Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Chromium trioxide use: Formulation of mixtures

ECHA/RAC/SEAC: AFA-O-0000006490-77-01/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:

Formulation of mixtures

Intrinsic property referred to in Annex XIV:

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

Applicant:

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

Reference number:

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11-2120088250-61-0006

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

THE OPINION OF SEAC

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

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

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

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

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

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

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

REVIEW

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

JUSTIFICATIONS

The justifications for the opinion are as follows:

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

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

2. Is the substance a threshold substance?

- ☐ YES
- ☒ NO

Justification:

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

3. Hazard assessment. Are appropriate reference values used?

Justification:

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

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

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

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

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

(RAC27/2013/06 Rev.1).

Are all appropriate and relevant endpoints addressed in the application?

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

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

Description:

Short description of the use

According to the applicant (organised in the Chromium Trioxide REACH Authorization Consortium - CTAC), the use applied for relates to the formulation of chromium trioxide containing mixtures, typically in a non-continuous batch process, using either an open or closed system. The use generally involves storage, decanting, weighing (if solid), transfer and charging of chemicals to a blend tank, mixing and/or reaction, transfer from the tank to packaging, maintenance and cleaning of equipment, transfer of waste and laboratory activities.

The tonnage of chromium trioxide involved is stated by the applicant to be 9,000 tons/year corresponding to **4,500 tons/year as Cr (VI)**. According to the applicant's Chemical Safety Report (CSR) the use may be conducted at **10-100 sites** in the EU (according to the applicant's Socio-Economic Analysis (SEA) – at up to 30 sites; this is also the total number of CTAC member companies in Use group 1).

The applicant presents one exposure scenario (ES) in the CSR: "Formulation of mixtures" of chromium trioxide with one environmental contributing scenario (ECS) and 11 worker contributing scenarios (WCS). Although formulation generally is a non-continuous batch process, the applicant has treated it as a continuous process in the assessment.

Worker exposure

Exposure estimation methodology:

In the case of WCSs 1 and 9, describing the storage of raw material in sealed containers and the storage of formulations, the applicant's consider that no potential for exposure exists (a qualitative assessment method was applied). The chromium trioxide used for the formulation is delivered in sealed containers and stored in a chemical storage room for dangerous substances and the final formulation is again stored in closed containers.

Transfer of chromium trioxide to a mixing vessel, decanting, weighing and mixing are covered by WCS 2-5, transfer of formulation to containers by WCS 6 and cleaning and maintenance of equipment by WCS 7-8 (Table 1). For WCSs 2-8 a summary of aggregated measurement data from six companies was described in the CSR. These data can be calculated to represent 20 % of the maximum number of formulators (n=30) in EU. The measured data is stated to represent both large and small formulators. Disaggregated exposure data from individual companies (average exposure concentrations in air measured from personal sampling) were provided at RAC's request and are presented in the annex (Table A1) to this opinion. The applicant used the 90^{th} percentile from these measurements in his further analyses.

Individual company exposure data does not include any information on the associated Operational Conditions (OC) or Risk Management Measures (RMM) applied during the actual measurement. According to the applicant, the OCs and RMMs used at the time of

the measurement vary between companies. The range of the averages (excluding the use of Respiratory Protective Equipment (RPE)) is high from 0.06 to 9.50 µg Cr(VI) /m^3. In addition, it is stated by the applicant that some variation in monitoring methodology is expected between companies. The implications of this are not specified by the applicant, but may include e.g. differences in detection limits.

For WCSs 10 and 11, inhalation exposure has been estimated using the ART 1.5 model. Input parameters for the model have been provided in the CSR. Associated operational conditions (OCs) and risk management measures (RMMs) are presented in Table 1.

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

RMMs applied

A general overview on WCSs and related OCs and RMMs applied in each contributing scenario are presented in Table 1.

Table 1: Operational Conditions and Risk Management Measures

Contributing scenario (PROC) and type of process	Name of the scenario	Duration and frequency of exposure	Concentration of the substance	LEV used + effectiveness[1]	RPE used + effectiveness	Other RMMs
WCS 1 (PROC 1)	Delivery and storage of raw material	< 8 h	Cr(VI) < 50%	no	no	closed system, basic general ventilation
WCS 2 (PROC 8b)	Decanting and weighing of solids	< 4h	Cr(VI) < 50%	Yes[3)]	Yes (respirator with APF 30[2])	basic general ventilation
WCS 3 (PROC 8a/8b) open, manual or automatic, closed	Transfer to mixing vessel – aqueous solution	< 8h	Cr(VI) < 50%	yes	No	basic general ventilation and RPE if no LEV is in place[4)]
WCS 4 (PROC 8b) normally manual	Transfer to mixing vessel – solids	< 4h	Cr(VI) < 50%	no	Yes (respirator with APF 30[2])	basic general ventilation
WCS 5 (PROC 2 to 5) closed or semi-closed with automatic mixing	Mixing by dilution, dispersion (closed or open process)	< 8h	Cr(VI) < 50%	yes	no	basic general ventilation
WCS 6 (PROC 9) manual or automatic	Transfer to small container (including filtering)	< 8h	Cr(VI) < 50%	yes	no	basic general ventilation and RPE if no LEV is in place[4)]
WCS 7 (PROC 8b)	Cleaning of equipment	< 1h	Cr(VI) < 50%	yes	no	basic general ventilation and RPE in cases where exposure to chromium trioxide in solid form may occur [4)]
WCS 8 (PROC 8a)	Maintenance of equipment	< 30 min	Cr(VI) < 50%	yes	Yes (respirator with APF 30[2])	basic general ventilation
WCS 9 (PROC 1)	Storage of formulation	< 8 h	Cr(VI) < 50%	no	no	basic general ventilation and containment: closed system (sealed steel drums or sealed containers)

Contributing scenario (PROC) and type of process	Name of the scenario	Duration and frequency of exposure	Concentration of the substance	LEV used + effectiveness[1]	RPE used + effectiveness	Other RMMs
WCS 10 (PROC 15) Subactivity: Drawing of sample and transfer to laboratory	Laboratory analysis (sampling)	< 30 min	Cr(VI) in mixture: Substantial (10-50%)	yes, fixed capturing hood) (90% reduction)	no	good natural ventilation
WCS 10 (PROC 15) Subactivity: Laboratory analysis	Laboratory analysis	< 60 min	Cr(VI) in mixture: minor (5 - 10%)	no	no	good natural ventilation
WCS 11 (PROC 8b)	Waste management	< 30 min	Powder weight fraction (Cr (VI): substantial (10-50%)	no	Yes (respirator with APF 30[2])	good natural ventilation and low level containment (90% reduction).

