Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Chromium trioxide

The use of Chromium trioxide-based functional chrome plating of components with diverse geometries and dimensions, requiring specialized equipment and process knowledge, for applications in demanding industry sectors such as mechanical engineering, metalworking and processing, aerospace, automotive, and medical technology.

Submitting applicant

Betz-Chrom GmbH

ECHA/RAC/SEAC: AFA-O-0000006970-69-01/F

Consolidated version

Date: 02/02/2022

Consolidated version of the Opinion of the Committee for Risk Assessment and Opinion of the Committee for Socio-economic Analysis on an Application for Authorisation

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 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 application for authorisation:

Applicant[1]	**Betz-Chrom GmbH** (position in supply chain: downstream)
Role of the applicant in the supply chain	Upstream ☐[group of] manufacturer[s] ☐[group of] importer[s] ☐[group of] only representative[s] ☐[group of] formulator[s] Downstream ☒ downstream user
Use performed by	☒ Applicant ☐Downstream user(s) of the applicant
Substance ID EC No CAS No	**Chromium trioxide** 215-607-8 1333-82-0
Intrinsic properties referred to in Annex XIV	☒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	**Chromium trioxide-based functional chrome plating of components with diverse geometries and dimensions, requiring**

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

	specialized equipment and process knowledge, for applications in demanding industry sectors such as mechanical engineering, metalworking and processing, aerospace, automotive, and medical technology.
	Other connected uses: CTAC (0032-03)
	Similar uses applied for:
Number and location of sites covered	Two sites – Gräfelfing and Maisach. AfA applies to Gräfelfing (DE). Industrial use.
Annual tonnage of the Annex XIV substance used total for all sites	10 to 30 tonnes CrO_3/year
Function(s) of the Annex XIV substance	Technical Function: Chromium trioxide is used in functional chrome plating by depositing a layer on a surface, usually a metal, via electrodeposition. The result is a metallic chrome coating which provides a range of desired properties to the finished article (e.g. hardness, wear resistance, corrosion resistance, microcracking for tribologically advantageous properties such as dry-running, sliding and anti-adhesion). These key functionalities constitute important traits that help to ensure the safety and correct functioning of components and machines used ultimately extending their service life.
Type of products (e.g. articles or mixtures) made with the Annex XIV substance and their market sectors	Components with diverse geometries and dimensions, requiring specialized equipment and process knowledge, for application in industry sectors such as mechanical engineering, metalworking and processing, aerospace, automotive and medical technology.
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 applicant (length)	14 years
Use ID (ECHA website)	0233-01
Reference number	11-2120880121-64-0001

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	15/02/2021
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	29/04/2021
Was the application submitted by the Latest Application Date for the substance and can the applicant consequently benefit from the transitional arrangements described in Article 58(1)(c)(ii)?	☐Yes ☒No
Date of consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	19/05/2021-14/07/2021
Were comments received in the consultation?	☒Yes ☐No https://echa.europa.eu/applications-for-authorisation-consultation/-/substance-rev/28004/term
Request for additional information in accordance with Article 64(3)	On 12/05/2021; 22/06/2021; 25/08/2021; 29/09/2021 Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/62903/del/200/col/synonymDynamicField_1512/type/asc/pre/2/view
Trialogue meeting	Not held – no need for additional information/discussion on any technical or scientific issues related to the application from the rapporteurs
Was the time limit set in Article 64(1) for the sending of the draft opinions to the applicant extended?	☐Yes, by Reason: ☒No

Did the application include all the necessary information specified in Article 62 that is relevant to the Committees' remit?	☒Yes ☐No
Date of agreement of the draft opinion in accordance with Article 64(4)(a) and (b)	RAC: 26/11/2021 agreed by consensus
	SEAC: 08/12/2021, agreed by consensus
Date of sending of the draft opinions to the applicant	01/02/2022
Date of decision of the applicant not to comment on the draft opinions, in accordance with Article 64(5)	02/02/2022
Date of receipt of comments in accordance with Article 64(5)	Not relevant
Date of adoption of the opinion in accordance with Article 64(5)	RAC: 02/02/2022, adopted by consensus
	SEAC: 02/02/2022, adopted by consensus
Minority positions	RAC: No minority positions
	SEAC: No minority positions
RAC Rapporteur RAC Co-rapporteur	Elena R.CHIURTU Pietro PARIS
SEAC Rapporteur SEAC Co-rapporteur	Jean-Marc BRIGNON Nikolinka SHAKHRAMANYAN
ECHA Secretariat	Jukka PELTOLA Fesil MUSHTAQ Petteri MÄKELÄ Ilze LEGZDIŅA

LIST OF ACRONYMS

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
EHLA	Extreme High-speed Laser Material Deposition
ES	Exposure scenario
ECS	Environmental contributing scenario
LAD	Latest application date
LEV	Local exhaust ventilation
OC	Operational condition
PBT	Persistent, bioaccumulative and toxic
PNEC	Predicted no-effect concentration
PPE	Personal protective equipment
PVD	Physical Vapor Deposition
RAC	Committee for Risk Assessment
REACH	European Union regulation on registration, evaluation, authorisation and restriction of chemicals
RMM	Risk management measure
RP	Review period
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

This document provides the opinions of the Committees for Risk Assessment and for Socio-economic Analysis based on their scientific assessment of the application for authorisation. 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,
- the assessment of the hazards and risks related to the alternatives as documented in the application taking into account the information submitted by interested third parties, as well as
- other available information.

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

SEAC concluded that there are no technically and/or economically feasible alternatives available for the applicant with the same function and similar level of performance by the date of adoption of this opinion. Therefore, RAC did not evaluate the potential risk of alternatives. RAC concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion.

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 and on 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 maximum combined exposure of workers and the general population to the substance is estimated to be, as 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 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 application, information submitted by interested third parties, as well as other available information. SEAC's evaluation is based on relevant guidance, which comprises Commission's Better Regulation guidance, the Guidance documents on applications for authorisation and the 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 applicant and in the EU. These are described in section 4. The applicant short-listed the following alternatives: Trivalent chrome and nickel electroplating, High velocity oxygen fuel spray (HVOF), Electroless nickel dispersion deposition, and BALITHERMTM PPD.

