Version 4.2

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Draft Opinion

on a Review Report for

Chromium trioxide; Sodium dichromate

Pre-treatments: Deoxidising, pickling, etching and/or desmutting using chromium trioxide or sodium dichromate in aerospace and defence industry and its supply chains

Submitting authorisation holder

Boeing Distribution Deutschland GmbH

ECHA/RAC/SEAC: [Opinion N°]

Consolidated version

Date: [date of adoption/agreement in RAC and/or SEAC

Format Version	Changes
4.2	Changes made in the SEAC opinion text and justification section 4.4 to provide SEAC conclusion on overall credibility of the substitution plan for the review period recommended by SEAC. Consistency with AoA and SEA is considered as one aspect of this credibility. Editorial changes to improve readability of the SEAC opinion and the justifications.
4.1	Changes made in the SEAC opinion text and justification section 4.4 to separate the question on credibility and consistency of the substitution plan into two. Editorial changes to improve readability of the SEAC opinion and the justifications.
4.0	Changes in the RAC and SEAC opinions and conclusions and technical adaptations and editorial changes in the justifications. These include: • Update of the conclusions of SEAC based on the request of the European Commission on 30 November 2020 • Restructuring the process-related tables in the beginning of the document • Section for the evaluation of the availability of alternatives in general in the EU identified • Systematically first summarising the applicant's/authorisation holder's analysis and then providing the evaluation by SEAC (section 5 of the justifications) • Update of the summary tables on impacts of authorisation (section 5) • Socio-economic benefits of continued use are referred to as societal costs of non-use for consistency with the updated SEAC conclusions. • The opinion options of RAC have been restructured and edited, mainly to reflect current practice. • The concluding statement regarding exposure and risk estimates for cases based on socio-economic assessment has been simplified. • Tables for comparing exposure and release levels between initial applications and review reports have been added in the justification to the opinions. • The reference to OELs has been moved from the opinion to section 3.4 of the justification to the opinions.
3.1	Update of the SEAC opinion texts, update of the Summary of RAC and SEAC conclusions, update of **Error! Reference source not found.** in the justifications section.

3.0	Changes made to the opinion text and the format to increase the clarity of the opinion text and justifications, taking into consideration the conclusions from the General Court's judgments in Cases T-837/16 and T-108/17.
2.0	Major adaptations based on experience and feedback received. The format includes now a summary as well as the conclusions of the opinions to facilitate decision-making. The justifications to the opinions include standardised tables to facilitate reading.
1.0	First version

HOW TO USE THIS TEMPLATE

1. The present page needs to be deleted.
2. The {green text} in the document are instructions meant to help you filling in the template and needs to be deleted.
3. When you are required to enter specific information, you will be prompted to choose between one or more options, which are provided in **[square brackets]**. Choose the relevant option or provide the requested information (e.g. date), as applicable.
4. This format assumes that the applicant is using the substance when submitting the application. This is referred to as "continued use". If the applicant is currently not using the substance but makes the application for the use in the future, the word "continued use" should be changed to "future use" throughout the document.
5. Singular form of "applicant" or "authorisation holder" is used in this document also to cover multiple applicants or authorisation holders.
6. When referring to the Committees' evaluation of the current application for authorisation/review report, use present tense and singular form (e.g. RAC/SEAC **agrees** with the applicant…).
7. Assign a caption to each additionally included table and figure by giving it the right label (see 'Captions' in the 'References' tab). Whenever you need to refer to a table or figure in the text, you should cross-reference it using the 'Cross-reference' option in the 'References' tab – under 'Insert reference to' select the option 'Only label and number'.

Instructions to rapporteurs on ADCR DOs:

- Text highlighted in Blue applies only to Review Reports

  Text highlighted in Green applies to (new) Applications for Authorisation

  The text is highlighted to point out the difference between 'applicant' vs 'authorisation holder' and 'AfA' vs 'review report' when copying the opinion text from the RR DO to the AfA DO for the same use. Note that certain text or tables are only applicable to RR DOs and that Section 9 does not apply to the RR DOs.

- Text highlighted in Yellow is to be filled in (e.g. figures) and/or adapted to the specific use and submission (AfA/RR)

- Green text are the guidelines already provided in the DO template (can be deleted when finalising the first DO version)

- Blue text is our proposal for either:

  - general text applicable to all DOs/ all uses or

  - options of standard text to be selected if relevant/ applicable to a section/ for the specific use

  Feel free to propose any modifications to the blue text but please do so in track changes so that we can see it and modify the same text in parallel across all DOs/ uses (where applicable).

- Text is *italics* is provided as an example of text in a use-specific section to illustrate the relevant content for the section taken from parts of the AfA/RR.

- Please provide your additional text in black.

Consolidated version of the Opinion of the Committee for Risk Assessment and Opinion of the Committee for Socio-economic Analysis on a Review Report

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 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 the following review report:

{This table is filled in by the ECHA Secretariat. Rapporteurs need to check that the information is consistent with the information in the opinion justification (e.g. the functions and type of products made)}

Authorisation holder[1]	**Boeing Distribution Deutschland GmbH** AD International BV Brenntag Chemicals Distribution (Ireland) Ltd Chemservice GmbH Cromital S.P.A.
Role of the authorisation holder in the supply chain **{more than one can be selected}**	Upstream ☒group of manufacturers ☒group of importers ☐group of only representatives ☐group of formulators Downstream ☒group of downstream users
Use performed by	☒Authorisation holder ☒Downstream users of the authorisation holder
Substance ID EC No CAS No	**Chromium trioxide** (EC: 215-607-8; CAS: 1333-82-0) **Sodium dichromate** (EC: 234-190-3; CAS: 10588-01-9, 7789-12-0)
Intrinsic properties referred to in Annex XIV	**Chromium trioxide** ☒Carcinogenic (Article 57(a)) ☒Mutagenic (Article 57(b))

[1] Singular form of 'applicant' or 'authorisation holder' is used in this document also to cover multiple applicants or authorisation holders.

	☐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) **Sodium dichromate** ☒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)
Use title	**Use 1: Pre-treatments: Deoxidising, pickling, etching and/or desmutting using chromium trioxide or sodium dichromate in aerospace and defence industry and its supply chains**
	Other connected uses: 0325-01 – 0345-02
	Similar uses applied for: 0032-02, 0032-04, 0032-05, 0043-02
Indicative number and location of sites covered	80 sites in EEA
Annual tonnage of the Annex XIV substance used [total for all sites]	< 25 t/y chromium trioxide[2]; < 45 t/y sodium dichromate
Function(s) of the Annex XIV substance	Corrosion resistance, Adhesion of subsequent coatings (including structural bonding); Surface preparation prior to further processing; Removal of contaminants/complexes after etching processes; Surface roughness modification; Selective removal of material to reveal the surface or to improve surface properties
Type of products (e.g. articles or mixtures) made with the Annex XIV substance and their market sectors	Civil aviation, military aircraft and ground/ sea-based defence systems and aeroderivative products, including their supply chains

[2] Represents total tonnage of substance across all applicants for this use (i.e. AfA and RR combined).

Annex XIV substance present in concentrations above 0.1% in the products (e.g. articles) made	☐Yes ☒No ☐Unclear ☐Not relevant
Review period requested by the authorisation holder (length)	12 years
Use ID (ECHA website)	0343-01, 0343-02
Reference number	cse_ref_no

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

{This table is filled in by the ECHA Secretariat}

Date of submission of the review report	14/02/2023
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	09/08/2023
Was the review report submitted at least 18 months before the expiry of the time-limited review period?	☒Yes ☐No
Date of consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	16/08/2023-11/10/2023
Were comments received in the consultation?	☐Yes ☐No [Link:]
Request for additional information in accordance with Article 64(3)	On [date] [and] [date] [Link:]
Trialogue meeting	[date] / [Not held – reason, e.g. no new information submitted in consultation, no need for additional information/discussion on any technical or scientific issues related to the review report from the rapporteurs]
Was the time limit set in Article 64(1) for the sending of the draft opinions to the authorisation holder extended?	☐Yes, by [date] Reason: [e.g. due to the need to ensure the efficient use of resources, and to synchronise the consultation with the plenary meetings of the Committees] ☐No
Did the review report include all the necessary information specified in Article 62 that is relevant to the Committees' remit?	☐Yes ☐No [Comment:]
Date of agreement of the draft opinion in accordance with Article 64(4)(a) and (b)	RAC: [date], agreed by [consensus] [a simple majority]
	SEAC: [date], agreed by [consensus] [a simple majority]

Date of sending of the draft opinions to the authorisation holder	[date]
Date of decision of the authorisation holder [not] to comment on the draft opinions, in accordance with Article 64(5)	[date]
Date of receipt of comments in accordance with Article 64(5)	[date] [Not relevant]
Date of adoption of the opinion in accordance with Article 64(5)	RAC: [date], adopted by [consensus] [a simple majority]
	SEAC: [date], adopted by [consensus] [a simple majority]
Minority positions	RAC: [No minority positions] [Links to the published minority positions]
	SEAC: [No minority positions] [Links to the published minority positions]
RAC Rapporteur RAC Co-rapporteur	BROVKINA Jūlija UŽOMECKAS Žilvinas
SEAC Rapporteur SEAC Co-rapporteur	CASTELLI Stefano JONES Derrick
ECHA Secretariat	LOGTMEIJER Christiaan MÄKELÄ Petteri NIEMELÄ Helena GERVASUTTI Simone

The Aerospace and Defence Chrome Reauthorisation consortium (hereafter: ADCR) submitted for same uses both new afa's and review reports for a variety of reasons (administrative, as well to secure supply chains). For reasons of process efficiency and easing discussion in SEAC, this document covers both the opinion for new afa's as well as review reports for the ADCR submissions.

After agreement in SEAC, the document will be adapted into separate opinions for AfA and review report.

At several places in this document a comment bubble is placed indicating where a difference exists between the review report and the 'new' authorisation. An indicative list is as follows

Section 0.1 text on Authorisation decision and conditions.
Section 4.2 differences in potential alternatives considered and progress made since the parent decision, where applicable.

To a large extent the text is the same, even more since the new afa's still have a origin in a number of previous application (in this document referred to as 'parent application), se also annex iii to the opinion

In most review reportss the scope in terms of substances (and tonnages) applied for is the same, where a different arises , this is indicated as well as any consequences this may have for the overall cost and monetised risks.

Where the document reads authorisation holder, this implies as well applicant and vice-versa.

LIST OF ACRONYMS

{The most common acronyms are included to this list. Please avoid use of acronyms and consider writing in full. Additional acronyms can be added when necessary.}

AfA	Application for authorisation
AoA	Analysis of alternatives
bw	Body weight
CBA	Cost-benefit analysis
C-E	Cost-effectiveness
CSR	Chemical safety report
DNEL	Derived no-effect level
ES	Exposure scenario
ECS	Environmental contributing scenario
HvE	Human via environment
LAD	Latest application date
LEV	Local exhaust ventilation
OC	Operational condition
PBT	Persistent, bioaccumulative and toxic
PEC	Predicted environmental concentration
PNEC	Predicted no-effect concentration
PPE	Personal protective equipment
RAC	Committee for Risk Assessment
REACH	European Union regulation on registration, evaluation, authorisation and restriction of chemicals
RMM	Risk management measure
RP	Review period
RPE	Respiratory protective equipment
RR	Review report
SDS	Safety data sheet
SEA	Socio-economic analysis
SEAC	Committee for Socio-economic Analysis
SP	Substitution plan
SSD	Sunset date
vPvB	Very persistent and very bioaccumulative
WCS	Worker contributing scenario
WWTP	Wastewater treatment plant

This document provides the opinions of the Committees for Risk Assessment and for Socio-economic Analysis based on their scientific assessment of the review report. It thus provides scientific input to the European Commission's broader overall balancing of interests.

THE OPINION OF RAC

RAC has formulated its opinion on:

- the risks arising from the use applied for,
- the appropriateness and effectiveness of the operational conditions and risk management measures described,
- taking into account the information submitted by interested third parties, as well as
- other available information.

RAC concluded that it was possible to determine a DNEL for the reprotoxic properties of sodium dichromate in accordance with Annex I of the REACH Regulation.

RAC concluded that it was not possible to determine DNEL(s) for the carcinogenic, mutagenic properties of the Cr(VI) substances in accordance with Annex I of the REACH Regulation.

SEAC concluded that there are no technically and/or economically feasible alternatives available for the authorisation holder or their downstream users with the same function and similar level of performance by the expiry date of the authorisation decision. Therefore, RAC did not evaluate the potential risk of alternatives.

Regarding the exposure to Cr(VI) associated with use of chromium trioxide and sodium dichromate, RAC concluded that the operational conditions and risk management measures described in the review report **are <u>not</u> appropriate and effective**[3] in limiting the risk for the **workers**. The proposed additional conditions for the review report are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

RAC concluded that the operational conditions and risk management measures described in the review report **are appropriate and effective** in limiting the risk for the **general population** via the environment.

Regarding the reproductive hazards associated with the use of sodium dichromate, RAC concluded that the risk assessment presented in the application demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the application are adhered to.

The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in exposure and releases during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently.

The exposure of workers and the general population to the substance is estimated to be as

[3] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls and compliance with the relevant legislation: 'Effectiveness' – evaluation of the degree to which the RMM is successful in producing the desired exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

described in section 2 of the justification to this opinion.

The risk for workers and the general population from exposure to the substance is estimated to be as described in section 3 of the justification to this opinion.

THE OPINION OF SEAC

SEAC has formulated its opinion on the socio-economic factors and the suitability and availability of alternatives associated with the use of the substance taking into account the information in the review report, information submitted by interested third parties, as well as other available information. SEAC's evaluation is based on relevant guidance, which comprises the Commission's Better Regulation guidance, the guidance documents on applications for authorisation and socio-economic analysis, as well as specific guidance related to how SEAC evaluates the applications (e.g. dose response functions, values of health endpoints).

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

SEAC has assessed the availability, and technical and economic feasibility of alternatives for the authorisation holder or their downstream users and in the EU. These are described in section 4. The authorisation holder short-listed the following alternatives:

- Sulfonitroferric acid
- nitric/sulphuric acid pre-treatments
- Phosphoric acid/sulphuric acid mixture
- sulphuric acid
- Sodium hydroxide
- Cr(III) anodic pickling
- Abrasive blast

SEAC concluded on the analysis of alternatives and the substitution plan that:

- The authorisation holder has demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the authorisation holder or their downstream users by the expiry date of the authorisation decision[4]].
- There is no information available in the review report and/or in the comments submitted by interested third parties in the consultation indicating that there are alternatives available that are technically and economically feasible in the EU.
- The authorisation holder submitted a substitution plan. The substitution plan is credible for the review period recommended

SEAC has assessed the information provided by the authorisation holder and third parties from a scientific perspective, using standard methodology, and following relevant guidance. Based on the elements listed below, SEAC concludes that the authorisation holder has demonstrated that the societal costs of not granting an authorisation are higher than the monetised risks to human health resulting from the granting of an authorisation.

The expected societal costs of not granting an authorisation, which are estimated to be €350 million per year over 12 years, consisting of loss in producer surplus, decommissioning costs and unemployment costs. Additional societal impacts of not granting an authorisation have been assessed quantitatively or qualitatively and consist of impacts on suppliers and EU

[4] {For review reports.}

customers.

The risks arising from authorisation, which consider:

- the endpoints relevant for listing the substance in Annex XIV of REACH;
- the 1750 directly exposed workers;
- the general population exposed at local scale (37 000 persons
- that the risk of continued use as assessed by RAC may result in approximately 0.05 expected additional cancer cases (lung, intestinal) per year over 12 years;
- the value of these expected additional cases has been monetised based on the willingness-to-pay methodology and corresponds to an estimate of approximately €0.26m per year over 12 years.

Risks to human health of alternatives have not been assessed.

SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

PROPOSED CONDITIONS, MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

Additional conditions for the authorisation are proposed. These are listed in section 7 of the justification to this opinion.

Monitoring arrangements for the authorisation are proposed. These are listed in section 8 of the justifications to this opinion.

Recommendations for the review report are made. These are listed in section 9 of the justifications to this opinion.

REVIEW PERIOD

Taking into account the information provided in the review report submitted by the authorisation holder [and the comments received in the consultation], a **x-year** review period is recommended for this use[, i.e. until 14 February 2034

JUSTIFICATIONS

0. Short description of use

This review report (RR) is submitted by the authorisation holders,[5] (AD International BV (SD), Boeing Distribution, Inc. (CT, SD), Brenntag Chemicals Distribution (Ireland) Ltd (SD), ChemService GmbH (CT), CROMITAL S.P.A. (CT)for the use ("Pre-treatments: Deoxidising, pickling, etching and/or desmutting using chromium trioxide, sodium dichromate, in aerospace and defence industry and its supply chains").

It forms part of a set of 11 review reports (RRs) and 10 new authorisation applications (AfAs) prepared by the Aerospace and Defence Chromates Reauthorisation (ADCR) Consortium on behalf of the authorisation holders and applicants. Review reports and applications for authorisation are organised in such a way as to make sure that in the future all members of the supply chain will be covered for further use. The consortium consists of 67 companies in the EEA and the UK that are active in the Aerospace and Defence (A&D) industry. These applications and review reports cover uses of five soluble chromates[6] which are relevant for the aerospace and defence sector and its supply chains. Although formally these are RRs/AfAs submitted by upstream actors i.e. manufacturers, importers or formulators of chromates, the applications and review reports are based on sector-specific data and detailed information obtained from actors throughout the supply chain. The overall set of AfA and RR submissions for the uses applied for by ADCR members is provided in Annex I to the opinion.

The starting point for the AfA is the set of applications originally submitted by the Chromium Trioxide Authorisation Consortium (CTAC) and Chromium VI Compounds for Surface Treatment (CCST), and the conditions placed on the continued use of the chromates by the relevant Commission decisions.

The use covered by the review report takes place in 80 sites in the European Economic Area (EEA) in the following levels of the supply chain:

- Original Equipment Manufacturer (OEM);
- Downstream user – Build-to-print manufacturer (BtP);
- Downstream user – Design-to-build manufacturer (DtB);
- Maintenance, Repair and Overhaul (MRO) companies and Ministries of Defence (MoDs, undertaking military maintenance, repair and overhaul work).

The use applied for covers an overall tonnage of (<25 tonnes/year of chromium trioxide[7] and <45 tonnes/year of Sodium DichromateThis figure is based on information about the annual consumption based on the maximum consumption per site identified from the Chemical Safety Report (CSR), Article 66 downstream user (DU) notifications, and the percentage of sites using chromium trioxide and Sodium Dicrhomate as identified in responses to the Socio-economic Analysis (SEA) questionnaire and from discussions with formulators and distributors.

A consultant was commissioned to conduct a DU survey on behalf of the applicant. More information about the survey is available in section 0.4 of this opinion.

[5] Singular form of 'applicant' or 'authorisation holder' is used in this document also to cover multiple applicants or authorisation holders.

[6] The Annex XIV substances covered by the ADCR applications are: chromium trioxide (including "Acids generated from chromium trioxide and their oligomers", when used in aqueous solutions), sodium dichromate, potassium dichromate, sodium chromate and di-chromium tris(chromate).

[7] Represents total tonnage of chromium trioxide across all applicants for this use (i.e. AfA and RR combined). See Annex I to this opinion.

According to the applicant, the use of chromates is critical in the aerospace and defence industry and its supply chains, as many parts of aircrafts have been designed and subsequently certified (e.g. marketing authorisation, certification, type-approval) with chromates, and these certifications stipulate that these aircrafts should be maintained with chromates as well. The substance is specifically referred to in the authorisation/certification documents and maintenance manuals in accordance with airworthiness requirements of the EU regulation 2018/1139[8] and with similar requirements in all countries where aeronautical products are sold.

In the initial ('parent') AfAs, submitted by various applicants in 2015-2016, the applicants had requested a review period of 12 years for the uses described in Annex II to this opinion. A 7-year review period was recommended for this use.

Authorisation decision

The relevant authorisation decisions from the European Commission's decisions[9] associated with the use applied for in the original application, (see Annex II to the opinion) granted a 7 year review period until 21 September 2024, i.e. 7 years after the Sunset Date. Moreover, these decisions contained conditions which required the authorisation holder to develop specific exposure scenarios for representative processes, operations and individual tasks; to implement annual monitoring programmes for air monitoring of occupational exposure and for emissions to the environment; to regularly review the effectiveness of the OCs and RMMs in place and to introduce measures to further reduce exposure and emissions. The authorisation decisions also require, in case of a review report, the authorisation holder to provide a detailed guidance on how to select and apply RMMs and to provide a refined exposure assessment – with a higher-tier model and site-specific emission information. More specific details about the conditions imposed by the relevant authorisation decisions and how these have been addressed by the authorisation holder in this RR can be found in Annex III to this opinion.

The applicant requested a review period of 12 years for this use.

0.1. Description of the process in which the Annex XIV substance is used

Due to the different levels in the supply chain and the variation in the size of the sites, the conditions under which the use is carried out can be variable, covering small sites and repair shops with rare and infrequent applications up to large sites with high throughput, and thus, a low to high level of automation for specific activities.

As shown in Figure 1, some main treatments (anodising, chemical conversion coating, electroplating or passivation of stainless steel) require one or more pre-treatment steps. These pre-treatments involving chromates can be deoxidising, pickling, etching and/or desmutting.

All these different types of treatments have the same general mode of action and the same purpose: the removal of oxides and for some processes of certain amounts of the base metal from the surface of the part, to achieve substrate levelling by eliminating large scale irregularities, micropeaks and valleys (up to a size of 0.01 µm).

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32018R1139
[9] https://ec.europa.eu/docsroom/documents/44374/attachments/1/translations/en/renditions/native

Figure 1: Schematic presentation of treatment steps

These treatments can be either non-electrolytical, or electrolytical processes, usually carried out by immersion of a metallic part in an aqueous solution containing dissolved chromates, together with acid compounds. The main difference between those treatments consists in the amount of surface impurities removed from the substrate. This thickness is dependent on the duration of the immersion, the Cr(VI) concentration in the bath, the temperature, and the pH of the bath solution.

Deoxidising, pickling, etching and/or desmutting are in most cases carried out by immersion of parts in treatment baths. Typically, the treatment baths for deoxidising, pickling, etching and/or desmutting are positioned in a large hall where baths for other immersion processes are also present. The immersion tanks can be placed individually or within a line of several immersion tanks. Usually, at least one rinsing tank with water is positioned after an immersion tank, for rinsing off the pre-treatment solution from the part(s).