[1)]LEV effectiveness is available only for modelled exposure

[2)]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)

[3)]some smaller formulators will conduct decanting and weighing of solids (WCS2) only occasionally and for a few minutes and then it might be that no LEV is in place, but RPE is worn.

[4)] at least half-mask with P3 filter (APF 30 according to German BG rule 190) is worn

Other Risk management measures used to control exposure:

According to the applicant, the Occupational Health and Safety Management System supporting all the WCS is advanced and the use of RPE is specifically required in cases where exposure to chromium trioxide in solid form may occur. The normal place of use is indoors for all WCS except WCS 9 (Storage of formulation), which may occur indoors or outdoors. Protective clothing, chemical-resistant gloves and goggles are required in case of potential exposure to chromium trioxide for all WCS except WCS 9 (Storage of formulation).

Discussion on the exposure information:

Exposure estimates for each WCS are presented in Table 2.

Table 2: Exposure –inhalation

Contributing scenario	**Route of exposure**	**Method of assessment**	**Exposure** µg Cr(VI)/m^3	**Exposure corrected for PPE** µg Cr(VI)/m^3
WCS 1	Inhalation	Qualitative	0	-
WCS 2 to 8	Inhalation	Measured data	• arithmetic mean: 2.63 • geometric mean: 0.71 • 90th percentile: 7.3	• arithmetic mean: 0.1 • geometric mean: 0.02 • 90^{th} percentile: 0.27
WCS 9	Inhalation	Qualitative	0	
WCS 10 Subactivity: Drawing of sample and transfer to laboratory. Subactivity: Laboratory analysis	inhalation	ART 1.5	90th percentile for both subactivities: 0.69	
WCS 11	inhalation	ART 1.5		90^{th} percentile: 0.22

As described above, the exposure values used for WCS 2-8 are the 90^{th} percentile of the values presented in Table A1 of the Annex to this opinion. The 90th percentile was calculated from personal measurements from six different companies formulating chromium trioxide in the EU (20 % of the maximum number of formulators in EU). The number of samples used for the final calculation was eight. According to the applicant, more than 20 personal and static measurements from 1997-2011 in four EU countries were available (France, Germany, Sweden and The Netherlands).

In addition, static measurement data are also available from these companies, which the applicant considers support the personal measurement data. However, these data were not made available to RAC, because the applicant felt that preference should be given to personal measurement data.

The most significant potential for exposure occurs during the weighing and transfer of flakes to the mixing vessel (WCS 2-6) where formulation takes place. The mixing vessel is typically closed, apart from during the time required for adding of the dry formulation constituents. The

exposure during cleaning (WCS 7) and maintenance (WCS 8) activities are included in the measured data. The exposure during infrequent maintenance activities outside the formulation process is not estimated. It is stated by the applicant that the long-term exposure from infrequent maintenance activities will be much lower than estimated in the WCS 8 (maintenance of equipment). No quantitative assessment to support this conclusion was provided.

The applicant corrected the 90th percentile exposure estimate of 7.3 µg Cr(VI) /m^3 for the use of respiratory protection to derive a value of 0.27 µg Cr(VI) /m^3. According to their description, respiratory protection is always worn during the handling of solid chromium trioxide. The effectiveness of respiratory protection was taken into account by the applicant by using company-specific information on the type of mask and filter used or, if not reported, the Assigned Protection Factor (APF) provided by the manufacturer of the RPE. In other cases, the APF provided by the German BG rule "BGR/GUV-R190" from December 2011 was used. Detailed calculations, presenting how the adjustments for use of RPE were made, were not made available to RAC.

For WCS 11, where ART 1.5 was used to estimate the exposure levels, only the value corrected for the use of RPE was provided (referred to by the applicant as 'extended ART').

The assessment of exposure was based on a standard daily frequency (in the absence of more specific information in the original application), but at the request of RAC, some further information on task frequencies were provided by the applicant. It was noted by the applicant that the formulation of chromium trioxide containing mixtures is generally carried out infrequently, and in discrete batches, but that the effect of this low frequency on the exposure has not been quantitatively addressed in the exposure estimation. As an example, the applicant describes one formulator who advises that formulation involving chromium trioxide is carried out as a master batch activity for two hours per month. Based on this the applicant calculated that the highest measured value (9.5 µg Cr(VI) /m^3, see table A1 in the Annex) during the dissolving/mixing of sodium chromium trioxide would be reduced to <1 µg Cr(VI) /m^3 if the frequency of exposure would have been considered in the assessment. In addition, in the SEA, the applicant has divided workers into different exposure groups according to their average exposure duration per day. This division is based on the data collected from the CTAC members. According to these data, the majority of the workers (73%) are exposed only infrequently (once per week or once per month or even less often), and only 5% are exposed >3 h/day (further see SEA annex B, table 19).

Combined exposure

According to the information provided by the applicant, there is no potential for combined exposure, other than that shown in the respective sub-scenarios. WCSs 2 to 8 are carried out by the same worker/s and the measured data presented represents exposure during these activities. It is expected that the laboratory tasks (WCS 10) are performed by workers other than those working in the formulation process. In addition, laboratory tasks are exempted from authorisation (under 'scientific research and development' conditions). Even in the case where the same worker/s would conduct all activities (WCS 1-9 and WCS 11) except laboratory work (WCS 10), the estimated combined potential exposure is considered by the applicant to remain below 0.5 µg Cr(VI)/m^3.

Uncertainties related to the exposure assessment:

As this exposure scenario (ES) would apply to many formulating sites (up to 30) and the use of

RMMs (e.g. LEV) varies between sites, the applicant stated that it is not possible to develop a description applicable to every individual situation in the ES. To cover the variability of conditions, the applicant added guidance / recommendations to the ES: for WCS 3 (Transfer to mixing vessel-aqueous solution) and WCS 6 (Transfer to small containers), in which it is advised that if no LEV is in place, at least half-mask RPE with a P3 filter (APF 30 according to German BG rule 190) is worn. Respiratory protection is not required during cleaning (WCS 7), but in the CSR it is added that in cases where exposure to chromium trioxide in solid form may occur, at least half-mask RPE with a P3 filter (APF 30 according to German BG rule 190) should be worn (Respirator with APF 30 and effectiveness against inhalation: 96.67%). protective clothing, chemical-resistant gloves and goggles in the case of potential exposure to chromium trioxide are also advised to be worn during cleaning. It was also added by the applicant that some smaller formulators may conduct decanting and weighting of solids (WCS 2) only occasionally and for a few minutes. In these cases, if LEV is not in place, RPE is worn.