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 no information available in the application for authorisation 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.
- The applicant submitted a substitution plan. The substitution plan is not credible for the review period requested but consistent with the analysis of alternatives and the socio-economic analysis.

SEAC has assessed the information provided by the applicant and third parties from a scientific perspective, using standard methodology, and following relevant guidance. Based on the elements listed below, 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.

The expected societal costs of not granting an authorisation, which are estimated to be €0.8-1.8 million per year, consisting of foregone profits, closure costs and social cost of unemployment. Additional societal impacts of not granting an authorisation have been assessed qualitatively but have not been monetised and consist of potential impacts on downstream users of articles coated by the applicant.

The risks arising from granting an authorisation, which consider:

- the endpoints relevant for listing the substance in Annex XIV of REACH;
- the 27 directly exposed workers;
- the general population exposed at local scale and at regional scale approximately 10 000 persons;
- that the risk of continued use as assessed by RAC may result in approximately 0.055 additional statistical (fatal and non-fatal) lung and intestinal cancer cases for workers and for humans via the environment;
- the value of these expected additional cases has been monetised based on the willingness-to-pay methodology and the value corresponds to an
- approximately €0.009 to €0.015 million per year

Risks to human health and the environment 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 application for authorisation submitted by the applicant and any comments received in the consultation, a **12-year** review period is recommended for this use, i.e. until 15/02/2033.

JUSTIFICATIONS

0. Short description of use

The applicant, Betz-Chrom GmbH, is a medium-sized company that is applying for the use of chromium trioxide in the functional chrome plating of components spanning several industry sectors, including, for example, plastics, mechanical engineering, metalworking, hydraulics, textiles, automotive and printing, at the site located in Gräfelfing, Germany.

The annual consumption is 10-30 tonnes of CT per year. 220 working days per year are considered by the applicant.

In general, the electroplating process of substrates is performed in a multistep process by dipping the substrates in successive plating baths containing an aqueous solution of the relevant treatment chemicals (wet-in-wet process). For some substrates, only the main process requires chromium trioxide, while for other substrates, the pre-treatment also requires chromium trioxide for surface preparation by etching (which is carried out in the same bath).

The final surface coating does not contain hexavalent chromium.

According to the applicant, the exposure assessment aims to provide estimates of the workplace exposure level at the applicant's facility for the use of chromium trioxide as a surface treatment for different types of substrates.

There are no consumer, professional downstream user or article service life exposure scenarios relevant to the use applied for.

The applicant is an industrial downstream user of the substance; the use applied for is currently covered by the Use 2 application for authorisation for Chromium trioxide submitted by the CTAC Submission Consortium.

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

Betz-Chrom GmbH is a medium-sized plating company using chromium trioxide for the functional chrome plating of components spanning several industry sectors, including, for example, plastics production, mechanical engineering, metalworking, hydraulics, textiles, automotive and printing. In these applications, where machines and their parts are used under highly demanding conditions (e.g. high temperature, constant friction and impact, exposure to acids, etc.), the deposited chrome layer acts as a barrier against corrosion and increases the components' resistance to wear, extending their lifetime and ensuring their correct and safe functioning. Furthermore, Betz-Chrom provides services for the refurbishment of worn-down components, consisting of the reapplication of chrome coating on the component's surface to extend its overall service life.

Functional hard chrome plating offers various advantages in terms of the plating process, including good bath stability, possibility to remove worn-down coating and reapply a new one, variable layer thickness and the possibility to offer different surface finishes. The result of the functional chrome plating process is a metallic chrome coating which provides a range of desired properties to the finished article (e.g. hardness, wear resistance, corrosion resistance, microcracking for tribologically advantageous properties such as dry-running, sliding and anti-adhesion). These key functionalities constitute important traits that help to ensure the safety and correct functioning of components and machines used in several industry sectors, ultimately extending their service life.

Figure 1: Overview of Betz-Chrom functional chrome plating process

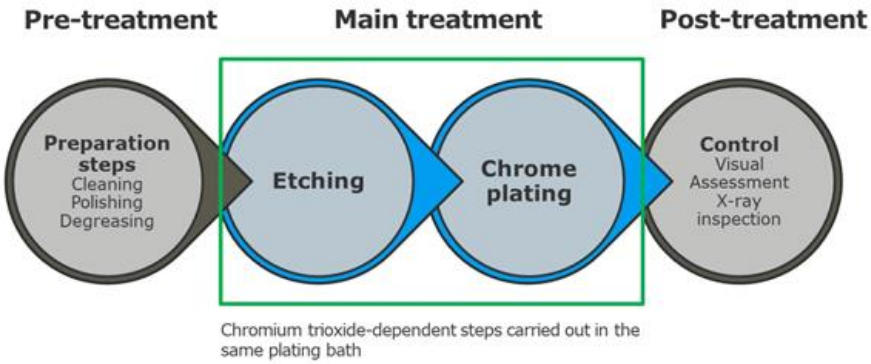

Table 1: Contributing scenarios presented in the use

Contributing scenario	ERC/PROC	Name of the contributing scenario	Size of the exposed population
ECS1	ERC 6b	Chromium trioxide-based functional chrome plating of components with divers geometries and dimensions, requiring specialized equipment and process knowledge, for application in demanding industry sectors such as mechanical engineering, metalworking and processing, aerospace, automotive and medical technology	Regional: 20 million inhabitants (default values according ECHA guidance). Not relevant[2] Local: 10 000 (default values according ECHA guidance)
WCS 1	PROC 1	Delivery and storage of raw material	No of workers: max. 2
WCS 2	PROC 13	Manual plating process	No of workers: max. 23
WCS 3	PROC 8b	Sampling	No of workers: max. 1
WCS 4	PROC 8b	Concentration adjustment in baths with solid CrO_3	No of workers: max. 2
WCS 5	PROC 28	Maintenance and cleaning of equipment performed by surface treatment staff Sub-scenario 1 Weekly maintenance including cleaning of anodes Sub-scenario 2 Less frequent maintenance activities – emptying and refilling of chrome baths	No of workers: max. 3
WCS 6	PROC 28	Maintenance and repair performed by maintenance staff Sub-scenario 1 Unscheduled maintenance activities involving	No of workers: max. 3

