also applied by spraying and occasionally, by brush or with a pen-stick, the latter especially to small, localised areas.

In addition, treated surfaces may be machined by various means.

The amount of chromium trioxide involved is stated by the applicant to be (combined for use 4 and 5) 1,000 tonnes/year corresponding to 500 tons/year as Cr(VI). According to the CSR the use described in this application may be applicable to more than 100 sites in EU (in SEA the number of 515 sites in EU has been given).

The applicant presents one exposure scenario (ES) in the chemical safety report (CSR): Use at industrial site – Other surface treatment, with 1 environmental contributing scenario (ECS) and 36 working contributing scenarios (WCS).

It is important to recognise that the final chromium coating does not contain chromium trioxide or any other Cr(VI) substances. Some residual Cr(VI) may however still be present, while the tasks described in the WCSs 31-34 (machining operations) are performed.

Worker exposure

Exposure estimation methodology:

Introduction: RAC noted the discrepancy in each use applied for, including this one between a) the total number of potential sites which the applicant (organised in the Chromium Trioxide REACH Authorization Consortium – CTAC) considers may be covered

by the application (Use 4/5: >100 sites or 374 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.

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

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, in particular for Uses 4/5. Significantly, the applicant also reports that when it 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*".

Working Contributing Scenarios: Operational Conditions (OC) and Risk Management Measures (RMM) for each Worker Contributing Scenario (ECS) are presented in Table 2a. Inhalation exposure has been estimated using the ART 1.5 model for WCSs 2-7, 16-34 and 36. Original input parameters for the model are included in the CSR. In response to RAC questions concerning these activities, the applicant modified the input parameters for combined exposure assessment for spraying operations. For the WCS 2, 4, 6, 16, 24, 25 and 26 the ART (extended) values corrected for use of RPE are presented in Table 2b.

For WCSs 8-15 exposure assessment is based on the measured data from 11 companies performing 'other' surface treatment covering uses 4, 5 and 6 (Surface treatment for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering and tin plating).

Measurement data provided by the applicant on request of RAC is presented in Annex 1, Table A1. The 90th percentile from the measurements from different companies is calculated and used in further analyses.

In the case of WCSs 1 and 35, covering delivery and 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

A general overview of the operational conditions and RMMs applied in each contributing scenario is presented in Table 2a, while table 2b presents the input parameters used in the exposure assessment for spraying operations, as modified by the applicant in response to RAC questions.

Table 2a: 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	< 50 % Cr(VI)	no	no	closed system, basic general ventilation
WCS 2 (PROC 8b)	Decanting – liquids	< 60 min	Cr(VI) in mixture: Substantial (10-50%)	no	no,	good natural ventilation and medium level of containment
WCS 3 (PROC 8b)	Decanting and weighing of solids	< 60 min	Powder weight fraction Substantial (10-50% Cr (VI))	no	yes, at least half mask with P3 filter (APF 30 *), effectiveness 96.67%	good natural ventilation
WCS 4 (PROC 5)	Mixing- liquids	<60 min	Cr(VI) in mixture: Substantial (10-50%)	no	no	good natural ventilation and low level of containment
WCS 5 (PROC 5)	Mixing –solids	< 60 min	Powder weight fraction Substantial (10-50% Cr (VI))	no	yes, at least half mask with P3 filter, (APF 30 *), effectiveness 96.67%	good natural ventilation and low level of containment
WCS 6 (PROC 8b)	Re-filling of baths – liquids	<10 min	Cr(VI) in mixture: Substantial (10-50%)	LEV	yes, at least half mask with P3 filter (APF 30*), effectiveness 96.67%	good natural ventilation
WCS 7 (PROC 8b)	Re-filling of baths – solids	< 10 min	Powder weight fraction Substantial (10-50% Cr (VI))	yes, fixed capturing hood (90% reduction)	yes, at least half mask with P3 filter (APF 30*), effectiveness 96.67%	good natural ventilation
WCS 8 (PROC 4)	Other surface treatment – loading of jigs	< 8h	Cr(VI) in mixture: Substantial (10-50%)	no	no	basic general ventilation-
WCS 9 (PROC 13)	Other surface treatment chemical pre-treatment	< 8h	Cr(VI) in mixture: Substantial (10-50%)	yes, if Cr(VI) or other dangerous substances are	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
				used in the pre-treatment		
WCS 10 (PROC 13)	Other surface treatment – by dipping/immersion	< 8h	Cr(VI) in mixture: Substantial (10-50%)	yes	no#	basic general ventilation
WCS 11 (PROC 13)	Other surface treatment – rinsing/drying	< 8h	Cr(VI) in mixture: Substantial (10-50%)	no	no#	basic general ventilation
WCS 12 (PROC 13)	Other surface treatment – chemical post-treatment	< 8h	Cr(VI) in mixture: Substantial (10-50%)	yes, if Cr(VI) or other dangerous substances are used in the post-treatment	no#	basic general ventilation
WCS 13 (PROC 4)	Other surface treatment – cleaning and unloading of jigs	< 8h	Cr(VI) in mixture: Substantial (10-50%)	no	no#	basic general ventilation
WCS 14 (PROC 8b)	Other surface treatment – 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 7)	Surface treatment by spraying in spray cabin/spray booth	< 120 min	Cr(VI) in mixture: small (1-5%)	yes, fixed capturing hood (90% reduction)	yes, at least half mask with P3 filter (APF 30*), effectiveness 96.67%	down-flow spray-room (80% reduction)

Contributing scenario	Name of the scenario	Duration and frequency of exposure	Concentration of the substance*	LEV used	RPE** used + effectiveness	Other RMMs
WCS 17 (PROC 7)	Surface treatment by spraying outside of spray booth	< 30 min	Cr(VI) in mixture: small (1-5%)	no	yes, full-face-mask with A2P3 filter (minimum APF 400*), effectiveness 99.75%	good natural ventilation, local extraction may or may not be available
WCS 18 (PROC 7)	Surface treatment in automatic spray tunnel	< 480 min	Cr(VI) in mixture: extremely small (0.1-0.5%)	yes, other enclosing hood (90 % reduction)	no	good natural ventilation and medium level containment (99% reduction)
WCS 19 (PROC 7)	Surface treatment by spraying in closed, extracted spray booth	< 10 min	Cr(VI) in mixture: < 15%	fume cupboard (99% reduction)	yes, full-face- mask with A2P3 filter (minimum APF 400*), effectiveness 99.75%	General ventilation rate 3 ACH per hour and medium level containment (99% reduction)
WCS 20 (PROC 10)	Surface treatment by rolling (small to medium sized areas)	< 180 min	Cr(VI) in mixture: minor (5-10%)	yes, fixed capturing hood (90% reduction)	yes, at least half mask with A2P3 filter (APF 30*), effectiveness 96.67%	good natural ventilation
WCS 21 (PROC 10)	Surface treatment by brushing or penstick (small areas/touch-up)	< 180 min	Cr(VI) in mixture: small (1-5%)	no	no	good natural ventilation
WCS 22 (PROC 26) activities of workers within one meter distance to the drying part	Drying/self-curing	30 min	Cr(VI) in mixture: minor (5-10%)	no	no	good natural ventilation

Contributing scenario	Name of the scenario	Duration and frequency of exposure	Concentration of the substance*	LEV used	RPE** used + effectiveness	Other RMMs
WCS 22 (PROC 26) activities of workers outside one meter distance to the drying part	Drying/self-curing	< 90 min	Cr(VI) in mixture: minor (5-10%)	no	no	good natural ventilation
WCS 23 (PROC 26)	Drying/heat-curing	< 480 min	Cr (VI) in mixture: minor (5-10%)	yes, fixed capturing hood (90% reduction)	no	good natural ventilation
WCS 24 (PROC 8b)	Cleaning of equipment – tools cleaning (closed system)	< 60 min	Cr (VI) in mixture: minor (5-10%)	yes, fixed capturing hood (90% reduction)		good natural ventilation, closed system
WCS 25 (PROC 8b)	Cleaning and maintenance of equipment – tools cleaning (spray cabin)	< 60 min	Cr (VI) in mixture: minor (5-10%)	no		specialized ventilation: more than 10 ACH, indoor in spray room
WCS 26 (PROC 8b)	Cleaning – Spray cabin and ancillary areas	< 60 min	Cr (VI) in mixture: minor (5-10%)	no		good natural ventilation
WCS 27 (PROC 8a)	Infrequent maintenance activities	240 min, 1 time /month	Powder weight fraction Cr(VI) minor (5-10%)	no	yes, at least half mask with A2P3 filter (APF 30*), effectiveness 96.67%	good natural ventilation
WCS 28 (PROC 15) sub-activity: drawing of sample and	Laboratory analysis (sampling, laboratory analysis)	< 30 min	Cr (VI) in mixture: minor (5-10%)	yes, fixed capturing hood (90% reduction)	no	good natural ventilation

Contributing scenario	Name of the scenario	Duration and frequency of exposure	Concentration of the substance*	LEV used	RPE** used + effectiveness	Other RMMs
transfer to the laboratory						
WCS 28 (PROC 15) sub-activity: laboratory analysis	Laboratory analysis (sampling, laboratory analysis)	< 60 min	Cr (VI) in mixture: minor (5-10%)	no	no	good natural ventilation
WCS 29 (PROC 21 and 24)	Machining operations on small to medium sized parts containing Cr(VI) on an extracted bench/extraction booth including cleaning	< 180 min	Solid weight fraction 0.1% Cr(VI)	yes, fixed capturing hood /Vacuum cleaner (HEPA filter with at least 99,00% reduction)	yes , at least half or quarter mask with P2 filter (APF 10*), if[1)], effectiveness 90 %	
WCS 30 (PROC 21 and 24)	Machining operations on small to medium sized surfaces containing Cr(VI) on an extracted bench/extraction booth including cleaning	< 180 min	Solid weight fraction < 3 % Cr(VI)	yes, fixed capturing hood /Vacuum cleaner (HEPA filter with at least 99,00% reduction)	yes, at least half mask with P3 filter (APF 30*), if[1)], effectiveness 96.67%	good natural ventilation
WCS 31 (PROC 21 and 24)	Machining operations in large work areas on parts containing Cr(VI) including cleaning	< 60 min	Solid weight fraction < 0.1 % Cr(VI)	no	yes, at least half or quarter mask with P2 filter (APF 10*), if[1)], effectiveness 90 %	good natural ventilation and wetting at the point of release/on-tool extraction/ vacuum cleaning (90% reduction)
WCS 32 (PROC 21 and 24)	Machining operations in large work areas on surfaces containing Cr(VI) including cleaning	< 60 min	Solid weight fraction < 3 % Cr(VI)	no	yes, at least half mask with P3 filter (APF 30*), if[1)], effectiveness 96.67%	good natural ventilation and wetting at the point of release/on-tool extraction/vacuum

Contributing scenario	Name of the scenario	Duration and frequency of exposure	Concentration of the substance*	LEV used	RPE** used + effectiveness	Other RMMs
						cleaning (90% reduction)
WCS 33 (PROC 21 and 24)	Machining operations on parts containing Cr(VI) in small work areas including cleaning	< 60 min	Solid weight fraction < 0.1 % Cr(VI)	no	yes, Full-face-mask with P3 filter (AFP 400*), if[1)], effectiveness 96.75%	good natural ventilation
WCS 34 (PROC 21 and 24)	Machining operations on surfaces containing Cr(VI) in small work areas including cleaning	< 60 min	Solid weight fraction < 3 % Cr(VI)	no	yes, Full-face-mask with P3 filter and air supply (APF 1000*), if[1)], effectiveness 99.9%	good natural ventilation
WCS 35 (PROC 1)	Storage of articles	< 8h	Cr(VI) not detectable in article	no	no	basic general ventilation
WCS 36 (PROC 8b)	Waste management	30 min	Powder weight fraction Substantial (10-50% Cr(VI))	no	yes, at least half mask with A2P3 filter (APF 30*), effectiveness 96.67%	good natural ventilation, low level of containment for solid process waste handling (90% reduction)

** 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*

[1)] According to the applicant if workplace monitoring data do not confirm negligible exposure clearly below 1 µg/m³ (e.g. < 0.1 µg/m³) RPE shall be used

#The applicant has not identified RPE as an RMM for WCS 8-15. However, RAC notes that exposure levels given in table 3a 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.