According to the SEA, up to 30 sites perform chromium trioxide formulation in the EU. The exposure assessment is based on measured data (eight measurements from six companies, including both large and small formulators and representing 20% of the maximum number of companies), but the variation between the measurements is high (range of means 0.06-9.5 $\mu g/m^3$) and the data does not provide any information on the OCs or RMMs in place during the measurements thus preventing further evaluation by RAC. According to the applicant, the number of measurements is limited since the exposures (as eight hour time weighted average) are well within prevailing national occupational exposure limits. Therefore, further measurements have not been obligatory or considered necessary. According to the applicant the OCs and RMMs applied at the time of the measurements vary between companies. In addition to the limited number of measurement data and the variability in observed exposure levels, the lack of detailed descriptions of the OCs and RMMs linked to the exposure data is a clear weakness of the assessment.

RAC considers that modelled exposure data would have reduced the uncertainties in the exposure assessment related to WCS 2-8. Modelled exposure data was requested from the applicant, but according to the applicant the available timeframe was too limited to carryout representative modelling and since measured data was available, it was not considered necessary or valuable to provide such data. The opportunity to corroborate the very limited measured data with standard modelling in either the preparation of the application or at the later suggestion of RAC was thus declined by the applicant.

In the CSR the applicant estimates exposures without taking the frequency of activities into account. Later on, at RAC's request, the applicant added that although the low frequency of the activity has not been quantitatively addressed, in reality it may have a significant effect, further reducing any long-term exposure estimates. RAC agrees that indeed this may have a significant effect but it is difficult to quantify it without any information on e.g. typical or maximum frequency of the tasks performed.

Related to the scenarios involving the use of RPE, the applicant has used an assigned protection factor (APF) provided by the German BG rule "BGR/GUV-R190" from December 2011 to account for the effect of RPE on exposures. It should be noted that other countries allocate lower APFs than Germany. In practise, 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 the formulation of chromium trioxide containing mixtures are a matter of best practice (as described by BREFs). Whilst emissions to air (via fine dust and particulates) are considered to occur at all use sites, the applicant states that not all sites will necessarily have releases of Cr(VI) to wastewater as both liquid and solid wastes containing Cr(VI) can rather be collected from sites by an external waste management company instead of being discharged in wastewater to the municipal sewer or directly to the environment. The applicant did not provide exposure assessment for waste disposal contracted out to specialised companies. The applicant considered that releases to soil, either at a local or regional level, do not occur.

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 2014. 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 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 1.6×10^{-5} is reported in the succinct summary of risk management measures and operating conditions for the use.

Table 3: Cr(VI) exposure concentrations in air, 100 meters from point source

No of sites	**Year**	**Range $C_{local_{air,\ ann}}$ (mg Cr(VI)/m^3)**	**AM (mg Cr(VI)/m^3)**	**GM (mg Cr(VI)/m^3)**	**90th percentile (mg Cr(VI)/m^3)**
6	2010-2014	8.5×10^{-8}-3.86×10^{-12}	1.76×10^{-8}	1.85×10^{-9}	4.86×10^{-8}

Note: Regional air concentrations of chromium trioxide, based on modelling with EUSES 2.1.2, are 9.05×10^{-17} mg/m^3 Cr(VI).

Based on the 90th percentile of these date, the applicant concludes a $PEC_{local,air}$ for use in the assessment of indirect exposure to humans via the environment of 4.86×10^{-8} mg/m^3.

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

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

Since the information on releases received from the applicant in the first set of questions was not supported with either data or reference to other publically available documentation, RAC asked for further information on environmental emissions of Cr(VI) to wastewater in a second round of questions. In response, RAC received summary data for 44 sites involved in chromium trioxide surface treatment activities or formulation of chromium trioxide mixtures, although the exact use of Cr(VI) at each of the sites i.e. formulation or surface treatment was not initially provided. 14 (32%) of the 44 sites reported that they had no wastewater emissions as all wastes were disposed of via some other route i.e. hazardous solid waste. For those sites reporting wastewater emissions, relevant information on annual Cr(VI) releases was received from 13 out of 30 companies. These data are presented in Table A2 in the Annex to this opinion.

The applicant also provided data on the concentration of Cr(VI) in wastewater for 10 of the 30 sites that reported wastewater emissions. Due to limited accompanying contextual information on the monitoring data, these data are considered difficult to interpret but in all cases effluent concentrations were <50 µg/l. The available wastewater monitoring data is included in Table A3 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. None of these three sites were involved in the formulation of chromium trioxide containing mixtures. Alongside this information the applicant also clarified which uses were conducted at each of the 44 sites from which data was provided. Four of the 44 sites (7, 10, 34, 35) were reported to undertake formulation with two of these sites (10, 35) reporting no emissions to wastewater. The other two sites reported wastewater effluent concentrations of <30 µg/L, both with subsequent treatment in a municipal WWTW before release to surface water.

Table 4: Summary of environmental emissions

Release route	**Release factor / rate**	**Release estimation method and details**
Water	usually <1× 10^{-4} % (10^{-6}) and Cr(VI) level in WW <0.05 mg/l	based on the applicant's assessment on good practises. See also Table A2 of the Annex to this opinion.
Air	1.6× 10^{-5}	estimated from C_{local}, which is based on measured data
Soil	0	no soil releases

Table 5: 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	4.86 × 10^{-8} mg/m^3 (local exposure 100m from point source – based on 90th percentile of measured releases) 9.054 × 10^{-17} mg/m^3 (regional exposure) estimated by EUSES 2.1.2.
Man via Environment - Oral	Not considered relevant by the applicant
Man via Environment - Combined	Not considered relevant by the applicant

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

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

RAC acknowledges that Cr(VI) will transform rapidly in the environment to Cr(III) under most environmental conditions. This has been previously discussed in the EU RAR for chromate substances (EU RAR 2005), and will reduce the potential for indirect exposure to humans to Cr(VI) via the environment, particularly from the oral route of exposure. Accordingly, the EU

RAR only assessed oral exposure to Cr(VI) as result of exposure from drinking water and the consumption of fish, rather than using the standard food basket approach that also includes contributions to oral exposure from the consumption of arable crops (root and leaf), meat and milk. This approach was considered appropriate at the time on the basis that whilst treatment to remove Cr(VI) from wastewater was considered to be effective it was not known how comprehensively this treatment was put into practice by users of Cr(VI). As such, an acknowledged worst-case approach, where treatment was not considered to be in place, was used as the basis for the assessment of indirect exposure to humans via the environment. This assessment concluded that the concern for human health via indirect exposure was low for all scenarios, although RAC notes that the basis for these conclusions i.e. the underlying dose-response relationship and effects thresholds for Cr (VI) were different in the EU RAR assessment to those agreed by RAC.