[2] EU risk assessment report (RAR) for Cr(VI) substances (20), pg. 26 for Cr(VI) substances (20), "releases of Cr(VI) from any sources are expected to be reduced to Cr(III) in most situations in the environment (…)" and "the impact of Cr(VI) as such is therefore likely to be limited to the area around the source."

		maintenance staff Sub-scenario 2 Scheduled maintenance activities involving maintenance staff	
WCS 7	PROC 8b	Waste and wastewater management	No of workers: max. 1
Total no of potentially directly exposed workers			27

WCS 1 Delivery and storage of raw material (PROC 1)

Solid chromium trioxide, as flakes is delivered in 50 kg sealed steel drums, visually checked for damage and tightness upon delivery, and stored in a designated storage facility clearly labelled and fenced. The access to the storage area is restricted via a key to authorized and trained personnel. The sealed drums are transferred from the storage to the plating area. There is no potential exposure for workers to Cr(VI) during normal operating conditions.

A maximum of two workers per shift are involved in this activity.

WCS 2 Manual plating process (PROC 13)

Five plating areas are present at the site in the production area, consisting of:

- small parts production,
- serial baths,
- deep baths,
- aviation parts production, and
- wall-facing baths.

They are used for the functional chrome plating of different sized parts (diameters/lengths between a few centimetres and several meters).
A switch-on protocol is in place at the beginning of each week, including walks through the halls, visual tightness and temperature checks.
Prior to the chrome plating process, manual mounting and assembly of the parts is performed, and articles or parts are partially masked.
The parts are manually loaded and unloaded from the jigs, before and after treatment. They are then moved to the open (wall-facing) plating baths or one of the semi-closed plating baths (with lids, all containing CrO_3 in concentrations between 250 to 300 g/L) using a hoist. No direct exposure to Cr(VI) is expected during this step, but there is potential for indirect exposure from plating lines in the same workspace (1-5 m distance between the loading and unloading station and the chromium baths).
Local exhaust ventilation is in place above the open/semi-closed baths (with lids).
Mist suppressants are used, except for the aviation bath (due to specific regulations in the aerospace sector).
Lids are used for all baths during the plating process except for the wall-facing baths.
After chrome plating, the treated parts are lifted with a hoist, manually rinsed by using a hose with a spray head, then de-masked and unloaded.
One worker per shift supervises all the plating lines, controlling the process by performing walk throughs and level monitoring. A maximum of 23 workers (max. 10 workers in the early shift) are involved in this activity (mounting on the jigs, partially masking, unmounting etc. across the 5 plating areas).

WCS 3 Sampling (PROC 8b)

Manual sampling of the CrO_3 solution is performed once per week, using a glass beaker, one for each of the baths. The beaker is dipped into the bath, then rinsed with water from outside, put in the carrier, and transported to the applicant's laboratory for analysis.
A maximum of one worker (from the plating line area/maintenance facility) is involved in this activity.

WCS 4 Concentration adjustment in baths with solid CrO_3 (PROC 8b)

The concentration adjustment of baths is manually performed with CrO_3 flakes once per week on Saturday morning (during the last shift) by the shift supervisor.
The worker opens the drum and adds the required amount of CrO_3 flakes of a respective number of containers directly to the process bath. No manual measuring cup is used. Empty drums are rinsed with low water pressure to remove chromium trioxide, the rinsing water is subsequently added to the electrolyte. LEV is in place during the activity.
A maximum of two workers (one worker from the plating line area and one worker to deliver the CrO_3 containers) are involved in this activity.

WCS 5 Maintenance and cleaning of equipment performed by workers from the surface treatment team (PROC 28)

Sub-scenario 1 Weekly maintenance including cleaning of anodes
The regular weekly maintenance activity consists of the inspection of anodes, including regular arrangement, cleaning of yellowish or encrusted anodes, aligning, and change of anodes (quarterly).
The activities are performed for a maximum of 1 hour during the final shift of the week, by the responsible workers from the plating lines area (not maintenance staff), according to the documented maintenance plans. Even though for some of the tasks RPE (half mask with P3 filter) is required, the applicant assumed as a worst case for modelling that RPE is not used for this sub-scenario.

Sub-scenario 2 Less frequent maintenance activities – emptying and refilling of chrome baths
The activity consists of emptying the baths by transferring the chromium solution into an empty container using a hose, followed by manual removing of the chromium sludge. The hose is checked for leaks and is not left unattended. The chromium sludge is disposed of as hazardous waste via an external licensed company.
The activities are performed once per year on seven different days, by a worker using RPE (full-face mask with P3 filter and air supply, APF 1 000). A second worker is supervising the emptying and cleaning of the baths.
LEV is in place during the maintenance activities.

A maximum of three workers are involved in these activities.

WCS 6 Maintenance and repair performed by maintenance staff (PROC 28)

Sub-scenario 1 Unscheduled maintenance activities involving maintenance staff
The activity consists of repairs in case of malfunction or defective components (duration up to 6 hours depending on the extent of the repair, 10 working days per year assumed as a worst case).
The activity is performed by trained and authorized personnel (locksmiths or electricians), under supervision and wearing adequate PPE.

According to the applicant, for example, the plate change on the heat exchanger can be repaired by a single maintenance worker or up to 3 maintenance workers (simultaneously), depending on the type.

Sub-scenario 2 Scheduled maintenance activities involving maintenance staff
Scheduled maintenance (e.g. cleaning of the baths, as described in WCS 5) is supervised by a maintenance employee outside of the bath (mainly operation of the crane).

A maximum of three maintenance workers are involved in this activity.

WCS 7 Waste and wastewater management

Process wastes (waste from cleaning activities, for example sludge) containing low amounts of Cr(VI) are stored in closed containers and collected by licensed companies for treatment, incineration and disposal of incineration residues at licensed landfills.
An internal sampling (0.5 L sample) is performed for every batch at the wastewater treatment unit (duration maximum 5 minutes, frequency twice per week). In case of elevated chrome values, 4-5 kg of lime in water are added, and the sampling is repeated. Applicant claims releases are very small/negligible, while the site is permitted to release 0.1 mg/L Cr(VI) content in wastewater.

A maximum of one worker from the maintenance staff is involved in this activity.