Table 2b: Operational Conditions and Risk Management Measures for spraying operations WCS 2, 4, 6, 16, 24, 25 and 26, modified by the applicant in response to the second set of RAC questions (CTAC Sub RAC addit questions CSR 131115 final)

Contributing scenario	Duration and frequency of exposure	Concentration of the substance*	LEV used	RPE used(effectiveness)	Other RMMs
WCS 2 (PROC 8b) Decanting – liquids	< 30 min (combined for WCS 2, 4 and 6)	Cr(VI) in mixture: Substantial (10-50%)	yes	yes, full-face-mask with A2P3 filter (minimum APF 400*), effectiveness 99.75%	good natural ventilation and medium level of containment
WCS 4 (PROC 5) Mixing-liquids		Cr(VI) in mixture: Substantial (10-50%)			good natural ventilation and low level of containment
WCS 6 (PROC 8b) Re-filling of baths – liquids		Cr(VI) in mixture: Substantial (10-50%)			good natural ventilation
WCS 16 (PROC 7) Surface treatment by spraying in spray cabin/spray booth	< 30 min	Cr(VI) in mixture: small (1-5%)	yes, fixed capturing hood (90% reduction)	yes, full-face-mask with A2P3 filter (minimum APF 400*), effectiveness 99.75%	down-flow spray-room (80% reduction)
WCS 24 (PROC 8b) Cleaning of equipment – tools cleaning (closed system)	< 15 min	Cr (VI) in mixture: minor (5-10%)	yes, fixed capturing hood (90% reduction)	yes, full-face-mask with A2P3 filter (minimum APF 400*), effectiveness 99.75%	good natural ventilation, closed system
WCS 25 (PROC 8b) Cleaning and maintenance of equipment – tools cleaning (spray cabin)	< 15 min	Cr (VI) in mixture: minor (5-10%)	no		specialized ventilation: more than 10 ACH, indoor in spray room
WCS 26 (PROC 8b) Cleaning –	< 15 min	Cr (VI) in mixture: minor (5-10%)	no		good natural ventilation

Spray cabin and ancillary areas					

** 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)

[1)] According to the applicant if workplace monitoring data do not confirm 'negligible' exposure clearly below 1 µg/m³ (e.g. < 0.1 µg/m³) RPE shall be used

Other Risk management measures used to control exposure:

Workers involved in these activities receive regular training with regards to chemical risk management and how to properly wear Personal Protective Equipment (PPE). According to the applicant, regular housekeeping and management systems should be in place in order to ensure high standards of operational procedures. Protective clothing, chemical-resistant gloves and goggles are required in case of potential for exposure to chromium trioxide for all WCSs except WCS 35 (Storage of articles).

The main activities with potential for exposure to Cr(VI) during surface treatment operations are the sequential process steps of the application in baths (WCSs 8-15), surface treatments by spraying (WCS 16-19), surface treatments by rolling or brushing (WCS 20-21), cleaning activities (WCS 24-26) and machining operations (WCS 29-34).

For the bath operations (WCS 8-15), potential exposure has been estimated using the available measurement data (Annex Table A1), which has been compared to literature data.

All other exposure estimations were modelled with ART 1.5. Although tasks related to surface treatment activities are by themselves very similar between different sites performing surface treatment, the OCs and RMMs differ between the facilities, depending on e.g. building layout, the scale and frequency of surface treatment 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 all situations. RMMs typically used in surface treatment 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 need to be adjusted individually for each facility, taking also into account the general principles of the hierarchy of control.

Discussion of the exposure information:

Exposure estimates provided by the applicant for each WCS are presented in Table 3a. Table 3b presents corrected by the applicant exposure estimates for spraying operations, reflecting changes in RMMs as presented in table 2b.

Table 3a: 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 4	Inhalation	ART 1.5	0,69	
WCS 6	Inhalation	ART 1.5	1,1	
WCS 7	Inhalation	ART 1.5	0.025	
WCS 3	Inhalation	ART 1.5	1.5	
WCS 5	Inhalation	ART 1.5	0.5	
WCS 8 to WCS 15	Inhalation	Measured	Combined for WCS 8-15: • arithmetic mean: 1.16 • geometric mean: 0.81 • 90th percentile: 2.94	Combined for WCS 8-15: • arithmetic mean: 0.60 • geometric mean: 0.33 • 90th percentile: 1.25
WCS 16	Inhalation	ART 1.5	0,57	
WCS 17	Inhalation	ART 1.5	1.55	
WCS 18	Inhalation	ART 1.5	0.4	
WCS 19	Inhalation	ART 1.5	1.4×10^{-5}	
WCS 20	Inhalation	ART 1.5	0.57	
WCS 21	Inhalation	ART 1.5	0.69	
WCS 22	Inhalation	ART 1.5	0.80	
WCS 23	Inhalation	ART 1.5	0.46	
WCS 24	Inhalation	ART 1.5	0,017	
WCS 25	Inhalation	ART 1.5	0,089	
WCS 26	Inhalation	ART 1.5	0,17	
WCS 27	Inhalation	ART 1.5	0.25	

WCS 28	Inhalation	ART 1.5	0.69	
WCS 29	Inhalation	ART 1.5	0.11	*
WCS 30	Inhalation	ART 1.5	1.13	*
WCS 31	Inhalation	ART 1.5	0.20	*
WCS 32	Inhalation	ART 1.5	2.03	*
WCS 33	Inhalation	ART 1.5	0.16	*
WCS 34	Inhalation	ART 1.5	1.9	*
WCS 35	Inhalation	Qualitative	0	
WCS 36	Inhalation	ART 1.5	0.22	

**Machining operations: according to the applicant in case of lower or higher Cr(VI) content, estimated exposure would be reduced or increased in a linear way. In these cases, if needed, OCs and RMMs could be adjusted to that specific situation.*

Table 3b: Exposure estimates for exposure assessment for spraying operations, amended in response to RAC questions.

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 2	Inhalation	ART 1.5	0,15	0,00036
WCS 4	Inhalation	ART 1.5		
WCS 6	Inhalation	ART 1.5		
WCS 16	Inhalation	ART 1.5	0,15	0,01*
WCS 24	Inhalation	ART 1.5	not given by the applicant, due to low levels	
WCS 25	Inhalation	ART 1.5		
WCS 26	Inhalation	ART 1.5		

**based on applicant's calculations. However, if RPE with APF 400 is used (as indicated in table 2b), this should result in much lower exposure.*

Exposure estimate for treatment in baths (WCS8-15) is derived from the measurement data provided by 11 companies either Use 4, Use 5 or Use 6. These data is presented in annex, table A1. The data is based on personal measurements (n=36, 11 companies) gathered during 2008-2013. In the surface treatment processes represented by the measured data variable use of automation, LEV and mist suppressant was noted. The majority of the results represented automatic processes with LEV in place, sometimes exposure was controlled by the use of mist suppressants. No further information on OCs or RMMs in place at the measured workplaces was made available. The 90th percentile of

these measurements was 2.94 µg Cr(VI)/m^3.

RAC considers that the larger dataset provided for use 2 (functional chrome plating under open, manual conditions with LEV at 23 sites) to be a reasonable worst case and when augmented by the Use 3 dataset on functional chrome plating with decorative character (at 10 sites) adds to the data from Use 4 and 5 covering various 'bath type' surface treatment processes, thus providing a stronger starting point for the evaluation of Use 4 and 5 as a whole.

In addition, static measurement data were collected which, according to the applicant, were generally in line with the personal measurement data. This data was not made available to RAC, because the applicant reasoned that preference should be given to personal measurement data. As a consequence, more than half of the companies that provided some measurement data were not directly represented in the final data set. RAC considers that this was an opportunity lost, as the relationship between the static (samplers usually placed in relation to the main emission sources) and personal measurements (reflecting the workers specific activities and thereby exposure) could have strengthened the dataset.

The applicant corrected the exposure estimate of 2.94 µg Cr(VI)/m^3 for the use of respiratory protection (at some locations, for varying periods of time) to derive an exposure level of 1.25 µg Cr(VI)/m^3. According to the applicant's description, in cases in which respiratory protection was used during surface treatment processes, the effectiveness of respiratory protection was assessed using the company information on type of mask and filter used. If available, the Assigned Protection Factor (APF) provided by the manufacturer of the RPE was used. In other cases, APF provided by the German BG rule "BGR/GUV-R190" from December 2011 was used. For a minority of sampling data, where the duration for which respiratory protection had been used clearly could be assigned to the measurement results, the measured values were adjusted accordingly by the applicant. In most of the cases in which the use of RPE for was indicated, the specific time period was not identified and the measured values were not adjusted to account for use of respiratory protection in these cases. Exact calculations on adjustment made due to use of RPE were not made available for RAC.

To support the measurement data, data from the literature is also presented (Annex, Table A2) by the applicant. Importantly, data on functional chrome plating (uses 2, 3) and ETP (use 6) can be used for comparison. RAC notes that although average levels presented in the literature are in the same range as the levels collected by the applicant, higher exposure levels are also reported.

According to the assessment of measurement data in the MEGA database published in Germany and referenced by the applicant in response to RAC (DGUV-I 213-716: Galvanotechnik und Eloxieren, Oktober 2014; http://publikationen.dguv.de/dguv/pdf/10002/213-716.pdf), the 90th percentile of personal measurements was 2.5 µg Cr(VI) /m^3 in decorative chrome plating and 24.6 µg Cr(VI)/m^3 in functional chrome plating. In conversion coating/passivation, i.e. most relevant to this application, the 90th percentile of the personal measurements was 6.8 µg Cr(VI)/m^3. In loading/unloading of jigs (for chrome plating in general but also relevant to this use) a 90th percentile (personal measurement) of 13.5 µg Cr(VI)/m^3 was calculated.

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

- the more recent German BG ETEM report, which shows 95th percentiles of 4.4 µg Cr(VI)/m^3 in personal measurements in 12 job shops (range <0.01-4.8 µg Cr(VI)/m^3).
- HSE data from 14 companies in the UK shows measurement values from <0.1 to 11 µg Cr(VI)/m^3 (10 out of 41 measurements were below 0.1 µg Cr(VI)/m^3). Companies 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 chrome plating (representing functional chrome plating for use 2). Exposure was modelled for both manual and automatic processes, with covered or uncovered baths and considering both 90 and 99% LEV efficiency. Two different room sizes were included (see the annex, table A4). The exposure modelling estimates varied between 0.27 to 130 µg Cr(VI)/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 are covered. The high exposure level of 130 µg Cr(VI)/m^3 is, however, not supported by the measured data provided either by the applicant or published in the literature. Thus, modelling is likely to overestimate the exposure.

It should be noted that the model did not take into account the use of RPE or mist suppressants. The average efficiency of mist suppressants is 68% according to the study by UK HSL (2014, referenced in applicant's response to the second set of RAC questions). Furthermore, according to the applicant, baths are usually covered or partly covered. However, RAC notes that covers cannot always be used. Also RPE is used to limit the exposure if other measures are not sufficiently effective. Otherwise, however, the modelling results are supportive of the measured data. RAC furthermore notes, that the exposures encountered in functional chrome plating are in general considered to be higher than in other plating processes such as surface treatment, because of the higher current density applied, the resulting higher formation of hydrogen and the higher temperature of electrolyte in the bath.

For activities other than bath immersion, i.e.: re-adjusting the electrolyte (WCS 6 and 7), preparatory steps (WCSs 2-5), spraying (WCS 16-21), drying (WCS 22-23), cleaning (WCS 24-26), maintenance (WCS 27), sampling (WCS 28), machining (WCS 29-34) and waste management (WCS 36) exposure estimates have been prepared by modelling using ART1.5. According to the applicant, each of these sub-scenarios represents on its own a worst-case scenario because the operational conditions (OCs) and RMMs offering the lowest level of protection reported for that one specific activity was used as input

parameters, taking into account the various details of the processes carried out and the RMMs applied and reported by different companies. It should be noted that for drying operations (WCS 22-23) the model gives significant Cr(VI) exposure levels, which in RAC opinion are unlikely to be found in practice, since chromium trioxide is not volatile.

In response to RAC questions, the applicant clarified that preparatory steps for the re-adjustment of the electrolyte (WCSs 2-5, 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 not happen on a daily basis (only e.g. 1 or 2 times per month).

The applicant claims that re-adjustment of the electrolyte with aqueous solutions of chromium trioxide is most commonly a fully automated process, and therefore potential for exposure is reduced. 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 36, with LEV in place, no RPE) is conducted once per day/shift or per week (and sometimes less often), depending on the process and number of parts being treated. As a general rule sampling once per day or shift is needed in companies with mass production.

It is assumed that the duration of the regular maintenance of the baths and related equipment (e.g. LEV, rectifier, pumps, panels etc.) is 60 minutes every day. According to the applicant, this is a conservative assumption. Regular maintenance is usually conducted when the bath solutions are at ambient temperature and no aerosol formation can be expected. Therefore, the applicant considers that the results of the air measurements conducted during the functional chrome plating process, represent a worst-case 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. For infrequent (once per month) maintenance activities with longer duration - up to 4 h - there is a separate WCS 27 (covers e.g. removal and replacement of filters). The exposure estimate (modelled using ART 1.5) for this is 0.25 µg Cr(VI)/m^3 (estimate takes the low frequency of the activity into account).