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

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

Equally, the data available on potential emissions to wastewater for this use is limited to four of the 30 sites across the EU reported to undertake the use and no contextual information to assess the representativeness of these four sites is available.

The absence of the oral route 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 any review report prepared for this application.

Regarding emissions to air and consequent inhalation exposure of the general population, the

assessment is based on measured data from six sites (representing 20% of the maximum number of formulators in the EU). However, since no accompanying contextual information is provided in the CSR, the representativeness of these data is uncertain. In response to a request from RAC the applicant provided additional information from two sites to support the use of the factor of 0.5 to estimate Cr(VI) emissions based on measurements of total chromium. Whilst the data from these two sites supports the use of a factor of 0.5, RAC considers that this factor may not be applicable across all sites / all uses and that measurement data should generally be obtained on the basis of Cr(VI) rather than as total chromium. Notwithstanding these observations RAC does not find any reason to disagree with the applicant's conclusions that highly effective systems to control air emissions of Cr(VI) are typical across the sites undertaking this use. In addition, RAC considers that reduction of Cr(VI) to Cr(III) in air is likely to further reduce the general population exposure, but that this may not occur so rapidly that emissions to air are not a relevant source of indirect exposure of Cr(VI) to humans via the environment at the local scale.

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

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

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

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

In addition, RAC notes that the default assumptions in EUSES for local assessment estimate $PEClocal_{air,ann}$ 100m from a point source[1]. 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)[2]. Alternative assessment

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

[2] 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."*

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

Conclusions

RAC concludes that:

- There are significant uncertainties in the worker exposure assessment covering about 30 sites due to the limited (8 measurements) and variable exposure data and the prevalent lack of contextual information. These could have been reduced by modelled data, which was not, however, provided by the applicant even though it was requested by RAC.
- A linkage between the OC and RMM and the claimed exposure levels was not demonstrated by the applicant due to the lack of contextual information on the scare measurements, preventing further evaluation of RAC.
- The frequency of the activities has not been taken into account in the CSR. If these activities are indeed infrequent, as suggested but not demonstrated by the applicant, it is likely to decrease the exposure and related risks significantly.
- There are uncertainties related to the applicant's claim that wastewater releases are "negligible".

With respect to emissions to air and exposure of the general population through inhalation, the assessment is based on measured data from six companies (representing 20% of the formulators in the EU). However, since no accompanying contextual information is provided in the CSR, the representativeness of these data is uncertain. RAC notes that the applicant's approach for assessing general population inhalation exposure is likely to significantly 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 using the RAC reference dose-response relationship for the carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1). The applicant has conservatively assumed, that all inhaled chromium trioxide particles are in the respirable range and contribute to the lung cancer risk. Thus, the calculated excess life-time lung cancer risk is 4×10^{-3} per µg of Cr(VI)/m^3.

Evaluation of the Risk Management Measures

Risk management for activities related to formulation are very much based on the use of LEV and RPE. According to the applicant, the use of LEV varies between the sites and it is not possible to develop a single description of the RMMs applicable to all sites. RAC does not consider that a description of each workplace is necessary but questions why it was not possible to describe typical workplaces and justify why these represent the rest in an efficient manner. To cover variability, the applicant has also advised that in WCSs in which dust may be formed, if no LEV is in place, at least a half-mask respirator with P3 filter (APF 30 according to German BG rule 190) is to be worn. According to RAC, the lack of LEV in these tasks can be considered as inadequate containment, breaching the principles of hierarchy of control and could be only acceptable in special, defined circumstances when the use of LEV is not technically possible. In addition, RAC notes that in these cases, workers may have to wear RPE for long periods. RAC observes that when this is the case, respiratory protective devices (RPD) should be used in accordance with the standard 'EN 529 (Respiratory protective devices. Recommendations for selection, use, care and maintenance. Guidance document.'). These procedures should include fit testing of the RPD masks to the wearer and checking of the medical fitness of the wearer. Adequate training and supervision for the use and maintenance of the RPE should be provided.

Risk characterisation

Occupational exposure has been assessed by measured data from six companies involved in formulating mixtures of chromium trioxide. A generalised estimation of maximum combined individual exposure level, 0.5 µg Cr(VI) /m^3, was made by the applicant on the basis of these measurement data (with 90^{th} percentile of 0.27 µg Cr(VI) /m^3 after the use of RPE has been taken into account). In the SEA, the applicant has used 0.27 µg Cr(VI) /m^3 for the human health impact assessment. There is, however, a high degree of variability in the measurement data. This, together with diverse OCs and RMMs, increase the uncertainty in the applicant's risk assessment. However, it should be noted that the exposure estimate above is based on the assumption that formulation tasks are conducted each day. This is not usually the case since formulation is generally a non-continuous batch process. In the SEA, the applicant presents data collected from CTAC members showing that the majority of the workers (73%) are exposed only infrequently (once per week or once per month or even less often), and only 5% are exposed >3 h/day. The infrequency of these tasks adds some margin of safety to the applicant's exposure assessment. Therefore, RAC proposes to use the applicant's maximum combined exposure level of 0.5 µg Cr(VI) /m^3 as an 8 h average, resulting in an excess risk of 2×10^{-3} as the basis of further analyses by SEAC.

RAC takes note of the applicant's view that this maximum combined exposure would set a "baseline reference value or *conditio sine qua*" and it implicitly already constitutes a use

condition in case the authorisation is granted. It should be noted that this value is proposed by the applicant and its use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC as any safe or acceptable level for this non-threshold substance. In addition, because of the uncertainties in the applicant's exposure assessment, RAC advises SEAC to perform human health impact assessment 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.

RAC acknowledged that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be a overestimates. In addition, RAC notes that the applicant has conservatively assumed that all chromium trioxide particles present in air are in the respirable range and contribute to the lung cancer risk.