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

Chromium trioxide is used for functional chrome plating of a layer deposited on a surface, usually a metal, via electrodeposition. The process uses an electric current to reduce dissolved Cr cations from an electrolyte to form a metallic chrome layer on the surface of the part to be coated.

The result of the functional chrome plating process is a metallic chrome coating which provides a range of desired properties to the finished article (e.g. hardness, wear resistance, corrosion resistance, microcracking for tribologically advantageous properties such as dry-running, sliding and anti-adhesion). These key functionalities constitute important traits that help to ensure the safety and correct functioning of components and machines used in several industry sectors, ultimately extending their service life.

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

Betz-Chrom performs plating of components with complex geometries and dimensions for applications in a very broad spectrum of industry sectors (e.g. piston rods for hydraulic systems, rollers for textile machines etc.). These applications include, for example, plastics production, metal processing, aviation, hydraulic systems, machinery, textiles, automotive and the printing sectors. In these applications, where machines and their parts are used under highly demanding conditions (e.g. high temperature, constant friction and impact, exposure to acids, etc.), the deposited chrome layer acts as a barrier against corrosion and increases the components' resistance to wear, extending their lifetime and ensuring their correct and

safe functioning. Furthermore, Betz-Chrom provides services for the refurbishment of worn-down components, consisting of the reapplication of chrome coating on component's surface to extend its overall service life.

1. Operational Conditions and Risk Management Measures

The overall operational conditions are as follows:

- Annual use amount at the sites: 10-30 tonnes chromium trioxide/year.
- Number of days of release per year: 220
- Concentration used: < 52 % of Cr(VI) in mixture.
- Physical form of the substance: solid at 20 °C.
- Daily release: water- Local release rate: 0.000172 kg/day;
  air- Local release rate: 0.029 kg/day;
  soil- Local release rate: 0 kg/day.
- Process temperature: 50-60 °C.
- Vapor pressure of substance: < 0.01 Pa.

1.1. Workers

The operational conditions (OCs) and risk management measures (RMMs) implemented in each WCS, with their effectiveness as described by the applicant, are summarised in Table 2. In addition, the following RMMs are implemented:

-Technical Risk Management Measures:

- Local exhaust ventilation (LEV) located in close proximity of and directed at the sources of emission, mist suppressants in the chromium baths during treatment (except for the aviation bath due to specific regulations in the aerospace sector) and lids that cover the baths (except for the wall-facing baths) are technical means to minimize concentrations of Cr(VI) and other components of treatment solutions in the workplace air.
- Local exhaust ventilation (LEV) functioning is automatically controlled. There are two independent LEV units in place, to continue functioning in case of one failing.
- General ventilation covers the production hall (4.7 ACH calculated, 3 ACH used for modelling as conservative approach).
- Access to the chrome plating lines and the chromium trioxide storage area restricted to authorised personnel and controlled via safety locks.
- Maintenance, examination and testing of the LEV systems performed according to the German legislation. Employees are required to use the LEV provided (which is automatically controlled) and to report any defects observed. Supervisors are required to keep a record of regular checks on the LEV systems; flow monitors are checked every new week.

-Organisational Risk Management Measures:

- Standard Operating Procedures (SOPs) in place.
- Selection of Personal Protective Equipment (PPE) performed according to the permeation performance and application range.
- Maintenance of Personal Protective Equipment (PPE) regularly performed and documented.

- Workers regularly trained (at least once per year and in case of amendments) on chemical risk management, including handling of chromium trioxide and on proper and safe use of the PPE; the compliance with the regulations is checked by the supervisors.
- Workplace exposure and air emission measurement programmes in place (internal and external).
- Regular housekeeping and management systems are in place.
- Good standard of personal hygiene implemented.

An Occupational Health and Safety Management System is in place, which includes:

- Requirement to ensure that only workers essential for repairs shall be permitted to work in the affected area, and only with appropriate protection. The exposure may not be permanent and shall be minimised.
- Requirement to ensure if a temporary, planned, higher exposure is unavoidable (e.g. maintenance), the employer shall consult workers/representatives on the measures to minimise exposure, and provide appropriate prevention, together with access control.
- Provision of appropriate hygienic conditions for workers:
    - Prohibition of eating/drinking/smoking in contamination risk areas;
    - Appropriate protective clothing;
    - Separate storage places for working/protective clothing and for street clothes;
    - Appropriate and adequate washing and toilet facilities;
    - Cleaned, checked and maintained protective equipment, stored in a well-defined place.
- Provision of appropriate training on potential risks to health, precautions to prevent exposure, hygiene requirements, protective equipment, clothing and incidents.
- Requirement to inform on objects containing carcinogens or mutagens, and label them clearly and legibly, together with warning and hazard signs.
- Requirement to inform workers and/or representatives on abnormal exposures as quickly as possible.

Personal Protective Equipment (PPE)

The workers wear mandatory PPE, according to their activities (see Table 2 below). They are regularly trained in the safe use of the PPE, including the check of the equipment before and after each use.
The wearing times for the Respiratory Protective Equipment (RPE) are determined based on recommendations published by HSE[3] and DGUV[4], and on the results of the workplace/task specific risk assessments and limited by company specific guidelines, as appropriate. The results of the company specific risk assessments are documented, regularly reviewed and updated, according to the legislation and national recommendations.

On RAC's request for additional information, the applicant explained that the use of Respiratory Protective Equipment (RPE) is not mandatory for the tasks described in WCS 2 "plating (manual)", WCS 3 "sampling" (manual), WCS 5 sub-scenario 1 "weekly maintenance by surface treatment staff", WCS 6 "maintenance & cleaning involving maintenance staff", considering that the aqueous solutions of chromium trioxide are expected to have a low

[3]British Control of Substances Hazardous to Health regulation (COSHH). http://www.hse.gov.uk/pUbns/priced/hsg53.pdf
[4] German BG rule "BGR/GUV-R190". http://publikationen.dguv.de/dguv/pdf/10002/r-190.pdf.

potential for generating mists, and the activities are performed in the capture area of the exhaust ventilation system. The applicant also mentioned that, in many cases, the use of RPE is recommended to the workers, but it is assumed as a worst-case that the activities are performed without RPE.