In response to RAC questions on the combined exposure for activities related to spraying applications, the applicant presented new calculations for the cumulative exposure estimates. These are presented in Tables 2b and 3b. These new estimates are based on use of stricter RMMs and shorter exposure times than those in Table 2a. According to the applicant, these are based on the information received from several downstream users and better represent the current practice. RAC also asked if the bystanders – workers not directly involved in the activity – are likely to be exposed during these spraying operations. According to the applicant there are no bystanders nearby these operations. The area which the activity is conducted is restricted either physically by means of barrier/signage or through strict procedures during the activity and applicable for a specified time after the application. It is also stated that workers do not remove the RPE used in spraying applications before leaving the area of application.

Combined exposure

According to the information provided by the applicant workers involved in the surface treatment process steps 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 WCSs will, according to the applicant, amplify the impact of conservative and worst-case assumptions across activities, resulting in potentially substantial over-estimation 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 there could be a potential for combined exposure for bath operator, spraying operator and machining operations.

Bath operator

- Maintenance work (WCS 15) and surface treatment work (WCS 8-14) are tasks conducted by separate 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 regular maintenance activities. Thus, the exposure estimate of 1.25 µg Cr(VI)/m^3 (as 8 h TWA) applies also for maintenance workers (WCS 15), whereas infrequent maintenance is represented by WCS 16 with a modelled exposure estimate of 0.25 µg Cr(VI)/m^3 (the value takes the low frequency into account). RAC notes however, based on experience with downstream chromate applications, that in small enterprises it is likely that the same workers are involved in / perform all operations/tasks.
- Sampling (sub-activity of WCS 28, exposure estimate 0.11 µg Cr(VI)/m^3) is conducted by laboratory workers - if the company has a laboratory; otherwise it might be performed by supervisors or by trained operators. Re-adjustment of the electrolyte (commonly done with solid chromium trioxide, WCS 7) is usually conducted by a trained operator under supervision or by the supervisor.
- According to the applicant, the surface treatment (bath) operators may typically perform tasks of WCSs 8-14, sampling (WCS 28, sub-activity sampling) and re-adjustment of the electrolyte with solid (WCS 7). Re-adjustment with liquid (WCS 6) is only rarely done and is not taken into account in calculations. The combination of these WCSs would result in an exposure estimate for Use 4 of 1.4 µg Cr(VI)/m^3, under the assumption that these are daily activities.
- Preparatory steps (WCS 2-5) are only done 1-2 times per month

Table 4a: Typical combination of tasks and related combined exposure for bath operator

Contributing scenario	Route	Exposure value (as 8 h TWA) corrected for PPE µg Cr(VI)/m³
WCS 7	Inhalation	0.073
WCS 8-14 (+15*)	Inhalation	1.25
WCS 16 (sampling)		0.11
Total exposure for 8 hours	Inhalation	1.4** (applicant's estimate on maximum individual exposure value 2 µg Cr(VI)/m³)

**In contrast to the applicant's view, RAC notes that in small companies, maintenance (WCS15) may be performed by the same workers as bath operations. However, the applicant's exposure estimate for regular maintenance operations is the same as for bath operations. Exposure estimate for infrequent maintenance is 0.25 µg Cr(VI) /m³ (takes into account the low frequency)*

***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 ART1.5 modelling, increase the exposure by 0.22 µg Cr(VI) /m³, if it is assumed that it is a daily activity. In addition, if the worker performs preparatory steps (WCSs 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) /m³*

Operator for spray applications

In response to RAC's request, the applicant listed worker contributing scenarios for operators in spray applications which may be performed by the same workers. These are e. g. the preparation of the formulation (WCSs 2, 4, 6), the preparation of the spray gun and the spray application in the booth (WCS 16) and the cleaning of the spray booth and the spray gun (WCSs 24-26). The applicant also modified the OC (lowered the total exposure time to 30 min in WCSs 2, 4 and 6) and RMMs (respiratory protection with AFP 400 is necessary) to give a more realistic picture of the current practice, and presented new calculations for daily inhalation exposure of spraying operators in different WCSs. According to the applicant, spraying is typically performed only once per day.

Table 4b: Combined exposure for spraying operator

Contributing scenario	Route	Exposure value corrected for PPE and frequency µg Cr(VI)/m³
WCS 2, 4, 6: preparation of the formulation	Inhalation	0.00036
WCS 16: preparation of spray gun and spray application in the booth	Inhalation	0.011*
WCS 24-26: cleaning of the spray booth and the spray gun	Inhalation	<0.28 (not corrected for exposure duration 15 min and RPE with APF 400, because not calculated by the applicant)
Total exposure for 8 hours	Inhalation	< 0.3 (calculated by RAC)

**based on applicant's calculations. However, if RPE with APF 400 is used (as indicated in table 2b), this should result in much lower exposure.*

Machining operations

- According to the applicant's response to the third round of questions from RAC these operations are performed by a specific group of workers, but workers conducting machining operations might also be involved in local chemical conversion coating activities, like the application by small brush or pen-stick on small surfaces (WCS 20 and WCS 21). Various combinations of different machining scenarios or machining scenarios and brush-application scenarios may occur.
- The levels of exposure for combined contributing scenarios are uncertain as the estimations are based on ART 1.5; the machining of surface-coated metallic objects is not covered by the model's design. The applicant used an option in ART 1.5 for 'fracturing and abrasion of stone' with a specific content of chromium to model the machining of metallic objects coated with a thin layer of Cr(VI) based coating - the same content of chromium was not available. No measurement data for Cr(VI) for these tasks is available for RAC to evaluate, but according to the applicant's statement based on the data from other comparable substances for other machining scenarios (no data provided), levels of exposure are much lower than the modelled values. RAC agrees that ART 1.5 cannot reliably assess the exposure caused by machining of surface-coated material and the modelled levels are likely to be overestimates. **RAC considers that measured data is needed in this case for the reliable assessment of the exposure.** Data should be from the specific machining tasks WCSs (29-34) and be representative of the most common combinations of tasks. It is advised to measure worst case situations, when combining different WCSs of the ES.

Uncertainties related to the exposure assessment:

Uncertainties related to surface treatment 'bath' operations

The number of potential sites in EU performing surface treatment for applications in the architectural, automotive, metal manufacturing and finishing and general engineering industries is according to the applicant up to 515. The applicant bases the exposure assessment of surface treatment activities in this scenario on measured data from 11 companies and literature data mainly from Western European countries. Although in general the most recent literature data is considered to support the applicant's estimate on a maximum individual exposure value of 2 µg Cr(VI)/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 their proposed limit of 2 µg Cr(VI)/m^3.

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

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

There are also uncertainties related to the maintenance activities of bath operations. For the regular maintenance of the baths and related equipment (e.g. LEV, rectifier, pumps, panels etc.), air measurements conducted during the chrome plating process were used as a worst-case estimate for regular maintenance activities. Based on the available data, RAC cannot verify the accuracy of this assumption, especially in cases where maintenance is needed during the on-going process (as opposed to when it is not operating).

Uncertainties related to spray applications and machining operations

Spray applications
Manual spraying is a task, in which there is a potential for high exposures unless a high level of personal protection is used. Occupational exposure related to spraying has only been modelled for this activity and no measurement data were provided. Although the applicant considers that the ART model is likely to overestimate, RAC does not agree with this statement in the case of spraying, especially without supporting measurement data. According to the study by Vincent et al. (2014, see annex, table A3), in spray painting (aeronautics sector) chromium levels varying between <0.02-896 µg Cr(VI)/m^3 were measured.

In addition, there are uncertainties with the combined exposure related to spraying applications. In his response, received on 13 November 2015, to RAC's request for combined exposure information during spraying operations, the applicant presented a revised exposure assessment with a) shorter activity durations and b) the use of RPE with a higher protection factor in several spraying–related WCSs. These OCs and RMMs are different from the original exposure scenario and should form part of any authorisation**.** Furthermore, they are based on the assumption that spraying tasks are performed only once per day. These modified OCs and RMMs should be reflected in an updated exposure scenario distributed to downstream users. Updated information concerning the RPE is considered especially important.

Machining operations
To better cover variability in the machining operations, the applicant also added additional instructions to the ES. During the machining operations (WCS 29-34) the use of RPE is dependent on the outcome of workplace monitoring. If the data does not confirm negligible exposure clearly below 1 µg/m^3 (e.g. < 0.1 µg/m^3, applicant's numbers), then the use of the RPE is proposed by the applicant.

No measurement data on machining operations were presented in CSR and according to the applicant ART is likely to overestimate the exposure in machining operations. The possible combinations of WCSs for workers conducting machining operations was not presented. It was stated by the applicant in his response, received on 13 November

2015, to RAC's request that various combinations of different machining scenarios and brush application scenarios do indeed occur. Thus, there are uncertainties related to the exposure of machining operators. However, RAC agrees with the applicant that the current exposure estimates derived by modelling most probably overestimate the real exposure in machining operations.

As this ES covered 36 different WCSs the applicant clarified some of the possible task combinations which may occur together, but as it was stated in the case of machining operations - it is possible, that the workers may conduct also other combinations of tasks, not presented in the application.

Uncertainties related to RPE, common for all processes

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 effectiveness of RPE on exposures. It should be noted that other countries may use lower APFs for the same type of RPE than Germany. However, in practice, the adequate protection of the RPE is very much dependent on the individual wearer. According to the standard EN 529, RPEs shall be fit tested for each wearer in order to ensure adequate protection. Workers should be adequately trained and supervised for the use and maintenance of the RPE, and their medical fitness should be examined if RPE is used for longer time-periods.

Environmental releases / Indirect exposure to humans via the environment

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

The applicant considers that measures to prevent or limit the release of Cr(VI) to the environment during surface treatment operations are a matter of best practice (as described by BREFs). Whilst emissions to air (via fine dust and particulates) are considered to occur at all use sites, the applicant states that not all sites will necessarily have releases of Cr(VI) to wastewater as both liquid and solid wastes containing Cr(VI) can rather be collected from sites by an external waste management company instead of being discharged in wastewater to the municipal sewer or directly to the environment. The applicant considered that releases to soil, either at a local or regional level, do not occur. RAC notes that the applicant considers that the use is consistent with the environmental release category (ERC) 6b[1]. Whilst the choice of ERC was ultimately not relevant for the exposure assessment described by the applicant RAC notes that according by ECHA guidance on use description (R.12) uses where a substance or its transformation products are included into or onto an article at industrial sites are intended to be captured by ERC 5[2]. RAC further notes that the breadth of applications covered by this use may not be consistent with a single ERC.

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

[2] In recently revised ECHA guidance on use description (December 2015) ERC 5 refers to "use at industrial site leading to inclusion into/onto article). The previous version of R.12 referred to ERC 5 as "Industrial inclusion into or onto a matrix". 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)

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 six EU sites sampled between 2010 and 2013. Individual site measurements were not reported but details of the calculation of the summary statistics were provided. Where measurements 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 six 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) / m³)	AM (mg Cr(VI) / m³)	GM (mg Cr(VI) / m³)	90th percentile (mg Cr(VI) / m³)
6	2010-2013	4.14×10^{-6}-5.70×10^{-8}	1.19×10^{-6}	3.45×10^{-7}	3.25×10^{-6}

Note: Regional air concentrations of chromium trioxide, based on modelling with EUSES 2.1.2, are 2.83×10^{-16} mg/m³ Cr(VI).

Based on the 90th percentile of these data, the applicant concludes a $PEC_{local,air}$ for use in the assessment of indirect exposure to humans via the environment of 3.25×10^{-6} mg/m³.

Where Cr(VI) is released to wastewater, the applicant considers that treatment (either on-site or off-site) is “generally highly effective”. Wastewater treatment methods can vary between sites, but the most common on-site technique to remove Cr(VI) from wastewaters appear to be via a batch reduction/precipitation process. The applicant states in the CSR that emissions to wastewater are very low and often below limits of

detection and can therefore be considered to be negligible. No further data or justification to support this conclusion was initially provided in the applicant's CSR, but the exposure scenario (and the "succinct summary of operating conditions and risk management measures" intended for enforcement) states that the use should result in "negligible discharge of Cr(VI) in wastewater from the site". Emissions to water were not incorporated into the applicant's assessment of indirect exposure to humans via the environment.

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

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

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

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

44 sites (1, 7, 9, 17, 18, 36, 40) were reported to undertake Use 5 with two of these sites (1, 36) reporting no emissions to wastewater. Release factors or effluent monitoring information were reported for three of the five sites with wastewater emissions (see Tables A5 and A6 in the Annex to this opinion).