Table 6: Excess risk estimates for 40 years exposure for workers

WCS	Inhalation route	
	Adjusted exposure (µg Cr(VI)/m^3)	**Excess risk**
total	0.5	2×10^{-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 was undertaken according to the RAC reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1). The applicant has conservatively assumed that all inhaled chromium trioxide particles are in the respirable range and contribute to the lung cancer risk. Thus, an excess life-time lung cancer risk is 2.9×10^{-2} per µg of Cr(VI)/m^3 for 70 years of exposure (24 h/day, 7 d/week).

For a local population living in the vicinity of formulation sites the applicant calculated an excess individual life-time lung cancer risk of 1.41×10^{-6}. The applicant has also calculated the excess individual risk related to regional exposure (2.63×10^{-15} for 70 years of exposure, 24 h/day, 7 d/week). However, as Cr(VI) is effectively reduced to Cr(III) in the environment, RAC agrees with the conclusions of the previous EU RAR for chromate substances that regional exposure may not be very relevant.

Table 7: Excess risk estimates for 70 years exposure for man exposed via the environment

ECS	Inhalation route	
	Exposure level (µg Cr(VI)/m^3)	**Excess risk**
ECS 1, local exposure	4.86×10^{-5}	1.41×10^{-6}
ECS 1, regional exposure	Not relevant	

This estimate does not take into account further conversion of Cr(VI) to Cr(III) in the atmosphere. On the other hand, the exposure estimate is based on a limited number of data points and does not incorporate any risks via oral exposure. RAC also notes that the applicant assumed that all environmental exposure was associated with particles within the respirable size range. This assumption could have led to an overestimate of risk as only respirable

particles are associated with life-time lung cancer risk. Inhalable particles are associated with the dose-response relationship for intestinal cancer, which is approximately an order of magnitude less sensitive than the dose-response for lung cancer. The relative proportion of particles in the respirable and inhalable size ranges in the atmosphere was not discussed by the applicant.

Risks from oral exposure via food or water were not considered by the applicant. After a request from RAC, the applicant calculated Cr(VI) concentrations in the environment for two sites that had direct emissions to surface water (sites 18 and 33 performing chromium surface treatments, see the Annex to this opinion). Based on these concentrations RAC calculated excess risks of 1.3-2 $\times$ 10^{-8}. RAC considers these risks are low but, as discussed in section 4, does not fully support the applicant's conclusion, based on the information provided, that risks via wastewater can simply be considered to be negligible.

Conclusion

RAC concludes that:

- There are significant uncertainties related to the description of OCs and RMMs and their ability to adequately limit the risk to workers as detailed in section 4 above.
- RAC proposes to use the applicant's estimated maximum combined exposure level of 0.5 µg/m^3 as an 8 h average, resulting in an excess cancer risk of 2 $\times$ 10^{-3} , as the basis of further analyses by SEAC. It should be noted that this value is proposed by the applicant in their CSR and its use should not be seen as an endorsement by RAC of this as a safe or acceptable exposure level for this non-threshold substance.
- According to the data presented in the CSR and in the SEA, the duration and frequency of formulation activities is usually limited. This adds some margin of safety to applicant's exposure and risk assessment. However, because of the uncertainties in the applicant's exposure assessment, RAC considers that in human health impact assessment 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 up to 1 h/d should be included. This would address some of the uncertainties related to the risk calculations for workers.
- There is an uncertainty related to the oral exposure of the general population via drinking water due to the applicant's assessment of the releases to the wastewater, which is not fully supported by RAC.
- For the local general population inhalation exposure, the exposure estimate is based on limited number of data points without contextual data. As described in section 4, highly effective RMMs to control air emissions are typical for the industry.
- RAC considers that the applicant's estimate of general population risk at the local scale is sufficient for further analysis by SEAC, but notes that the applicant's approach is based on several assumptions that are likely to significantly overestimate risks to the majority of the population. The possible transformation of Cr(VI) to Cr(III) in the atmosphere is also not considered. Regional exposure, which was estimated by the applicant, is not considered to be relevant by RAC due to transformation of Cr(VI) to Cr(III) that will occur rapidly under most environmental conditions.
- Considering the risks and the uncertainties, particularly in relation to exposure control, RAC proposes to apply conditions and monitoring arrangements.

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

Chromium trioxide is used in surface treatment processes in different industry sectors such as aerospace, automotive, general engineering, sanitary and household goods, architectural and many more. Use 1 covers the formulation of the mixtures that are used within these surface treatment processes and applications. For this use, 9,000 tonnes per annum of chromium trioxide are used. According to the applicant, surface treatment based on chromium trioxide delivers unique technical functions, such as wear resistance, hardness, corrosion resistance, low friction coefficient, adequate layer thickness, anti-stick properties, etc. However, at the formulation stage, chromium trioxide has no (separate) function, hence no Analysis of Alternatives was performed by the applicant. Analyses of Alternatives have been performed for the subsequent uses 2 to 6 of this application for authorisation. For use 1 no alternatives have been identified.

Technical feasibility

Not applicable.

Economic feasibility

Not applicable.

Conclusion

See summary above.

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

☐ YES

☒ NO

Justification:

Not applicable.

Conclusion

At the formulation stage, chromium trioxide has no (separate) function, hence no Analysis of Alternatives was performed by the applicant for use 1. Analyses of alternatives have been performed for the subsequent uses 2 to 6 of this application for authorisation.

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

Description:

This application covers the formulation of mixtures of chromium trioxide. At the formulation stage, chromium trioxide has no separate function, hence no alternatives have been identified

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

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

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

Not relevant as alternatives are not currently suitable.

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

☒ YES

☐ NO

☐ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:

Additional statistical cancer cases estimated by RAC

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 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 8 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.

In the applicant's approach (see table 8) SEAC's estimate on the additional statistical cancer cases is about two times higher than what was estimated by the applicant. This is due to a more conservative exposure estimate by RAC, i.e. 0.5 µg/m^3 instead of 0.27 µg/m^3. 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 less than 0.007 additional non-fatal cancer cases per year following the applicant's approach and SEAC's approach.