The applicant confirmed that the use of RPE is mandatory for the activities involving the handling of chromium sludge (WCS 4 "concentration adjustment", WCS 5 sub-scenario 2 "less frequent maintenance activities – emptying and refilling of chrome baths").

In addition, the applicant mentioned in the CSR that mandatory preventive and follow-up occupational medical examinations for all employees with potential exposure to hexavalent chromium are conducted at the site every 6-24 months, according to German regulations (BG rule G15).

The biomonitoring of chromium is performed two times per year and include total Cr in urine and blood, and, in addition, blood parameters since the end of 2018 (such as C-reactive protein and Immunoglobulin E) for workers of the plating line area. The results are confidential, but the occupational safety specialist is informed on the anonymised biomonitoring results. Additional training on occupational hygiene and examinations are conducted in case of exceeding of the guidance values and follow-up measurements are scheduled, and the manager is also informed.

Table 2: Operational Conditions and Risk Management Measures (sub-set of Succinct Summary of RMMs and OCs)

Contributing scenario	**Concentration of the substance (Cr(VI))**	**Duration and frequency of exposure**	**Engineering controls** (e.g. containment, segregation, automation, LEV) **+ effectiveness as stated by the applicant**	**PPE** (RPE and Skin protection used) **+ effectiveness as stated by the applicant**	**Organisational controls** (access control, procedures, training)
WCS 1 Delivery and storage of raw material PROC 1	< 52 %	Duration: 2 hours Frequency: 3-4 times/year	- Containment: Closed system (minimal contact during routine operations)	- safety gloves (leather), chemical protective clothing, safety shoes	- raw material delivered in sealed 50 kg drums - designated locked storage area, clearly labelled and fenced - access restricted to authorised, trained personnel only - safety training -specific hygiene instructions
WCS 2 Manual plating process PROC 13	250-300 g/L	Duration: < 8 h Frequency: daily	- manual process, partial-open baths, - lids, except for the wall-facing baths - general ventilation: 3 ACH* - LEV and wetting agents in place (mist suppressants, except for the aviation bath)	-safety goggles, safety gloves, chemical protective clothing, safety shoes	- access restricted to authorised, trained personnel only - safety training -specific hygiene instructions
WCS 3 Sampling PROC 8b	substantial	Duration: < 5 min. Frequency: 1 time/week	- manual open process, - general ventilation: 3 ACH* - LEV (fixed capturing hood, effectiveness 90 %**)	-safety goggles, safety gloves, chemical protective clothing, safety shoes	- same as in WCS 2
WCS 4 Concentration adjustment in baths with	< 52 %	Duration: < 30 min. Frequency:	- manual open process - general ventilation:	-half mask with P3 filter (APF 30***,	- same as in WCS 2

solid CrO_3 PROC 8b		1 time/week	3 ACH* - LEV (fixed capturing hood, effectiveness 90 %**)	effectiveness 96.6 %), safety goggles, safety gloves, chemical protective clothing, safety shoes	
WCS 5 Maintenance and cleaning of equipment performed by surface treatment staff	substantial				- same as in WCS 2
<u>Sub-scenario 1</u> Weekly maintenance including cleaning of anodes PROC 28		Duration: < 1 h Frequency: 1 time/week	- manual open process - general ventilation: 3 ACH* - LEV (fixed capturing hood, effectiveness 90 %**)	-safety goggles, safety gloves, chemical protective clothing, safety shoes	
<u>Sub-scenario 2</u> Less frequent maintenance activities – emptying and refilling of chrome baths PROC 28		Duration: < 8 h Frequency: 7 times/year	- manual open process - general ventilation: 3 ACH* - LEV (fixed capturing hood, effectiveness 90 %**)	- RPE (full-face mask with P3 filter and air supply, APF 1 000***, effectiveness 99.9 %), chemical protective clothing	
WCS 6 Maintenance and cleaning of equipment performed by maintenance staff	substantial				- same as in WCS 2
<u>Sub-scenario 1</u> Unscheduled maintenance activities involving maintenance staff PROC 28		Duration: < 6 h Frequency: 10 times/year	- manual open process - general ventilation: 3 ACH* - LEV (fixed capturing hood, effectiveness 90 %**)	-safety goggles, safety gloves, chemical protective clothing, safety shoes	
<u>Sub-scenario 2</u> Scheduled maintenance activities involving maintenance staff PROC 28		Duration: < 8 h Frequency: 7 times/year	- manual open process - general ventilation: 3 ACH* - LEV (fixed capturing hood, effectiveness 90 %**)	-safety goggles, safety gloves, chemical protective clothing, safety shoes	
WCS 7 Waste and wastewater management	minute	Duration: < 5 min. Frequency:	- manual open process - general ventilation:	-safety goggles, safety gloves, chemical	- same as in WCS 2

PROC 8b		2 times/ week	3 ACH*	protective clothing, safety shoes	

** General ventilation: 3 ACH is assumed for modelling, as a conservative approach (the calculated value is 4.7 ACH, resulted from the extraction capacity of 31 974 m^3/h and the total volume of the production hall of 6 700 m^3)*

*** The 90 % reduction is a default value, estimated via modelling using ART 1.5 for this type of exhaust ventilation.*

**** According to German BG rule BGR/GUV-R190.*

1.2. Consumers

Not applicable.

1.3. Environment/Humans via the environment

Air

All workspaces with potential release to air are equipped with exhaust ventilation systems to remove residual particulates; the exhaust air is passed through wet scrubbers and/or downstream demister according to best available technique before being released to atmosphere.

In particular, a wet scrubber with a downstream demister is used for the deep baths. The exhausted air is guided through the wet scrubber (7 000 m^3/h), the harmful gases are dissolved in an electrolyte, water is withdrawn from this through evaporation, which leads to cooling. Entrained drops and residual moisture are filtered out in the following demister (according to the manufacturer: 99.9 % of all droplets larger than 8 µm are removed). The air is then released into the atmosphere through the chimney 1.
At the serial bath, the small parts production, the wall-facing baths and the aviation baths, the exhaust air is only transferred to a demister where it is transferred from the gaseous to the liquid phase and 99.9 % of all droplets larger than 15 µm are removed from the airstream. The cleaned air is then released into the atmosphere through the same chimney 1.
At the beginning of every week, the wet scrubber and demisters are rinsed, and the resulting water is recycled, by adding it to the chrome baths.