Table 6: Summary of environmental emissions

Release route	Release factor / rate	Release estimation method and details
Water	usually $<1\times10^{-4}$% and Cr(VI) level in WW <0.05 mg/L	Based on the applicant's assessment on good practises. See Table A5 and A6 in the Annex to this opinion.
Air	0.001%	Estimated from Clocal, which is based on measured data
Soil	0	No soil release

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

Protection target	Exposure estimate and details (i.e. methodology and relevant spatial scale)
Man via Environment - Inhalation	3.25×10^{-6} mg/m^3 (local exposure 100m from point source – based on 90th percentile of measured releases) 2.83×10^{-16} mg/m^3 (regional exposure) estimated by EUSES 2.1.2.
Man via Environment - Oral	Not considered relevant by the applicant
Man via Environment - Combined	Not considered relevant by the applicant

In summary, the applicant's assessment of exposure via air is based on measured data combined with EUSES modelling. Exposure via air is the only element included in the assessment of indirect exposure to humans via the environment. Exposure via food and drinking water (oral route of exposure) has been waived 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 via 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 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 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 the emissions to wastewater for this use is limited to three from a maximum of 374 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 route of exposure should be more comprehensively addressed in a review report prepared for this application.

Regarding emissions to air and consequent inhalation exposure of the general population living in the vicinity of the plants, the assessment is based on measured data from 6 sites (representing <2% of the site reported to undertake this use 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, 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.

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

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

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

Although it is acknowledged that release to **air** of Cr(VI) are generally low due to the low volatility of chromium trioxide and modern abatement technology with high efficiency, the estimated $Clocal_{air,\ ann}$ is based on rather limited number of data which RAC was not able to fully evaluate due to the absence of accompanying contextual information. RAC notes that the applicant's use of a 90^{th} 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 90^{th} percentile. Median exposure values would also have been useful to present.

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

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

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

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 the surface treatment processes described in the application is based on measured data from 11 companies (representing 3% of companies considered by the applicant to perform surface treatment in the scope of this application; 10% if the actual CTAC membership reported for Use 4/5 is considered). In addition, there are literature data available on occupational exposure in chrome plating and modelled data provided by the applicant. Although these data generally support the applicant's exposure estimate of 2 µg Cr(VI) /m^3 (claimed as the maximum individual exposure value), there is also clear evidence of higher exposures.
- For other activities (including surface treatment by spraying, rolling, brushing or 'penstick' and machining operations) only modelling data are provided and the applicant has not been able to fully assess the combined exposure related to all these tasks. Especially manual spraying may result in high exposures if adequate personal protection is not used. RAC considers that measured data is needed in this case for the reliable assessment of worker exposure.
- The greatest uncertainty arises from the lack of a clear link between the OCs, RMMs and exposure values reported for specific tasks and sites, which could justifiably be considered as representative for the application. RAC sees this as a substantial weakness of the application, considering that there is a wide variability between the chromium surface treatment sites in relation to e.g. building layout, the scale and frequency of plating/spraying/machining operations, level of the automation of the processes, 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 of local exposure is based on measured data from six companies (representing <2% of the site reported to undertake this use in the EU). Therefore, since no accompanying contextual information is provided in the CSR, the representativeness of these data are uncertain. RAC notes that the applicant's approach for assessing general population inhalation exposure is likely to overestimate exposures for the majority of the general population and should be interpreted with caution. Regional exposure of the general population was estimated by the applicant, but is not considered relevant by RAC. Reduction of Cr(VI) to Cr(III) is likely to further reduce the general population exposure.

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

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

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

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

☐ YES

☒ NO

Justification:

Workers

The applicant has estimated cancer risk according to the RAC reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev 1). The applicant has conservatively assumed that all inhaled chromium trioxide particles are in the respirable range and contribute to the lung cancer risk. Thus, an excess life-time lung cancer risk calculated for the combined, shift-long exposure of 2 µg Cr(VI) /m^3 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 chromium surface treatment 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 chromium surface treatment by dipping or immersion of parts in chromium trioxide baths are by themselves very similar between the 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 chromium surface treatment. 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.

For the activities other than bath immersion, i.e. surface treatment by spraying, brushing/rolling or penstick and machining operations, the exposures have been modelled by ART 1.5 and the related RMMs have been described. However, because of the lack of supporting measurement data and the inadequate assessment of combined

exposure caused by different combinations of WCSs, there are uncertainties in the appropriateness and effectiveness of RMMs to limit the exposure and risks. Surface treatment by spraying may potentially result in high exposures, but if the OCs and RMMs specified in table 2b are followed, exposures may remain relatively low.

According to the applicant, it is 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 chrome surface treatment. The guidance will be provided to Downstream Users attached to the 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 the REACH this kind of "guidance" (exposure scenarios) is mandatory.

Risk characterisation

Occupational exposure in surface treatment using chromium trioxide has been assessed by using modelled data for WCS2-7 and 16-36 and by measured data from 11 companies for bath operations. A general estimate on a maximum combined individual exposure level of 2 µg Cr(VI)/m^3 has been derived on the basis of information on most probable combinations of different WCSs and expert judgement by the applicant. The exposure assessment includes uncertainties related especially to the representativeness of the exposure estimates across the wide-range of companies in 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 different chromium plating facilities) it is possible to reach combined exposure levels well below 2 µg Cr(VI) /m^3 in chromium surface treatment by dipping or immersion of parts to chromium trioxide baths. Also if OCs and RMMs specified in table 2b are applied in spraying applications, exposures are likely to remain well below this level. In the case of machining operations, the modelling data presented in CSR is likely to overestimate the exposure, and the real exposure should be estimated by measuring to ensure low exposure levels.

However, taking these uncertainties and the broad scope of the use into account, RAC considers that the exposure level of 2 µg Cr(VI) /m^3 calculated by the applicant as a 8 h maximum combined individual exposure value, resulting in excess risk of 8×10^{-3} is an appropriate starting point for socio-economic analysis by SEAC. RAC takes note of the applicant's statement 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 the SEA the applicant presents data collected from the CTAC members describing average exposure times of potentially exposed workers (SEA, Annex B, table 17). According to this data, only 31% of workers are exposed for 6-8 h/day, 13% are exposed for 3-6 h/day, 9% are exposed for 1-3 h/day and 10% are exposed for less than 1 h/day. In addition, 38% of workers are exposed only infrequently (e.g. once a week, month, year). This data has been used to correct exposure times for human health impact assessment (HHIA) in SEA. RAC considers that the representativeness of this data across the whole field of industry is uncertain.

Therefore RAC is bringing this uncertainty to SEAC's attention and notes, that 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/m³)	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 according to the RAC reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/rev 6, agreed at RAC 27). The applicant has conservatively assumed that all inhaled chromium trioxide particles are in the respirable range and contribute to the lung cancer risk. Thus, an excess life-time lung cancer risk is 2.9×10^{-2} per µg Cr(VI)/m³ for 70 years of exposure (24 h/day, 7 d/week).

For a local population living in the vicinity of sites undertaking this use the applicant calculated an excess individual life-time lung cancer risk of 9.43×10^{-5}. The applicant has also calculated excess individual risk related to regional exposure (8.21×10^{-15} for 70 years of exposure, 24 h/day, 7 d/week). However, as chromium(VI) is effectively reduced to Cr(III) in the environment, RAC agrees with the conclusions of the previous EU RAR for chromate substances that regional exposure may not be very relevant.

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

ECS	Inhalation route	
	Exposure level (µg Cr(VI)/m³)	Excess risk
ECS1, local exposure	3.25×10^{-3}	9.43×10^{-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 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 surface treatment sites (varying depending on e.g. building layout, the scale and frequency of surface treatment operations, level of the automation of the process, size of the parts treated etc.) resulting in variation in exposure levels and RMMs applied. While it is appreciated that it is difficult to define a single, specific set of OCs and RMMs suitable for all these workplaces, RAC would have expected to receive at least exposure data clearly linked to specific OCs and RMMs and for representative operations, including e.g. automatic versus manual, open versus closed, with the 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 individual exposure level for 8 hours of 2 µg Cr(VI)/m^3, resulting in an excess life-time lung cancer risk for workers of 8 × 10^{-3} as the basis of further analyses by SEAC. It should be noted that this value is proposed by the applicant in the CSR and its use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC as a safe or acceptable level for this non-threshold substance.
- According to the data on exposure durations (presented in SEA), the duration and frequency of exposure of some worker groups in surface treatment 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 human health impact assessment (HHIA) using 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 performed. 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 applicant's assessment of the 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 informs that the use applied for covers a number of surface treatment processes and steps that may be applied to a number of different metal substrates (e.g. aluminium, steel, zinc magnesium, titanium, alloys and composites with metallic areas). Chromium trioxide is used in surface treatment processes in many different sectors such as automotive, defence, marine, energy, oil and gas, electricity, building and construction, steel and non-ferrous metal, food packaging, material science, printing, paper, etc., which are all claimed to depend on the use of chromium trioxide in order to meet high requirements on products, public safety as well as regulatory compliance. Specific considerations affecting the availability of potential alternatives are given in the application for the architecture sector, the automotive sector, food packaging and general engineering. Examples of application areas within different industry sectors are depicted in Table 10 (taken from the Analysis of Alternatives, non-confidential report).

Table 10. Examples of applications of surface treatment using chromium trioxide

Sector	Critical Functionalities	Example of components
Automotive	Wear and corrosion protection Adhesive properties High hardness Chemical resistance Variable coating thickness	Shock absorbers, gas springs, steering and differential components, power trains, piston rods, hydraulics, fuel injection components, piston rings, break pistons, cold roll cylinders, and bearings. Coil coated metals are used e.g. in car bodies, trailer bodies, recreational vehicles, oil filter caps, wiper blade assemblies.
Architecture & building construction	Corrosion protection Adhesion	Use of coil coated aluminium or steel in the building envelope, gutters, partitions, ceiling systems and a variety of ancillary components.

General engineering	Corrosion resistance Adhesion Chemical protection Layer thickness Optical properties	➢ Specialized screens ➢ Printed circuit boards (PCB) production ➢ Power transformers, shunt reactors, power generators - Coil coated metals are used wherever the end use demands a high-quality painted finish on a component fabricated from sheet metal.
Food Packaging	Corrosion resistance Adhesion Food safety	- crown corks, twist-off caps and aerosol bottoms and tops

The process and the chemistry behind chromium based surface treatment is claimed to be complex. Typically, numerous steps are involved, including in addition to the main treatment process, important pre- and post-treatment steps. Figure 1 gives an overview of the individual steps of the surface treatment process (taken from the Analysis of Alternatives for use 5, non-confidential report).

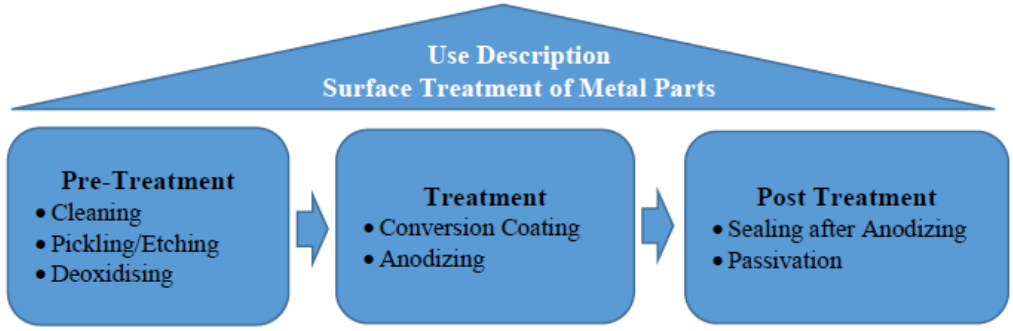

Figure 1. Surface Treatment Processes steps where chromates might be involved

The applicant explains that it is important to understand that chromium trioxide has important functionalities within different steps of the process. The substance cannot be entirely replaced without impacting the technical performance of the final product. It is important to consider the surface treatment system as a whole when evaluating alternatives, and not only single steps of the overall process. According to the applicant, there is at present no complete chromium trioxide-free treatment system industrially available, which would provide all the required properties to the surfaces of all articles in the scope of this application.

For the use 5 applied for, less than 900 tonnes per annum of chromium trioxide are used. Examples of applications and the sectors in which chromium trioxide formulations are used such as covered by use 5 are outlined in Table 11 below (taken from the Socio-Economic Analysis, non-confidential report).