Table 8. 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/m^3)**	**Excess lung cancer risk**	**Number of exposed people**	**Estimated statistical fatal cancer cases (years of exposure)**	
					12 y	**1 y**
Workers – Combination of WCS	<1	0.0625	0.00025	124	0.009	0.0008
	1-3	0.1875	0.00075	139	0.03	0.003
	4-6	0.375	0.0015	13	0.006	0.0005
	6-8	0.5	0.002	43	0.03	0.002
	Not regularly exposed	0.0625	0.00025	842	0.06	0.005
Workers total				1,161	0.14	0.01
	Exposure 24h (µg/m^3)				**12 y**	**1 y**
Man via environment - Local	4.86×10^{-5}		1.41×10^{-6}	10,000 × 30 sites = 300,000	0.07	0.01
Man via environment - Regional	Not relevant					
Total					**0.21**	**0.02**

Table 9. Estimated additional statistical fatal cancer cases, based on SEAC's alternative approach (review period applied for and 1 year of exposure)

	Exposure duration per day (h)	**Exposure 8h adjusted TWA (µg/m³)**	**Excess lung cancer risk**	**Number of exposed people**	**Estimated statistical fatal cancer cases (years of exposure)**	
					12 y	**1 y**
	Up to 8	0.5	0.002	319	0.192	0.016
	Not regularly exposed	0.0625	0.00025	842	0.063	0.005
Workers total				1,161	0.25	0.02
	Exposure 24h (µg/m³)				**12 y**	**1y**
Man via environment - Local	4.86×10^{-5}		1.41×10^{-6}	10,000 × 30 sites = 300,000	0.07	0.01
Man via environment - Regional	Not relevant					
Total					**0.33**	**0.03**

The estimated additional statistical fatal cancer cases reported in Tables 8 and 9 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 presented 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 was performed to consider all health impacts related to this use. The basis for the extrapolation was data gathered from CTAC use group 1 members that was extrapolated to cover also those members that did not provide information. It was assumed that the average number of exposed workers and the respective distribution regarding exposure times is equal. According to the applicant it has substantially overestimated the health impacts. Most of the cancer cases (more than 90% for some of the uses, 50% for use 1) 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 (12 years) and the actual hours of potential exposure per day. Furthermore, average mortality rates for lung cancer in the EU-27 were taken into account, namely 82.8% for both sexes. In order to evaluate the additional cancer cases in monetary terms, monetary values as suggested by the ECHA 2011 guidance on socio-economic analysis in applications for authorisation were used by the applicant: a Willingness to Pay (WTP) to avoid a cancer case of €400,000 per non-fatal case and €1,052,000 (lower bound based on the median value) or €2,258,000 (upper bound based on the mean value) per fatal cancer case (VSL). As the WTP values are based on a 2003 study, the applicant adjusted them to the year of the sunset date by using GDP deflator indexes. Based on these assumptions (upper bounds have been used by the applicant), the health impacts for workers were monetised (price-adjusted) and sum up to an amount of €0.2 million over 12 years.

- **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 (300,000 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 been used (2.9×10^{-2} per µg Cr(VI)m³). These figures are claimed by the applicant to be conservative and to highly overestimate the occurring impacts. Respectively, the Predicted environmental concentrations (PECs) local and regional have been used. Again, the assessment was adapted to the time frame of 12 years (requested review period). As a whole, based on these assumptions (upper bounds have been used by the applicant), the health impacts for man via the environment (local+regional) sum up to €0.2 million over 12 years.

SEAC's view:

In general, SEAC agrees to the approach taken by the applicant. The methodologies used are regarded as being appropriate for assessing the human health impacts due the exposure to chromium trioxide. At request, the applicant provided the calculation spreadsheets, in order for SEAC to be able to verify the calculations made. The economic concepts were applied correctly. However, several assumptions taken within the human health impact assessment have underlying uncertainties, such as the different exposure durations for workers. It is not possible, either for RAC, or for SEAC to verify the exact number of workers exposed/the allocation of workers between the different exposure duration groups as set up by the applicant. SEAC therefore set up an additional (worst case) scenario with only two different exposure duration groups and with a RAC corrected exposure value of 0.5 µg Cr(VI)/m³, as depicted in table 9 above. For the calculation of human health impacts for workers, using sensitivity values for VSL this results in monetised impacts of €735,800 instead of €200,000 as

originally calculated by the applicant and €391,300, taking into account the applicant's assumptions and the exposure value adapted by RAC of 0.5 µg Cr(VI)/m³. 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 8 above) but using the by RAC adapted exposure value of 0.5 instead of 0.27 µg Cr(VI)/m³ which results in total human health impacts in the amount of €291,300 - €600,800.

Table 10. Human health impacts according to applicant's approach

Monetised health impacts, workers	€189,700 - €391,300
Monetised health impacts, man via environment (local)	€101,600 - €209,500
Total:	€291,300 - €600,800

Scenario 2: SEAC's approach (2 different exposure duration groups, see table 9 above), which results in total human health impacts in the amount of €458,300 - €945,400.

Table 11. Human health impacts according to SEAC's approach

Monetised health impacts, workers	€356,700 - €735,800
Monetised health impacts, man via environment (local)	€101,600 – €209,600
Total:	€458,300 - €945,400

The applicant's estimate of exposure, which is used for the 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. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be overestimated.

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

The applicant's assessment:

For calculating the benefits of the continued use of chromium trioxide the applicant took into account two cost factors: **social impacts (job losses)** and **economic impacts (lost purchasing volumes)**, whereas social impacts account for around 90 % of the estimated total costs. Assessments are based on information received by the applicant from their 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. Furthermore, the applicant described the efforts they had made to collect additional information and explained briefly why specific information requests from SEAC could not be provided, e.g. due to not being able to disclose certain kind of company specific information (compliance with EU competition law) and due to other confidentiality aspects within the consortium.

- The **non-use scenario:** the non-use scenario was, 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[3], a series of bilateral discussions as well as site visits and meetings with companies. The applicant concludes that as there is no alternative to the formulation of mixtures containing chromium trioxide, formulation could no longer take place within the EEA (which is the geographical scope of this application for authorisation) in case of a non-granted authorisation. This means that formulators would shut down (completely or partially) their facilities in the EEA and/or relocate their facilities to non-EEA countries. In case downstream users are granted an authorisation under REACH, the necessary mixtures would then be imported from non-EEA countries.

- **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). As this was not possible for the respective companies, impacts of job losses were calculated for the lowest education level (low skilled) only. For the calculation of social impacts the applicant furthermore assumed that workers that lose their job due to a closure or relocation will either remain unemployed for the entire duration of the requested review period (12 years) or will replace another unemployed person in case of re-employment.

  The present value of the total social impacts for a period of 12 years (requested review period) sum up to €143.6 million, reflecting a loss of 347 jobs (lower bound estimate). The upper bound estimate on the social impacts is based on a loss of 684 jobs.

[3] The consortium members comprise of sample of companies that are impacted in the non-use scenario.