Some characteristics of the pre-treatments process are presented below:

- The sites operate between 8 and 24 hrs per day (1-3 shifts per day), 5-7 days per week and up to 365 production days per year.
- The shift duration is usually 8 h but may also be up to 12 h.
- The temperature of the treatment baths ranges from room temperature and 95 °C with Cr(VI) concentrations up to 15.6%.
- The treatment bath sizes range between 0.4 – 10 m^3 (up to 45 m^3 at some sites).
- Cr(VI) substances can be delivered in solid form (pure substance) or as an aqueous solution (up to 40% Cr(VI)).

The use of CT and SD for pre-treatments typically involves one environmental contributing scenario for the use of these chromates at industrial sites. Table 1 lists the exposure scenario (ES) presented for this use in the CSR, consisting of five worker contributing scenarios (WCS). The WCS were structured by the authorisation holder based on "Similar Exposure Groups" (SEGs) of workers, comprising of groups of workers performing similar tasks and, hence, are assumed to experience similar exposures. According to the authorisation holder, a task-based description would not have been adequate to describe the exposure scenario since workers perform various tasks in relation to chromates during one shift, they potentially handle several chromates and may be involved in several uses in parallel.

Each WCS covers relevant processes and individual tasks performed by the respective group of workers in relation to the use. The indirectly exposed workers are described in a separate WCS.

Table 1: Contributing scenarios presented in the use

Contributing scenario	Size of the exposed population (local) (1)	Description
ECS 1 Deoxidising, pickling, etching and/or desmutting at industrial site not leading to inclusion (of Cr(VI) or the reaction products) into/onto article	General population: 36 609	• Releases: 365 days per year • Exhaust air is treated in wet scrubbers or by air filters before it is released via stack • Cr(VI)-containing wastewater is gathered and, either directly sent to an external company for disposal of, recycled after evaporation in an on-site evaporation system or treated on-site • There is no direct release to soil, based on equipment and procedures in place
WCS 1 Line operators	400 (average 5 per site)	• **Task 1:** Manual, semi-automated or automated dipping/immersion process • **Task 2:** Manual sampling from the baths • **Task 3:** Regular cleaning of equipment using a hose, wiper mops, towel or rags
WCS 2 Storage area workers	320 (average 4 per site)	• **Task 1:** Transfer of the chromate solution into a graduated container by pouring or using a hand pump • **Task 2:** Transfer of the required quantity of the substance with a shovel from the storage container into a measuring container (e.g., bucket) or bag • **Task 3:** Cleaning of containers by immersing in the rinsing bath and rinsing with a water hose above the rinsing bath • **Task 4:** Collecting hazardous solid waste in waste bag, which once full, is sealed and transported to the storage area to be disposed of by an external licensed company • **Task 5:** Manual bath make-up or addition by using the appropriate amount of chromates already aliquoted or directly from the original container into the bath • **Task 6:** Bath cleaning by pumping and rinsing with water jet using a hose
WCS 3 Laboratory technicians	320 (average 4 per site)	• **Task 1:** Laboratory analysis of the bath samples (exempted from authorisation)[10]
WCS 4 Maintenance and/or cleaning workers	240 (average 3 per site)	• **Task 1**: Maintenance/cleaning or replacement of equipment performed in-situ or in workshop or externally
WCS 5 Incidentally exposed	480 (average 6 per site)	Tasks required to be performed in the working area but not with direct Cr(VI) exposure potential

[10] According to the authorisation holder, the activity falls under the exemption for authorisation for the use of substances in scientific research and development according to REACH Art. 56(3).

workers (2)		

1) Average values, the exact number of workers varies depending on the characteristics of the site
2) New WCS compared to the original application

WCS 1: Line operators

Line operators are usually involved in numerous activities related to the pre-treatment process. Most of their working time they spend in a hall where the treatment tanks are located and where the immersion process takes place, on activities either with direct or indirect Cr(VI) exposure.

Typical activities with possible Cr(VI) exposure performed by line operators are:

- **Task 1**: Pre-treatment of parts via immersion or dipping, followed by rinsing and drying of parts

  After the parts are loaded on the jig/grid/hook, the line operator either:

  - manually transports the jig to the bath and hangs it in the bath;
  - moves it to the bath and immerses it by means of a crane or crab; or
  - controls a pre-programmed, crane-controlled immersion process from a monitor located in a separate control area/room.

  During a manual or semi-automatic process, the line operator will leave the bath area during immersion processes of longer durations (several minutes up to several hours) if the process allows. In case of an automated process, the line operator is not in the proximity of the bath during the treatment process.

  After the pre-treatment, the parts are rinsed (immersion in rinsing tanks or spray rinsing) and dried (room temperature or with compressed air).

- **Task 2**: Sampling of pre-treatment baths

  The line operator uses the following techniques:

  - immersion of a sampling bottle by hand into the treatment bath;
  - immersion of sampling bottle attached to a metal or plastic rod;
  - using a specific plastic sampling rod or a pipette;
  - the sample is taken from a sampling tap installed at the bath.

- **Task 3**: Diverse cleaning activities – Cleaning of workplace, equipment, jigs.

  The cleaning tasks entail:

  - cleaning of floors around the bath (rinsing with a hose or wiping the floor with a mop).
  - cleaning of external tank surfaces (e.g., grids, around and under tanks), and equipment (e.g., jigs, perforated baskets, hooks, or containers) by rinsing the in the rinsing tanks or wiping the contaminated surfaces with paper towels or rags.
  - clean the secondary containment pit (e.g., with a hose) at some sites.

Line operators are also involved in secondary tasks (Section 9.2.3.2 of CSR).

WCS 2: Storage area workers

Storage area workers are responsible for ordering, storing, transporting, delivering, and managing the chemicals used at a site. They spend a considerable part of their working time on transport and handling of chemicals in closed containers, where no opportunity for Cr(VI) exposure exists.

Typical tasks with potential Cr(VI) exposure are:

- **Task 1**: Aliquot chemicals – Decanting of liquids
    - To aliquot liquids, the storage area worker pours the required volume of the product into a graduated container or transfers it via a small hand pump. The measured volume per aliquot is at maximum 60 kg chromate solution.

      At some sites, the container is placed next to the tank and the required volume of product is pumped from the container directly and transferred into the treatment bath, then aliquoting is not required. This activity is performed especially for bath make-ups or concentration corrections where large amounts are necessary (up to 1400 kg Cr(VI)).

- **Task 2**: Aliquot chemicals – Measuring and weighing of solids
    - For measuring or weighing solids, the worker transfers the required quantity of the substance with a shovel into a measuring container or bag. The amount of substance to be aliquoted is at maximum 25 kg chromate per aliquot for bath addition and up to 500 kg for bath make-up. Whenever possible, entire containers or bags are used for bath additions and bath make-ups (up to 500 kg of solid chromate), then aliquoting is not required.

- **Task 1 and 2:** The closed containers, bags or bottles are transported to the treatment bath. In cases where large quantities of chromates are required, the measuring of the solution or solid product is typically carried out at the bath.

- **Task 3**: Waste management – Cleaning of empty chemical containers/bags
    - The worker typically immerses the containers in the rinsing bath and then carefully rinses them with a water hose above the rinsing bath until the wash water is clear. At some sites, the worker directly rinses the containers above a drainage channel.

- **Task 4**: Waste management – Handling of solid waste
    - The hazardous solid waste is disposed of in a waste bag. When the waste bag is full, the storage area worker transports it to the storage area. Afterwards the wastes are sent to an external waste management company.

- **Task 5**: Bath make-up or addition, including decanting of substances and mixing them with water
    - For bath make-up or addition, the storage area worker uses the appropriate amount of chemical which is already aliquoted and mixes with water and stirs it with a metal rod to prepare a homogenised pre-mixture or fills it as it is in the treatment bath.
    - In rare cases of make-ups where high amounts of chromates are required, the storage area worker transfers the product directly from the original chemical container into the bath.
    - In case of bath make-up the pouring is performed at a minimum distance from the bottom of the bath or the water surface to avoid dust and/or splashing, and then tops it up with water.
    - For bath addition the bath is already filled with treatment solution and the storage area worker only adds some chromate to adjust the Cr(VI) concentration in the bath.
    - Homogenous dilution of the chromate in the bath is often supported by permanent bath internal circulation or agitation.

- **Task 6**: Bath emptying and cleaning
    - The cleaning of the baths is carried out during a bath renewal. The storage area worker drains the old bath solution by gravity or by means of a pump.
    - When the bath is drained, at some sites the storage area worker rinses it thoroughly with a hose and removes potential solid deposits with the water jet or wet and dry vacuum cleaner.

Storage area workers are also involved in secondary tasks (Section 9.2.3.3 of CSR).

WCS 3: Laboratory technicians

Laboratory technicians are responsible for analysis of samples from the treatment baths, as well of wastewater after the reduction process at the reduction facility.

Typical task with potential Cr(VI) exposure is:

- **Task 1:** Laboratory analysis of treatment bath sample

The authorisation holder claims that the laboratory analysis of the treatment bath samples falls under the exemption for authorisation for the use of substances in scientific research and development (REACH Article 56(3)). Based on this consideration, this group of workers was not taken forward by the authorisation holder in the exposure/risk assessment.

WCS 4: Maintenance and/or cleaning workers

Maintenance and/or cleaning workers are responsible for maintenance and cleaning of equipment related to the use with potential direct exposure to Cr(VI).

Typical task with potential Cr(VI) exposure is:

- **Task 1**: Maintenance and cleaning of equipment
    - Typical maintenance tasks comprise, for example, maintenance or replacement of pipes, pumps, sensors, filters, rectifiers, and scrubbers, machining equipment, repair of electrical installations, such as heating and mixing equipment installed in the treatment baths, pumps and valves, joints of baths/hydraulic installations and LEV systems.
    - For some maintenance tasks, the worker enters the empty bath and either repairs the equipment (e.g., heater) in situ or removes the equipment and transports it to the workshop for repair.

Maintenance and/or cleaning workers are also involved in secondary tasks (Section 9.2.3.5 of CSR).

WCS 5: Incidentally exposed workers

Incidentally exposed workers are defined as workers who spend a relevant part of their working time in the work area where the treatment baths for pre-treatment are located, but do not carry out tasks with direct Cr(VI) exposure potential themselves.

The tasks of incidentally exposed workers of pre-treatments can be very diverse including, but not limited to, the following tasks:

- line operations at other process baths (not using Cr(VI));
- supervision of processes;
- quality assessment of parts;

- un-/jigging of parts and cleaning of jigs;
- un-/masking of parts;
- transportation of closed chemical containers;
- machining activities (on parts, where no Cr(VI) exposure is possible).

These workers may incidentally be exposed from such activities due to inhalation background exposure in the work area.

0.2. Key functions provided by the Annex XIV substance and technical properties/requirements that must be achieved by the products made with the Annex XIV substance

The use of chromium trioxide (Cr(VI)) for pre-treatments to prepare the surface is crucial to the treatment system as a whole. A variety of pre-treatment processes including deoxidising, pickling/etching, and desmutting are requited for the preparation of surfaces prior to subsequent treatments. Pre-treatment processes are routinely used prior to a host of main-treatments including; anodising, electroplating, chemical conversion coating, and passivation of stainless steel.and must not adversely impact the functionality of subsequent treatments.

Consequently pre-treatment, although a discrete process which can be assessed separately, is not considered a standalone process when evaluating candidate alternatives but as part of a whole treatment system process chain.If a pre-treatment alternative cannot meet all key function and performance requirements for all down-stream processes, multiple pre-treatment alternatives may need to be approved in parallel to replace the universal incumbent Cr(VI) pre-treatment.

The key performance requirements are:

Table 2: Key requirements for overall process

Key functionality	Performance requirement
Corrosion resistance	ASTM B117, ISO 9227, and ISO7253, minimum of 168 hours must be achieved in the salt spray chamber with acceptably low appearance of pitting or corrosion in the test samples as a minimum requirement at the laboratory testing scale and members use more stringent internal performance requirements when validating test candidates
Adhesion of subsequent coatings (including structural bonding);	ISO 2409 (GT0 dry, GT1 wet after 336 hours water immersion). GT0 and GT1 are classifications of the cross-cut test for adhesion.
Surface preparation prior to further processing	Typically, no more than 1µm of the surface is removed, subject to operating conditions
Removal of contaminants/complexes after etching processes	Must not impact fatigue strength beyond specified limit, Needs to equal performance of Cr(VI)
Surface roughness	Dye penetrant inspection (e.g., ASTM E 1417) is used to check

modification: Removal of mechanically deformed layers/oxides/other compounds from the substrate	for defects including pits, corrosion products, discolouration, uneven etching, increased surface roughness etc., that could impact subsequent treatment processes.
Selective removal of material to reveal the surface or to improve surface properties.	Must not impact fatigue strength beyond specified limit, Needs to equal performance of Cr(VI)

The corresponding validation tests are reported in Section 3.2.1.1 of the AoA/SEA document and more detail has been provided by the applicant responding to specific SEAC questions.

Test candidates to Cr(VI) for pre-treatments must remain compatible with relevant following stages and may also need to be modified for compatibility with the non-Cr(VI) proposed candidate in other stages. While it may be possible to get a Cr(VI)-free pre-treatment, the overall objective is to remove Cr(VI) from the entire process, which is a much higher technical challenge.

For pre-treatment, specifically, this means:

- *Shall neither cause end grain pitting nor intergranular attack in certain excess and depth;*
- *Metal removal of the substrate shall not exceed certain limits;*
- *Adequate etch rate;*
- *Minimum impact on fatigue performance – no degradation;*
- *Tensile strength testing – no degradation;*
- *Water-break free surface without streaks or discolorations;*
- *No pitting or selective attack to the substrate;*
- *No non-rinseable residuals or contamination from the deoxidising solutions observed on the surface;*
- *Must not induce de-gassing from surface under vacuum;*
- *Must not induce pits, corrosion products, discolouration, uneven etching, increased surface; roughness, or other defects that would prohibit further chemical processing; and*
- *Must not impact shot-peen compressive layer.*

Because of the extensive range of A&D parts produced, the exact technical requirements will differ depending on the (sub) system where a part will be used.

The applicant stresses that performance required in the final component extends beyond the key functions. Essential attributes or performance requirements of the use must be considered in addition to key functions to ensure substitution with an alternative does not lead to unintended consequences which could impact safety and/or reliability of a component. For this reason, the delivery of the key functionalities cannot be considered in isolation; due regard must be paid to additional performance requirements associated with the successful performance in testing of more complete systems containing the final part or even of the final product (e.g. aeroplane).

Based on some of the (confidential) information supplied to SEAC after the rounds of questions and information supplied after the trialogue it can be said that tests that are performed on subsequent levels are based on panels or components with more complete surface protection systems and consist of various anticorrosion tests and surface inspections.

Figure 1 below shows how key performance requirements for an aircraft (the whole system) are flowing to the right, as the elements are split further into specific subsystems. This is to illustrate the challenge of replacing one element, as part of the system, as it must meet the requirements and then be compatible with other subsystems.

The applicant highlighted that the key performance requirements are valid for all products for all sectors described in section 0.3

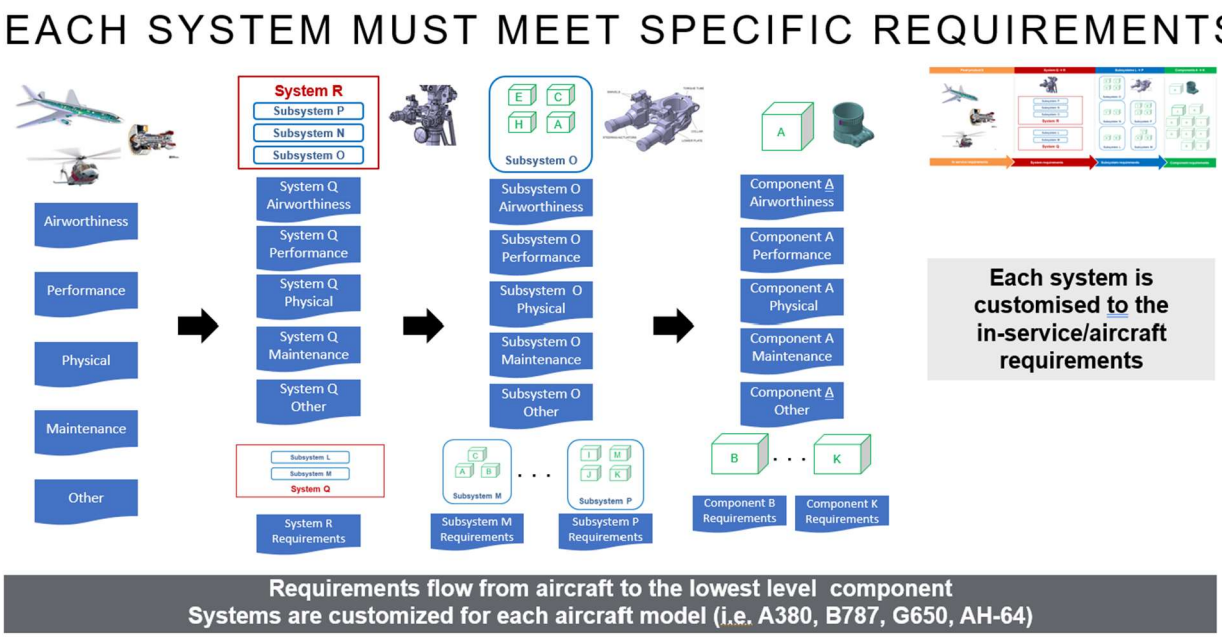

Figure 1: Specific requirements

0.3. Type(s) of product(s) made with the Annex XIV substance and market sector(s) likely to be affected by the authorisation

{For review reports, please specify whether the types of products are similar/identical to those of the original AfA/previous review report.}

The authorisation holder provided a table of corrosion and wear prone areas of A&D products where chromates are used (see Table 3).

Table 32: Examples of corrosion and wear prone areas of aerospace and defence products (non-exhaustive) [source: applicant's AoA/SEA]

Structural/flight	Propeller/rotor	Engine/power plant	Additional Space- and Defence-specific
Aileron and flap track area	Blade tulip and hub	Auxiliary Power Units	Air-transportable structures

		(APUs)	
Centre wing box	Gearbox	Carburettor	Fins
Cockpit frames	High bypass fan components	Data recorders	Gun barrels and ancillaries
Differential	Main and tail rotor head assemblies	Engine Booster and Compressors including Fan Containment	Interstage Skirts
Emergency valve landing gear	Propeller speed controller	Engine control unit	Launchers (rocket, satellite, etc.)
Environmental control systems	Propellers	Engine external components	Missile and gun blast control equipment
External fuel tanks	Transmission housing	Fuel pump	Missile launchers
Flight control systems		Gearbox	Pyrotechnic Equipment
Fuselage		Hydraulic intensifier	Radomes (Radar Domes)
Hydraulic damper		Ram air turbine	Rocket motors
Hydraulic intensifier		Starter	Safe and arm devices
Landing equipment		Vane pump	Sonar
Nacelles			
Pylons			
Rudder and elevator shroud areas			
Transall (lightning tape)			
Undercarriage (main, nose)			
Valve braking circuit			
Window frames			
Wing fold areas			
Source: (GCCA, 2017)[11]			

The applicant mentions specific examples of parts and systems where chemical conversion coating is important:

- Fuselage skins and bulkheads;
- Wing skins, panels, and covers;
- Stabilisers;
- Wheels and landing gear links;
- Gearbox and engine inlet cases.

[11] Dichromium tris(chromate) AoA, use 2 (0116-01).

Civil Aviation

The applicant highlighted that all civil aircrafts operating in the EU are subject to Airworthiness Directives issued by the EASA[12] on behalf of the EU and its Member States, and European third countries participating in the activities of EASA. Changes to design of a product are subject to certification and can only be made following approval from EASA and compliance with the requirements of the appropriate Airworthiness Regulation, such as (EU) 2018/1139[13]. To reinforce this point, a civil aircraft's Certificate of Airworthiness is not valid until the Type Certificate has been approved by the Regulator (EASA, 2012)[14]

Military Aviation

Military planes and helicopters are subject to stand-alone change protocols including approval by the relevant Member State Ministries of Defence. Generally the requirements are reported to be more stringent than for comparable civil aircraft. However, in many cases actual performance requirements as well as design specifications are classified.

Other military equipment & Space Equipment

This kind of equipment (satellite launchers, satellites, gun barrels, armoured vehicles, rocket launchers, etc) is based on military specifications set by local defence authorities or defence alliances like NATO. Not many details on such specifications are known, other than they are classified and at a much higher level than comparable civil requirements.

0.4. For upstream review report: Downstream user survey

The authorisation holder explained in detail how it has conducted the DU surveys. From 2019 to 2022, the ADCR consortium collected a range of data relevant to both the AoA and the SEA.

For pre-trteatments the SEA survey questionnaire was filled by 37companies operating over 53 sites (out of the total of 71 companies over 100 sites in EEA and UK undertaking pre-treatments

As the period when the survey was conducted is around the time of Brexit (and many companies had sites both in the UK and EEA), UK site were included but are recorded separately where feasible.

These companies represent different sizes, from micro enterprises to large organisations across many countries and sites[15] and with multiple uses. The results also show a good coverage across the main types of companies (BtP, DtB, MROs and OEMs) with percentage share of their production related to electroplating.

Consultation took place over four different phases (for details on each phase, see Section 2.4.3 of the AoA/SEA document):

Phase 1 involved collection of information on surface treatment activities that each member undertook on their own.

[12] EASA | European Union Aviation Safety Agency (europa.eu)
[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32018R1139
[14] EASA (2012) European Aviation Safety Agency GOOD PRACTICES Coordination between Design and Maintenance First Installation of a Change to a Product.
[15] Table 4.1 in the AoA/SEA document of each use has more details on these companies.

Phase 2 involved collection of data on R&D activities undertaken by each company (including confidential and non-confidential information).

Phase 3 took the form of detailed one-on-one discussions between ADCR members and the AoA technical service team, with a focus on collecting additional critical details concerning core aspects of the AoA/SP sections of the dossiers.

Phase 4 collected information for the SEA component of this document.

1. Operational Conditions and Risk Management Measures

{Delete not relevant sections. For review reports, present especially what has changed during the review period in terms of OCs/RMMs, and in particular as a result of any additional conditions as per the decision of the Commission. Insert as a footnote a hyperlink and references to the relevant parts of the decision of the Commission}

1.1. Workers

{Character limit: 700 per WCS}

{Present:

- Hierarchy of control
- Technical measures;
- Design and organisational measures to prevent exposures;
- PPE.}

With the initial ('parent') authorisations (see Annex II to the opinion), the European Commission issued several obligations and RAC/SEAC provided recommendations in their joint opinion on initial applications. Annex III to the CSR outlines how the applicants (authorisation holder; AH), together with downstream users (DUs) represented by the ADCR consortium, reacted to these tasks.