Betz-Chrom regularly monitors and reports Cr(VI) emissions as part of permit conditions.

Water

Chromium trioxide contained within the preparation and the water used to rinse out the equipment is collected and recycled or disposed of in specialist facilities. Reductive treatment of wastewater additionally ensures negligible release of Cr(VI) to water. Cr(VI) containing wastewater from the chrome plating baths is first pumped into a batch unit tank. The pH value and the redox potential are regulated to guarantee an optimal reduction from Cr(VI) to Cr(III) in the tank and the values are regularly monitored. After that, Cr(III) containing wastewater is pumped in the settling tank for sedimentation of Cr(III) and heavy metal containing sludge. Either the clear water phase or the sludge phase is pumped through a chamber filter press to get filtered clear water. Remaining condensed sludge pellets are collected and drained, then they are disposed of by an external service provider.

After the filter press, the filtered clear water is pumped through a gravel filter to remove remaining undissolved particles and a selective exchanger for removing heavy metals. Prior to discharging the water is analysed for Cr and the pH value. The competent authorities perform sampling of wastewater three times per year. External monitoring results are compared with values determined by Betz-Chrom in order to take action in case of any discrepancies. The wastewater treatment plant is regularly maintained.

Soil

Cr(VI) is neither directly nor indirectly released to soil due to adequate technical and organizational measures and therefore releases to soil are considered negligible.

Waste (other than wastewater)

Solid and liquid waste containing Cr(VI) is collected and treated as hazardous waste by a licenced contractor, according to EU and German regulations.

Table 3: Environmental RMMs – summary

Compartment	RMM	Stated effectiveness
Air	Wet scrubber/ downstream demister	99.9 % demister (deep bath) for droplets > 8 µm 99.9 % other two demisters > 15 µm
Water	On-site WWTP	N/A, according to the applicant, negligible release to wastewater
Soil	N/A	N/A

1.4. RAC's evaluation on the OCs and RMMs

The RMMs described in the CSR and in the responses to RAC's questions include mainly: LEV (fixed capturing hood), general mechanical ventilation, lids over the plating baths (except for the wall-facing baths), mist suppressants (except for the aviation bath), restricted access to working areas, and personal protective equipment (PPE) such as RPE (half mask with P3 filter and full-face mask with P3 filter and air supply for the tasks with high potential exposure to Cr(VI)), safety gloves and goggles, protective clothing and shoes, etc. Organisational measures (distance to the baths during the plating process, regularly training, supervising) are also included.

RAC notes that there are no measured data to estimate the LEV effectiveness. The applicant explained in the CSR that switching off the LEV during the process, will result in undesirable releases to the workplace atmosphere. The 90 % effectiveness is a default value (assigned by ART 1.5 for this type of exhaust ventilation).
The capacity of the general mechanical ventilation (4.7 ACH) was estimated based on the extraction capacity and the total volume of the production hall, but the applicant has used the default value of 3 ACH for modelling as a conservative approach.

With respect to the hierarchy of control principles, and the properties of the substance included in Annex XIV, the applicant was asked to provide a short description/comparison of the potential risks for workers regarding the use of solid flakes versus liquid chromium trioxide.
RAC notes that in response to these questions, the applicant has highlighted mainly the environmental risks during transportation, and possible accidents due to in house handling and storage of the concentrate liquid chromium trioxide solution (750 g/L Cr(VI)), such as burns, spillages.
The applicant has considered and explained in the responses to RAC's questions that the exposure risks to solid chromium trioxide can be properly controlled inside the facility, compared with the concentrated liquid chromium trioxide transportation risks. The applicant

also mentioned that there are no dosing pumps and automated lines in the plant to allow the switch to liquid chromium trioxide use, and an expansion of the chemical storage capacity is not possible due to limited space and storage restriction of the local authority. RAC notes that the applicant has investigated the technical feasibility (risk assessment and cost-benefit analysis for switching to liquid chromium trioxide), claiming that the limited space for the required additional equipment (automated dosing pumps and lines) makes the switch to liquid chromium trioxide use impractical (and very costly). In addition, the applicant has indicated that the monitoring performed in April 2021 shows a relatively low exposure during concentration adjustment with solid chromium trioxide (< 1 µg/m³, worker wearing RPE).

Regarding the use of mist suppressants in the chromium plating baths, the applicant explained in the response to RAC's question that currently a polyfluorinated mist suppressant is used, although it is PFOS-s free. The applicant is planning to test fluorine-free mist suppressants containing oleylamine ethoxylated. Due to the biodegradability of the oleylamine ethoxylate, the applicant has considered the possible effects/disadvantages of its use, such as:

- the considerable higher amount of the product to be used
- the presence of the degradation products in the baths
- the possible shortening of the lifetime of the lead anodes in the plating baths.

The applicant also mentioned that a best practice solution for the substitution of polyfluorinated mist suppressants in functional chrome plating was not yet identified (Willand et. al. (2020)[5]).

With respect to the ban on the use of the mist suppressants for the aviation bath, the applicant explained that due to the binding standards in the aerospace sector it is not possible to introduce changes in the composition of the hard chrome plating baths[6]. The aviation bath is located separate from the other baths and it is covered with a lid.

Regarding the RMMs to reduce workers' exposure, RAC has identified shortcomings due to the fact that RPE is not mandatory for tasks with potential exposure to Cr(VI), even if it is considered to be low by the applicant (e.g. "plating (manual)", "sampling" (manual), "weekly maintenance by surface treatment staff", "maintenance & cleaning involving maintenance staff"). The applicant explained in the responses to RAC's questions that the activities are performed in the capture area of the exhaust ventilation system, and, it is assumed as a worst-case that the activities are performed without RPE. In many cases in practise, RPE is recommended to the workers to further protect themselves but it is not mandatory.

The applicant also explained that breaking down the manual plating process into smaller tasks to allow the use of RPE will provide disruptions in the production flow and lead to a possible cross-contamination of the respiratory equipment (mask). The applicant mentioned that the wearing of the RPE for long time tasks, for example during the 'manual plating process' (WCS 2) will introduce an additional burden for the workers, as it is stated also in the German TRGS 910[7].