Table 11. Examples of applications and the sectors in which chromium trioxide formulations are used such as covered by use 5

Functionalities and applications	Main industrial sectors
Chemical Conversion Coatings (CCC), Electrolytic chromium coated steel (ECCS), pickling, chromic acid anodising (CAA), Sacrificial and Diffusion Coatings, and passivation processes which provide: ➢ Corrosion resistance ➢ Paint adhesion ➢ Barrier function ➢ Lacquer adhesion ➢ Self-healing properties ➢ Ability to be stripped	➢ Steel processing industry ➢ Steel packaging industry ➢ Architecture ➢ General engineering

The applicant informs that he carried out an extensive literature survey and a consultation with industry experts in order to identify and assess potential alternatives to chromium trioxide used in surface treatment processes. All in all, 23 potential alternatives (substances and processes) for all parts of the process chain were identified. The applicant classified those into 3 categories (see also Appendix 1 – Initial list of alternatives to chromium trioxide containing surface treatments):

- **Category 1:** alternatives that are considered promising, where considerable R&D efforts have already been carried out within the different industry sectors. These are: *acidic surface treatments, manganese-based treatments, silane/siloxane, sol-gel coatings, Cr(III)-based processes, Zr/Ti-based coatings, other oxide-baed coatings, low tin steel, non-chrome deoxidiser solution based on mineral acids or iron, as well as inorganic acids and hydrogen peroxide activated benzyl alcohol with acid for pre-treatments.*
- **Category 2:** alternatives with clear technical limitations, which may only be suitable for a limited number of applications but not as a general alternative (see Appendix 1, initial list of alternatives)
- **Category 3:** alternatives which have been screened out at an early stage of the analysis and which are not applicable for the use applied for (see Appendix 1, initial list of alternatives)

7 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. A brief reasoning of why they have been excluded by the applicant is given in Appendix 1 of this opinion. 11 potential alternatives (processes as well as substances for all parts of the process chain), classified as either category 1 or 2, are further discussed in the application for authorisation. They are currently under R&D programmes, some being considered promising for substituting chromium trioxide in the future, other being considered promising only for specific applications.

The applicant concludes that at present none of the alternatives is technically feasible for 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-based surface treatment. The applicant explains that it is challenging and complex to

replace the substance in applications that demand superior performance for corrosion and/or adhesion in order to deliver safety over extended periods and extreme environmental conditions. Several potential alternatives (those classified into category 1 and 2) are currently under intense investigation across industry sectors. However they are not expected to be commercially available within the next 8 - 10 years. According to the applicant, the review period requested for this use (7 years) coincides with best case (optimistic) estimates by industry of the required time to industrialise alternatives to chromium trioxide.

Technical feasibility

According to the applicant, the use of chromium trioxide delivers specific technical characteristics which are key requirements in the following different steps of surface treatment processes: pre-treatment, passivation processes, chemical conversion coating, chromic acid anodising including associated CrO3 processes, grain-oriented electrical steel insulation and electrolytic chromium coated steel. The key functionalities offered by chromium trioxide (mainly based on the characteristics of the Cr(VI) compound) and necessary for the respective industries applying chromium-trioxide-based surface treatment are amongst others corrosion resistance, active corrosion inhibition, adhesion promotion, low electrical contact resistance, wear resistance, optimal layer thickness, chemical resistance, biostatic properties and inhibition of growth and proliferation of biological organisms. The key requirements for different sectors covered by this application for authorisation are given in Appendix 2 of this opinion. Table 12 below summarizes the alternatives categorised under category 1 & 2 (taken from Analysis of Alternatives for Use 5 – non confidential report).

Table 12. List of main treatment alternatives categorised (Category 1, highlighted in yellow; Category 2, highlighted in red)

Application with Definition	Industry sector			
Passivation of copper foils	**General Engineering**	PVD		
Chemical conversion coating (CCC)	**Automotive**	Silane/Siloxane, sol-gel coatings	Cr(III)	
	Architecture	Organometallics (Zr-/Ti-based)	Silane/Siloxane, sol-gel coatings	Manganese-based processes
		Cr(III)	Acidic surface treatments	Molybdenum-based processes
	General engineering	Cr(III)	Organometallics (Zr-/Ti-based)	5-methyl-1H-benzotriazol
Grain-oriented electrical steel	**General engineering**	Other oxide-based	Cr(III)	
Electrolytic chromium coated steel (ECCS)	**Packaging**	Low tin steel (LTS)	LTS with Silane/Siloxane	
Chromic acid anodising (CAA) including subsequent sealing	**Automotive**	Acidic surface treatments	Silane/Siloxane, sol-gel coatings	
	Architecture	Acidic surface treatments		

Table 13. List of pre-treatment alternatives categorised

Alternative	Surface pre-treatment	Substrate
Inorganic acids (plus additives)	Functional cleaning/ Pickling/Etching/Desmutting	Aluminium and aluminium alloys, Steel, copper, brass, molybdenum
	Deoxidizing	Aluminium and aluminium alloys
	Stripping of inorganic finishes	Aluminium and aluminium alloys
	Stripping of paint	Magnesium and magnesium alloys
Hydrogen peroxide activated benzyl alcohol (with acids)	Stripping of paint	Aluminium and aluminium alloys, steel (CRES), nickel/cobalt alloys, titanium and magnesium

As already stated and as indicated in the table above, the applicant identified 11 alternatives which are considered as promising to replace chromium trioxide in the future (category 1 and 2 alternatives). According to the applicant these alternatives show at present substantial technical deficiencies. The applicant assessed each of these 11 alternatives against the above mentioned technical criteria, which are indispensable for surface treatment within the affected industry sectors. Furthermore, the applicant states how important it is that the surface treatment process, which consists of numerous steps, is considered as a whole: the steps are almost always inter-related and cannot be separated or individually modified without impairing the overall process or the performance of the treated product. The applicant's overall conclusion is that although chromium trioxide-free alternatives are available and used by industry for some individual steps of the process, currently there are no technically feasible alternatives available for the overall surface treatment process. In other words, within the overall process, the replacement of chromium trioxide is currently not possible. Several potential alternatives are subject to ongoing R&D, but these do not yet deliver the necessary combination of key functionalities in order to be considered technically feasible. Table 14 summarises the main findings of the Analysis of Alternatives, carried out by the applicant (taken from the Analysis of Alternatives for Use 5, non-confidential report).

Table 14. Summary of findings of Analysis of Alternatives (x marks technical failure, (x) marks failure not for all applications)

Sector	Potential Alternative (basis of process &/or coating)	Corrosion resistance	Adhesion	Robustness	Fatigue resistance	Long-term experience	Food Safety	Complex parts/geometry	Reproducibility	Application speed	Layer thickness	Machinability	Maturity	Coating tension	Magnetic properties	One-step process
		Performance Failure According to Critical Criteria / Functionality														
Architecture	Acids	x				x										
	Silane/siloxane					x		x	x							
	Organometallics (Zr, Ti)	(x)	(x)	(x)		(x)										
	Cr(III)		(x)			(x)			x							
Automotive	Acids		x		x						x					
	Silane/Siloxane							x	x							
	Cr(III)	(x)	x						x							
Gen Engineering - Passivation	PVD									x	x					
Gen Engineering	Other oxide										x	x	x			
	Cr(III)										x			x	x	
Gen Engineering – conversion	Organometallics (Zr, Ti)	x		x												
	Cr(III)	(x)	(x)						x							
	5-Methyl-1H-benzotriazol												x			x
Packaging - ECCS	Low tin steel (LTS)		x				x									
	LTS with Silane/ Siloxane		x													

In addition to the need for a technically equivalent alternative, there are several specifications, such as e.g. specific approval processes within the different industry sectors, which also affect substitution possibilities. The applicant gives a brief summary of such specifications for the architecture sector (product certification schemes, quality label systems, etc.), the automotive sector (type approval schemes, etc.), general engineering (approval processes, etc.) and food packaging (EU legislative requirements for food contact materials, etc.). As reported above, extensive R&D is ongoing in order to find substitutes to chromium trioxide in surface treatment processes. However, alternatives are not expected to be commercially available within the next 8 - 10 years. According to the applicant, the review period requested for this use (7 years) coincides with best case (optimistic) estimates by industry of the required time to industrialise alternatives to chromium trioxide.

Economic feasibility

Economic feasibility aspects have been provided for category 1 alternatives (those being considered as promising substitutes in the future) as well as for category 2 alternatives

(those being suitable for a limited number of applications only). The applicant states that due to the fact that all of the above mentioned alternatives show significant technical failures or they are at a too early stage of the development process, 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 the 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. While the applicant concludes that for most of the processes there is no indication that alternatives are not economically feasible, for some of the processes discussed, cost-intensive investments are expected. Table 15 below summarises the information provided by the applicant on economic feasibility of the alternatives – category 1 & 2.

Table 15. Economic feasibility of alternatives

Alternative	Economic feasibility considerations
Acidic surface treatments	• No indication that these alternatives are not economically feasible
Cr(III)-based surface treatments	• Indication that these alternatives are in general economically feasible • General engineering: for grain oriented steel insulation, there would be costs for the implementation of capture systems
Silane/siloxane and sol-gel coatings	• No indication that these alternatives are not economically feasible
Manganese-based processes	• No indication that these alternatives are not economically feasible
Molybdates and molybdenum-based processes	• No indication that these alternatives are not economically feasible • The chemical cost might be twice higher
Organometallics	• No indication that these alternatives are not economically feasible • There might be some investment needed for modification of the surface treatment line as fluoric acids are very aggressive products in general
Benzotriazole-based processes	• Costs due to collecting waste • Process costs as the former one-step process has to be adapted to a two-step process
PVD	• Completely new production lines would need to be implemented as the PVD-based process cannot be performed in existing coating installations: €1 - 3

	million for a new plant including machine lines Additional costs for cleaning lines
Other oxide-based coatings	• No indication that these alternatives are not economically feasible • Comparable process costs for grain oriented steel insulations
Low tin steel (LTS)	• Diverging opinions on the economic feasibility based on the consultation of companies
CVD	• No indication that these alternatives are not economically feasible • Increased costs for line speed and energy input due to longer reaction times
Inorganic acids (pre-treatment)	• No indication that these alternatives are not economically feasible • However, not all the alternatives are qualified through all industry sectors • Electrolytic pickling: higher investment costs
Pickling/etching of copper (pre-treatment)	• No indication that these alternatives are not economically feasible • However, not qualified as general alternatives • There might be higher investment and waste management costs

Conclusion

In SEAC's view the applicant has made an extensive assessment of alternatives, especially when it comes to the aspect of technical feasibility. However, SEAC notes that the use applied for in fact covers many specific technical applications e.g. pre-treatment, passivation processes, chemical conversion coating, chromic acid anodising including associated CrO3 processes, Grain-oriented electrical steel insulation and electrolytic chromium coated steel which are all covered by the generic use name 'surface treatment'. The analysis of alternatives provided by the applicant does not fully differentiate between the various uses and process steps which is considered by SEAC a clear shortcoming of the analysis. All in all, 23 potential alternatives were identified, screened and classified into the above listed 3 categories (see also Appendix 1 – Initial list of potential 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 being promising candidates to be substitutes in the future (category 1 alternatives) or for those that might be a promising solution for a limited number of applications (category 2 alternatives), a description of the substance ID & properties and the process was provided. Furthermore, a sector specific assessment (such as for architecture, the automotive sector, general engineering, food packaging) was provided in order to conclude on the technical feasibility followed by a brief discussion about the availability of each of the techniques.

Only a qualitative and very brief discussion on economic feasibility was 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 is currently regarded feasible from a technical point of view or they are in a too early stage of the development phase. 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. The lack of a detailed assessment on economic feasibility does not allow SEAC to conclude on this aspect.

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

☐ YES

☒ NO

Justification:

Applicant's conclusion on technical feasibility: the applicant concludes that currently there are no technically feasible alternatives to chromium trioxide used in surface treatment processes in the above listed sectors. Based on experience and with reference to the status of R&D programs as well as qualification and certification regimes within some of the affected sectors (such as automotive, architecture, food packaging, etc.) alternatives are not foreseen to be commercially available before 8 - 10 years after the sunset date. The applicant's reasoning for this conclusion is given in section 7.1 above.

Applicant's conclusion on economic feasibility: the applicant states that because all of the shortlisted alternatives (category 1+2 alternatives) fail significantly when it comes to technical aspects, or because they are at a too early stage of the development process, no quantitative analysis of the economic feasibility was conducted. Economic feasibility is discussed very briefly, only qualitatively and only in broad terms without further substantiation. According to the applicant, costs cannot be determined until the technical issues are solved and it is known what article parts can be covered by the alternative. It is reported that for most of the alternative processes discussed, there is no indication that they are not economically feasible. For others, cost intensive investments are expected.

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 and only qualitatively. For assessing the economic feasibility of alternatives in general, not only production costs, once the technical issues are solved, could be taken into account but also the costs of developing and transitioning to achieve technical feasibility can be considered. These costs were, however, not considered by the applicant. The applicant concludes that for most of the alternative processes, there is no indication that would not be economically feasible. For some, cost-intensive investments are expected. 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, 23 potential alternatives were identified, screened and classified into the above listed 3 categories (see also Appendix 1 – Initial list of potential alternatives). This categorisation gives a good overview of why certain alternatives were considered further and why others have been excluded from any further assessment.