Information about the OCs and RMMs in place has been presented in the CSR and additional information has been provided in response to RAC's questions.

Technical RMMs

(Include a **brief summary** of the **technical RMMs** described for the specific use in Section 9.2.2.3.1 of the CSR, adding relevant information in Table 4)

Example: Text in CSR for Passivation of (non-Al) metallic coatings: The technical measures implemented at the sites include:

*• Requirement for SD and PD: **Closed systems** and **automation** are used for tasks involving measuring and weighing of solids, where possible.*

*• Requirement for SD and PD: Where use of closed systems and automation is not possible, **local exhaust ventilation (LEV) systems** that are appropriately designed, dimensioned, located and maintained to capture and remove the substances are used. Technical information on the LEV systems used is given for the respective worker contributing scenarios in sections 9.2.3.2 to 9.2.3.7.*

• Chemical treatment baths are equipped with LEV, as described in the respective worker contributing scenarios in sections 9.2.3.2 to 9.2.3.7. LEV systems are designed and installed for the specific baths to remove contaminants from the workers' breathing zone through

*exhaust extraction. The **efficiency of the installed LEV system** depends on the exhaust air flow rate of the system per time unit. The sites follow the manufacturer requirements as well as recommendations from national guidelines, where applicable, and perform preventative maintenance of equipment to maintain the stated efficiencies of the LEV systems.*

Organisational RMMs

(Include a **brief summary** of the **organisational RMMs** described for the specific use in Section 9.2.2.3.1 of the CSR, adding relevant information in Table 4)

Example: Text in CSR for Passivation of (non-Al) metallic coatings: The following organisational measures to reduce workplace exposure are implemented at all sites:

*• **Annual monitoring programmes** are implemented for **air monitoring of occupational exposure to Cr(VI)**, which are representative of the range of tasks undertaken where exposure to Cr(VI) is possible, including tasks involving **process and maintenance operations**(requirement for CT, SD and PD) as well as **machining activities** (requirement for SD).*

*• The **effectiveness of the risk management measures and operational conditions** in place are regularly reviewed and, as applicable, measures are introduced to further reduce exposure and emissions.*

*• Requirement for SD and PD: Appropriate **standard operating procedures** are implemented to minimise release of dust into the air during the preparation, transfer and storage of empty bags, filters, and other process waste, in accordance with the hierarchy of control provisions set out in Article 5 of Directive 2004/37/EC.*

*• **LEV systems** are inspected and **maintained** according to the manufacturer´s specification.*

*• Standard procedures are available for use and maintenance of **respiratory protective equipment (RPE)** (including procedures for fit testing of RPE masks which are applied in accordance with relevant standards).*

*• The provision of **PPE** for the workers is organised by a designated responsible person.*

• The conditions of the PPE are checked regularly.

*• A program of PPE management is implemented on-site which includes **PPE selection, training** for correct wear/removal of the PPE, storage of PPE, cleaning or renewal and distribution of the PPE, communication via workplace signage or working instructions at the workplace.*

*• **Training** on chemical risks is periodically done for workers handling chemicals. Safety Data Sheets and instructions for hazardous chemicals handling are available.*

• Training at the workplace is given periodically and work instructions are available on how to carry out specific tasks through standard operating procedures.

*• Cleaning of company supplied uniforms is organised by the site, or **contaminated clothes** are renewed.*

• In the production area reducing chemicals are available, which are suitable to remove Cr(VI) from the skin (e.g., ascorbic acid, formation of Cr(III), which can be washed off easily).

*• Small **splashes** or amounts are taken up with wipes. Wipes are disposed of as solid waste.*

*• Chemical products are **stored in a designated area**.*

• Effective cleaning practices are implemented in the vicinity of the tanks.

• *At some sites, **water** in rinsing tanks is **recirculated** and water quality is ensured by regular visual verification and scheduled water changes. At some sites, water quality is monitored by testing conductivity. When the quality of the water is no longer sufficient after visual verification or a certain conductivity limit is exceeded, the rinse water is treated as wastewater and renewed in the rinsing tanks. This prevents elevated Cr(VI) concentrations from being present in the rinsing tanks in the working area.*

Personal protective equipment

(Include a **brief summary** of the **PPE** described for the specific use in Section 9.2.2.3.1 of the CSR, adding relevant information in Table 4)

Example: Text in CSR for Passivation of (non-Al) metallic coatings: For all tasks with potential direct Cr(VI) exposure, standard operating procedures are available at the sites, wherein the appropriate PPE to be worn is specified (selected based on risks and in accordance with the exposure scenarios). The following PPE is applied for activities where exposure to Cr(VI) is possible, in order to control Cr(VI) exposures:

- ***Chemical protective clothing**, where necessary (plus coveralls or aprons for specific tasks);*
- ***Eye protection** as per relevant risk assessment;*
- ***Chemical resistant gloves;***
- ***Respiratory protection**, worn during all tasks not performed under an LEV for which industrial hygiene exposure assessment confirms RPE use is required.*

Table 4: Operational Conditions and Risk Management Measures (sub-set of Succinct Summary of RMMs and OCs) {*}

Contributing scenario	**Concentration of the substance {**}**	**Duration and frequency of exposure**	**Engineering controls** (e.g. containment, segregation, automation, LEV) **+ effectiveness as stated by the [applicant] [authorisation holder]**	**PPE** (RPE and Skin protection used) **+ effectiveness as stated by the [applicant] [authorisation holder]**	**Organisational controls** (access control, procedures, training)
WCS 1 {add WCS name} PROC:					
WCS 2 {add WCS name} PROC:					

{* if the table extends over several pages, consider placing it in an annex.}

{** if the concentration does not change throughout the process, delete this column and report the concentration separately in the text }

{Identify OCs and RMMs identified as input parameters for exposure modelling and those that were amended / added during the opinion development.

Description of other, not mentioned in the table above, RMMs used that are applicable for individual WCSs.}

[Add text]

1.2. Environment/Humans via the environment

{Character limit: 700 per element.}

Air

{Effectiveness of the RMMs to be described.}

(Include a **brief summary** of the **OCs/RMMs** to reduce **air** emissions described for the specific use in Section 9.2.2.3.2 of the CSR, adding relevant information in Table 5)

Example: Text in CSR for Passivation of (non-Al) metallic coatings: The following technical and organisational measures are implemented to reduce environmental air emissions:

*• All chemical treatment baths are equipped with **LEV systems**. The local exhaust air is collected and released via exhaust stacks.*

*• The local exhaust air is treated in **wet scrubbers** or by **air filters** before it is released to the environment. For sites using only low Cr(VI) concentrations in the bath and where low emissions are expected, exhaust air treatment in a wet scrubber or by air filter is not considered essential.*

*• Wash water in the wet scrubber is regularly exchanged when a certain threshold value of either conductivity, pH, or Cr(VI) concentration is exceeded. Regular replacement of the wash water helps to ensure that the **cleaning** performance of the wet scrubber does not decrease.*

*• **Regular monitoring programmes** for Cr(VI) emissions to air from LEV systems are implemented and the effectiveness of the risk management measures and operational conditions in place are regularly reviewed.*

Efficiency of air emission abatement technology

*• Wet scrubbers are **regularly checked** by measuring conductivity, pH, or Cr(VI) concentration ensuring proper function.*

• The usual way to check the performance of air filters is to measure pressure loss.

• The efficiency of the wet scrubbers or air filters can also be checked by comparative measurements with and without the use of the wet scrubber/filter or between the duct inlet and outlet. At sites where such measurements are performed, very high efficiencies for air abatement can be demonstrated. As an example, such measured values from one site show a purification of the exhaust air from Cr(VI) concentrations in the range of several mg/m3 (before the filter) to a concentration below the detection limit of the measurement method used (after the filter).

Water

{Effectiveness of the RMMs to be described.}

(Include a **brief summary** of the **OCs/RMMs** to reduce **wastewater** emissions described for the specific use in Section 9.2.2.3.2 of the CSR, adding relevant information in Table 5)

*Example: Text in CSR for Passivation of (non-Al) metallic coatings: Cr(VI)-containing wastewater is gathered and either sent to an **external waste management company** (licensed contractor) or treated **on-site in a reduction facility** and/or evaporated in an **on-site evaporation system** (the residue is discharged as hazardous solid waste or liquid waste) and/or **recycled or discharged** in accordance with regulatory requirements. For the reduction of environmental emissions to wastewater to the maximum extent possible, the technical and organisational measures implemented at the sites include:*

*• Wastewater is sent to a reduction facility (typically on-site), where Cr(VI) in wastewater is reduced to Cr(III) by addition of a **reducing agent** (e.g., sodium bisulfite or ferrous sulfate). After the reduction process, Cr(III) is precipitated and separated from the wastewater by a filter press (the filter cake is disposed as waste), and the treated **wastewater is either reused, evaporated, or discharged to a wastewater treatment plant (WWTP) or municipal sewage treatment plant (STP)** (depending on local regulatory requirements).*

*• **Regular monitoring programmes** for Cr(VI) emissions to wastewater are implemented and the effectiveness of the risk management measures (i.e., the efficiency of the wastewater reduction) and operational conditions in place are regularly reviewed.*

Soil

{Effectiveness of the RMMs to be described.}

(Include a **brief summary** of the **OCs/RMMs** to reduce emissions to **soil** described for the specific use in Section 9.2.2.3.2 of the CSR, adding relevant information in Table 5)

Example: Text in CSR for Passivation of (non-Al) metallic coatings: The following technical and organisational measures are implemented to prevent environmental emissions to soil:

*• The indoor and outdoor **surfaces** where chemicals are handled are **sealed**. Chemicals and solid waste containing Cr(VI) are stored in **closed containers**, either inside or outside.*

*• Treatment baths are surrounded by a **secondary containment** pit and the solution collected in the containment pit is **treated or disposed of as hazardous waste**.*

Waste (other than wastewater)

{Effectiveness of the RMMs to be described.}

(Include a **brief summary** of the **OCs/RMMs** to dispose of **solid waste** described for the specific use in Section 9.2.2.3.3 of the CSR)

*Example: Text in CSR for Passivation of (non-Al) metallic coatings: Solid waste generated at the sites may include the **filter cake** from the filter press (only contains Cr(III)), **solid residues** from the evaporation system for wastewater, and **Cr(VI) contaminated waste** from activities related to the surface treatment process (e.g., empty chemical containers and bags, filters, waste from cleaning activities, sorbents, brushes, used sandpaper, contaminated equipment and PPE).*

*The **filter cake** containing Cr(III) is collected and stored in containers and forwarded to an **external waste management company** (licensed contractor) for disposal as waste.*

*The **solid residues** from the evaporation system for wastewater are collected and discharged*

*as hazardous solid waste by an **external waste management company** (licensed contractor).*

*The **Cr(VI)-contaminated solid waste** such as contaminated wipes, rags, brushes and PPE (e.g., gloves, overalls, aprons), contaminated equipment or empty chemical containers (canisters, bags, drums) are usually disposed as hazardous waste unless they are cleaned prior to their disposal (if they are cleaned, they are disposed as non-hazardous solid waste). This hazardous solid waste is stored in closed drums and containers and forwarded to an **external waste management company** (licensed contractor) for disposal.*

Table 5: Environmental RMMs – summary

Compartment	RMM	Stated effectiveness
Air		
Water		
Soil		

{Identify OCs and RMMs amended / added during the opinion development.}

[Add text]

1.3. RAC's evaluation on the OCs and RMMs

{Character limit: 1700}

{Assess the OCs and RMMs implemented in the context of hierarchy of control principles and relevant legislation (e.g. Chemical Agents Directive, Carcinogens and Mutagens Directive, BATs), and identify any relevant shortcomings and uncertainties, potential for improvement – for workers' (per WCS).

Assess environmental release, as well as prevention or minimisation of releases and when applicable exposure of humans via the environment. Identify any relevant shortcomings and uncertainties.

Include the evaluation of effectiveness of RMMs stated by the applicant/authorisation holder – is it as predicted by design (e.g. flowrate of LEV), is it supported by regular maintenance, measurements, appropriate PPE – supported by training and supervision?

Describe any relevant shortcomings or uncertainties related to the RMMs in place – especially in relation to the effectiveness of RMMs estimated by the applicant/authorisation holder - and their impact on the exposure / releases.

When evaluating OCs & RMMs for consumers, in line with ECHA guidance R13, the emphasis should be on product integrated RMMs under the control of the supplier (measures that are integrated into the design of the product and how it subsequently is used) and to a lesser degree on consumer instructions on safe use. Consumer instructions cannot be expected to be highly effective, unless consumer behavioural data suggest that a sufficient degree of implementation can be assumed.

For review reports and when the authorisation was subject to additional conditions related to OCs/RMMs, evaluate to what extent the authorisation holder has fulfilled these conditions as per the decision of the Commission. Insert a footnote with a hyperlink and references to the relevant parts of the decision of the Commission.

In light of the above, conclude on the need for any conditions or monitoring for the authorisation or a recommendation for the review report.}

[Add text]

1.4. RAC's conclusions on the OCs and RMMs

Overall conclusion

Are the operational conditions and risk management measures appropriate and effective[16] in limiting the risks?

Workers	☐Yes	☐No	☐Not relevant
Consumers	☐Yes	☐No	☐Not relevant
Humans via the environment	☐Yes	☐No	☐Not relevant
Environment	☐Yes	☐No	☐Not relevant

{Please provide the **specific** reason for the conclusion (as short as possible), also if 'not relevant' is ticked. Connect the reason (the problem) to the proposed actions. You can use the following standard sentences for this purpose:

[Additional conditions for the authorisation and monitoring arrangements for the authorisation are proposed. These are listed in sections 7 and 8 of the justifications to this opinion.]

[Monitoring arrangements for the authorisation are proposed. These are listed in section 8 of the justifications to this opinion.]

[Recommendations for the review report are made. These are listed in section 9 of the justifications to this opinion.]}

The OCs and RMMs implemented for the workers' protection are [not] considered to be generally appropriate and effective and they [do not] follow the hierarchy of control principles.

[RAC considers that the new RMMs and OCs reported by the authorisation holder in the review report have led to a significant reduction of the (consumption/risks/emission) of Cr(VI) compared to the initial ('parent') applications (see Annex III to the opinion).]

[However,] RAC has moderate/major concerns about the operational conditions of [list key issues for OCs and RMMs for specific activities undertaken by workers].

RAC takes note that the authorisation holder is currently evaluating [describe commitment of the authorisation holder to improve OCs/RMMs for one or more activities].

In terms of environmental release minimisation, the OCs and RMMs in place are [not] considered to be appropriate and effective in limiting the risk to the general population via the environment for the amount of Cr(VI) used. [However,] RAC has some minor concerns due to [describe concern related to OCs and RMMs for HvE].

The abovementioned concerns lead to conditions for the authorisation (section 7) and monitoring arrangements (section 8) ~~and recommendations for the review report (section 9)~~.

[16] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls as well as prevention or minimisation of releases in application of OCs and RMMs and compliance with the relevant legislation. 'Effectiveness' – evaluation of the degree to which the OCs and RMM are successful in producing the desired exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

2. Exposure assessment

{Delete not relevant sections. For review reports, present also what has changed during the review period in terms of assessing the exposures or releases, and in particular as a result of any monitoring arrangements as per the decision of the Commission. Insert as a footnote a hyperlink and references to the relevant parts of the decision of the Commission}

A grouping approach for the Cr(VI) compounds (CT, SD, PD, SC, DtC) was used by the authorisation holder in the review report, because:

- All substances share this common toxic moiety (Cr(VI)), and are therefore expected to exert effects in an additive manner;
- At many sites various chromates are used in parallel, the exposures of which are additive.

For some uses, different chromates can be used interchangeably, as they provide the same performance properties and functionalities.

2.1. Inhalation exposure

{Character limit: 3000}

The authorisation holder's general approach to the assessment of the workers' exposure to Cr(VI) resulting from the industrial use of chromates covered by this review report is described in Section (9.1.2.5 or different section) of the CSR.

The authorisation holder assigned exposed workers to "Similar Exposure Groups" (SEGs), which were defined for each use and comprise groups of workers performing similar tasks and, hence, are assumed to experience similar exposures. The Cr(VI) exposure from these activities is quantified by personal air measurements. In this way, Cr(VI) inhalation exposures from all relevant tasks performed by a SEG during its daily work are considered and combined for risk assessment.

Monitoring

{Describe personal and Static monitoring. For measured data: methodology used, LOD/LOQ, **assessment** of representativeness: in relation to the number of sites, number of samples, but also tasks performed and number workers potentially exposed. Which values (e.g. median / 90th percentile) were used for risk characterisation?}

The authorisation holder provided measured and modelled exposure estimates for the different WCSs.

Annual/regular monitoring campaigns, including personal (long and short term) and static (stationary) measurements were performed between 20xx-20xx across the different sites covered by this review report (inhalable fraction; method xxx).

Modelling

{Use of Tier 1 or higher. **Assessment** of the appropriateness of the modelling tool (within the applicability?), statement on the availability and appropriateness of the input parameters (if printouts provided e.g. from ART – can be attached in the annex) and reproducibility of results.}

Exposure modelling was performed by the authorisation holder, where required, with Advanced REACH Tool (ART), version 1.5, using the 90th percentile of the resulting distribution for risk

assessment, according to ECHA guidance.[17] Modelling was applied for specific activities only which cannot be adequately covered by measurements, such as: activities of very short duration, infrequent activities and activities using small amounts of mixtures with low concentrations of Cr(VI).

2.2. Dermal exposure

{Character limit: 2000}

1: For uses not involving SD, PD and/or SC:

Dermal exposure was not assessed by the authorisation holder. RAC agrees with this approach since, according to RAC/27/2013/06 Rev.1[18], there are no data to indicate that dermal exposure to Cr(VI) compounds presents a potential cancer risk to humans.

Modelling

{**Assessment** of the appropriateness of the modelling tool (within the applicability?), statement on the availability and appropriateness of the input parameters and reproducibility of results.}

2: For uses involving SD, PD and/or SC: Include dermal exposure assessment

A quantitative dermal exposure assessment (Riskofderm or other model) was undertaken with respect to effects on reproduction due to sodium dichromate exposure. (Sodium dichromate, potassium dichromate or sodium chromate) is used in (xx) sites.

The results are presented in Table 6.

Monitoring

{If applicable.}

[Add text]

2.3. Biomonitoring

{Character limit: 1500}

{Description of methodology; Conversion to exposure levels where needed; Interpretation of the results; Background level consideration.}

Biological monitoring data was not used in the authorisation holder's exposure assessment.

Table 6: Summary of exposure information – dermal and inhalation

Contributing scenario	Route of exposure	Method of assessment	Exposure value (8h TWA)	Exposure value corrected for PPE	Exposure value corrected for PPE and frequency

[17] Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.14: Occupational exposure assessment. Version 3.0, August 2016 https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

[18] RAC/27/2013/06 Rev.1 (ECHA, 2013) – Application for authorisation: Establishing a reference dose response relationship for carcinogenicity of hexavalent chromium. https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf

WCS 1	Inhalation				
	Dermal				
	Biomonitoring				
WCS 2	Inhalation				
	Dermal				
	Biomonitoring				

{Please include the equations used to calculate the adjustment factors.}

[Add text]

[Comparison of current exposure data with the exposure values from the initial application]

{For review reports, include a table comparing the exposure data that was used by RAC in the opinion on the initial application for authorisation and is used by RAC for the risk characterisation in this opinion on the review report.}

Table 7: Comparison of exposure data

WCS	**Route of exposure**	**Initial application**		**Review report**	
		Days per year	Exposure value (8-h TWA) corrected for PPE and frequency	Days per year	Exposure value (8-h TWA) corrected for PPE and frequency
WCS 1	Inhalation				
	Dermal				
	Biomonitoring				
WCS 2	Inhalation				
	Dermal				
	Biomonitoring				

{Short discussion of the comparison. Values that are significant (especially high, big difference to the initial applications for authorisation) might be highlighted in the table (e.g. bold font).}

[Add text]

2.4. Environmental [exposure] [releases]

{Character limit: 3000}

The authorisation holder's general approach to the assessment of the exposure of humans to Cr(VI) via the environment (HvE) as a result of air and wastewater emissions from the sites of the applicants and downstream users covered by this review report is described in Section (9.1.2.4 or different section) of the CSR.

In the environmental contributing scenario of this review report, the assessment of HvE is considered via the inhalation route and the oral route. Environmental monitoring data for

releases to air and wastewater serve as a basis for EUSES modelling of human exposure via [several] environmental compartments [(ambient air, drinking water, fish)].

Data for monitoring of Cr(VI) releases to air and water are available from several sites in EEA, as required by national legislation (and by the relevant authorisation decisions). Release fractions for Cr(VI) emissions to air, water and soil were derived from the site-specific emission data and tonnages of used chromium trioxide [and SD, PD, SC, DtC …]. These releases are generally governed by, and comply with, local worker and environmental regulatory requirements.

Air

{Description of the methodology / data used to estimate releases to the environment and resulting environmental exposure (at local and regional scales, where appropriate). Key assumptions should be described.}

[Add text]

Water

{Description of the methodology / data used to estimate releases to the environment and resulting environmental exposure (at local and regional scales, where appropriate). Key assumptions should be described.}

[Add text]

Soil

{Description of the methodology / data used to estimate releases to the environment and resulting environmental exposure (at local and regional scales, where appropriate). Key assumptions should be described.}

No direct or indirect release in the soil is expected due to the technical and organisational measures in place at the sites (reason).