Measured data (personal and static sampling) are available to support the appropriateness of the OCs and RMMs for WCS 2 "manual plating process". For the other WCSs presented in the application, the applicant has presented qualitative and modelled assessment (see section 2.1 below).

[5] https://www.umweltbundesamt.de/sites/default/files/medien/5750/publikationen/2020_11_17_texte_211_2020_bvt_susbtitutions-pfos.pdf
[6] LN 29 748 LAT 4-3200
[7] https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/TRGS-910.html

Regarding releases to the environment and human exposure via the environment, the Applicant provided in the CSR, and in the information subsequently provided an exhaustive and detailed description of the OCs and RMMs implemented to minimize the releases and the exposure of the HvE. RMMs include both the treatment of releases into the air and the management of liquid waste.
Before being released into the environment, the wastewater is analysed to check the chromium concentration and the pH value.
Concentrations of Cr measured in wastewater are typically lower than the limit of quantification and at least one order of magnitude below the limit allowed in the permit conditions. Air emissions are measured by an accredited and certified external institute every three years. RAC noted that the frequency of air emission measurements appears not adequate to intercept potential fluctuations. The applicant explained that although the emission control is in line with the requirements of the environmental permit for the operating of the plating lines, it is intended to take place annually in the future.

Solid and liquid waste containing Cr(VI) is collected and treated as hazardous waste by a licenced contractor, according to EU and German regulations.

RAC considers that the OCs and RMMs implemented are appropriate to reduce releases to the environment and exposure of the HvE resulting from their use of chromium trioxide.

Even though some shortcomings (lack of lids for wall-facing baths, lack of mist suppressant on the aviation bath) have been identified, they were explained and clarified by the applicant in their responses to RAC's questions and RAC considers that the RMMs implemented follow the hierarchy of control principles and is of the opinion that overall RMMs and OCs implemented as proposed in the application are appropriate and effective in limiting the risk for workers in the production's steps and humans via the environment compartment, provided that they are adhered to.

Furthermore, RAC takes note of the continuous effort of the applicant to improve the OCs and RMMs aimed at minimizing exposure to Cr(VI). The applicant is currently involved in the research project LEGOLAS[8], which aims to use a combination of blow-off and suction devices in the working hall to remove the contaminated vapours. A special lid for the small-parts bath was designed within this project and it can now be used as a prototype for other lids in the plating area.

1.5. RAC's conclusions on the OCs and RMMs

Overall conclusion

Are the operational conditions and risk management measures appropriate[9] and effective[10] in limiting the risks?

[8] https://www.faps.fau.de/neuigkeit/bundesministerium-fuer-bildung-und-forschung-foerdert-forschungsprojektlegolas/

[9] '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.

[10] 'Effectiveness' – evaluation of the degree to which the OCs and RMM are successful in producing the desired effect – exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

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

RAC considers that the risk management measures and operational conditions as proposed in the application are appropriate and effective in limiting the risk to workers, humans via the environment and the general population
RAC considers that, taking into account the open and manual nature of the plating lines, the applicant should continue their efforts to minimize the workers' exposure to Cr(VI) by implementing state of the art RMMs as a result of research projects, therefore an additional condition for the authorisation was proposed in Section 7.

In addition, RAC recommends to the applicant to select the type of the respiratory protective equipment (RPE) to be used also for the tasks with potential exposure to Cr(VI) (e.g. "plating (manual)", "sampling" (manual), "weekly maintenance by surface treatment staff", "maintenance & cleaning involving maintenance staff"), considering the comfort of the workers during the use.

There is no consumers exposure scenario relevant to the use applied for.

2. Exposure assessment

For the inhalation exposure assessment, the applicant used a combination of qualitative assessment, measured data and modelling using the Advanced REACH Tool 1.5 (ART, version 1.5).

Qualitative assessment was presented for WCS 1 "delivery and storage of raw material", as there is no potential for exposure due to closed system with minimal contact for workers. The qualitatively exposure estimate of 0 µg Cr(VI)/m³ was used for risk characterisation.

2.1. Inhalation exposure

Monitoring

For WCS 2 "manual plating process", personal and static worker's exposure measurements were performed during three measurement campaigns in 2017, 2019 and 2020. The measurements were undertaken for specific tasks including loading and unloading of the parts and plating supervision, and also for locations near or between the plating baths. A layout map of the production hall, including the sampling points is presented by the applicant as confidential, but available for RAC.

The sampling durations varies between 120 and 134 minutes for all 6 personal and 9 static measurements. The limit of quantification for the analytical method used to measure the

concentration of Cr(VI) in the workplace atmosphere (IFA 6665, 2014)[11] is 0.32 µg/sample or 0.27 µg/m^3 (for an air volume of 1.2 m^3), values presented for 2020.

The measured data are expressed as 8 h TWA Cr(VI) concentration and are presented in Annex 2 of the CSR.

The maximum measured value of 0.99 µg Cr(VI)/m^3 was registered in 2020, during a static sampling between the wall-facing baths 4 and 5.

A 90th percentile value of 0.60 µg Cr(VI)/m^3 was considered by the applicant for the risk characterisation.

No personal or static measurements are currently available for WCSs 3-7.

The applicant has clarified in a response to RAC's question that short or rare tasks were not performed in previous monitoring programmes, but specific tasks such as sampling and maintenance activities are included in a new elaborated monitoring programme. In addition, three internal exposure measurements campaigns per year are performed by the applicant.

Measurements according the new programme were performed in April 2021 and the results will be reported as required in the EC decision for the current CTAC authorisation.

Modelling

The applicant provided modelled data using ART 1.5 for WCSs 3-7.

The modelled exposure estimated using ART 1.5 (90th percentile values of the data) as a second tier model are expressed as 8h TWA Cr(VI) concentration. The input data is provided in the CSR. The applicant was assuming a conservative approach, as taking worst case values for the input parameters. The estimated values were adjusted for frequency (WCSs 3-7) and for the use of RPE (WCS 4 "concentration adjustment with solid CrO_3 and WCS 5 sub-scenario 2 "less frequent maintenance activities – emptying and refilling of chrome baths").