During the public consultation, comments supporting the conclusion of the applicant were submitted on technical feasibility. Many of these comments were submitted by downstream users who outlined their past efforts to find alternatives and gave additional information on why they had not been able to substitute to date. No comments were submitted that would indicate that substitution is indeed already possible for these specific surface treatment processes within the affected industries.

Nevertheless, due to the broadly defined scope of the use applied for, SEAC cannot exclude that there are indeed "surface treatment" uses or process steps using chromium trioxide where substitution is already feasible or will become so at short-term. Furthermore, it is not clear to SEAC when alternatives will eventually become available for specific applications/specific sectors covered by this use. Ideally, SEAC would have been provided with an exhaustive list of all the applications/components covered by use 5 in order to judge the actual feasibility/infeasibility and to ensure that substitution takes place where already possible. 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. According to the applicant, applications where substitution is already possible are not covered by the application anyhow. The applicant does, however, not specify such applications or their related technical requirements. SEAC finds the applicant's approach to resolve this issue not fully appropriate and emphasises the need to ensure that substitution takes place where indeed already feasible. This could have been achieved by e.g. further narrowing down the scope of the use applied for. Generally, it should be made clear by the applicant which technical applications are covered by the use applied for and which are not. This information allowing differentiation across technical applications was not provided by the applicant, which is considered a shortcoming of the analysis.

However, based on the available information, SEAC agrees to the applicant's conclusion that *overall,* technically feasible alternatives for chromium trioxide in surface treatment for applications in various industry sectors 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 10 different alternatives for the purpose of surface treatment (except ETP) for applications in various industry sectors namely architectural,

automotive, metal manufacturing and finishing, and general engineering.

The use covers a number of surface treatment processes and steps that may be applied to a number of different metal substrates (e.g. aluminium, steel, zinc, magnesium, titanium, alloys and composites with metallic areas). The use is also intended to cover the downstream use of chromic acid and dichromic acid. However, the analysis of alternatives shows that there are no technically feasible alternatives to the use of chromium trioxide in the surface treatment of metal for key applications. Several potential alternatives are subject to ongoing R&D, but do not currently support the necessary combination of key functionalities to be considered technically feasible alternatives. Therefore, a detailed risk assessment of the alternatives to facilitate a comparison with chromium trioxide has not been conducted, the only information provided by the applicant was the hazard classification and labelling of the alternatives and these were compared to the classification of chromium trioxide to indicate less or more severe toxicity of the alternatives.

- Alternative 1: Acidic surface treatment

Boric acid is an alternative to chromium trioxide, however the substance is classified as Repr. 1B. Boric acid is a SVHC and included on the Candidate list. Therefore, the use of BSA as alternative may become time limited by potentially transferring boric acid to REACH authorisation (Annex XIV). Apart from boric acid, tartaric acid constitutes the toxicological worst case scenario and is classified as Acute Tox. 4, Skin Irrit. 2, Skin Sens. 1, Eye Irrit. 2, STOT SE 3, and Eye Dam. 1. A transition to nitric acid as an alternative would contradict the tendency to reduce the use of this substance in order to avoid NOx emissions. 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, as some of the alternate substances used are as well under observation, the replacement has to be carefully evaluated case by case.

- Alternative 2: Cr (III) based surface treatment

Chromium (III) chloride is classified as Skin Irrit. 2, Eye Irrit. 2, STOT SE 2, Acute Tox. 4. As such, transition from chromium trioxide, which is a non-threshold carcinogen to Cr (III) would constitute a shift to a less hazardous substance.

- Alternative 3: Silane/Siloxane and sol-gel coating

The exact substance identity and composition of products used in the Sol-Gel process is very often not known as is confidential business information. Therefore, only the hazard classifications for the Sol-Gel matrix could be taken into account. In a worst case they are classified as Flam. Liq. 3, Acute Tox. 4, Eye Dam. 1, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Asp. Tox 1, Muta. 1B, Carc. 1B. The substance vinyl trimethoxysilane (VTMS) constitutes the worst case scenario and is included in the CoRAP (Community Rolling Action Plan), indicating substances for evaluation by the EU Member States in the next three years. As such, a transition from chromium trioxide – which is a non-threshold carcinogen – to one of the above mentioned alternative products could constitute a shift to less hazardous substances. However, as at least one of the alternate substances is itself classified for mutagenicity and carcinogenicity, any replacements will need to be carefully evaluated on a case by case basis.

- Alternative 4: Manganese-based processes

A worst case assumption as alternative is Potassium permanganate and is classified as Ox. Sol. 2, Acute Tox. 4, Aquatic Acute 1, Aquatic Chronic 1, Skin Corr. 1C. As such, transition from chromium trioxide, which is a non-threshold carcinogen, to one of these substances would constitute a shift to a less hazardous substance.

- Alternative 5: Molybdates and Molybdenum-based processes

Sodium molybdate is classified as Skin Irrit. 2, Eye Irrit. 2, Acute Tox. 4, STOT SE 3. As such, transition from chromium trioxide, which is a non-threshold carcinogen, to one of these substances would constitute a shift to less hazardous substances.

- Alternative 6: Organometallics (Zr- and Ti-based products)

The exact substance identity and composition of products used is very often not known as this is confidential business information of suppliers. As worst case assumption, fluorotitanic acid is classified as Met. Corr. 1, Acute Tox. 2, Skin Corr. 1B, Eye Dam. 1. As such, transition from chromium trioxide, which is a non-threshold carcinogen, to one of these substances would constitute a shift to less hazardous substances.

- Alternative 7: Benzotriazole-based processes, e.g. 5-methyl-1H-benzotriazol

Based on the available information on the substances used within this alternative, 5-methyl-1H-benzotriazol would be the worst case with a classification as Acute Tox. 4, Skin Irrit. 2, Skin Irrit. 2 and STOT SE 3. As such, a transition from chromium trioxide, which is a non-threshold carcinogen, to one of these substances would constitute a shift to less hazardous substances.

- Alternative 8: Physical vapour deposition (PVD)

Most material used in PVD are nitrides or carbides of transition metals. As toxicological worst case scenario, silicon carbide is classified as Carc. 1B, STOT RE 1, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3. As such, transition from chromium trioxide, which is a non-threshold carcinogen, to one of these substances would constitute a shift to a less hazardous substance. However, as at least one of the alternate substances is itself classified for mutagenicity and carcinogenicity, any replacements will need to be carefully evaluated on a case by case basis.

- Alternative 9: Other oxide-based coatings

The exact substance identity and composition of products used in this alternative is not known as this is confidential business information. Consequently no comparison of the hazard classification of these substances with Chromium trioxide could be performed.

- Alternative 10: Low tin steel (LTS)

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

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:

With respect to the 11 alternatives for chromium trioxide included in the applicant's non-use scenario predominantly Cr(III) and mineral-acid based system are being investigated. A transition from chromium trioxide – which is a non-threshold carcinogen – to Cr(III) would constitute a shift to less hazardous substances, however a shift to mineral-acid based systems is would also constitute a shift to less hazardous substances. However, as some of the alternative substances used are subject to further regulatory scrutiny for possible concern for risk for human health, the replacement must be carefully evaluated on a case by case basis.

Conclusion

Use of some of the alternatives may constitute a shift to less hazardous substances, however, as some of the alternatives considered are under evaluation for possible concern for risk for the environment or human health, the 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 overall 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 16 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 as relevant for assessing the human health impacts.

Furthermore, the applicant derived non-fatal cancer cases using the survival rate based on average mortality rates for lung cancer in the EU-27, namely 82.8% for both sexes. This gives 2 additional non-fatal cancer cases per year following the applicant's approach and also less than 2 following SEAC's alternative approach.

Table 16. Estimated additional statistical fatal cancer cases, based on the applicant's assumptions (review period applied for and 1 year of exposure)

	Exposure duration per day (h)	Exposure 8h adjusted TWA (µg/m³)	Excess lung cancer risk	Number of exposed people	Estimated statistical fatal cancer cases (years of exposure)	
					7 y	1 y
Workers – Combination of WCS	<1	0.25	0.001	2,233	0.39	0.06
	1-3	0.75	0.003	866	0.46	0.07
	4-6	1.5	0.006	772	0.81	0.12
	6-8	2	0.008	887	1.24	0.18
	Not regularly exposed	0.25	0.001	3,287	0.57	0.07
Workers total				8,045	3.47	0.5
	Exposure 24h (µg/m³)				**7 y**	**1 y**
Man via environment - Local	3.25×10^{-3}		9.43×10^{-5}	10,000 x 515 sites = 5,150,000	48.56	6.94
Man via environment - Regional	Not relevant					
Total					**52.04**	**7.43**

Table 17. Estimated additional statistical fatal cancer cases, based on SEAC's alternative (worst case) approach (review period applied for and 1 year of exposure)

	Exposure duration per day (h)	Exposure 8h adjusted TWA (µg/m³)	Excess lung cancer risk	Number of exposed people	Estimated statistical fatal cancer cases (years of exposure)	
					7 y	1 y
	Up to 8	2	0.008	4,758	6.66	0.95
	Not regularly exposed	0.25	0.001	3,287	0.58	0.08
Workers total				8,045	7.24	1.03
	Exposure 24h (µg/m³)				**7 y**	**1y**
Man via environment - Local	3.25×10^{-3}		9.43×10^{-5}	10,000 x 515 sites = 5,150,000	48.56	6.94
Man via environment - Regional	Not relevant					
Total					**55.80**	**7.97**

The estimated additional statistical fatal cancer cases reported in Tables 16 and 17 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 (based on the extrapolation of the number of sites) was performed to consider all health impacts related to this use. The basis for the extrapolation was data gathered from CTAC use group 5 members that was extrapolated first to cover consortium members that did not provide information and second to whole surface treatment 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 it has substantially overestimated the health impacts. Most of the cancer cases (over 90%) 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)/m³). This ELR refers to a working lifetime exposure with continued working-daily exposure. In order to use this ELR within this application for authorisation, it was adapted by the applicant to the review period applied for (7 years) and the actual hours of potential exposure per day. Furthermore, average mortality rates for lung cancer in the EU-27 were taken into account, namely 82.8% for both sexes. In order to evaluate the additional cancer cases in monetary terms, monetary values as suggested by the ECHA 2011 guidance on socio-economic analysis in applications for authorisation were used by the applicant: a Willingness to Pay (WTP) to avoid a cancer case of €400,000 per non-fatal case and €1,052,000 (lower bound based on the median value) or €2,258,000 (upper bound based on the mean value) per fatal cancer case (VSL). As the WTP values are based on a 2003 study, the applicant adjusted them to the year of the sunset date by using GDP deflator indexes. Based on

these assumptions (upper bounds have been used by the applicant), the health impacts for workers were monetised (price adjusted) and sum up to an amount of €10 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 (5,150,000 as a whole) and the DRR as confirmed by RAC has been used (2.9×10^{-2} per µg Cr(VI)/m³). For the regional assessment, following a worst-case approach, the population of the EEA was taken as a basis, i.e. 512,888,463 people and the DRR as confirmed by RAC has also been used (2.9×10^{-2} per µg Cr(VI)/m³). These figures are claimed by the applicant to be conservative and to highly overestimate the occurring impacts. Respectively, the Predicted environmental concentrations (PECs) local and regional have been used. Again, the assessment was adapted to the time frame of 7 years (requested review period). Based on these assumptions (upper bounds have been used by the applicant), the health impacts for man via the environment sum up to €140 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 to exposure to chromium trioxide. Upon request, the applicant provided the calculation spreadsheets, in order for SEAC to be able to verify the calculations made. The economic concepts were applied correctly. However, several assumptions taken within the human health impact assessment have underlying uncertainties, such as the exact number of workers exposed, 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/allocation of workers between the different exposure duration groups as set up by the applicant. Therefore, SEAC set up an additional (worst case) scenario with only two different exposure duration groups, as depicted in Table 17. For the calculation of human health impacts for workers, using sensitivity values for VSL, this results in monetised impacts of €21 million instead of €10 million as calculated by the applicant. For the health impacts related to man via the environment, RAC concluded that the applicant's assessment related to the regional exposure of the EEA population is not relevant as chromium (VI) is effectively reduced to chromium (III) in the environment (conclusion within the EU RAR). For SEAC, the regional assessment is therefore not regarded as being relevant for assessing the human health impacts man via environment regional.

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

Scenario 1: the applicant's approach (5 different exposure duration groups, see Table 16 above) which results in total human health impacts in the amount of €72.9 million – €150.3 million.

Table 18. Human health impacts according to the applicant's approach

Monetised health impacts, workers	€4.9 million - €10 million
Monetised health impacts, man via environment (local)	€68 million - €140.3 million
Total:	€72.9 million – €150.3 million

Scenario 2: SEAC's alternative (worst case) approach (2 different exposure duration groups, see Table 17 above), which results in total human health impacts in the amount of €78.1 million – €161.3 million.