Table 8: Summary of releases to the environment

Release route	**Release factor**	**Release per year** [tonnes] [kilograms] [grams]	**Release estimation method and details**
Air			
Water			
Soil			

Table 9: Summary of exposure to the environment and humans via the environment

Parameter	**Local**	**Regional**
PEC in air (mg/m^3)		
Daily dose via oral route (mg/kg bw/d)		

{PECs other than those included in the table may be added, where relevant.}

[Comparison of current release, exposure to the environment and humans via the environment data with those from the initial application

{For review reports, include a table comparing the release}

[Table 10: Comparison of release data

Release route	Initial application		Review report	
	Release factor	Release per year [tonnes] [kilograms] [grams]	Release factor	Release per year [tonnes] [kilograms] [grams]
Air				
Water				
Soil				

{Short discussion of the comparison.}

[Add text]]

[Table 11: Comparison of exposure to the environment and humans via the environment data

Parameter	Initial application		Review report	
	Local	Regional	Local	Regional
PEC in air (mg/m^3)				
Daily dose via oral route (mg/kg bw/d)				

{Short discussion of the comparison.}

[Add text]

2.5. RAC's evaluation of the exposure assessment

{Character limit: 3500}

{Please provide RAC's evaluation of the exposure and releases assessment, including the following elements:

- Methodology of assessment;
- Representativeness of the exposure assessment in relation to the number of sites, tasks and number of workers (including indirectly exposure workers);
- Reliability of the measured and / or estimated exposure levels for workers and humans via the environment or the environment;
- Shortcomings or uncertainties in the exposure assessments for a route of exposure,

WCS or release to the environment that lead to proposed monitoring for the authorisation or a recommendation for the review report;

- Input parameters of modelling;
- Assumed effectiveness of RMMs with reference to sections 1.4 and 1.5;
- Other assumptions made by the authorisation holder;
- Factors that are likely to lead to increase of exposure, and those that may result in its overestimation;
- Verify whether all relevant routes of exposure were considered;
- Relevant shortcomings or uncertainties (it is well understood that no scientific assessment is 100% certain but uncertainties that would not challenge the conclusions or risk estimates do not have to be highlighted in the same way as those that do). Include a concluding statement on the potential impact of such shortcomings or uncertainties and whether the exposure is more likely to be overestimated or underestimated;
- For review reports and when the authorisation was subject to monitoring arrangements, evaluate to what extent the authorisation holder has fulfilled his obligations as per the decision of the Commission. Insert a footnote with a hyperlink and references to the relevant parts of the decision of the Commission;
- The need for additional conditions / monitoring arrangements for the authorisation;
- The reasons/explanation for any exposure calculations performed by RAC.

In light of the above, conclude on the need for any conditions or monitoring for the authorisation or a recommendation for the review report.}

Workers exposure

RAC takes note that measurement data (personal and static), and modelled exposure estimates are used for the inhalation exposure assessment. Contextual information about the measurements (sampling period, tasks performed during sampling) and modelling estimates (ART reports) has been provided by the authorisation holder.

[Add text]

RAC takes note that the authorisation holder is performing [annual] workers' exposure measurements. RAC considers regular monitoring [during the review period] relevant to guarantee the adequateness and effectiveness of OCs and RMMs in time and, if needed, to introduce corrective measures.

RAC takes note that the authorisation holder is not performing biomonitoring for the workers potentially exposed to Cr(VI). RAC considers that regular biomonitoring can provide useful information about the potential exposure to Cr(VI) including also other exposure routes than inhalation.

1: For uses not involving SD, PD and/or SC:

RAC agrees that dermal exposure has not been assessed as dermal exposure to Cr(VI) compounds is not expected to present a cancer risk to humans (RAC27/2013/06 Rev 1)[19].

[19] RAC/27/2013/06 Rev.1 (ECHA, 2013) – Application for authorisation: Establishing a reference dose response relationship for carcinogenicity of hexavalent chromium. https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf

2: For uses involving SD, PD and/or SC: Include RAC's evaluation of dermal exposure assessment

[The dermal exposure assessment is based on total Cr(VI) exposure, which includes chromium trioxide and (sodium dichromate, potassium dichromate and sodium chromate) use. This leads to an overestimate as the reproductive toxicity effect is associated with (sodium dichromate, potassium dichromate and sodium chromate) only.

[Chromium trioxide, (sodium dichromate, potassium dichromate and sodium chromate) are corrosive. Consequently, measures are taken at the workplace to avoid skin contact due to local acute effects, and also it is readily noticeable when exposure occurs. Furthermore, the tasks with potential for skin contact are of short duration. Consequently RAC considers that workplace exposure is negligible, and that the modelled exposure is likely to be an overestimate.]

Humans via the environment

Include only relevant conclusions from below:

[RAC takes note that the environmental release factor for the air emission has been calculated using monitored data obtained at the sites covered in this review report.]

RAC takes note that the authorisation holder does (not) perform air emission measurements on an annual basis, but (frequency).

RAC considers it important to perform at least yearly measurements to determine the releases of Cr(VI) in the air to ensure that the OCs and RMMs will remain adequate and effective in time and, if needed, to introduce corrective measures.

[If no releases to water/soil: RAC takes note that no releases of Cr(VI) to the water environment take place (reasons), and nor to the soil, due to the RMMs in place (reasons).]

[RAC acknowledges that the calculated air release factor can be considered conservative since the authorisation holder assumed that all measured total Cr releases are entirely attributable to Cr(VI)].

[RAC notes that the authorisation holder's estimate of $PEC_{local,air}$, which is used for the general population exposure assessment, was based on the concentration of 100 m from a point source, which is consistent with the default assumptions used in the EUSES model for local scale assessments. RAC acknowledges that the assessment of indirect exposure to humans via the environment using default assumptions in the EUSES model is likely to overestimate exposure, particularly at the local scale, leading to an overestimation of risk (and the number of statistical cancer cases).]

[RAC agrees with the authorisation holder's approach to considering only the oral exposure (by drinking water and fish) and exposure via air (direct inhalation exposure) relevant.]

[RAC takes note that the authorisation holder did not apply the 97% reduction factor of Cr(VI) to Cr(III) (according to the EU RAR) for the calculation of the daily dose via the oral route for the local population, and therefore the predicted exposure via the oral route is an overestimation.]

2.6. RAC's conclusions on the exposure assessment

{Character limit: 1500}

{Please provide a very brief, clear and condensed conclusion on the exposure assessment.}

RAC identified minor/moderate/major shortcomings/ concerns in the exposure estimates for workers, in particular concerning [list key issues identified in exposure assessment for workers and HvE].

RAC considers it important that the authorisation holder continues the yearly monitoring of the workers' exposure to Cr(VI) covering all WCSs, initiates biomonitoring of potentially exposed workers and continues the yearly monitoring of the releases of Cr(VI) into the air and water to ensure that the OCs and RMMs will remain adequate and effective in time and if needed, to introduce corrective measures.

1: For uses not involving SD, PD and/or SC:

RAC agrees that dermal exposure has not been assessed as dermal exposure to Cr(VI) compounds is not expected to present a cancer risk to humans (RAC27/2013/06 Rev 1)[20].

2: For uses involving SD, PD and/or SC: Include RAC's conclusion on dermal exposure assessment

The abovementioned shortcomings and statements lead to proposed monitoring arrangements for the authorisation (section 8) ~~and recommendation for the review report (section 9).~~

3. Risk characterisation

{Delete not relevant sections. For review reports, present also what has changed during the review period.}

The authorisation holder addressed all endpoints listed in Annex XIV for chromium trioxide (and sodium dichromate, potassium dichromate and sodium chromate) in the assessment.

The lung and intestinal cancer risk is estimated according to the RAC reference dose-response relationship for the carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1, agreed at RAC 27)[21].

The authorisation holder has conservatively assumed that all inhaled CrO_3 particles are in the respirable range and contribute to the lung cancer risk and therefore no exposure via the oral route (mucociliary clearance and swallowing of non-respirable fractions) needs to be considered, taking into account also that the excess lifetime risk for intestinal cancer is one order of magnitude lower than that for lung cancer.

For uses involving SD, PD and/or SC: Include reproductive toxicity risk characterisation:

The authorisation holder used the DNELs for reproductive risk associated with (sodium dichromate, potassium dichromate and sodium chromate) recommended by RAC

[20] RAC/27/2013/06 Rev.1 (ECHA, 2013) – Application for authorisation: Establishing a reference dose response relationship for carcinogenicity of hexavalent chromium. https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf

[21] RAC/27/2013/06 Rev.1 (ECHA, 2013) – Application for authorisation: Establishing a reference dose response relationship for carcinogenicity of hexavalent chromium. https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf
For workers for 40 years of exposure (8 h/day, 5 d/week):
-Inhalation: excess life-time lung cancer risk of 4×10^{-3} per µg Cr(VI)/m^3
-Oral intake: excess lifetime intestinal cancer risk of 2.0×10^{-4} per µg Cr(VI)/kg bw/day
For general population: for 70 years of exposure (24 hours/day, 7 days/week)
-Inhalation: excess lifetime lung cancer mortality risk of 2.9×10^{-2} per µg Cr(VI)/m^3
-Oral intake: excess lifetime intestinal cancer risk of 8.0×10^{-4} per µg Cr(VI)/kg bw/day.

(RAC/35/2015/09, agreed at RAC-35)[22].

3.1. Workers

{Character limit: 1400}

{Combined exposure level and/or highest daily exposure level: To present an average exposure of a worker for the duration of 1 shift. Which WCSs can be performed within single shift, why, what are the variations and what are the resulting exposures?

Please provide the basis of risk characterisation (DNELs, dose response relationship) and include the following standard text when RAC has derived reference DNELs or dose response relationships:

[The authorisation holder has [not] used the [DNELs] [Dose response relationship] recommended by RAC.]

Verify whether the applicant has addressed all endpoints listed in Annex XIV in the assessment.}

[Add text]

Table 12: Combined exposure and risk characterisation {This table can be amended depending on the way the information is presented. For example information on the group of workers can be added. If needed, add footnotes to the table.}

Contributing scenario	**Exposed population**	**Route**	**Exposure value corrected for PPE and frequency**	**RCR or excess risk***	
					Combined
WCS 1	{number of workers exposed}	Inhalation			
		Dermal			
WCS 2		Inhalation			
		Dermal			
		Inhalation			
		Dermal			
WCS 3 + WCS 4		Inhalation			
		Dermal			
Total exposure for 8 hours		**Inhalation**			
		Dermal			

* Estimated individual risk resulting from exposure

{Discussion of potential over or under estimations:

- RCR or
- Excess risk.}

[Add text]

[22] https://echa.europa.eu/documents/10162/21961120/rac_35_09_1_c_dnel_cr-vi-_en.pdf

3.2. Humans via the environment

{Character limit: 1500}

{To present the

- RCR or
- Excess risk, on: Local scale; Regional scale

Include the discussion of potential over or under estimations.}

[The risk assessment for humans exposed via the environment considers both the inhalation of airborne residues of CrO_3 and the oral intake via the food chain at the local level using the approach reported in EU RAR (2005)[23]. As mentioned in section 2.4, RAC is the opinion that the regional exposure, and therefore the corresponding excess risk is not particularly relevant.]

[RAC notes that the excess risk corresponding to the daily dose via the oral route for the general population is an overestimation since the authorisation holder did not apply the 97% adjustment factor related to the reduction of Cr(VI) to Cr(III) in the environment (see also section 2.5).]

Table 13: Exposure and risk to humans via the environment – local and regional scale

Parameter	**Local**		**Regional**	
	Exposed population: {number at local scale}		**Exposed population:** {number at regional scale}	
	Exposure	**RCR or excess risk***	**Exposure**	**RCR or excess risk***
Humans via the environment – Inhalation				
Humans via the environment – Oral				
Humans via the environment - Combined	Not applicable		Not applicable	

* Estimated individual risk resulting from exposure. {combine only RCRs or excess risk when relevant (e.g. same endpoint).}

3.3. RAC's evaluation of the risk characterisation

{Character limit: 700}

{Describe / list any relevant shortcomings or uncertainties affecting the risk characterisation and indicate whether risks are realistic, underestimated, or overestimated; comment on use of any conservative corrections and assumptions in the derivation of the DNELs or dose response.}

[Add text]

[For reference, the current indicative (IOEL) or binding Occupational Exposure Limit (BOEL)

[23] European Union Risk Assessment Report for chromium trioxide, sodium chromate, sodium dichromate, ammonium dichromate and potassium dichromate" report 3rd Priority List Volume 53, European Commission, Joint Research Centre EUR 21508 EN: http://echa.europa.eu/documents/10162/3be377f2-cb05-455f-b620-af3cbe2d570b

for this substance is: [x] [mg] [µg] /m^3.] {Optional sentence for when there is an OEL at EU level. Please provide the relevant context to the comparison of the exposure level with the EU OEL, for example:

- Whether there are indications of additional exposure to the substance or to a similar substance (e.g. a salt of the same metal species) that is relevant to the EU OEL (such exposure does not need to be assessed or quantified by RAC -a simple statement is sufficient)
- The importance of systemic exposure via the dermal route
- When the EU OEL was derived}

RAC takes note that the authorisation holder has distinguished the general population from the indirectly exposed workers, which were addressed in a separate WCS, unlike the approach followed in the parent applications.

RAC notes that the risk characterisation is affected by minor/ moderate/ major shortcomings/ concerns in the workers' exposure assessment. These shortcomings are addressed and discussed in section 2 and summarised in section 2.6. RAC concludes that these shortcomings are not likely to affect the risk characterisation significantly.

[Regarding exposure to (sodium dichromate, potassium dichromate and sodium chromate) and associated reproductive risk, RAC considers that the authorisation holder has derived a conservative estimate of the exposure and used the DNELs recommended by RAC.]

RAC acknowledges that the assessment of indirect exposure to humans via the environment using default assumptions in the EUSES model is likely to overestimate exposure, particularly at the local scale, leading to an overestimation of risk (and the number of statistical cancer cases).

3.4. RAC's conclusions on the risk characterisation

{Character limit: 700}

{Please provide a very brief, clear and condensed conclusion on the risk characterisation.}

RAC is of the opinion that the review report includes all relevant tasks and routes of exposure, as well as endpoints and populations in cancer risk assessment and that there are [no] significant uncertainties in the characterisation of risk.

RAC considers that the estimates of excess cancer risk for workers based on the modelled exposure estimates and the measured exposure values and indirect exposure of humans (workers and general population) via the environment at the local level, as presented by the authorisation holder [with the adaptations made by RAC (if applicable)], allow a health impact assessment.

RAC also reiterates that for the calculation of the excess risk, the authorisation holder has conservatively assumed that all inhaled chromium trioxide particles are in the respirable range and contribute to the lung cancer risk and that the dose-response relationship was derived by linear extrapolation. Since extrapolating outside the range of observation inevitably introduces uncertainties, as the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be an overestimate.

Furthermore, the conservative default assumptions in EUSES and other assumptions described previously regarding the risk to humans via the environment lead to a conservative characterisation of the risk.

4. Analysis of alternatives and substitution plan

4.1. Summary of the analysis of alternatives and substitution plan and of the comments received during the consultation and other information available

Potential alternatives and required steps in the substitution of chromium trioxide are assessed from the perspective of the applicant and their DUs.

The applicant highlights that a major factor that determines progress in substitution is the complexity of the A&D sector. Namely, it is the Design Owners (DO) that provide technical specifications, according to which aircraft or other equipment is produced. Additionally, an aircraft is certified for airworthiness by regulatory bodies such as the EASA[24] and the FAA[25] based on these specifications. Once certified the specifications of an aircraft are fixed and parts production as well as maintenance and repairs (MRO) can be performed only if they comply with these specs. The applicant provided a more detailed description of the work organisation within the industry and how this influences development and implementation of alternatives.

The Aerospace & Defence Industry

The term "Aerospace & Defence (A&D) industry" describes the global industrial network involved in the production of civilian and military aircraft (be it for freight or passenger transport), as well as those companies involved in the production of military material like armoured vehicles, artillery, rocket launchers, etc.

The applicant states that vis-à-vis the substitution process as foreseen under REACH, the complex nature of the A&D industry presents several technical and organisational challenges when it comes to identification and implementation of an alternative.

These companies are incorporated in a complicated network of suppliers and developers for parts and systems for A&D. This network encompasses e.g. companies supplying parts designing and building final systems (e.g. aircraft or parts of aircraft). To illustrate the complexity of the A&D supply chain the applicant provided the following "simplified" graphic representation (see **Error! Reference source not found.**).

The A&D companies that design and integrate the final product (e.g., aircraft, engines, radar, and other defence systems), are each responsible for their own product qualification, validation, and certification, according to airworthiness regulations or defence/space customer requirements[26].

[24] European Aviation Safety Agency: https://www.easa.europa.eu/en
[25] FAA – Federal Aviation Administration (faa.gov)
[26] See Figure 2 for more details.

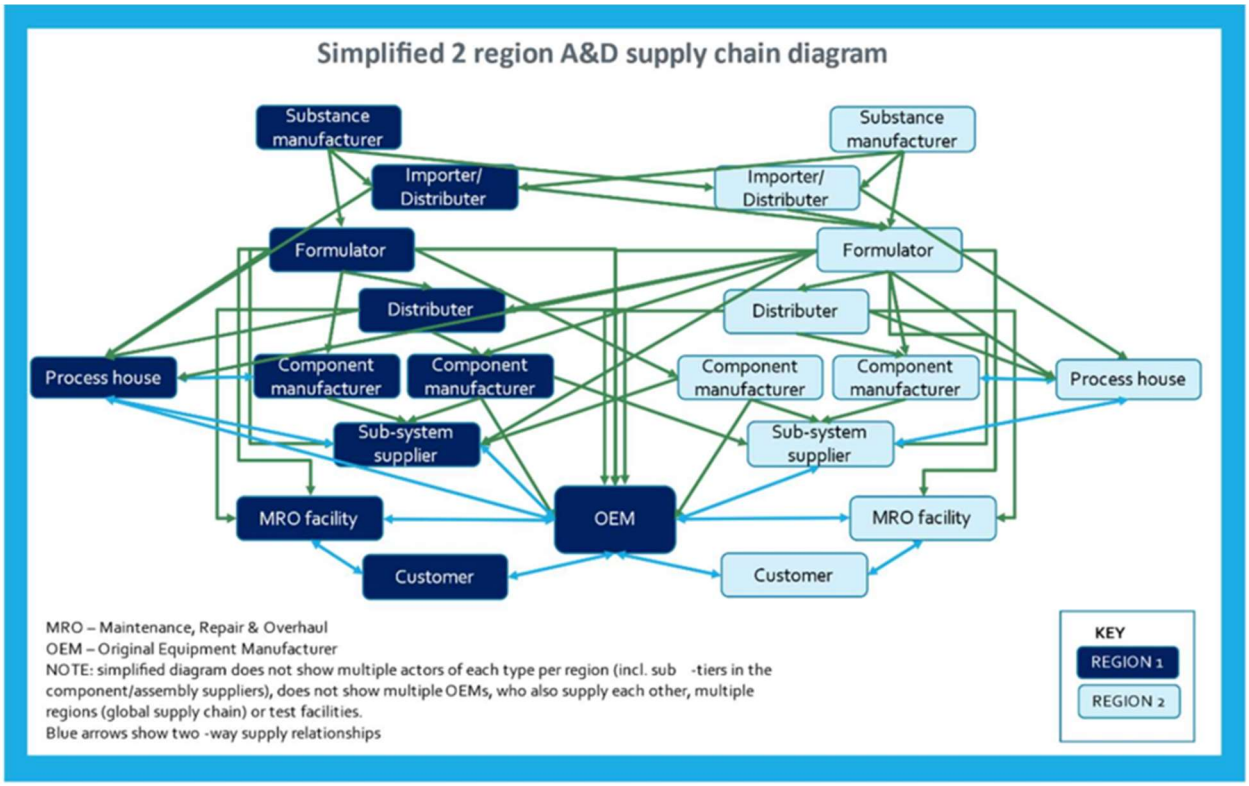

Fig 2: Simplified supply chain diagram for A&D over 2 regions.

Besides fulfilling the stringent safety requirements governing the sector, the test candidate needs to demonstrate at least equivalence in performance on all types of components where the original formulation/process is used, as the applicants need to demonstrate (by law) that by substituting Cr (VI) the overall airworthiness of an aircraft is not negatively impacted. This can often encompass hundreds of different components.

The aforementioned requirements have created a rigid industry structure, led by Design Owners, which governs product development and changes to existing items.

In this context, the civil aircraft is subject to the airworthiness requirements which are governed by 'critical to flight safety' principle, while defence equipment is subject to a principle of 'mission readiness' that dictates the key performance requirements.

For civil aviation, the meaning of 'critical to flight safety' highlights the direct role of Cr(VI) on flight safety and airworthiness. The use of Cr(VI) to perform its intended functions (such as corrosion resistance, adhesion promotion etc) is related to the performance of the parts in which it is used and the correct performance of the Cr(VI) reliant parts is essential to ensure the performance of assemblies, sub-systems, systems and ultimately the whole A&D product where they are integrated (e.g., aircraft or defence product)[27].

Military 'mission readiness' means that at any given time, the military equipment is ready to perform according to its intended design, and its performance is not compromised by degradation resulting from e.g., corrosion of parts. In other words, the equipment must be reliable or else it may not perform when called upon. Unreliable equipment could result in a myriad of consequences including putting service personnel's lives at risk. The link between the use of Cr(VI) and military mission readiness is similar to that described above regarding

[27] See figure 1 in section 0.2 on how the system looks like

flight safety.

The use of Cr(VI) in the process is to ensure that the final products will perform their intended functions as set out in the dossiers (such as corrosion resistance, adhesion, etc.) Any potential alternative should ensure that the parts perform as intended and according to the design and maintenance manuals.

Within both contexts (civil aviation and military equipment) the implementation of any alternative[28] in varying scenarios of use must be individually assessed, validated, and certified across the components, subsystems and systems that make up the final product, for example an engine, aeroplane, helicopter, missile, or tank (AoA-SEA application, p 35-37). Where an alternative is considered, it must demonstrate a similar performance and face a lengthy approval process, including official updates to maintenance manuals. Adhering strictly to these manuals is considered crucial for maintaining aircraft airworthiness, ensuring the availability of parts produced using original methods. Maintenance Manuals, specifying surface treatment performance, currently prescribe the use of hexavalent chrome.

The applicant makes it clear (in response to questions) that adherence to the maintenance manuals is obligatory, as EU law mandates the use of approved data / manuals in a maintenance facility. EU No. 1321/2014 Annex II 145.A.45(a) states "The organisation shall hold and use applicable current maintenance data which is necessary in the performance of maintenance, including modifications and repairs". Airlines also are bound by a similar requirement in Regulation EU No. 1321/2014 Annex I Subpart D M.A.401(a): "The person or organisation maintaining an aircraft shall have access to and use only applicable current maintenance data in the performance of maintenance including modifications and repairs".

An additional challenge is the close relationship between all the uses. The various surface treatments constitute a complete system, which means that each use cannot be considered in isolation and a non-authorisation decision for any one of them, will lead to severe consequences for the applicant and wider sector, which would lead to the most likely NUS of relocation outside of the EU.