- **Economic impacts (lost purchasing volumes)**: the applicant's assessment of economic impacts is based on lost purchasing volumes. No extrapolation was performed for this assessment, i.e. only data that was directly reported by companies of the consortium was used. These impacts present the lost purchase volume at EEA suppliers of consortium member companies and sum up to a present value in 2017 of €16.7 million.

- **Sensitivity analysis**
  In order to account for uncertainties for the calculation of job losses, the applicant performed a sensitivity analysis which covers 12 different scenarios with the following assumptions:
  -> 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). The outcome of the analysis shows that in each of the 12 developed scenarios the benefits of granting an authorisation outweigh the risks of continued use of chromium trioxide. This outcome is also valid if the sensitivity check is performed with the alternative "worst case" approach developed by SEAC. The results of the applicant's sensitivity check are summarised in table 12 below.

Table 12. Outcome of the sensitivity analysis (social impacts and human health impacts tested for sensitivity)

Scenario	Health impacts [million €]	Social impacts [million €]	Economic impacts [million €]	Total socio-economic impacts [million €]	Balance (social impacts + economic impacts - health impacts) [million €]	Ratio [health impacts : social impacts]
S1	0.2	143.6	16.7	160.3	160.1	1: 801.5
S2	0.2	286.5	16.7	303.2	303.0	1: 1516.0
S3	0.2	13.6	16.7	30.3	30.1	1: 151.5
S4	0.2	27.2	16.7	43.9	43.7	1: 219.5
S5	0.2	52.6	16.7	69.3	69.1	1: 346.5
S6	0.2	105.0	16.7	121.7	121.5	1: 608.5
S7	0.4	143.6	16.7	160.3	159.9	1: 400.8
S8	0.4	286.5	16.7	303.2	302.8	1: 758.0
S9	0.4	13.6	16.7	30.3	29.9	1: 75.8
S10	0.4	27.2	16.7	43.9	43.5	1: 109.8
S11	0.4	52.6	16.7	69.3	68.9	1: 173.3
S12	0.4	105.0	16.7	121.7	121.3	1: 304.3

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 as not fully appropriate. Furthermore, the calculations performed lack clarity and transparency, e.g. when it comes to the representativeness of data used. 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 an even more transparent and clear approach is needed in order for SEAC to properly verify the calculations and the outcome of the assessment.

- The **non-use scenario:** In general, SEAC agrees to the definition of the non-use scenario. It is a logic consequence that EEA formulators (at least those who do not additionally formulate other products or cannot easily switch to formulating other products) would shut down their businesses (completely or partially) and/or relocate it outside the EEA if the formulation of mixtures is no longer possible within the EEA, which most probably will lead to supply disruptions in the EEA. If downstream users are granted an authorisation, they would then need to purchase the formulations from outside the EEA.

- The assessment of **job losses (social impacts)** and **lost purchasing volumes (economic impacts)**: SEAC does not agree that the approach taken by the applicant is fully appropriate in order to assess the negative economic consequences and the welfare loss to society due to the substance being no longer available for the use applied for:
    - Instead of assessing job losses as the main negative (economic) impact of not granting an authorisation other relevant economic impacts to society or loss of profits could have been assessed.
    - The costs related to lost purchasing volumes are not elaborated and are not justified as representing losses in terms of a net economic welfare analysis. As such, they would merely represent cost savings, rather than losses.
    - Although SEAC certainly notes the dimension of the unemployment effects due to a non-authorisation, it is not clear, or demonstrated otherwise by the applicant, that the effects arising from unemployment due to a closure or relocation of a company have merely distributional consequences at the societal level. Moreover, the assumptions taken by the applicant (workers that lose their job due to a closure or relocation will either remain unemployed for the entire duration of the requested review period (12 years) or will replace another unemployed person in case of re-employment) are regarded by SEAC as being highly unrealistic and do not fit to the applicant's argument of having taken an "underestimation approach" for calculating the costs of the non-use scenario.

- 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 (see information provided above in table 12). The result shows that for all assessed scenarios, a net benefit from granting the authorisation is expected. SEAC notes that the sensitivity analysis includes the estimated lost purchasing volumes which are in SEAC's view not an appropriate parameter to measure net welfare impacts. Furthermore, the additional information on profit and revenue losses, value added foregone, etc., which was provided as part of the case studies for different sectors on request of SEAC for the remaining uses 2 - 6, is not included in this sensitivity check. However, as the downstream users can import the

mixture from outside the EEA, SEAC cannot confirm that these impacts would occur in case the authorisation is not granted. SEAC acknowledges that any disruption in the supply is expected to lead to substantial impacts in the EEA as described in the additional information on the supply chain impacts provided by the applicant for uses 2 - 6 during opinion-making.

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 information provided by the applicant is sufficient to conclude that the benefits of continued use would be significant and allow a comparison with the health impacts. This comparison is based on the social cost of job losses and the qualitative information on subsequent impacts in the supply chain (such as reported for uses 2 – 6) due to potential disruptions in the supply in the EEA.

Regarding the human health impact assessment, SEAC agrees to the applicant's approach although the assumptions taken are uncertain, e.g. 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. 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 estimated impacts:

- Monetised health impacts range between €291,300 and €945,400 calculated over 12 years (potential overestimation)
- Expected social costs of €13.6 million due to job losses (lower bound of workers assumed being unemployed for 1 year) based on salary costs
- Expected negative impacts for different industrial sectors due to supply chain disruptions

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 (based on salary costs, job losses considered for one year only, lower bound of potentially affected workers).

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 list of expected impacts above that the social cost of job losses alone would outweigh the monetised human health impacts, which are regarded as being an overestimation. Any negative impacts in the supply chain due to potential disruptions in the

supply in the EEA would strengthen this conclusion.

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

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation:

Exposure scenarios

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

Supply chain communication is considered to be a prerequisite to achieve the objective of reducing exposure to workers and humans via the environment. Recognising the applicant's obligation to include representative exposure scenarios (ES) in their Chemical Safety Report (CSR) as defined in Annex I sections 0.7 and 0.8 of REACH, specific ES shall be developed for the typical formulation processes and individual tasks, 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 formulators covered by this application and for the inspection of the enforcement authorities, **without delay and at the latest 3 months after the applicant has been informed that an authorisation is granted for this use**.

RAC notes that based on their assessment, maximum individual exposure values for workers (as provided in chapter 10 of the CSR) and release values for the environment (see table 4) 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.