Table 19. Human health impacts according to SEAC's approach

Monetised health impacts, workers	€10.1 million - €20.9 million
Monetised health impacts, man via environment (local)	€68 million - €140.4 million
Total:	€78.1 million – €161.3 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 16 and 17 above, considering a 7 years exposure for workers and humans via the environment, the figures range between 52 and 56 statistical fatal cancer cases. These should be considered in the context of the wide scope of the application, covering 8,045 workers and 5.2 million of general population.

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

The applicant's assessment:

For calculating the benefits of the continued use of chromium trioxide the applicant took into account two cost factors: **social impacts (job losses)** and **economic impacts (lost purchasing volumes)**, whereas social impacts account for around 65 % of the estimated total costs. Assessments are based on information received by the applicant from his supply chains. 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. In order to back up the assessments made, the applicant provided case studies during the opinion-making process of RAC and SEAC, on SEAC's 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. Member companies from across all sectors directly and indirectly affected were involved in the process. Due to the extremely broad scope of the use applied for as well as highly complex supply chains, the applicant stated 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 surface treatment facilities are expected to shut down their activities related to chromium trioxide in the EEA. Those who additionally offer other surface treatment or business activities (without chromium trioxide) may partially shut down or seek to apply alternative technologies. However, these technologies are regarded as not technically feasible (see section on assessment of alternatives above) and it is therefore regarded very likely that customers will look for other sources of chromium surface treatment (non-EEA suppliers) to cover their demand. Relocation of facilities might be another response to a non-authorisation, but there are also companies which reported that relocation cannot be (financially) afforded, so a shut-down of business would be the most likely response. Article manufacturers and assemblers of chromium trioxide components with in-house surface treatment processes are expected to either (partially) shutdown their facilities and sub-contract these operations to companies outside the EEA, or relocate their chromium-related production lines to non-EEA countries. In the latter case, it is likely that further sub-assembly steps are relocated to non-EEA countries as well, meaning that even larger parts of these businesses will be migrated to non-EEA territory. Companies that do not operate in-house surface treatment are expected to subcontract these operations to companies outside the EEA. The relocation of the before mentioned activities are expected to have major implications for product safety, supply times and security of supply. Moreover, a shift of know-how/technology to non-EEA countries is expected which would affect

Europe's position as a technology leader. And lastly it is argued that a non-authorisation of chromium trioxide for surface treatment leads to increased import of products.

The applicant concludes that all non-use scenarios lead to a different extent to losses for the EEA, jeopardising the competitiveness of the EU and workplaces.

- **Social impacts (job losses)**: the applicant assessed the impact of loss of earnings related to job losses following a production stop or relocation of business outside the EEA. SEAC was informed that other further social impacts may occur due to a non-authorisation, such as foregone productivity of the workers, secondary and tertiary job losses, additional costs for the society due to unemployment and impacts of loss of purchasing power, but these impacts have not been considered or quantified in the cost-benefit analysis. Data gathering was performed through sending questionnaires to member companies of the consortium. These companies were asked how many jobs related to the use of chromium trioxide would be lost as a consequence of their individual non-use scenarios. In addition, companies were asked to classify the jobs that would be lost according to their education levels (low skilled/high skilled/academic). In case this was not possible for companies, impacts of job losses were calculated for the lowest education level (low skilled) only. For the calculation of social impacts the applicant furthermore assumed that workers that lose their job due to a closure or relocation will either remain unemployed for the entire duration of the requested review period (7 years) or will replace another unemployed person in case of re-employment. Compared to the number of sites taken into account in the human health impacts assessment, the lower bound of the number of sites has been used by the applicant to estimate the job losses (i.e. 215 sites). The present value of the total social impacts for a period of 7 years (requested review period) sum up to €1,354 million, reflecting a loss of 6,074 jobs (lower bound estimate). The upper bound estimate on the social impacts is based on a loss of 14,197 jobs.

- **Economic impacts**: the applicant's assessment of economic impacts is based on lost purchasing volumes. No extrapolation was performed for this assessment, i.e. only data was used that was directly reported by companies of the consortium. These impacts have been calculated as the present value of future expenses for raw materials and energy in the year of the sunset date and sum up to €701 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 information on expected negative economic impacts for job platers covered by use 2 and 3 of this application for authorisation: 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 surface treatment in the sectors covered by this use (which is not carried out by job platers), and assuming a partial or complete shut-down (depending on the size of the companies) of affected facilities covered by use 5, employing 6,074 people, this would result in profit losses of €49 million per year.

- **Impacts in the supply chain**: During the opinion-making process the applicant provided case studies on SEAC's request showing the impacts on downstream users within different sectors in order to complete the assessment of social and economic impacts as described above. The case studies provided for use 5 covered the defence industry (non-aero military), the automotive sector (OEMs and suppliers) and the steel packaging industry.

  For the defence industry, the applicant stated that a non-granted authorisation would result in all new products relying on the use of chromium trioxide for one or more component parts will be stopped. The production interruption for the majority of the products will last until either the affected production processes are re-located to a non-affected country or an alternative is developed and substituted. Aftermarket repair activities will be disrupted by impact on supply of spare parts for both legacy and non-legacy products, and through an inability to repair products in Europe. The applicant claimed that the impact of a non-granted authorisation can be conservatively estimated as a minimum of 50% of the turnover, as chromium trioxide is needed for thousands of components and disrupted supply for even one component may affect delivery of any assembled product. Based on an annual turnover of €47 billion for the non-aero military defence industry, the applicant estimated that the affected turnover would be €24 billion and that, based on an average profit margin of 10%, the profit loss would be €2.4 billion per year.

  For the automotive sector, the applicant stated that non-authorisation would, as a first step, result in an interruption of the supply chain. According to the applicant, the absolute best case would be a 90% loss of the European vehicle production during the first month after the sunset date (assuming that 10% of the lost EU production volume can be compensated by non-EEA supply), 80% loss during the second month and full production after 10 months. Overall, this would result in a loss of 6.3 million vehicles. Assuming an average EBIT[5] of €1,000 per manufactured car, the overall loss of EBIT would be €6.3 billion. The loss of value added is estimated to be €46.3 billion.

  For the steel packaging industry, the applicant did not explain how non-authorisation would affect the sector as such. Instead, the applicant estimated that the turnover of the European metal packaging industry is €19.8 billion (assuming that it represents 15% of the whole European packaging industry). Considering the net margin of 3.49% of the "Containers and packaging" industry, the applicant concluded that this represents an annual net result of approximately €0.7 billion, which is also the claimed profit loss in the non-use scenario. The impacts are summarised in Table 20.

Table 20. Summary of the case studies performed for use 5, surface treatment in different sectors

Case study	Economic impact [€ billion per year]	Metrix
Military, non-aero	2.4	Loss in profit
Automotive sector (OEMs and suppliers)	46.3	Value added foregone
Steel packaging industry	0.7	Profit loss

[5] Earnings before interest and tax

- **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 surface treatment different sectors 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 losses and value added foregone, which was provided on the request of SEAC, is not included in this assessment.

SEAC's view:

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

- The **non-use scenario(s):** SEAC agrees that the extremely broad scope of the use applied for as well as highly complex supply chains make the description of the non-use scenario difficult. SEAC acknowledges that the detailed description of all possible non-use scenarios would not be feasible for such broad upstream applications. 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, and SEAC agrees to that, 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. what are the expected profit losses to actors in different levels of the supply

chain (suppliers of raw materials, job platers, article manufactures, any other relevant actor). Furthermore, it would have been 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 possible consequences within different sectors, the overall information at hand is not detailed, substantiated and verifiable enough to allow defining (a) robust non-use scenario(s) 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 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 would not have merely distributional consequences at the societal level. Moreover, the assumptions taken by the applicant (workers that lose their job due to a closure or relocation will either remain unemployed for the entire duration of the requested review period (7 years) or will replace another unemployed person in case of re-employment) are regarded by SEAC being highly unrealistic and do not fit to 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 €49 million per year for companies providing surface treatment. 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 cost information cannot be thoroughly verified by SEAC, as little to no information about assumptions taken and methodologies used is available, the information gives an indication of the dimension of the expected economic impacts and supports the overall conclusion of the applicant that the negative economic effects in the supply chain of not granting an authorisation 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 economic welfare

impacts. Furthermore, the additional information on profit losses and 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 wider impacts would strengthen the argument of the applicant, that the socio-economic benefits of continued use of chromium trioxide outweigh the risks. Despite of the deficiencies, this sensitivity check supports the overall conclusion that there are net benefits from granting the authorisation.

Conclusion on benefits and costs

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

- Information on possible profit losses (based on the applicant's information on profit losses of job platers covered by use 2 and 3, used as a benchmark for the use applied for) of €49 million per year
- The social cost of job losses of €208 million based on the assumption of a 1 year unemployment period and lost salaries as presented in the sensitivity analysis
- Significant supply chain impacts for the affected sectors, i.e. the military sector, the automotive sector and the steel packaging industry

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 chain are significant. SEAC notes that even if there is less uncertainty in the non-use scenario for the companies applying surface treatment, SEAC cannot confirm that all of them would shut-down if the authorisation is not granted. Additionally, SEAC takes note that the possible profit losses do not reflect the net changes in profit in the EU over time as the resources may be used to generate profits in other companies.

Regarding the human health impact assessment, SEAC agrees to the applicant's approach although the assumptions taken are uncertain e.g. the exact number of sites covered by the application for authorisation, the number of workers exposed and the allocation of workers between different exposure durations. In order to test the robustness of the cost-benefit ratio, SEAC set up an additional (worst case) scenario, which considers some of the respective uncertainties present in the applicant's approach. The human health impacts of these two scenarios range from €73 to €161 million for the seven 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 €72.9 and €161.3 million, calculated over 7 years (potential overestimation)
- Possible profit losses of €49 million per year based on information submitted by the applicant on turnover/profits of job platers covered by uses 2 and 3
- Expected social costs of €207.7 million due to job losses (workers (lower bound of potentially affected workers) assumed being unemployed for 1 year) based on salary costs
- Expected significant negative impacts in the supply chain for different affected end-user industries, such as military, automotive and steel packaging

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 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 surface treatment 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 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 possible profit losses (based on information from the applicant on profits of job platers covered by use 2 and 3) or social cost of job losses (lower bound of affected workers, assuming 1 year of unemployment only) alone would outweigh the monetised human health impacts, which are regarded as being an overestimation.

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

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation:

Exposure scenarios

RAC takes note of the applicant's intention to develop a detailed set of Risk Management Measures (RMM) guidance document to be provided in support of their Downstream Users (DUs) by the sunset date for chromium trioxide. While supporting this effort, RAC sees the clear need for further conditions.

Supply chain communication is considered to be a prerequisite to achieve the objective of reducing exposure to workers and humans via the environment. Recognising the applicant's obligation to include representative exposure scenarios (ES) in their Chemical Safety Report (CSR) as defined in Annex I sections 0.7 and 0.8 of REACH for the different types of processes and individual tasks, specific ESs shall be developed for representative surface treatment operations, including e.g. automatic versus manual, open versus closed systems. These shall describe typical Operational Conditions (OCs) and RMMs 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**.

Regarding spraying applications, updated OCs and RMMs presented by the Applicant in table 2b of this opinion must be followed. The area in which spraying is conducted should be restricted either physically by means of barrier/signage or through strict procedures during the activity and applicable for a specified time after the spray application has ceased. Workers should not remove the RPE used in spraying applications before leaving the area of application.

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

Validation of Exposure Scenarios

Such ESs shall be validated and verified by the applicant through representative programmes of occupational exposure and environmental release measurements relating

to all processes and tasks described in this use applied for.

Downstream User Monitoring

Workers

The downstream users covered by this application and where relevant the applicant shall implement at least annual programmes of occupational exposure measurements relating to the use of the substance described in this application. These monitoring programmes are needed to demonstrate that OCs and RMMs are appropriate and effective in limiting the exposure. Monitoring programmes shall be based on relevant standard methodologies or protocols and be representative of (i) the range of tasks undertaken where exposure to the substance is possible (i.e. the programme shall include both process and maintenance workers), (ii) the operational conditions and risk management measures typical for these tasks and (iii) the number of workers that are potentially exposed.

In addition to monitoring of surface treatment activities, exposure monitoring should be performed also related to machining operations in order to confirm low exposures in machining.

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

Environment

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

Continuation of monitoring requirements

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

Whilst monitoring programmes are essential for the development and verification of ES by the applicant, it is not the intention that all DUs of this application should continue monitoring programmes for the duration of the validity of the authorisation granted. Where, following the implementation of the OCs and RMMs of the ESs, the DU can clearly demonstrate that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible, and where it is demonstrated the OCs and RMMs function appropriately, the monitoring requested for this authorisation may be discontinued.