The applicant argues that in case of non-authorisation, this would imply a stop of production of aircraft and spare parts as well as maintenance, repair and overhaul and therefore the ability of the EU to keep operational fleets. This would also affect Defence and Military in the EU. In case of non-authorisation, industries would consider relocation of activities outside the EU.

Concerning defence material, the applicant explains that requirements (be it aircraft or weapon systems) are set by the Ministry of Defence of the nation involved. When an aircraft or other military equipment becomes operational these authorities become Design Owners and will allocate budget for changes and approve any changes. According to the applicant these requirements are stricter than for civil equipment (i.e. often they set a higher performance level), partly due to the 'mission readiness' principle mentioned above. To complicate matters more, different nations may set different rules. Additionally, all or some parts of the technical specifications may be classified.

Following SEAC's question, and during ongoing communications, the applicant made it clear, that any change of materials or production process in non-aerospace military sector will need to go through the same process as described in the Figure 3. An additional hurdle in the defence sector is that the process is tied to government funding decisions, which may affect the

[28] Any alternative specifically means alternative substrates, materials technology and processes, etc).

development timelines of the substitution process.

The applicant highlights that once a potentially technically available surface treatment is identified for the A&D industry, various actors then need to complete several steps, such as certification, qualification and testing. Finally, the alternative needs to be fully industrialised across the supply chain. Only when a potential alternative has been generally accepted by the majority of the industry, can the manuals and repair procedures be updated to reflect the use of the new alternative. Additionally, alternatives suitable for some parts may not be suitable for others. This means that the substitution will progress according to different timelines. The process details are explained in Figure 2.

Applicant's approach to the AoA

The applicant's point of departure for the search of alternatives is the original 'parent applications[29]' for which SEAC concluded that no alternatives existed that were technically and economically feasible by the date of the adoption of the opinion. Since the implementation of the Commission decision for these parent applications, the applicant undertook the following activities:

1. Over the period of 2019 to 2022 the applicant has carried out an extensive consultation to gather data relevant to the development of AoA and SEA documents for all uses. This process covered all downstream members, irrespective of their role in the supply chain. This was done in 4 phases and the applicant provided good level of detail as to what was gathered from this consultation. Furthermore, the data gathered during this consultation was instrumental in shaping the application process for all relevant uses.
2. The applicant has reviewed eleven global Research Collaborations within the A&D industry that have been active over the last 30 years and which aimed at replacing Cr(VI) in chemical conversion coating (see page 60-62 in the AoA/SEA document of the application). However, apparently not all results of these collaborations are available in the public domain because of intellectual property issues related to business confidentiality.
3. A patent search was performed with the aim to identify patents related to conversion coating. The search was performed using Espacenet, the European Patent Office (EPO) open access search portal. A list of 159 patents were identified as broadly relevant. However, the applicant notes that although these sources may give valuable insight into innovative chemistries and underlying mechanisms, novelty does not necessarily translate to feasibility or applicability and no suitable candidates are known to have been proposed in the industry based on these references.
4. High level literature search for the broad topic was performed covering the period 2014-2021, resulting in six papers relevant for the A&D sectors.

A list of 11 potential test candidates for alternatives to Cr(VI) in pre-treatments is reported in tab 3-8 at page 77 of the AoA. This list comprises some of the alternatives that were reported in the parent AfAs, and others that have been investigated more recently.

Seven shortlisted alternatives are then described more in detail.

- Sulfonitroferric acid and derived proprietary formulations;

[29] Although this is a new application, the document contains specific references to the 'parent' application in a similar way, in which it is done for review reports. Furthermore, the applicant explicitly states that they rely on additional information contained in the 'parent' application when justifying their request. This means that this AfA is much more closer to a review report, and should be treated as such.

- Nitric/sulphuric acid mixture;
- Phosphoric acid based solutions;
- Sulphuric acid (including electrolytic sulphuric acid pickling);
- Sodium hydroxide containing additives;
- Cr(III) for anodic pickling;
- Mechanical cleaning/Abrasive blast.

The functionalities and the related performance requirements for pre-treatments are reported in table 2 in section 0.2.

It is important to underline that the performances of the pre-treatments are actually measured on the sample at the end of the main process.

Pre-treatments are carried out on substrates that can be composed of different metals. Substrates identified include the following (the list is not exhaustive):

- Aluminium and its alloys
- Magnesium and its alloys
- Steel, including stainless-steel
- Nickel
- Brass
- Copper.

The pre-treatment process is tailored to the nature of the surface preparation required. Depending on the substrate and the process that follows the pre-treatment, this may consist of deoxidation, desmutting and pickling/etching.

Further details of the analysis of alternatives and progress made are described in sections 3.4 – 3.6 and their conclussions can be found in table 3-16 of the AoA/SEA.

When assessing the technical feasibility, the applicant assessed the performance of the alternatives in the laboratory environment, through tests: corrosion resistance (salt spray test chamber), temperature(heat) resistance, coating weight test/analysis (layer thickness), electrical contact resistance and pre-treatment compatibility. The list of key functionalities and technical requirements is described in section 0.2.

The applicant furthermore brings forward that the process needs to be equally well applicable to different substrates such as aluminium, magnesium and titanium alloys.

The applicant clarifies that while performance values during early-stage screening within the development phase may offer some insight, they have limited value in assessing the technical feasibility of potential alternatives. Passing such tests merely permits progression to more intricate, bespoke testing phases typically conducted at Technical Readiness Level[30] 4-6. In these tailored tests, stakeholders seeking material or process changes for aircraft parts must conduct extensive testing to ensure compliance with EASA regulations. These include the aspects such as mass, balance, structural strength, reliability, operational characteristics, noise, fuel venting, and exhaust emissions. Ultimately, any modifications must demonstrate adherence to EASA requirements for overall airworthiness to obtain certification or approval from relevant authorities or design owners, which means that each component must meet the performance and safety standards set by the current Cr(VI)-based treatment.

[30] Technology Readiness Levels (TRL) are **a type of measurement system used to assess the maturity level of a particular technology**.: https://www.nasa.gov/directorates/somd/space-communications-navigation-program/technology-readiness-levels/

Therefore, passing screening tests, usually conducted on coupons[31], does not conclusively establish technical feasibility; rather, it signifies advancement within the process. Each component must meet performance and safety standards set by the current Cr(VI)-based treatment to secure certification or approval. Specifically, regarding conversion coating, evaluating its technical feasibility should consider its compatibility with different alloy substrates and other complementary treatments within the broader surface treatment system. Alterations to these system variables may result in irregular or unacceptable performance of the conversion coating, potentially delaying approval for various component designs until more comprehensive testing, sometimes encompassing an entire aircraft body, is conducted.

The applicant, in their application, in responding to SEAC questions and in discussion at the trialogue clearly stated that chromium trioxide is unique, in that its properties have very broad applications, that have been successfully utilised and embedded in the A&D supply chain over the last 30 years. Furthermore, the applicants' states that its experience in trying to find alternatives for Cr(VI), gathered over the last 30 years, has yielded limited results in effective substitution across broader product types or uses. The applicant states that should a potential alternative be found, it would most likely only be for a few uses or surface treatments and the applicant is adamant that an alternative to chromium trioxide for every use will not be discovered for a number of years.

The applicant stresses that, within the framework of air safety and airworthiness regulations for A&D applications, use of a certain alternative on one part does *not* allow the use on other parts, without further extensive qualification testing and certification. See also ECHA-EASA's publication *'An elaboration of key aspects of the authorisation process in the context of aviation industry'*[32]

Applicant's approach to Substitution Plans

Even though the applicant does not consider that there are alternatives available in General[33], they have included their SPs as a demonstration of a clear commitment to substitute Chromium Trioxide

To show the complexity of substitution efforts in the A&D industry an overview of a substitution process for this industry is taken as a generic representation of a substitution plan as it is to be followed by all members in the A&D supply chain. Upon request of SEAC some more detailed Substitution Plans (though not for this pre-treatments use) were provided (confidential).

[31] See footnote in section 0.3
[32] Available online at: https://www.easa.europa.eu/en/downloads/17236/en
[33] This is further evaluated by SEAC in section 4.2.

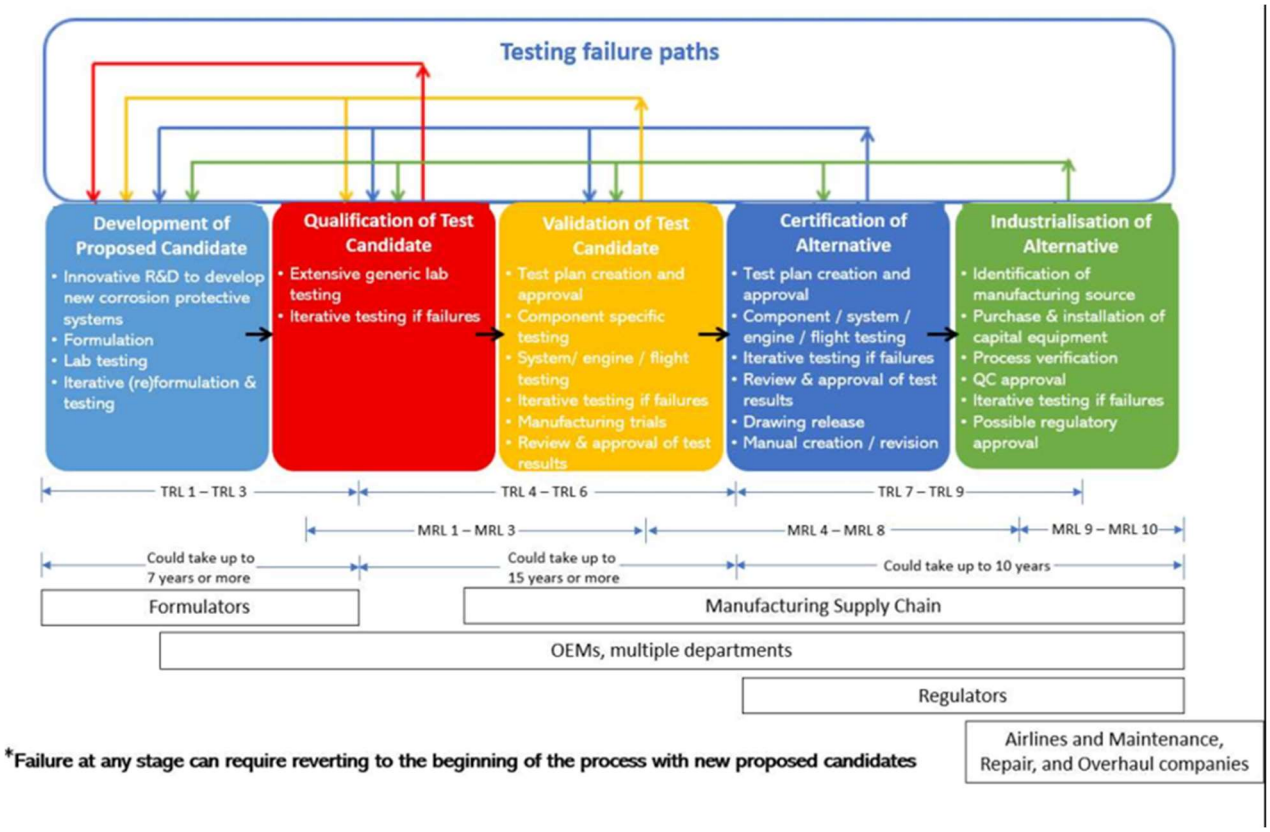

Fig. 2: Generic represention of substitution process

Figure 2 shows how the stages of each phase are tied to so called TRL and MRL (Technical, Manufacturing/Readiness, Levels). The process has five stages:

1. Development of Proposed Candidate,
2. Qualification of Test Candidate,
3. Validation of Test Candidate,
4. Certification of Alternative,
5. Industrialization of Alternative.

For each phase the main actors involved as well as the relevant TRL and MRL levels are shown. Indicative timing for the stages shows that the total process from start to end may take more than 30 years. The applicant also indicated that because of the strict 'gated process' (i.e. a next stage of investigation can only start after meeting specific targets and/or after a management decision) the potential for performing investigations in parallel is limited.

To confirm the commitment of the consortium members and their downstream users to the substitution efforts, the expected progress of the active Substitution Plans that were reported for this use is presented in terms of the phases discussed above and shown in the picture below (copied from the application). The applicant also explained that this represents an aggregated overview. It is very well possible that some companies may have more than one active Substitution Plan if they are investigating alternatives for parts with different requirements.

In the trialogue discussions the applicant also indicated that the timeline of up to 12 years represents an optimistic scenario for parts with requirements of moderate complexity. It is very well possible that for other parts with more demanding requirements, the substitution timeline will be much longer. The applicant furthermore underlined that the substitution plans of the Design Owners have impact on their suppliers (other DtBs, BtPs) and MROs, who are

unable to also substitute until the Design Owners have fully implemented the alternatives (i.e., progress to TRL9 and MRL10).

SEAC's evaluation of the authorisation holder's approach to the analysis of alternatives and the substitution plan

In the opinion of SEAC the applicant has made good use of information that was available in patents, scientific literature and the results from R&D collaborations as far as these were available in the public domain, as well as the progress already made within the consortium based on 'parent' applications. These efforts made since the 'parent' application and presented by the applicant are based on participation in several R&D projects and on progress made by different ADCR member in the development alternatives considered.

SEAC understands that the applicant's approach to the AoA is based on the legal framework for airworthiness and civil aviation safety in the EU (regulation (EC) no 216/2008)[34] and its implementing rules ((EC) No 1702/2003)[35]

SEAC's evaluation of the applicant's approach to the analysis of alternatives

Presentations and discussion with EASA, during the opinion forming process, in that respect have clarified that:

1. *'a type design of an aircraft encompasses 'Information on **materials and processes** and on **methods of manufacture and assembly** of the product necessary to ensure the conformity of the product' (EC 1702/2003, 21a.31)'*

2. ***'Changes to the approved production organisation – Significant changes** …to be approved by the competent authority include: - significant changes to production capacity or methods… (GM 21A.147(a)'*

3. *'And that: 1.a. **Structures and materials**: the **integrity of the structure must be ensured throughout, and sufficiently beyond, the operational envelope for the aircraft, including its propulsion system**, and maintained for the operational life of the aircraft. (EC No 216/2008 annex 1)'*

These clarifications together with the legal text quoted by the applicant corroborate the applicant's arguments that a type design of an aircraft not only dictates the production and operation of it but also its maintenance throughout its operational life. Therefore, the use of chromates is 'locked-in' and to substitute towards alternatives requires a change throughout

[34] Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (Text with EEA relevance), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0216

[35] COMMISSION REGULATION (EC) No 1702/2003 of 24 September 2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AL%3A2003%3A243%3A0006%3A0079%3AEN%3APDF

the entire supply chain from the development, certification through to changing maintenance manuals.

SEAC therefore considers credible the applicant's assessment, that a long time is required for implementing any potential alternatives for this use. Such a process has several milestones in terms of identifying an alternative, obtaining authority approval (certification) for changes in materials or processes as well as mandatory adaptations needed for implementing the alternative including re-drafting maintenance manuals, etc.

SEAC assessed the scope and the depth of the assessment of alternatives undertaken by the applicant and considers them described in sufficient detail. The applicant has been involved in an industry-wide search for an alternative to Cr(VI) for the last 30 years. They have described their effort in detail in the application as well as subsequent information requests and linked that effort to the previous 'parent' application and the progress made since.

In addition, the applicant gave various indications that required performance levels may vary depending on the planned use of a part of component. However, the key underlying feature of all surface treatments across all uses is the corrosion and wear resistance and/or protection of the treated parts.

The applicant has also provided examples of alternatives that were not successful, illustrated in the case of SurTec650 that was declared suitable by some OEMs but failed to meet their qualification tests for both immersion and local touch up. Another large OEM provided specific information regarding failures in Chemical Conversion Coating using as alternatives a Silane Sol-gel process, a molybdate process and electrolytic paint technology.

SEAC considers that the statement, that 'to date' there is no alternative that can immediately replace Cr(VI) in any of the surface treatments for the applicant and its downstream users to be justified. The issue is further exacerbated by the fact that Cr(VI) has been quite embedded in many complex processes along the supply chain and the progress in search of alternative substances is not yet sufficient for successful substitution across all uses within this application. This is because even if a single surface treatment process could be replaced with an alternative there are a number of other processes linked, which have to be matched as otherwise the alternative can become infeasible for the whole system.

During the third-party consultation, six comments were received from companies and industry associations working in aerospace and defence sectors. All the comments were in support of the application. One comment on potential alternatives for this use were received in the Third-Party Consultation which is related to the use of PVD only for electroplating and anodising.

A trialogue was organised where the applicant provided further clarification on technical and scientific aspects of the application.

SEAC notes that the shortlisted alternative was assessed against both the process requirements and the surface functionalities. SEAC also notes that the qualification, certification of authorities and subsequent industrialisation are necessary for the successful implementation of an alternative. SEAC also notes, that the applicants (qualitatively) concluded on the economic feasibility of the shortlisted alternative.

SEAC notes the applicant's Analysis of Alternatives describing the substitution methodology and activities undertaken until the submission of the authorisation application. In SEAC's view, the applicant's approach and methodology concerning the selection and substitution of

preferred alternatives to chromium trioxide in the chemical conversion coating process are clear and well described and that the available information enables SEAC to conclude on the Analysis of alternatives.

SEAC's evaluation of the applicant's approach to the substitution plan

SEAC understands that the SP summaries provided by the authorisation holder describe the number of plans that exist, as well as their projected progress in the generic stages of the substitution process as expected during the requested Review Period.

SEAC understands from the individual substitution plans, as well as from the general substitution schedule (Figure 2), that there is a clear set of activities any applicant must go through to perform substitution in the A&D Sector. There are with clear milestones in form of the qualification, certification and industrialisation of an alternative. The process is clearly monitored, if not just on a level of an individual company but also on a higher regulatory level with clearly defined legal roles.

The applicant explains that the summary of substitution plans show the expected progress of 24 distinct substitution plans for Cr(VI) in pre-treatments, covering different plans across different members, and also multiple plans within individual members. These SP's cover a total of 71 companies.

SEAC recognises that the applicant's substitution plans contain the elements required (activities, timeline and monitoring plan). Together with the applicant's responses to the round of SEAC questions and with the information obtained from the third-party consultation comments, the trialogue and the applicant's response, the available information enables SEAC to conclude on the substitution activities and the substitution plan.

SEAC considers the presentation of the Substitution Plans, as a general illustration of ongoing activities now and in the future. SEAC considers that the substitution plans together with clarifications by the applicant in response to SEAC questions and in the trialogue were sufficient to represent the wide variety of the substitution plans. The variety of the companies that provided the SPs (in terms of their size as well as their role in the whole supply chain) allows for a meaningful assessment. This leads to a conclusion that the plans are representative of the industry and present a realistic direction towards substitution of chromates.

4.2. Availability and technical and economic feasibility of alternatives for the authorisation holder and in the EU in general

Has the authorisation holder demonstrated that there are no alternatives with the same function and similar level of performance that are technically and/or economically feasible for the authorisation holder and their downstream users before the expiry date of the authorisation decision

☒Yes ☐No

Is there information available in the review report or the comments submitted by interested third parties in the consultation indicating that there are alternatives

available that are technically and economically feasible in the EU?

☒Yes ☐No

After assessing recent scientific literature and collecting information from companies actively practicing the chemical conversion coating, the applicant shortlisted 11 possible alternatives. For each of them there is a description of the status reported in the 'parent' application and progression reported by ADCR members with regard to the technical and economic feasibility, availability, and health and safety considerations of alternatives.

A number of test candidates are considered more promising based on the current level of development and progress achieved in substitution plans, these are:

A list of 13 Cr(VI)-free proposed candidates for pre-treatments coming from the parent application is reported at page 76-77 of the AoA (table 3-7).

For two of them no progress has been achived since the commission decision and these alterntaives were discarded.

Eleven possible alternatives, still considered in the new application, are reported in table 3-8 of the AoA. and are discussed further rin this opinion

Table 3: Cr(VI)-free proposed candidates for pre-treatments reported by ADCR (shortlisted)

Nitric/sulphuric acid mixture	Deoxidising
Sulfonitroferric acid [(a)]	Pickling/etching
Phosphoric acid with fluoride	Deoxidising
Nitric/hydrofluoric acid mixture	Deoxidising/Desmutting
Sulphuric acid	Pickling/etching
Shot peening	Deoxidising
Cr(III)	Pickling (anodic)
Sulphuric/Hydrofluoric acid mixture	Etching (anodic)
Phosphoric/sulphuric acids	Electropolishing
Sub-layer before Cr(III) plating[(b)]	Surface preparation prior to electroplating
Mechanical cleaning/Abrasive blast (sand, grit, glass beads)	Deoxidising

(alternatives in bold are shortlisted)

Some of these test candidates are in use by some ADCR members for some components on some alloys (components with less complex geometry or lower demands for fatigue), however significant technical challenges remain before any of these test candidates can be used in all situations. The main limiting factors are failure to meet technical performance requirements, the specifics of which are discussed in detail in the following sections.

The applicant reports that progress in technical readiness has been made for all shortlisted alternatives but that none of these shortlisted alternatives can be considered as generally

available and suitable alternatives to all applications of Cr(VI)-based conversion coating. The applicant furthermore states that Cr(III)-based treatments were considered as the best alternative to conventional Cr(VI)-based conversion coating at the time of the previous applications and that this is still the case.

The applicant considers that Cr(III) remains the most promising and by far the most investigated test candidate to hexavalent chromate for conversion coating.

Test candidates that are also discussed by the applicant that are either considered in general to be less promising or not viable, or have not been a key development focus by the members or have not been further investigated since the parent applications are:

Table 4: Dismissed alternatives

Dismissed alternatives	**Reason for dismissing**
Phosphoric/sulphuric acids	not advanced beyond the TRL reported in parent AfA
Nitric/hydrofluoric acid mixture	not advanced beyond the TRL reported in parent AfA
Shot peening	not advanced beyond the TRL reported in parent AfA
Sulphuric/Hydrofluoric acid mixture	not advanced beyond the TRL reported in parent AfA

In all the above areas, a test candidate not deemed available from a regulatory standpoint would not meet all required criteria within the definition of 'suitable' used by the applicant.

This means that any alternatives that may emerge because of REACH authorisation requirements will initiate a complicated chain of testing and re-certification of parts and systems in the industry. This will have significant consequences for all levels in the industry regarding costs involved, and the service readiness of civil planes and also of defence equipment.

Current status of shortlisted alternative: technical feasibility

Due to the complexity of the substitution process within the A&D sector, none of the short-listed test candidates can be implemented for all substrates and components by the date of adoption of this opinion.