<u>Validation of Exposure Scenarios</u>

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

Monitoring

Workers

The formulators covered by this application shall implement at least annual programmes of occupational exposure measurements relating to the use of the substance described in this application. These 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 of (III) the number of workers that are potentially exposed.

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

Environment

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

Continuation of monitoring requirements

The information gathered in the monitoring programmes shall be used 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 formulator 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 formulator's site shall be documented. The formulator 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 formulation plant, 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 ES (lacking clear information on the linkage between OCs and RMMs and exposure levels) is a significant source of uncertainty in this application.

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

10. Proposed review period:

☒ Normal (7 years)

☐ Long (12 years)

☐ Short (…. _years)

☐ Other:

Justification:

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

RAC's advice:

- The possible lack of containment described by the applicant at some sites, possible high reliance on the use of RPE and lack of exposure monitoring raises concerns on containment and the appropriateness of OCs and RMMs in limiting the risk, hence the need for conditions and monitoring arrangements. Although there are significant uncertainties, the conservative approach, assuming that formulation tasks are

conducted each day suggests that the risks of these tasks may compensate for this in the worker exposure assessment. Therefore RAC considers that the risk at most formulation sites is not likely to be substantially higher than the risk estimated on the basis of the data presented by the applicant.

RAC gave no advice to SEAC 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:** As described above, chromium trioxide has no function at the formulation stage and no analysis of alternatives was performed by the applicant for this use. Analyses of alternatives have been performed for the subsequent uses 2 to 6 of this application for authorisation, for use 1 no alternatives have been identified. The applicant states that the review period for this use, i.e. the formulation stage, is linked with the review periods for uses 2 to 6. Therefore, the applicant performed its assessment based on a 12 years review period, due to feedback from industry on estimates of the schedule required to industrialise alternatives to chromium trioxide mixtures used in functional chrome plating, functional chrome plating with decorative character and other surface treatment processes. Additionally, this period reflects the standard long review period of ECHA. However, the applicant in principle requests a longer review period than 12 years. SEAC acknowledges that the formulation stage of a mixture is interlinked with subsequent uses of this mixture. However, SEAC emphasises that this use applied for is not exclusively linked to the 5 other uses of *this* application for authorisation.

- **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. However, the applicant performed a sensitivity check for the calculations of social costs. Within this check, more reasonable assumptions (e.g. for the length of the unemployment period) have been made. Although the way the economic impacts have been assessed by the applicant gives rise to uncertainty about the actual consequences of the non-use scenario, SEAC considers the provided information 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, which was adapted by RAC (exposure value of 0.5 µg/m^3 instead of 0.27 µg/m^3 such as suggested by 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. 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 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 no associated discounting was undertaken. The (worst case) scenario set up by RAC and SEAC provides an additional margin of safety for the assessment of human health impacts.

- **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 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 further substantiated by the additional (worst case) scenario for assessing the impacts to human health, as set up by RAC and SEAC.

Although some of the criteria for recommending a long review period[4], as requested by the applicant, could be regarded as being fulfilled for some industrial sectors using chromium trioxide-containing mixtures for functional chrome plating and surface treatment processes respectively (e.g. alternatives are not likely to become available within the normal review period), SEAC notes that this is not the case for all industries affected and applications covered. Furthermore, SEAC has reservations about the appropriateness of the applicant's approach. The deficiencies present in the application such as outlined in this opinion lead to uncertainty regarding the order of magnitude of the actual negative economic impacts of not granting an authorisation. However, it is clear from the information given in the authorisation application that not granting an authorisation for the use applied for would lead to social costs related to unemployment, most probably to supply disruptions in the EEA and consequently to further negative economic impacts down the supply chain.

In conclusion, taking into account

- the applicant's argumentation regarding the lack of alternatives for this use and the requested review period of 12 years,
- the expected social costs due to unemployment,
- the expected negative economic consequences further down in the supply chain,
- the expected human health impacts,
- the uncertainties arising from the applicant's approach (due to the lack of an appropriate assessment of economic costs of a non-use),
- that the criteria for long review period have not been met,
- RAC gave no advice on the length of the review period,

SEAC recommends a normal (7 years) review period.

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

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

☒ YES

☐ NO

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

☒ YES

☐ NO

☐ NOT APPLICABLE

Justification:

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

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

ANNEXES

Table A1. Calculations based on aggregated company/site data Use 1

Company	Result (µg/m3)*	No of measurements available	No of measurements finally used for the calculation of result	Period
Company 1	0.400	6	1	2006-2012
Company 2	9.500	2	1	2009-2011
Company 3	0.060	2	2	2013
Company 4	5.090	4	2	2001-2007
Company 5	0.500	3	1	2005-2013
Company 6	0.217	2	1	1997
Total		19	8	

* Not adjusted for use of respiratory protection

Arithmetic Mean 2.63
Geometric Mean 0.71
90th Percentile 7.30

Table A2: Data from the applicant on release of Cr(VI) to the aquatic environment. Since there were limited data on use 1, also data from uses 2-6 are included in the table. Specific use is mentioned in the last column.

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

**Calculated by ECHA*

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

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

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

Table A3: Wastewater monitoring data. Since there were limited data on use 1, also data from uses 2-6 are included in the table. Specific use is mentioned in the last column.

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

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

NA-data not available

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

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

As regards site 33 the applicant informed that the data was incorrect and that the annual release of Cr(VI) to water over the last two years was 49 – 150 g and not 314g as informed by the applicant in the second round of questions from RAC. This resulted in a Cr(VI)

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

Support document

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response of RAC and SEAC

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

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

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

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

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

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

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

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

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

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

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III. General Comments on Review Period, Good Administrative Practice

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

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

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

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

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

Response of RAC and SEAC

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

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

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

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

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

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

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

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

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

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

[4] P. 39 draft Opinion Use 3.

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

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

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

Response of RAC and SEAC

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

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

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

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

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

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IV. Other Comments on Individual Uses

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

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

Response of RAC and SEAC

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

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

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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).

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

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

Response of RAC and SEAC

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

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

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Comment received

V. Comments on Conditions

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

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

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

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

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

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

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

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

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

Review Reports

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

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

Response of RAC and SEAC

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

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

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

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

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

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

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21/07/2016		10

Comment received

VI. Presentation of the Opinion

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

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

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

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

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

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

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

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

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

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

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

Response of RAC and SEAC

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

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Comment received

Annex A

Detailed Comments

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

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

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

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

Response of RAC and SEAC

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

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

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All Uses: AoA, specifically economic feasibility of alternatives

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response of RAC and SEAC

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

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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.

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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.