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

Review reports

In any subsequent review report, in order to facilitate the assessment of the exposures resulting from the use, the applicant shall provide the exposure scenarios for typical, representative surface treatment plants, listing OCs and RMMs together with resulting exposure levels. A justification as to why the selected scenarios are indeed representative for the use shall be provided along with a justification that the OCs & RMMs follow the hierarchy of control principles and are appropriate and effective in limiting the risks. Furthermore, more detailed task descriptions shall be provided with a discussion and justification regarding the choice of OCs & RMMs.

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

Justification:

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

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

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

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

Justification:

SEAC notes that the wide scope of the use applied for (Surface treatment for applications in various industry sectors) includes technical applications for which suitable alternatives

may already be available and implemented or will become so in short term. The related assessment performed by the applicant is too general to exclude these from the scope of the authorisation.

10. Proposed review period:

☐ Normal (7 years)

☐ Long (12 years)

☒ Short (4 years)

☐ Other:

Justification:

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

RAC's advice:

Considering that

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

Therefore strict additional conditions and monitoring arrangements are proposed

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

Other socio-economic considerations

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

- **Alternatives:** The applicant performed its assessment based on a 7 years review period, due to feedback from industry on (best/optimistic) estimates of the schedule required to implement alternatives to chromium trioxide mixtures used in surface treatment processes. Additionally, specifications of some of the affected sectors (such as the automotive sector, general engineering, architecture, steel for packaging, etc.) are briefly explained. No contradicting information was received during public consultation. Furthermore this period reflects the normal review period of ECHA. According to the applicant, the requested 7 years form the minimum period required for industry to industrialise alternatives to chromium trioxide. SEAC agrees to the applicant's conclusion that currently, an *overall* technically feasible alternative for chromium trioxide-based surface treatment for key applications does not 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, and value added foregone 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 the continued use of chromium trioxide in surface treatment processes within various industry sectors. 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. 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. However, SEAC takes notes of the potentially overestimated statistical fatal cancer cases for this use applied for, ranging from 52 to 56 considering a 7 years (review period requested by the applicant) exposure for workers and man via the environment.

- **Risk/benefit ratio:** with the information (both, quantitatively and qualitatively) available in the application, provided during the opinion making process by the applicant and submitted during the public consultation, SEAC agrees to the applicant's conclusion, that the benefits of continued use of chromium trioxide for surface treatment for applications in various industry sectors, 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 normal review period[6], such as requested by the applicant, could be regarded as being fulfilled for some of the industrial sectors and applications covered by this use (e.g. certification and qualification schemes in the automotive sector), SEAC notes that this is not the case for the full scope of this use applied for and for all sectors and applications covered respectively. SEAC has reservations about the appropriateness of the applicant's approach. The deficiencies present in the application lead to substantial uncertainty on the actual consequences for the different actors in the supply chain and the actual negative economic impacts of not granting an authorisation. However, it is clear from the information given in the authorisation application and case studies that not granting an authorisation for the use applied for would lead to negative economic impacts for many different sectors in the EEA and to social costs related to unemployment. Overall a net benefit from granting the authorisation is expected.

In conclusion, taking into account

- the applicant's argumentation regarding the time required to industrialise alternatives put forward to justify the requested review period of 7 years,
- the expected negative economic consequences down the supply chain,
- the expected social costs due to unemployment,
- the expected human health impacts,
- and the substantial 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 requirements for normal review period have not been met,
- RAC gave no advice on the length of the review period

SEAC recommends a short (4 year) review period.

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

☒ YES

☐ NO

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

☒ YES

☐ NO

☐ NOT APPLICABLE

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

Justification:

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

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

ANNEX

Table A1. Calculations based on aggregated company/site data Use 4/5/6

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
C1	2.94	8	8	2009-2012	no	automatic	no
C2	0.50	1	1	2011	yes	automatic	nr
C3	3.00	2	2	2012	yes	automatic	yes
C4	0.48	2	1	2011	no	manual	no
C5	1.35	3	3	2012	yes	nr	nr
C6	0.38	4	4	2013	yes	automatic	yes
C7	0.91	5	5	2012-2013	yes	manual	no
C8	1.25	1	1	2008	yes	automatic	yes
C9	1.00	4	1	2013	yes	automatic	yes
C10	0.10	5	5	2012	yes	closed	no
C11	0.81	5	5	2013	yes	manual/ automatic	no
Total		40	36				

* Not adjusted for use of respiratory protection

Arithmetic Mean 1.16
Geometric Mean 0.81
90th Percentile 2.94

This specific data on uses 4/5 comes from CTAC companies in France or in Germany.

Table A2: Background literature data provided by applicant

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

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

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
Aeronautics painting	77	82.3	3.67	17.08	<0.02–896	58.4

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
Spray painting	45	135.50	10.38	<0.02–896	75.6

* 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 1, 2, 3 and 6 were considered as useful for the assessment of releases from functional chrome plating, also these are included in the table. Specific use is mentioned in the last column.

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

**Calculated by ECHA*

***discharge subject to further treatment in municipal 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 the RMMs at the site

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

Table A6: Waste water monitoring data. Since also the data from uses 1, 2, 3 and 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 waste water reflected the situation to the end of June 2015. After June 2015 the amount of Cr(VI) release to waste water 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 waste water treatment system and the solid waste will be treated as hazardous waste with zero release to waste water.

As regards site 18 the applicant informed that the 11 g of Cr(VI) discharged to waste water 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 waste water 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 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 waste water between 0.1 and 0.5 µg/l. The applicant informed further that this level of discharge to water resulted in 5 x 10^{-8} mg/L of Cr(VI) in surface water when the treated waste water 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. Initial list of potential alternatives to chromium trioxide-containing surface treatments

ID	Alternative	Category	Reason for Screening out
1	Acidic surface treatments	1	
2	Iridite NCP (Al, F, Oxygen)	2 (Summarised under Zr/Ti-based treatments)	
3	Manganese-based treatments	1	
4	Mineral Tie-Coat (cathodic mineralisation)	3	This is no alternative for surfaces treatment discussed within this dossier--> Process is related to functional chrome applications.
5	Molybdate based coatings	2	
6	Plasma electrolytic oxidation	3	This is no alternative for surfaces treatment discussed within this dossier--> Process is related to functional chrome applications.
7	Polymer coatings	3	This is no alternative for surfaces treatment discussed within this dossier --> Process is related to primer applications.
8	Self-Assembling molecule systems	3	Adhesion and corrosion protection poor on relevant Al alloys, not seen as general alternative for surfaces treatment discussed within this dossier.
9	Silane/Siloxane	1	
10	Sol-gel coatings	1	
11	Tagnite (inorganic Silica or vanadate)	3	This process is only applicable on Mg and its alloys, no general alternative for surfaces treatment discussed within this dossier.
12	Cr(III)-based processes	1	
13	Zr/Ti-based coatings	1	
14	Vapor deposition based technologies	1 (summarized under LTS with Silane/siloxane	
15	Benzotriazole or 5-methyl-1H- benzotriazole	2	
16	Hot water sealing	3	This is no alternative for surfaces treatment discussed within this dossier.
17	PVD	2	

18	Other oxide-based coatings	1	
19	Low tin steel	1	
20	Tannic acid	1(summarized under acidic surface treatments)	
21	Non-chrome deoxidiser solution based on Mineral acids or Iron	1	
22	Formic acid	3	Stripping of organic coatings: -- Not suitable for assemblies with dissimilar metals Not allowed for the use with high strength steels
23	Hydrogen peroxide activated benzyl alcohol with acid	1	

Appendix 2: Key requirements/functionalities provided by chromium trioxide-based surface treatments within different sectors (taken from the Analysis of alternatives, non-confidential report):

Table 1. Key requirements within the automotive sector

	Process	Quantifiable key functionality	Requirements (on Al alloys)
Automotive sector	Chromic acid anodising (CAA) with subsequent sealing after anodizing Chromium trioxide/ chemical conversion coating	Corrosion resistance	48 h (CASS), ISO 9227) (CAA) >240 h (Neutral salt spray (NSS), ISO 9227) (Passivation)
		Layer thickness	<15 µm (ISO 2177)
		Resistivity	Simultaneous thickness and electrode potential measurement (STEP, ASTM B 764)
		Chemical resistance	DIN EN ISO 20105
		Adhesion	No delamination (ASTM B533, TL 528, ISO 1464)

Table 2. Key requirements within the Packaging industry

	Process	Quantifiable key functionality	Requirements
Packaging industry	Electrolytic chromium coated steel (ECCS)	Corrosion resistance	> 3 years, tests with simulants for performance evaluation while pack tests required with customers
		Adhesion	Tests with simulants for performance evaluation, pack tests required with customers cross hatch to evaluate lacquer adhesion
		Optical properties	Pack tests required with customers visual evaluation
		Heat resistance	>100 °C
		Food safety	Food contact materials must not create any unacceptable risks for consumer of packed food

Table 3. Key requirements within the steel processing sector

	Process	Key functionality	Requirements
General engineering (including steel)	Chromium trioxide / chemical conversion coating	Corrosion resistance	*On steel:* 1000 h (ISO 9227) 350-500 h without delamination (EN 13523-8)
		Layer thickness	< 1 µm (EN 13523-1), measurement of coating weight
		Adhesion of subsequent layer	*On steel:* Adhesion with degree of delamination 0-1 (EN 13523-6, ISO 2409) *on metallic chromium:* Equal to chromium trioxide-based conversion coating (internal specifications)
		Wear resistance	*on metallic chromium:* Equal to chromium trioxide-based conversion coating (internal specifications)
		Chemical resistance	> 100 MEK DR (EN 13523-11)
		(Thermo) Optical properties: Aesthetic/ brightness/ impression	In the current highly competitive market customers are more and more sensitive to aesthetic aspects. Candidates for substitution will have to fulfil the same aesthetic criteria as the current chromium trioxide-based coating.
	Grain oriented steel insulation	Corrosion resistance	Coating must resist to the working conditions in an electrical transformer i.e. T° up to 300°C (IEC 60404-1-1)
		Layer thickness	3-5 µm (Permascope measurement)
		Coating tension	>4MPa
		Electric insulation	>3 MΩ/mm^2 (normalized Franklin test, in compliance with standard CEI 60404-11).
		(Thermo) Optical properties: Aesthetic/ brightness/ impression	Surface uniform grey, without white spots Candidates for substitution will have to fulfil the same aesthetic criteria as the current chromium trioxide-based coating.
	Passivation of copper foil	Corrosion resistance	>1 year (no oxidation, visual inspection)
		Heat resistance	No oxidation after thermal cycle 2 h at 200°C
		Conductivity	No change of conductivity

		Application speed	<20 seconds per dipping process
		Compatibility with substrate	copper foil has to be laminated on various resins
		Layer thickness	<0.7 nm

Support document

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

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

Date	CTAC	Comment number
21/07/2016		1
Comment received		

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

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

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

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

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

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

Date	CTAC	Comment number
21/07/2016		2

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

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

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

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

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

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

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

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

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

Response of RAC and SEAC

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

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

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

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

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

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

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

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

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

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

Date	CTAC	Comment number
21/07/2016		3

Comment received

III. General Comments on Review Period, Good Administrative Practice

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

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

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

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

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

Response of RAC and SEAC

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

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

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

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

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

Date	**CTAC**	**Comment number**
21/07/2016		4
Comment received		

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

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

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

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

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

[4] P. 39 draft Opinion Use 3.

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

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

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

Response of RAC and SEAC

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

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

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

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

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

Date	CTAC	Comment number
21/07/2016		5

Comment received

IV. Other Comments on Individual Uses

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

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

Response of RAC and SEAC

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

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

Date	CTAC	Comment number
21/07/2016		6

Comment received

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

Response of RAC and SEAC

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

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

Date	CTAC	Comment number
21/07/2016		7

Comment received

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

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

Response of RAC and SEAC

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

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

Date	**CTAC**	**Comment number**
21/07/2016		8

Comment received

V. Comments on Conditions

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

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

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

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

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

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

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

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

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

Review Reports

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

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

Response of RAC and SEAC

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

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

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

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

Date	**CTAC**	**Comment number**
21/07/2016		9

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

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

Date	CTAC	Comment number
21/07/2016		10

Comment received

VI. Presentation of the Opinion

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

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

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

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

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

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

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

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

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

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

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

Response of RAC and SEAC

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

Date	**CTAC**	**Comment number**
21/07/2016		11

Comment received

Annex A

Detailed Comments

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

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

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

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

Response of RAC and SEAC

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

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

Date	**CTAC**	**Comment number**
21/07/2016		12

Comment received

All Uses: AoA, specifically economic feasibility of alternatives

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response of RAC and SEAC

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

Date	**CTAC**	**Comment number**
21/07/2016		13

Comment received

Use 4: AoA

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response of RAC and SEAC

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

Date	CTAC	Comment number
21/07/2016		14

Comment received

Annex B: ADS comment

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

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

Response of RAC and SEAC

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

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