However, in the period since the publication of the previous applications, some ADCR companies appear to be closer to TRL 8/9 and several companies have been able to complete the qualification and industrialisation for some uses.

Key technical performance issues that remain to be solved are inadequate corrosion protection, inconsistent performance, and suitability for all types of alloys. Barriers to achieve higher TRL levels include the need for acceptance by OEMs or the airlines/Ministries of Defence by demonstration of acceptable performance, lack of vendors to apply the coating, and the necessity to complete the relevant qualification and certification requirements.

For seven possible alternatives a detailed description is reported in the AoA with an evaluation regarding technical feasibility, economic feasibility, health and safety considerations, availability.

There is no alternative considered more promising than the others and described in more detail.

A short summary of the technical caracteristics and limitanions of the seven shortlisted alterantives is reported below:

- Sulfonitroferric acid is reported as technically feasible and implemented for a number of substrates utilised for aerospace and defence applications and prior to different main treatments as anodising and chemical conversion coating. However, development work is ongoing to refine operational process parameters of use for substrate/design configurations where the performance requirements are more demanding. An example includes fatigue sensitive parts which are less tolerant to more aggressive treatments resulting in increased etch rate.

- Applications of nitric/sulphuric acid pre-treatments are reported for deoxidising, and pickling/etching pre-treatment processes on selected aluminium substrates. Maturity of substitution varies. TRL 4 to 5 for pickling/etching prior to anodising aluminium alloy, and TRL 9 for deoxidising prior to anodising. Although technical feasibility for the purposes of deoxidising substrates such as copper and some aluminium alloys is fulfilled, further work is required to certify this test candidate for use with some alloys if the pre-treatment pickling process is too aggressive.

- Phosphoric acid/sulphuric acid mixture is identified as achieving good results for specific pickling uses, including electropolishing, for steel and stainless steels. Phosphoric acid/fluoride mixtures are reported as permitted for the removal of heavy oxides from copper and brass and also the treatment of titanium to deoxidise and enhance adhesion. Further work is required to certify this test candidate for pre-treatment with some alloys. Therefore this is not considered a suitable alternative for all current Cr(VI) pre-treatment process applications (substrates) subject to electropolishing.

- Members reported the use of sulphuric acid for the reactivation of metallic coatings, for example cadmium, following plating onto steel substrates. It is not certified as an alternative for use with a wide array of substrates, components and main-treatments.

- Sodium hydroxide is used as a pre-treatment etchant and typically produces a smut residue after use. These contaminants require removal with a suitable desmutting process where specified by the design owner. This limits the extent of use of this alternative.

- Cr(III) anodic pickling is not stable in the presence of iron. Due to the sensitivity of Cr(III) electrolyte, adequate filtration to remove the iron not practical in a production environment. Therefore, Cr(III) anodic pickling is not technically feasible for the vast majority of applications.

- Abrasive blast is reported as limited to deoxidising, removal of light deposits of scale, and hint-tint. It may be necessary to supplement with additional chemical pre-treatment using a chromate. Use is further limited due to its line-of-sight application method preventing use with complex geometries.

Economic feasibility

The cost of the alternative is in general higher but no significant economic feasibility barriers are reported.

Safety considerations

The applicant argues that, if certified and widely industrialised, due to a lower hazard class, the alternatives would reduce risk. Currently SEAC does not have information to agree or disagree with this argument.

Availability

The alternatives are expected to be accessible on the EU market in the required quantities, The main factor impacting availability is qualification of the test candidate for use on all relevant A&D.

Conclusion on shortlisted alternatives

Table 3-16 at page 95 in the AoA summarises the current development status of the test candidates to replace Cr(VI) for pretreatments.

According to the applicant, some alternatives are at a high TRL level (6-9). However, the shortlisted alternatives are by no means fully implemented due to performance failures for some parts/alloys and further significant testing is still needed and ongoing.

The applicant has found several shortlisted alternatives that it is further pursuing. Most alterntaives alternatives still need to be further developed due to corrosion performance failures for some parts/alloys and further significant testing is still needed and ongoing. This, given the timeline for qualification, subsequent certification and industrialisation, makes the applicant conclude that there are no alternatives available that are technically and economically feasible to the applicant and their DUs.

SEAC's evaluation of the availability and technical and economic feasibility of alternatives for the authorisation holder and in the EU in general

Required level of performance

As a starting point SEAC notes the applicant's description that the required performance of an alternative is based on the process described in Figure 3, based on which, Cr(VI) compounds have been certified. The performance level is based on the premise that, in order to achieve certification or approval by the relevant authority and/or design owner, each component must meet the required performance and safety requirements provided by the incumbent Cr(VI) based treatment.

In response to SEAC questions the applicant clarifies that the use of chromates is warranted as most types of aircraft have been designed with the use of chromates for corrosion protection as part of the specification of the aircraft. This obliges maintenance repair and overhaul (MRO) activities (i.e. all maintenance) to follow maintenance manuals, which specifically require the use of chromates. Any change in the substance used, be it major or minor, of the aircraft design, needs to undergo several additional steps (detailed in the section above). To support their argument, the applicant has provided (in response to SEAC questions) several excerpts of current maintenance manuals (3 of these maintenance manuals were claimed confidential, but the applicant also referred to 2 manuals that were public) highlighting the obligatory use of chromates:

- Maintenance manuals for defence equipment posted online by 3rd parties. For example, the Chinook helicopter maintenance work requirement manual contains several references to Alodine[36] (a Cr(VI)-containing conversion coating touch-up pen)
- A maintenance manual specifying the use of Bonderite M-CR 1132 in a repair. Bonderite M-CR 1132 is a formulation containing dichromium (tris)chromate supplied in a touch-up pen, commonly used to apply a chemical conversion coating.

The applicant has also provided an indicative list of parts to be treated (See Table 3). In response to SEAC questions the applicant made it clear that this list is not exhaustive but merely included to show the width and breadth of the selection of parts that require corrosion protection.

The applicant explained that even though a potential alternative could pass the certification stage, there are other important steps which need to be completed in order for the alternative to be fully industrialised across the supply chain[37]. For example, it is possible that an alternative is certified for a specific area or an environment within one use on one part, but not for another one for the same part.

Furthermore, in SEAC's view, the key performance requirements as described in section 0.2 are only to be considered as minimum requirement for base material. Each surface treatment must complete a series of testing within controlled environment and it must also withstand testing in the real environment which will require a long period of time (as detailed in Figure 2).

[36] http://www.chinook-helicopter.com/Publications/CH47D_Technical_Publications/Depot_Maintenance_Work_Requirement/DMWR1-1520-240.pdf

[37] See Figure 2, for details

According to EASA rules any material change in those parts, where failure could adversely affect safety must:

a) be established based on experience or tests (see AMC[38] no 1 to CS 25.603(a)
b) conform to approved specifications that ensure their having the strength and other properties assumed in the design data (See AMC 25.603(b) and
c) take into account the effects of environmental conditions such as e.g. temperature and humidity expected in service.

These explanations provided by EASA corroborate the applicant's requirement of the extensive testing that alternatives to Cr(VI) must undergo, as corrosion prevention and the required performance levels are critical to safety in the design and operation of an aircraft. Each new surface treatment must be substantiated by a test programme and the material strength properties must be based on enough tests to meet approved specifications to establish original design values of an aircraft.

SEAC also understands that any change in materials and processes used in corrosion protection on an aircraft constitute a change that impacts the fatigue and strength of an overall aircraft and is considered as a major change. For such changes, the Design Owner needs to demonstrate that levels of fatigue and corrosion protection provided by the incumbent process are maintained in such a way, that it does not impact on airworthiness. Furthermore, this must be carefully evaluated and justified with substantive tests.

SEAC accepts that, even though it has not been provided with exact requirements for all components, the information received on the overall process of changing the minimum requirements for materials or processes (including all the certification steps that would be needed before any alternative is able to be used) allows SEAC to conclude that there are no alternatives available for the applicant for the complete, wide scope of parts, within this use, by the time of adoption of the opinion.

SEAC notes that the level of evidence provided for non-aviation military equipment is less detailed than that provided by the applicant to cover the civil aviation sector. The evidence that was submitted still allows for a meaningful assessment. The applicant has stated that the specific requirements for each product are classified. However, the minimum requirements provided in the application were supported by three Ministries of Defence (UK, FRE, DE) in a letter of support, as well as by supporting evidence provided by the US MoD. Additionally, SEAC knows from previous AfA cases that dealt with military equipment, that the key requirements are always at least as high as for the civilian sector.

Any change in the surface treatments must perform equally well as the Cr(VI) surface treatments originally foreseen in the design specifications of an aircraft. Based on the evidence that the applicant has supplied to support this argument, SEAC finds the description of the key requirements and the required level of performance sufficient well justified.

Technical feasibility

SEAC takes note of the applicant's conclusion on technical feasibility of alternatives and of the progress made since the COM decision on relevant parent cases, focusing the research on the shortlisted alternative (Cr(III) based solutions). SEAC also notes that Cr(III)-based

[38] Acceptable Means of Compliance (AMC): Acceptable Means of Compliance (AMC) documents describe how a person or organisation can meet the requirements for the issue of a certificate, licence, approval or other authorisation

alternatives are by no means fully developed; corrosion performance failures for some parts/alloys have been observed and further significant testing is ongoing which must extend beyond the current review period.

During the rounds of questions, the applicant was asked to supply examples of failed substitution. From these examples SEAC observed that failure in substitution is caused by:

- Failure to meet basic standards on component level with materials that are then no longer pursued on component levels.
- Delays in meeting customer approval. Various components are used for various customers who all need to validate any material change, before it can be considered further for surface treatments.
- Unexpected failures in more advanced test, more closely representing real life situations, resulting in a need to start again the substitution process.
- Portfolio complexity. Where successful substitution has taken place, this often happens for a few parts only and used for MRO for those part only.
- Limited maturity of formulations which are often not yet on the market. Coating formulations are still in development.
- Part geometry (many parts have angles that are out of the line of sight, or multi angled with surface not in the same angle as the spray pattern). The complexity ranges from Low complexity parts (like e.g. shafts), Medium (like e.g. impellor housing, shaft flange, etc) to high complexity (like e.g. diffuser, gas generator case)

Considering the contents of the application, responses to applicant questions, and discussions during the trialogue, SEAC concludes that there are presently no alternatives capable of achieving the required level of technical performance. SEAC particularly emphasizes the extensive qualification, certification, testing, and industrialization procedures, which necessitate several additional years for completion. In essence, even if suitable alternatives were to emerge soon, the aforementioned processes would significantly extend the time required for alternative to be implemented within the supply chain.

Availability in general

The applicant considers that there are no suitable alternatives generally available (SAGA) for them, due to the regulatory process discussed above. This is also in line with the criteria which were already agreed on in the cited ECHA/EASA report from 2014. However, at the same time it should be noted that in some specific cases successful substitution has been reported already. However, none of these are technically and/or economically feasible for the applicant and their DUs before the date of the adoption of this opinion.

In this respect SEAC notes a difference in the meaning of "generally available in the EU" as used by the applicant and its recent use by SEAC (i.e. in use in a different market segment, possibly with other requirements). As explained under *Current status of shortlisted alternative: technical feasibility* above, the applicant has put forward this argument as an element of availability whereas SEAC considers this as an issue of technical feasibility.

Observing as well that the applicant clearly brings forward that successful substitution has taken place, SEAC does not agree with the applicant's assessment that there are no alternatives available in general. However, even if SEAC considers such alternatives that are already in use in specific cases as "generally available", this does not imply that SEAC expects that such an alternative may be expected to be close to general acceptance for this use.

A practical consequence of SEAC's disagreement with the applicant is that under the recent court ruling ECJ 837/16, the applicant has the obligation to submit a Substitution Plan, and SEAC considers that the aggregate Substitution Plans presented by the applicant, fulfil this criterion.

Conclusion on technical feasibility

Based on the above SEAC considers it clear that the status of the alternative development work is such that the required technical feasibility for the applicants and their DUs is not yet reached. Not only does the potential alternative not yet meet all requirements, but the process described in Figure 2 would have to be completed for the alternative to meet the technical requirements.

SEAC accepts, that to date there is no alternative that can currently replace Cr(VI) in all of the uses covered by the application (See also explanation in section 0.1). The issue is further exacerbated by the fact that Cr(VI) has been quite embedded in many complex processes along the supply chain and the progress in search of alternative substances is evident but proves still to be challenging.

Regarding economic feasibility of any potential alternative that has successfully completed all the steps listed in Figure 2, the applicant is of the opinion that in the A&D industrial environment, economic feasibility will not be an issue that will hinder implementation. Additionally, the applicant having had ample opportunities to raise this as an issue did not. Therefore, it is safe to assume that any additional costs incurred would be manageable over time for the applicant and their DUs.

To conclude: in SEAC's view the AoA demonstrates that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the applicant and their DUs by the date of the adoption of this opinion.

4.3. Risk reduction capacity of the alternatives

Would the implementation of the short-listed alternative(s) lead to an overall reduction of risks?

☐Yes ☐No ☒ Not applicable

SEAC concluded that currently there are no technically and economically feasible alternatives available for the applicant with the same function and similar level of performance. Therefore, RAC did not evaluate the potential risks of the alternatives.

4.4. Substitution plan/activities

Did the authorisation holder submit a substitution plan?

☒Yes ☐No

Is the substitution plan credible for the review period recommended?

☒Yes ☐No

The applicant provided a general overview of the substitution plans that exist within the ACDR consortium for this particular use. This overview describes the number of plans that exist as well as their projected progress in the generic stages of the substitution process as expected

during the requested review period.

Error! Reference source not found. below shows expected progression of ADCR members' substitution plans to replace Cr(VI) in chemical conversion coating. The progressive stages of the substitution plan (development, qualification, validation etc.) are detailed in the application (section 3.16.2 of the AoA/SEA document). These data have been aggregated to present the expected progress of the substitution of Cr(VI) for the ADCR consortium as a whole.

The applicant explains that of the 24 distinct substitution plans for pre-treatments assessed, 8% of them are expected to have achieved MRL 10 by September 2024. MRL 10 is the stage at which it is expected production will be in operation and there will be a significant reduction in Cr(VI) use for the components covered in that substitution plan. In this way the graph also shows the reduction in the use of Cr(VI) over time.

The applicant highlights that for the years 2031 and 2036 there is more uncertainty, and progress could be faster or slower depending on the progress made.

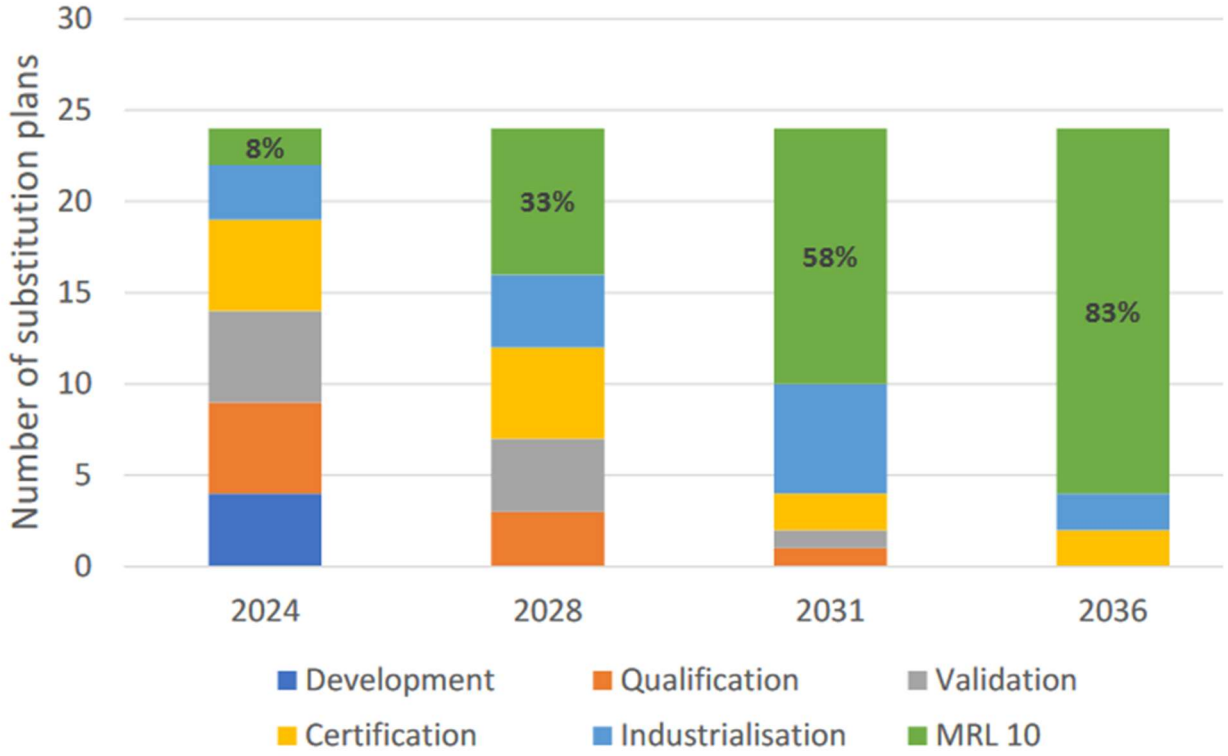

Figure 3: Expected progression of substitution plans for the use of Cr(VI) in pre-treatments

The vertical axis refers to number of substitution plans (some members have multiple substitution plans for conversion coating). The percentage value shown on each of the green bars indicates the proportion of substitution plans that are expected to have reached MRL 10 by the date indicated. MRL 10 is the stage at which there is expected to be a significant reduction in Cr(VI) usage.

The figure represents the percentage of plans in the six phases of the process at four different points in the future (2024, 2028, 2031, 2036) and how this percentage changes over time.

During the trialogue the applicant provided several more detailed examples of active Substitution plans in the ADCR consortium for various uses. They made it clear that these substitution plans vary in concreteness and in some cases (given that no suitable alternatives

were yet identified) should be considered as development plans (i.e. R&D plans). Yet, the applicant also stated that they would submit the plans as substitution plans to show their commitment towards substitution.

The applicant submitted a summary of substitution plans to justify their request for a review period of 12 years.

Even though only a limited set of individual examples of substitution plans were made available to SEAC, this set of substitution plans is of such breadth and variety across different actors in the supply chain, that it gave sufficient insight to SEAC to have confidence in the level representativeness of the overall substitution summary.

The data presented indicate that, at least for some plans, completion (i.e. the use of an industrialised alternative in MRL10[39] for a specific part) may happen before the requested review period has expired. On the other hand, the applicant presented credible information that also indicated that for other parts, substitution may take much longer than 12 years.

Is the substitution plan credible for the review period recommended?

☒Yes ☐No]

The applicant submitted a summary of substitution plans to justify their request for a review period of 12 years.

In view of the description of the lengthy qualification process in the A&D industry the length of the presented Substitution Plans is credible. Even though only a limited set of individual examples of substitution plans were made available to SEAC, this set of SP's gave sufficient insight to SEAC to have confidence in the level representativeness of the overall substitution summary.

The data presented indicate that, at least for some plans, completion (i.e. the use of an industrilalized alternative in MRL10 for a specficic part) may happen before the requested Review Period has expired. On the other hand, the applicant presented credible information that also indicated that for other parts, substitution may take much longer than 12 years.

SEAC's evaluation of the substitution plan/activities

SEAC evaluated the summary of the substitution plans as well as the relevant parts in the AoA/SEA document. The description of the potential alternatives and the research that the applicant has carried out since the Commission decision on the parent applications is considered convincing by SEAC.

Although the summary of the substitution plans for each use was concise and remained on a general level, individual (confidential) substitution plans that were submitted together with the information in the AoA/SEA document provided enough insight to SEAC to consider that more time is still needed to develop any alternative further and then consequently certify and industrialise it. These substitution plans, despite their general character, contain the necessary elements of a substitution plan showing a clear commitment to substitute.

[39] MRL 10 is considered as a stage at which alternatives have been completely validated and can be proposed for certification (See also https://www.dodmrl.com/MRL_Deskbook_V2.pdf)

SEAC acknowledges the difficulty of presenting a generally relevant Substitution Plan for an Upstream Application, where different companies and different parts with widely different requirements may be subject of the ongoing alternative development work across the supply chain.

SEAC notes the presentation of the substitution plans in Figure 4 above, based on the input collected by the consortium from sending questionnaires to the various companies in the supply chain.

SEAC finds that the substitution plans made available, together with the clarifications provided by the applicant answering SEAC questions, were sufficient to conclude on the representativeness of the overall substitution plan. SEAC understands that in a case of an upstream AfA, a provision of a separate substitution plan from each company would be impractical. It would require increased use of confidential information, which could decrease transparency and potentially cause problems for companies in this competitive sector. SEAC also considers that, in the way presented by the applicant, the information given on the structure and progress of a typical substitution plan is sufficient, although it provides limited information on the progress of each specific case.

As discussed above, (the technical development and) certification of a potential alternative must be completed before it can be considered useable (technically feasible and available) and even then useability applies only within the specific context of the certification.

In view of the explanation on the lengthy processes for alternatives in the A&D industry SEAC considers the general structure of the substitution plan and the projected length for each phase credible. In that respect SEAC notes that:

A) Non of the shortlisted alternatives have not been validated across the entire range of parts in scope; they have only reached e.g. TRL and MRL 10 for a limited set of parts (with MRL 10 being considered as a stage at which alternatives have been completely validated and can be proposed for certification).
B) The use of any of the shortlisted alterntives for this use has not been certified across the entire range of parts in scope , which impacts the availability of alternatives.
C) The timelines as suggested by the applicant are aligned largely with timelines that have been suggested within the context of other authorisations but also more recently by SEAC in its opinion on terphenyl, hydrogenated where SEAC recommended a 10-year derogation for aviation[40]. SEAC acknowledges, that the conditions under different regulatory instruments may differ, but considers this as supporting evidence.

SEAC finds that the total projected length of 12 years as requested by the applicant is credible, even taking into account that for some parts substitution may happen faster and in other cases it may take longer. SEAC in that respect notes that:

- A single review period for all components would be practical as SEAC cannot expect a different application for each component
- SEAC notes a clear commitment to substitution by the applicant, and notes that there are no indications that having a longer review period will delay substitution for the products that are ready to substitute.

SEAC considers it encouraging that the information on planned activities in the Substitution Plan indicates that the industry is focussing on the most promising alternative(s), with a range

[40] https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e1862d9f6a

of formulations available on the market that are being investigated by ADCR members. SEAC concurs with the applicant that the time needed for substitution on the level of an individual parts with a different surface treatment is long. Furthermore, SEAC also considers that the entire process for the aviation industry to move to the Cr(VI) free alternatives is a complex, iterative route involving a high number of types of aircraft and a wide variety of corrosion sensitive parts. Such a process, is a resource intensive task and the applicant convincingly demonstrates that it cannot be completed within a normal review period.

Additionally, SEAC also considers the MROs, and the need for the spare parts to be available beyond the requested review period. Even after successful substitution there may be cases where repair and maintenance activities will still require Cr(VI) treated parts.

4.5. SEAC's conclusions on the analysis of alternatives and the substitution plan

SEAC concluded on the analysis of alternatives and the substitution plan that:

- The authorization holder has demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the applicant and heir downstream users] by the date of adoption of this opinion[41].
- There is information available in the review report indicating that there arealternatives available that are technically and economically feasible in the EU. However, RAC is unable to conclude on whether these alternatives are safer.
- The applicant submitted a substitution plan. The applicant justified their request for the 12-year review period. The substitution plan is credible for the review period recommended. SEAC notes that some substitution will be ongoing throughout the review period but considers that this does not affect its overall recommendation.

SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

5. Socio-economic analysis

Did the authorisation holder demonstrate that the societal costs of not granting an authorisation are higher than the risks to human health?

☒Yes ☐No ☒Not relevant (the risk cannot be compared with the costs of non-use)

This application is one of several AFA and RR submitted by the Aerospace and Defence Chromates Reauthorisation (ADCR) Consortium for its members, all downstream users of chromates. SEAC notes that having multiple applications from the consortium results in the SEA elements of the applications sharing common features. It also introduces some uncertainties into the analysis, since the respondents are a heterogenous group of downstream users, rather than a single applicant. Information has been collected through SEA questionnaire surveys[42].

In addition to the SEA questionnaires (discussed in section 0.4), SEAC had a look at the percentage turnover of the companies that reponded. The 37 respondent companies represent

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[42] See section 0.4 for more details.

€49.6bn out of the 146 companies in ADCR doing electroplating, with turnover extrapolated based on weighted average of €87.3bln. Considering both of these factors, makes the survey representative of the electroplating sector as well as the whole A&D industry.

like 1Further information on SEA questionnaires is covered in section 4.2.3 of the AoA/SEA document.

SEAC additionally notes that the different uses that have been applied for are interdependent (any single treatment may be only one part of a process) and that there are potential overlaps between applicants, which may risk double counting of impacts. SEAC has attempted to address this in its assessment of the impacts, particularly when assessing potential job losses.

5.1. Human health and environmental impacts of continued use

Impacts on the environment

The applicant did not include the environmental impacts of continued use in their assessment. These impacts are not considered relevant since in the Annex XIV of REACH Regulation, chromium trioxide is not classified for risk to the environment.

Impacts on human health

Chromium trioxide (CT; Entry No. 16) has been included in Annex XIV of REACH due to its carcinogenic and mutagenic properties as it is classified as carcinogenic (Cat. 1A) and mutagenic (Cat. 1B). As CT is mainly used as aqueous solution in the processes described below, this review report also covers Entry No. 17 of Annex XIV of REACH, which refers to **Acids generated from CT and their oligomers**.[43]

Sodium dichromate (SD; Entry No. 18)) has been included in Annex XIV of REACH due to their CMR properties as they are all classified as carcinogenic (Cat. 1B), mutagenic (Cat. 1B) and reproductive toxicants (Cat. 1B).

For CT and its acids, only carcinogenic and (for some of these substances also) mutagenic properties must be considered for risk characterisation. Reproductive toxicity has also to be taken into account for Cr(VI) exposure related to SD, PD and SC as these chromates affect both fertility and development.

The main focus of the risk characterisation, the quantitative exposure estimation and the monetisation of human health impacts carried out by the authorisation holder is on the carcinogenic effects in terms of **lung cancer** by inhalation for directly exposed workers and local population, as well as small **intestinal cancer** via oral exposure for local population.

The main focus of the risk characterisation, the quantitative exposure estimation and the monetisation of human health impacts carried out by the applicant are on the carcinogenic effects in terms of **lung cancer** by inhalation for directly exposed workers and local population, as well as small **intestinal cancer** via oral exposure for local population.

Reproductive toxicity for the above chromates is an effect of oral exposure. However, according to information from the Chemical Safety Report (CSR), the calculated exposure levels were

[43] In the AfA documents and this opinion, when referring to CT, this always also implies acids generated from CT and their oligomers.

below the DNEL for reproductive toxicity. Therefore, the risks associated with that endpoint are considered adequately controlled and as such it will not be examined further in this SEA.

In their monetisation of the human health impacts, the applicant used a value of statistical life (VSL) of €3.5 million, corresponding to the lower bound value endorsed by ECHA. This in turn has been uprated to 2021 price levels using a GDP deflator, resulting in a VSL of €3.92 million.

A value of cancer morbidity (VCM) of €0.41 million (2012 prices), adjusted to 2021 prices at €0.46 million (NPV) and an annual medical treatment cost (to be weighted by survival rate over years) of €12 055 were also used by the applicant to monetise non-fatal cancer cases.

Excess cancer risk is considered by the applicant for the maximum total tonnage of up to 25 t/y Chromium trioxide and up to 45t/Y of Sodium dichromate are used in pre-treatments (substances and formulations (the applied for use).

SEAC observes that RAC considers that the estimates of excess cancer risk and the RCR for reproductive risk for workers. These are based on the measured exposure values and modelled data, respectively, and the measured exposure values and indirect exposure of humans (workers and general population) via the environment at the local level, as presented by the applicant, allow a health impact assessment.

SEAC observes the RAC view that, in line with the EU risk assessment report (RAR) for Cr(VI) substances, that Cr(VI) will transform rapidly in the environment to Cr(III) under most environmental conditions and the impact of Cr(VI) as such is therefore likely to be limited to the area around the source. Therefore, RAC agrees with the Applicant's/AH's approach that **regional exposure** is not particularly relevant. As a result, SEAC does not separately assess the regional health impacts

SEAC notes RAC conclusion that due to the different approaches in the assessment described in the RR and initial applications, no meaningful comparisons of the exposure and risk levels can be made nor any conclusions can be drawn on whether exposures have been reduced during the review period of the authorisation.

Table 5: Willingness-to-Pay values for monetised health impacts

WTP Values	2012	2021
Value of Statistical Life (VSL)	€3 500 000	€3 920 000
Value of Cancer Morbidity (VCM)	€410 000	€460 000

Health impacts on workers

In their risk assessment, the applicant has considered that a total of 1760 workers could be directly exposed to chromium trioxide via inhalation, based on average exposure values obtained from the consultation questionnaire distributed across co-applicants, which in turn has been extrapolated across the entire group of applicants to arrive at the final figure.

According to the applicant's exposure estimates, under the applied for use scenario, there would be a total of 0.03 excess lung cancer cases for directly exposed workers per year over the 12 year review period.

For this use, the total monetised health impacts (fatal + non-fatal) for directly exposed workers amount to around €0.49m or around €0.05m[44] per year over the requested 12 -review period.

Health impacts on local population

In their risk assessment, the applicant has considered that, at the local level, 36,600 people in the EEA could be potentially exposed by inhalation or by oral route via the environment, based on population size and density within the areas and countries where each site is located. This differs from the default value for local population exposure of 10 000 people per site, as recommended by the European Union System for the Evaluation of Substances (EUSES). In response to SEAC's questions, the applicant has stated that for most (if not all) sites, local population exposure to Cr(VI) is driven by inhalation rather than oral exposure. Hence, in their calculations they only considered the number of people living within a 100 metre radius of each relevant site, in line with the EUSES model for local air concentration, since assuming a default exposure value of 10 000 people per site would significantly overestimate the risks of continued use. The applicant has also provided a breakdown of their calculations in Excel files.

According to the applicant's exposure estimates, under the applied for use scenario, there would be total of 0.02 excess cancer cases in the EEA general population over the 12-year review period.

For this use, the total monetised health impacts (fatal + non-fatal) for the local population amounts to €0.26m or approximately €0.03m per year over the requested review period of 12 years.

The applicant has assumed a 20-year latency period for both lung and intestinal cancer, which differs from standard ECHA guidance which recommends a 10-year latency period for lung cancer and 26 years for intestinal cancer. A discount rate of 4 % has been applied throughout, in line with ECHA guidance. The applicant has also sought to calculate morbidity costs both for fatal and non-fatal cancer cases, together with an estimate of annual medical treatment costs related to morbidity resulting from both types of cancer, with reference to a range of studies conducted across Europe in relation to the measurement of such costs. These medical treatment costs have been estimated at €30,843 and €84,789 per lung and intestinal cancer case respectively, over the requested 12-year review period.

In total, the present value of monetised health impacts have been estimated by the applicant at approximately €0.75m over the requested 12-year review period, or approximately €0.08m per year over the requested review period of 12 years.

SEAC's evaluation of the impacts on human health and the environment

SEAC considers the applicant's methodological approach and assumptions suitable for the assessment. SEAC considers that the applicant's estimated economic burden reflects the welfare loss in the continued use scenario due to increased mortality and morbidity from both lung cancer and intestinal cancer. The mortality rates used are appropriate and the calculations are in line with ECHA guidance.

SEAC observes the applicant's use of ECHA's 2016 report on valuing selected health impacts of chemicals with updated values from 2012 prices to 2021 using a GDP deflator. Nonetheless,

[44] Throughout this opinion SEAC uses the approximated per-year values estimated By dividing the total NPV costs by 10. This value is used as a proxy to derive the annual values from the applicant's estimation of impacts over the full review period of 12 years.

SEAC also notes that the applicant has used the lower bound estimate of the VSL for the monetisation of human health impacts and assumed a 20-year latency period for both lung and intestinal cancer.

In addition, SEAC notes that the applicant has included monetised costs of medical treatment for both cancers, reflecting the burden on the healthcare system. SEAC notes that WTP values do not incorporate other types of indirect costs (such as decreased labour productivity) associated with cancer. SEAC therefore concurs with the applicant's methodology, while noting that additional costs (in terms of productivity loss) could be expected in the continued use scenario and have not been covered in the applicant's socio-economic analysis.

SEAC notes that the applicant did not perform a separate assessment for the fertility/reprotoxic endpoint of substance **Sodium dichromate** (SD; Entry No. 18) as the RCR was considered to be below the DNEL.

SEAC notes that RAC's evaluation concluded that, the risk characterisation ratio for the relevant endpoint is below 1 and that therefore, the risks for reproductive toxicity are negligible. SEAC notes that this means that this risk is adequately controlled and therefore an impact assessment for this endpoint is not needed. The Human health impact performed by the applicant is therefore complete and covers all relevant endpoints.

Table 13: Summary of additional statistical cancer cases

	Excess lifetime cancer risk[1]	**Number of exposed people**	**Estimated statistical cancer cases (per year over 12 years)**	**Value per statistical cancer case**	**Monetised excess risk (per year over 12 years)**
Workers					
Directly exposed workers[2]	$6.96*10^{-5}$-$1.00*10^{-3}$	1,760	0.03	€4.38 million (fatal + non-fatal lung cancer)	€0.05m
Indirectly exposed workers[3]	Included above				
Sub-total					€0.05m
General population					
Local	$3.54*10^{-5}$	37,000	0.02	€4.38 million (fatal + non-fatal lung cancer) €4.38 million (fatal + non-fatal intestinal cancer)	€0.03
Regional					
Sub-total					€0.08m
Total			**0.05**		**€0.08M**

Latency (years)	20 years for both lung and intestinal cancer

Notes:

1. Excess risk is estimated over a typical lifetime working exposure (40 years) and via the environment over a typical lifetime exposure (70 years).
2. Directly exposed workers perform tasks described in the worker contributing scenarios, typically characterised by an 8-hour Time Weighted Average (TWA) exposure of a representative worker.
3. Indirectly exposed workers (bystanders) do not use the substance.
4. [Per average year during the time horizon used in the analysis.] {Annualisation can be done following the Guidance on the preparation of socio-economic analysis as part of an application for authorisation (see Appendix 1 – footnote 70) or by simply dividing the total cost by the years used in the analysis. When latter approach was used by the applicant or by SEAC, recognise this and qualify the results as a "rough approximation of annual cost".}
5. Derived from the lifetime risk of 40/70 years.

5.2. Societal costs of not granting an authorisation

Non-use scenario

The applicant has considered five potential non-use scenarios (NUSs) under authorisation refusal, given the lack of readily available alternatives as well as current research and development efforts. These NUSs have been identified as part of a consultation process that was undertaken across the co-applicants, with responses covering 37 companies across EEA and UK, and 53 sites (of which 35 were in EEA). The responses have been classified according to both the preferred NUS as well as the nature of the respondent, i.e. OEM, build-to-print, design-to-build and MRO companies.

The Non-use scenarios assessed are:

1. Leaving the decision to the customers on which NUS to pursue (i.e. other companies forming part of this consortium e.g., OEMs)
2. Cessation of all operations
3. Shifting of company focus to other aerospace or non-aerospace (non-defence) uses
4. relocation of pre-treatments and associated pre and post treatment activities (Temporary) cessation of chromate related activities until a feasible alternative becomes available

The starting point, according to the applicant, is the decision of OEMs and design-to-build (DtB) operators, since these are the companies that are primarily involved in R&D and testing of new alternatives, coupled with assessments regarding feasibility and the qualification process for components using the new alternative. They also certify their suppliers based on the use of the new alternative, and may even assist them in adapting their equipment and risk management processes. The applicant also stated in this point that the regulatory requirements involved within the sector mean that these companies will require 12 years to fully develop and certify suitable alternatives across their components and supply chains.

The applicant has concluded that the most-likely NUS for OEMs would be relocation of their manufacturing activities outside the EU/EEA. As part of this process, OEMs would have to undertake a technical and industrial qualification on any new suppliers or existing suppliers who also relocate outside the EEA to make sure that stringent industry standards are adhered to. The applicant envisages that even OEMs who do not use pre-treatments would relocate in order to be close to key design-to-build and build-to-print operators, creating new clusters and facilitating the overall production and repair process. Indeed, several build-to-print businesses are expected to relocate outside the EU given their reliance on the aerospace and defence

sector.

According to the applicant, MRO operators would be heavily impacted since it is technically and economically challenging to repair components outside the EU and ship them back. In practise, this would mean that the large MROs (based on their responses) are likely to cease their pre-treatments activities until a new alternative is certified, with others potentially relocating outside the EU. In response to SEAC's questions, the applicant further elaborated on the interconnected nature of the different industry operators, since OEMs are responsible for qualifying and certifying a particular alternative in a given process, and would then roll it out across their supply chain. The choice of NUS will largely be dictated by what is selected by OEMs as design-to-build companies must adhere to the alternatives specified by OEMs and MROs cannot deviate from what is set out in maintenance manuals.

Evaluation of Most-Likely NUS

SEAC notes the applicant's analysis of the likely non-use scenarios that would occur under authorisation refusal is based on the consultation process undertaken with ~~3~~7 of the consortium companies (across both EEA and UK) and 53 sites (35 in EEA) (The applicant estimated that there were 100 sites undertaking pre-treatment across the EEA and UK (80 in EEA and 10 in UK).

SEAC finds that the diversity of responses obtained broadly reflects the different business realities faced by the different types of companies and their operations within the sector as different as build-to-print, design-to-print, MROs and OEMs. SEAC notes that the coverage of the surveys and the number of respondents is not always very high and, as such, the representativeness of the responses and of the meaningfulness of the extrapolations made by the applicant/authorisation holder remain uncertain.

SEAC notes that based on the consultation responses (p. 137, Table 5.1 of the AoA/SEA) neither of the two OEMs opted for relocation as their most-likely NUS, which questions the conclusion that the most-likely NUS would be relocation outside the EEA.

Given that none of the consulted companies opted for the relocation and the applicant's view that the relocation would be unlikely, SEAC finds the relocation as a most favoured NUS somewhat artificial.

SEAC considers that, all the non-use scenarios identified during the consultation could be considered as relevant and credible for some companies depending on their specific situations. Finally, in terms of socio-economic impacts, SEAC considers that the choice of the non-use scenarios has minor consequences as cost elements are similar to all NUSs and they would result in some profit loss and unemployment

Economic impacts of non-use

The applicant has listed a number of economic benefits resulting from continued use. In all cases, the monetised impacts have been considered by the applicant over the 12-year requested review period, with the Net Present Value (NPV) in 2021 calculated using a discount rate of 4 %. The applicant has quantified profit losses and social costs of expected job losses in the most-likely NUS. No other economic benefits have been monetised, with the applicant providing a qualitative discussion on the likely economic impacts on competitors, customers, macroeconomic conditions, the environment, as well as wider indirect employment impacts. The applicant has provided SEAC with spreadsheets including all relevant calculations pertinent to the monetisation of economic impacts.

Profit losses

SEAC notes that the applicant didn't follow the current practice for the monetisation of taking into account 4 years for producer surplus losses for NO-SAGA cases[45] but considered two years of profit losses (for the years 2025-2026) instead. To makesuch estimates more conservative, SEAC used the two years values in its assessment of the economic impacts.

The Applicant has sought to quantify losses in producer surplus emanating from authorisation refusal under the most likely NUS. The applicant has used two different approaches for this quantification.

The first approach is based on the number of jobs lost at each site due to authorisation refusal, multiplied by the average annual Gross Value Added (GVA) per job for 2018, which varies depending on the type of company under consideration, based on Eurostat data. In turn, average annual personnel costs, also based on Eurostat data using the relevant NACE codes for each type of business, are subtracted from this GVA figure to arrive at the estimated annual operating surplus associated with these job losses, which is used as a proxy for lost profits per annum, estimated by the applicant at €2451 million per year, with the discounted value of profit losses for 2 years totalling €4623- million.

The second approach is based on the expected percentage loss in turnover, extrapolated over the entire consortium, estimated at €16.5 billion per year. To obtain gross operating margins, the applicant utilised average gross operating surplus (GOS) as a percentage of turnover, with the data obtained from Eurostat using relevant NACE codes for each type of business. Thus, the gross operating surplus losses were estimated at € 1752 million per year, with discounted profit losses over a 2-year period reaching €3304 million.

The applicant has also provided a discussion of potential items that could offset these profit losses, including the resale of retired assets and potential benefits accruing to rival EU-based operators. In both cases, the applicant has cited the fact that this is a sectoral application with impacts covering the entire industry, limiting the potential for both equipment resale or indeed the potential for rival firms to benefit from authorisation refusal. In addition, the applicant has also considered a number of additional (qualitative) impacts on aerospace and defence companies resulting from authorisation refusal. These include cancelled future orders due to supply disruptions, customer penalties for late or missing deliveries, extended duration of maintenance, repair and overhaul services, leading to out of service aircraft and associated penalties, higher logistical costs and reputational damages.

In response to SEAC's questions, the applicant has stated that the use of EBITDA was indeed discussed with consortium members; however, several suppliers (mainly SMEs) could not provide such a figure, since it was deemed impossible to ascertain the EBITDA specifically related to aerospace and defence components manufactured using chromates for specific processes. Thus, the applicant decided to eschew this approach in favour of their proxy method. Nonetheless, the applicant has stated that the use of EBITDA would not have led to lower profit loss estimates, particularly when considering the large global companies, whose

[45] See SEAC's note How to evaluate the changes in producer surplus (https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138)

profit losses under the most-likely NUS would probably have been much higher.

SEAC notes that estimates from the two methods employed by the applicant rely heavily on the questionnaire responses (number of relevant employees in the GVA method and percentage of turnover in the GOS method) and on the assumptions made when aggregating the SEA questionnaires. This may account for the different results obtained from the two methods. It is unclear to SEAC which method captures the avoided producer surplus loss more accurately, and it is possible that both methods may be overestimates. This is compounded by the possible interdependence of the uses applied for. SEAC has therefore chosen to take a deliberately conservative approach and use figures for two years of profit losses, using the lower of the values obtained from the two methods. Therefore, SEAC has carried forward a profit loss estimate of €3304 million in the analysis.

SEAC notes that the non-use scenarios and the associated impacts were identified by the applicant by consulting via a questionnaire a large number and variety of companies that are members of the ADCR consortium (build-to-print, design-to-print, MROs and OEMs companies). However, SEAC notes that the coverage of the surveys and the number of respondents are not always very high (in this case, 37 of the consortium companies representing 53 sites across the EEA and UK. (35 in EEA) The applicant estimated that there were 80 sites undertaking pre-treatment in EEA and, as such, the representativeness of the responses and of the meaningfulness of the extrapolations made by the applicant remain uncertain.

Economic impacts on competitors

The applicant has provided a detailed discussion of the likely economic impacts from authorisation refusal on competitors. Those located within the EEA will be equally impacted, since this application for authorisation is intended to cover the use of pre-treatment across the entirety of the EEA's aerospace and defence sector, funded and supported by all the major global players within this sector with additional support by suppliers and defence ministries. Hence, the major global OEMs and design-to-build companies will ultimately determine the uptake of any alternative to chromium trioxide since they validate, qualify and certify components using the new alternative substance.

The applicant has also discussed likely impacts on non-EEA competitors, stating that these would benefit from the creation of new supply chains outside the EEA due to relocation, resulting in reduced logistical costs, while also continuing with their pre-treatment .

SEAC notes these qualitative remarks.

Wider socioeconomic impacts

The applicant has (qualitatively) discussed a number of additional economic impacts from non-authorisation. Firstly, air transportation is likely to experience a negative impact from the reduced ability of MRO companies to undertake normal repairs and maintenance works. Indeed, any such work requiring pre-treatment will have to be undertaken outside the EEA, resulting in various potential challenges including prolonged grounding of aircraft as they await repairs, logistical costs due to the need to disassemble and transport parts outside the EEA, potential delays, higher environmental impacts from transportation, increased operational

costs due to higher fuel use, etc. The grounding of aircraft would also have significant repercussions for air passengers and the global tourism industry.

The applicant has also outlined various impacts on the defence sector, particularly due to potential disruptions to MRO activities, which may lead to removal of relevant military equipment and machinery from use. This would limit the availability of such equipment in case of military emergencies, as well as the size of operational forces. The applicant has noted that in general, military procurement agencies prefer key defence components to be manufactured within the EEA, and may be reluctant to send equipment outside the EEA for repair, maintenance and overhaul. The applicant has cited the size of the European Defence sector, which generates nearly €100 billion in turnover annually, supporting over 500 000 employees, stating that authorisation refusal would have notable implications for the continued growth of this sector, particularly if relevant EU-based companies relocate outside the EEA.

SEAC notes these qualitative remarks. In particular, SEAC considers that the aforementioned repercussions for air passengers and the global tourism industry discussed by the applicant could be extremely significant and quantitatively very large, although these have only been discussed qualitatively in the application.

Environmental impacts

The applicant has briefly mentioned the likely environmental impacts from authorisation refusal. These largely stem from the increased distances that aircraft would have to travel to undergo MRO activities since these services would be located outside the EEA, resulting in higher carbon dioxide emissions. Similarly, for aircraft manufacturing lines, assembly would consist of a regular back and forth of components within and outside the EEA, further increasing the industry's carbon footprint. SEAC notes these qualitative remarks.

Social impacts related to job losses

The applicant/authorisation holder has sought to quantify the social costs related to job losses under authorisation refusal, based on the 11 700 job losses that were reported by respondents during the consultation process, extrapolated over the entire consortium to 30 000 jobs. In response to SEAC's questions, the applicant authorisation holder has clarified that the job losses include jobs directly related to the use of chromates, as well as additional staff involved in relevant processes or manufacturing activities (e.g., assembly of parts manufactured using chromates at the same site). The applicant authorisation holder's approach to monetisation is based on SEAC's note on the social cost of unemployment (Dubourg, 2016)[46], using a welfare cost factor value for each country (depending on where each site is located) as well as site-specific average wages, to estimate the social value of the lost jobs, which is calculated at €. €3 450 million

However, SEAC has some concerns regarding the number of jobs directly attributable to each use, which as mentioned earlier is compounded by potential interdependencies across uses. Adopting a conservative approach to overcome these uncertainties, SEAC has used the average social costs of unemployment (i.e., cost per job) as calculated by the applicant authorisation holder, but only applied it to the number of employees directly undertaking the

46 https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

use in question and directly exposed to the chromates. Hence in this case, SEAC has taken a total of 1760 job losses, resulting in a social value of job losses of approximately €203 million [47] over the review period as opposed to €3 450 million. This recalculated value has been carried forward by SEAC in the analysis.

Wider indirect and induced job losses

The applicant has also provided a discussion on the broader job losses that would result from authorisation refusal due to spillover effects. Given both the scope of the application and the importance of the aerospace and defence sector, the applicant argues that there would be notable indirect unemployment effects across the European economy, quoting employment multipliers supplied by the European Commission[48] of between 2.2 and 2.4 covering indirect and induced employment, reflecting the industry's significant economic contribution. Similarly, the applicant has discussed the indirect employment impacts resulting from the potential impacts of authorisation refusal on the air transport sector.

SEAC notes these qualitative remarks.

SEAC's evaluation of the societal costs of non-use

As indicated in the health impact section, in line with RAC's doubts about the representativeness of the exposure of directly exposed workers, and considering that the number of people potentially exposed at local level might be underestimated, SEAC notes that the already significant monetised health impacts over the entire period are uncertain and likely underestimated.

SEAC notes that the non-use scenarios and the associated impacts were identified by the applicant by consulting via a questionnaire a large number and variety of companies that are members of the ADCR consortium (build-to-print, design-to-print, MROs and OEMs companies). However, SEAC notes that the coverage of the surveys and the number of respondents are not very high (in this case, 9 companies over the … that participated to the questionnaire) and, as such, the representativeness of the responses and of the meaningfulness of the extrapolations made by the applicant remain uncertain.

Based on the responses to the questionnaires as reported by the applicant and considering the complexity of upstream applications concerning multi-tiered supply chains in the Aerospace & Defence sector, SEAC considers that, in case of a non-granted/non-extended authorisation, the non-use scenarios identified during the consultation going from relocation outside the EEA to scaling back to closing down can all be considered as relevant and credible for different companies. SEAC notes that for different consortium members one or another of these non-use scenarios might be the most likely one depending on their specific situations.

SEAC also notes that to different extents, all these non-use scenarios would result in some profit loss and job losses. Therefore, SEAC acknowledges that these two impact categories are

[47] This has been calculated by deriving the social value per job los~~1~~s of € (€3 450 million/29 963 workers) multiplied by 1760 jobs as per table 4-11

[48] European Commission (2017): Issue papers for the High Level Group on maximising the impact of EU research and innovation programmes. Prepared by the Research and Innovation DGs. Available at: https://www.evropskyvyzkum.cz/cs/storage/bf5134fec407f6e005288c0e2631ad232c38c013?uid=bf5134fe c407f6e005288c0e2631ad232c38c013

relevant in case of all non-use scenarios identified by the consortium via the consultation.

SEAC notes that, in its assessment of the benefits of continued use, the applicant/authorisation holder considers foregone profit for two years along the supply chain and social costs of direct unemployment.

Though the current SEAC practices for NO-SAGA cases[49] considers 4 years producer surplus losses, to be conservative, SEAC accepts the two years of profit losses (for the years 2025-2026 after the end of the CTAC authorisation) as calculated by the applicant/authorisation holder, as being a relevant measure of the changes in producer surplus in case an authorisation is not granted/extended.

SEAC notes that profit losses for the entire supply chain were estimated by the applicant combining the responses obtained via the SEA questionnaire and discussions with the consortium members subsequently extrapolated to the derive the values of the non-respondent companies. SEAC notes that in their responses to SEAC questions, the applicant/authorisation holder clarified that this extrapolation approach was adopted by the ADCR to deal with the confidentiality issues concerning the profit losses within the consortium members that are competitors. However, SEAC notes that this methodology might not always be able to meaningfully fill the gaps as some companies could have not responded simply because they might be not concerned by a certain impacts, for instance they might not need to dismiss workers.

Concerning the assessment of social impacts of direct unemployment, SEAC notes that the applicant/authorisation holder estimated the costs of direct unemployment by following the ECHA guidelines[50]. Adopting a conservative approach to overcome the uncertainties related to the size of the potential direct unemployment, SEAC decided to consider only social costs of unemployment related to the loss of jobs of directly exposed workers. However, in its assessment, SEAC still used the same average cost per job as indicated by the applicant/authorisation holder.

SEAC underlines that indirect and induced social costs were not included in the applicant/application holder's assessment. SEAC notes that, in case these impacts were included in the assessment, the societal impacts of the non-use scenario would be higher.

In addition, SEAC considers that the applicant/authorisation holder discussed potentially significant repercussions that can be expected for civil aviation and the global tourism industry, emergency services and military forces. SEAC underlines that in case all these impacts were included in the assessment, the societal impacts of the non-use scenario would be higher than those indicated by the applicant.

As far as environmental impacts are concerned, SEAC notes that the applicant/authorisation holder has explained that there would be higher CO2 emissions due to the increased fuel consumption resulting from longer distances for planes to undergo MRO.

Finally, considering the high level of interdependence and overlaps/linkages between uses in the three batches of applications and review reports submitted by the ADCR consortium when trying to assess all these cases and to monetise impacts, SEAC has decided to adopt a conservative approach to avoid overestimating the overall costs of the non-use of the

[49] See SEAC's note How to evaluate the changes in producer surplus (https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138)

[50] See SEAC's note The social cost of unemployment and Valuing the social costs of job losses in applications for authorisation

chromates in the A&D sector.

As a reasonable estimate of the socio-economic impacts of the non-use scenario on the EU, in its quantitative assessment, SEAC has included two years' profit loss for the supply chain as well as social costs of unemployment of directly exposed workers. SEAC takes forward the order of magnitude of billion euros per year until the end of 2036 which is the review period recommended by SEAC.

The societal costs of the non-use scenario resulting from SEAC's assessment are summarised in the table below, with the societal costs of non-use estimated at approximately €**~~6~~ 3398** million over the requested 12-year review period, annualised at around €350 million per year.

Additionally, SEAC notes that even if the loss of producer surplus were excluded entirely from the socio-economic analysis, the estimated social costs of unemployment alone are several orders of magnitude greater than the monetised human health costs.

In conclusion, based on the information submitted by the applicant/authorisation holder in the application/review report or in answer to SEAC questions, SEAC sees no reason to challenge the applicant/authorisation holder's assessment.

Table 14: Societal costs of non-use

Description of major impacts	Monetised/quantitatively assessed/qualitatively assessed impacts
1. Monetised impacts	**€ over 12 years and per year**
Producer surplus loss due to authorisation refusal	€3,304 million Annualised: €330 million
Social cost of unemployment	€203 million Annualised: € 20 million
Sum of monetised impacts	**€3500 million** **Annualised: €350 million**
2. Additional quantitatively assessed impacts	**€ over 12 years and per year**
Please specify	N/A
3. Additional qualitatively assessed impacts	
Please specify	Economic impacts on competitors Wider socioeconomic impacts on air transportation, defence and tourism Environmental impacts Induced job losses

5.3. Combined assessment of impacts

SEAC's evaluation of the combined assessment of impacts

The table below summarises the monetised values included in SEAC's assessment of the socio-economic benefits and costs associated with continued use by the applicant, expressed both

in aggregate terms over the requested review period as well as in annualised terms. Based on the analysis conducted below, the estimated net societal benefits from continued use are approximately **€3 500 million over the review period**, with the benefits-to-costs ratio being around 4660:1.

Table 15: Societal costs of non-use and risks of continued use

Societal costs of non-use		**Risks of continued use**	
Monetised impacts (€ over 12 years) (per year)	€ **3 500** million NPV Annualised: €350 million	Monetised excess risks to directly and indirectly exposed workers (€ over 12 years) (per year)	€0.49 million NPV Annualised: €0.05 million
Additional quantitatively assessed impacts (€ over 12 years) (per year)	Not applicable	Monetised excess risks to the general population (€ over 12 years) (per year)	€0.26 million NPV Annualised: €0.03 m
Additional qualitatively assessed impacts (€ over 12 years) (per year)	Economic impacts on competitors Wider socioeconomic impacts on air transportation, defence and tourism Enviromental impacts Induced job losses	Additional qualitatively assessed risks (€ over 12 years) (per year)	Not applicable
Summary of societal costs of non-use	**€3 500 million NPV** **Annualised: €350 million**	**Summary of risks of continued use**	**€0.75 million NPV** **Annualised: €0.08 million**

5.4. SEAC's conclusion on the socio-economic analysis

SEAC concludes that the applicant has demonstrated that the societal costs of not granting an authorisation are higher than the monetised risks to human health resulting from the granting of an authorisation.

This conclusion of SEAC is made on the basis of:

- the application for authorisation,
- SEAC's assessment of the societal costs of non-use,
- SEAC's assessment of the availability, technical and economic feasibility of alternatives,
- [SEAC's assessment of the information submitted by interested third parties,]

- Additional information provided by the applicant, and
- RAC's assessment of the risks to human health.

SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

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6. Proposed review period

☐Normal (7 years)

☐Long (12 years)

☐Short (4 years)

☐Other: … years

☐No review period recommended

SEAC concluded on the analysis of alternatives and the substitution plan that:

- The applicant has demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the applicant by the date of adoption of this opinion.
- There is information available in the application for authorisation indicating that there are alternatives available that are technically and economically feasible in the EU. However, RAC is unable to conclude on whether these alternatives are safer.
- The applicant submitted a substitution plan. The applicant justified their request for the 12-year review period. The substitution plan is credible for the review period recommended. SEAC notes that some substitution will be ongoing throughout the review period but considers that this does not affect its recommendation.

When recommending the review period SEAC took note of the following substitution and socio-economic considerations:

- A single review period for each component would not be possible nor practical considering that this is an upstream application covering several companies and numerous components.

- SEAC observes that it is not realistic to expect that all components would be substituted according to similar timelines, but rather some components would achieve substitution before the end of the RP whereas others might need more time.
- SEAC notes a clear commitment to substitution by the applicant, and notes that there are no indications that having a longer review period will delay substitution for the products that are ready to substitute.

- The applicant's downstream users face investment cycles that are demonstrably very long. This is due to the above discussed substitution process as well as additional regulatory requirements.

- The costs of moving to alternatives are high and requires time, not only due to the cost of the alternative substances or needed technological changes but due to the strict regulatory requirements that have to be met to ensure airworthiness and safety.

- The fact that the socio-economic benefits of continued use are calculated to be much higher than costs (even if costs down the supply chain e.g. for airlines and their customers, have not been taken into account). Avoided profit losses or job losses alone tend to be clearly higher than the estimated human health benefits in the non-use scenarios.
- SEAC assessed the contents of different general substitution plans presented by the applicant and finds them credible and necessary if the applicants are to switch to an alternative. SEAC also assessed the duration of these plans and considers the time allocated to each activity and the direction of the overall substitution process credible.
- SEAC has no substantial reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the risks to the environment associated with the continued use of the substance.

Taking into account all of the above points, a **12-year** review period is recommended for this use, i.e. until 22 December 2034.

7. Proposed additional conditions for the authorisation

Were additional conditions proposed for the authorisation?

☐Yes ☐No

7.1. Description

{Character limit: 2500}

{**Additional conditions for the authorisation are proposed to be included in the authorisation decision of the Commission, thus they may be enforced by the Member States**.

Additional conditions for the authorisation are typically proposed when OCs and RMMs are **not** appropriate and effective in limiting the risk or the risk is **not** adequately controlled.

Additional conditions for the authorisation can also be proposed in cases where OCs and RMMs **are** appropriate and effective in limiting the risk but further confirmation is needed or there may be scope for further limiting exposure or releases. For example:

- A requirement to carry out and document a feasibility study to further limit exposure or releases.
- Applicants have already planned and committed to implement improvements to the OCs and RMMs and RAC proposes a condition to require these improvements to be implemented.

Examples of additional conditions for the authorisation:

- A **requirement to implement specific (well-defined) OCs and RMMs** for WCSs or compartments where there is a concern (typically a high concern). Please consider specifying proposed timelines for their implementation. Such conditions may result in the conclusion that the proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk.
- In case the authorisation holder indicates that specific OCs and RMMs are in place or will be implemented but they are not clearly part of the conditions of use in the ES it may be an option to propose to make them binding through additional conditions for the authorisation.
- **Monitoring and review conditions** (section 7 and 8 combined)
    - Where RAC is not able to propose specific OCs and RMMs, or they are not considered sufficient to alleviate the concerns, RAC may propose **monitoring** of exposure or emissions for the authorisation in **section 8**, with specified frequency, and if relevant limited to specific WCSs.
    - The purpose of such monitoring is to require the authorisation holder to **review** the OCs and RMMs and to take actions as appropriate to further reduce exposures/emissions based on the results of monitoring programs. This review step is part of **section 7**.
- A requirement to carry out and document a **feasibility study** to further limit exposure or releases of non-threshold substances
- Requirement to develop representative ESs, guidance, formats for downstream users
- A modification of the scope of the use may be proposed as a condition for the authorisation. As a general rule, please consult the applicant in such cases.}

RAC

[Add text]

[SEAC]

{This has been used, for example, to reduce/clarify the scope of use applied for, to recommend different review periods for different products, to strengthen the requirement to follow a substitution plan and to decrease volumes with a certain trend.}

[Add text]

7.2. Justification

{Character limit: 1500}

{Based on the concerns noted and conclusions in sections 1 and 2, 4 and 5.}

RAC

[Add text]

[SEAC]

[Add text]

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements proposed for the authorisation?

☐Yes ☐No

8.1. Description

{Character limit: 700}

{**Monitoring arrangements for the authorisation are proposed to be included in the authorisation decision of the Commission, thus they may be enforced by the Member States.**

Monitoring arrangements for the authorisation are typically proposed when (further) measurements are needed:

- for 'monitoring and review' (see section 7): the applicant can be required to review the OCs and RMMs and to take actions as appropriate to further reduce exposures/emissions based on the results of monitoring programs (this review step is part of section 7)
- to provide further confirmation that the appropriateness and effectiveness of OCs and RMMs in limiting the risk*
- to monitor the proper functioning of implemented OCs and RMMs (regular check points)
- to verify the effectiveness of newly implemented OCs and RMMs when RAC proposes additional conditions (especially changes in OCs and RMMs) it is usually necessary to also propose monitoring in order to assess the effectiveness of the proposed conditions.
- to (further) improve the exposure assessment (e.g. representativeness, uncertain monitoring) and thereby the risk characterisation and the risks of continued use*
- In case the authorisation holder indicates that monitoring is in place or will be implemented but this is not clearly part of the conditions of use in the ES it may be an option to propose to make them binding through monitoring arrangements for the authorisation

Depending on the situation, for example the cases indicated with an asterisk (*) may instead be recommendations for the review report when there is no clear need (see section 9).

Please clearly justify the need for monitoring arrangements. Please specify the frequency and the type of the monitoring and specify as far as possible the contextual information that should be collected and reported.

Please indicate in section 8 that the results shall be documented in a possible review report.}

RAC

[Add text]

8.2. Justification

{Character limit: 500}

{Based on moderate concerns identified in the assessments and noted in the conclusions in sections 1 and 2.}

RAC

[Add text]

~~9. Recommendations for the review report~~

10. Authorisation holder's comments on the draft opinion

Did the authorisation holder comment the draft opinion?

☐Yes ☐No

10.1. Comments of the authorisation holder

Was the opinion or the justifications to the opinion amended as a result of the analysis of the authorisation holder's comments?

☐Yes ☐No ☐Not applicable – the authorisation holder did not comment

10.2. Reasons for introducing changes and changes made to the opinion

{Character limit: 1000}

{Reasons for amending the opinion include incorrect interpretation of information provided in the review report and mistakes made in the calculations.}

[Add text]

10.3. Reasons for not introducing changes

{Character limit: 1000}

[Add text]

Annex I – Overview of new AfA/ RR submissions by ADCR applicants/ authorisation holders

Use	Submission type	Chromium trioxide (CT)		Sodium dichromate (SD)		Potassium dichromate (PD)		Sodium chromate (SC)		Di-chromium tris(chromate) (DtC)	
Formulation of mixtures	**RR**	Boeing Distribution Deutschland GmbH; ChemService GmbH; Cromital S.P.A.	<600 t/ y*	**Brenntag Chemicals Distribution (Ireland) Ltd;** AD International BV	<100 t/ y	Brenntag Chemicals Distribution (Ireland) Ltd	<42 t/ y	Boeing Distribution Deutschland GmbH; Haas Group International SP. Z.O.O.	<1.1 t/ y		
	AfA	**Haas Group International SP. Z.O.O.;** Henkel Global Supply Chain B.V									
Pre-treatments: Deoxidising, picklinig, etching and/or desmutting	**RR**	**Boeing Distribution Deutschland GmbH;** ChemService GmbH; Cromital S.P.A.	<25 t/ y*	AD International BV; Brenntag Chemicals Distribution (Ireland) Ltd	<45 t/ y						
	AfA	**Haas Group International SP. Z.O.O.;** Henkel Global Supply Chain B.V									
Electroplating	**RR**	**Boeing Distribution Deutschland GmbH;** ChemService GmbH; Cromital S.P.A.	<500 t/ y*								
	AfA	**Haas Group International SP. Z.O.O.;** Henkel Global									

		Supply Chain B.V									
Passivation of non-Al metallic coatings	**RR**	Boeing Distribution Deutschland GmbH; ChemService GmbH; Cromital S.P.A.	<15 t/ y*	**Brenntag Chemicals Distribution (Ireland) Ltd;** AD International BV	<50 t/ y*	Brenntag Chemicals Distribution (Ireland) Ltd	<12 t/ y*				
	AfA	**Haas Group International SP. Z.O.O.;** Henkel Global Supply Chain B.V		Haas Group International SP. Z.O.O.		Haas Group International SP. Z.O.O.					
Passivation of stainless steel	**RR**	**Boeing Distribution Deutschland GmbH**; ChemService GmbH; Cromital S.P.A.	<8.4 t/ y*	AD International BV; Brenntag Chemicals Distribution (Ireland) Ltd	<17.5 t/ y*						
	AfA	Henkel Global Supply Chain B.V		**Haas Group International SP. Z.O.O.**							
Chemical Conversion Coating	**RR**	**Haas Group International SP. Z.O.O.;** Boeing Distribution Deutschland GmbH; ChemService GmbH; Cromital S.P.A.	<125 t/ y*	AD International BV; Brenntag Chemicals Distribution (Ireland) Ltd	<40 t/ y*	Brenntag Chemicals Distribution (Ireland) Ltd	<18 t/ y*			Henkel Global Supply Chain B.V; Haas Group International SP. Z.O.O.	<2.6 t/ y
	AfA	Henkel Global Supply Chain B.V;		**Haas Group International SP. Z.O.O.**		Haas Group International SP. Z.O.O.					
Anodising	**RR**	**Boeing Distribution Deutschland GmbH;** ChemService	<125 t/ y*								

		GmbH; Cromital S.P.A.									
	AfA	**Haas Group International SP. Z.O.O.;** Henkel Global Supply Chain B.V									
Anodise sealing	**RR**	Boeing Distribution Deutschland GmbH; ChemService GmbH; Cromital S.P.A.	<2.5 t/ y*	**Haas Group International SP. Z.O.O.;** AD International BV; Brenntag Chemicals Distribution (Ireland) Ltd;	<10 t/ y	Brenntag Chemicals Distribution (Ireland) Ltd; Haas Group International SP. Z.O.O.	<12 t/ y	Boeing Distribution Deutschland GmbH; Haas Group International SP. Z.O.O.	<2 t/ y		
	AfA	**Haas Group International SP. Z.O.O.;** Henkel Global Supply Chain B.V									
Slurry coatings	**RR**	**Haas Group International SP. Z.O.O.;** Boeing Distribution Deutschland GmbH; ChemService GmbH; Cromital S.P.A.	<3.5 t/ y								
Chromate rinsing after phosphating	**RR**	**Boeing Distribution Deutschland GmbH;** ChemService GmbH; Cromital S.P.A.	<0.6 t/ y*								
	AfA	**Haas Group International**									

		SP. Z.O.O.									
Inorganic finish stripping	**RR**	Boeing Distribution Deutschland GmbH; ChemService GmbH; Cromital S.P.A.	<50 t/ y*	**Brenntag Chemicals Distribution (Ireland) Ltd;** AD International BV	<1 t/ y						
	AfA	**Haas Group International SP. Z.O.O.;** Henkel Global Supply Chain B.V									
* Represents total tonnage of substance across all applicants for this use (i.e. AfA and RR combined)											

Annex II – Overview of initial applications (for RR only)

Application ID	Authorisation numbers	Substance	Applicants	Authorised use
text				

(Copy table 9-11 of RRs)

Annex III – Addressing authorisation decision obligations in RRs (for RR only)

Obligations in authorisation decisions	Review report
text	

(Copy table 9-12 of RRs)

Annex IV – xxx