The results of the inhalation exposure assessment are presented in Table 4. Figures in bold are considered for risk characterisation.

2.2. Dermal exposure

Dermal exposure has not been assessed as exposure to Cr(VI) compounds through the skin is not expected to present a cancer risk to humans (RAC27/2013/06 Rev 1).

2.3. Biomonitoring

Biomonitoring is conducted two times per year, as part of the medical examination according to German regulation (BG rule G15). The examinations include total Cr in urine and blood, and, in addition, blood parameters since the end of 2018 (such as C-reactive protein and Immunoglobulin E) for workers of the plating line area. The results are confidential, but the occupational safety specialist is informed on the anonymised biomonitoring results.

An overview of the measured values for total chromium in urine and blood in 2015-2019 and 2019-2021 was presented by the applicant in Annex 1 of the confidential

[11] https://www.ifa-arbeitsmappedigital.de/IFA-AM_6665

CSR.

The background values for chromium corresponds to 0.6 µg/L in urine and 1 µg/L in blood according to TRGS 561[12]. Exposure equivalent for carcinogenic substances (EKA[13] values) for chromium is 12 µg/L in urine and 9 µg/L in blood.

Values above 12 µg/L for chromium in urine were registered in 2016 (> 25 µg/L) and 2018 and in blood (>9µg/L) in 2015.

The applicant did not provide contextual information on the biomonitoring data since the biomonitoring and exposure measurements were not performed on the same time and person, and the chromium biomonitoring does not differentiate between exposure to Cr(VI) or other form of chromium.

Biomonitoring data were not used by the applicant to estimate or support the exposure assessment.

Table 4: Summary of exposure information – inhalation

Contributing scenario	Route of exposure	Method of assessment	Exposure value (8h TWA) (µg Cr(VI)/m³)	Exposure value corrected for PPE (µg Cr(VI)/m³)	Exposure value corrected for PPE and frequency (µg Cr(VI)/m³)
WCS 1 Delivery& storage	Inhalation	Qualitative	0	-	0
WCS 2 Manual plating process	Inhalation	Measured data (n = 6 personal and n = 9 static) 90th percentile	0.60	-	**0.60**
WCS 3 Sampling	Inhalation	Modelled data 90th percentile	0.008	-	**0.0016** (frequency factor 0.2[a])
WCS 4 Concentration adjustment with solid CrO_3	Inhalation	Modelled data 90th percentile	1.60	0.053 (RPE factor 0.033[b])	**0.01** (frequency factor 0.2[a])
WCS 5 Maintenance& Cleaning by surface treatment team	Inhalation	Sub-scenario 1 Modelled data 90th percentile	0.096	-	0.02 (frequency factor 0.2[a])
		Sub-scenario 2 Modelled data 90th percentile	0.77	0.00077 (RPE factor 0.001[c])	2.3×10^{-5} (frequency factor 0.03[d])
		Total			**0.02**
WCS 6 Maintenance& Repair by maintenance staff	Inhalation	Sub-scenario 1 Modelled data 90th percentile	0.17	-	0.0085 (frequency factor 0.05[e])
		Sub-scenario 2 Modelled data 90th percentile	0.023	-	0.0007 (frequency factor 0.03[d])

[12] https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/pdf/TRGS-561.pdf
[13] Expositionsäquivalente für krebserzeugende Arbeitsstoffe", EKA: exposure equivalents for carcinogenic substances

		Total			**0.009**
WCS 7 Waste& wastewater management	Inhalation	Modelled data 90th percentile	9.0×10^{-4}	-	**3.6×10^{-4}** (frequency factor 0.4[e])

Notes:

a. frequency factor 1 day/5 days = 0.2
b. respiratory protective equipment factor (effectiveness 96.6 %)= 0.033
c. respiratory protective equipment factor (effectiveness 99.90 %)= 0.001
d. frequency factor 7 days/220 days = 0.03
e. frequency factor 2 days/5 days = 0.4.

Combined exposure:

According to the applicant, workers in the functional chrome plating process can perform combined site-specific tasks. The highest combined exposure, expressed as 8h TWA values, corrected for PPE and frequency, and estimated as a worst case can occur from the combination of WCS 2 + WCS 3 + WCS 4 + WCS 5.

The maximum combined exposure estimated by the applicant is **0.63 µg Cr(VI)/m³**.

2.4. Environmental releases

The environmental releases of Cr(VI) occur in the atmosphere (wet scrubber and/or demister) and water (from onsite wastewater treatment plant) and are carefully controlled by Betz-Chrom and monitored by regulators. The applicant measured the local concentration of Cr(VI) in the air and wastewater during 2019 that are used for a quantitative assessment of the environmental releases.

The exposure of humans via the environment takes into account the inhalation of airborne residues of chromium trioxide and the oral route through the ingestion of contaminated food and drinking water. On a local scale, the exposure concentration for the inhalation route of HvE is correctly assumed equal to the PEC air, while on a regional scale the applicant includes the contribution of different food sources as well as drinking water when assessing the exposure through the oral route. To this end, the EUSES 2.1.2 modelling has been used.

The data presented by the applicant for each compartment is summarised below.

Air

Air emissions are passed through a wet scrubber and/or demister to separate Cr(VI) containing liquid from the exhaust air prior to release to atmosphere according to best available technique.

Betz-Chrom regularly monitors Cr(VI) emissions as part of permit conditions. Air emissions are measured by an accredited and certified external institute every three years. The results of these measurements from August 2019 have been used, in line with the applicable models and guidance, to determine the local concentration of Cr(VI) in air, and exposure to man via the environment. The estimates are based on the highest result of the measurements at each potential emission source. Three consecutive measurements (30 minutes each) were conducted at each of the exhaust air ducts of the two chimneys. The measurements were

following a defined measurement and analytic plan according to EN 15259 and EN 14385 during normal operating conditions at the plants. The results of the Cr(VI) measurements were reported as mass concentration (mg/m³) and as mass flow (g/h or kg/h). The estimates used for exposure and risk assessment are based on the sum of highest measurements at each emission source.

The operating hours per year and the mass flow were used to estimate the total annual release at the site, resulting in a release factor to air of 5×10^{-3} %. This release factor was then applied to Cr(VI) tonnage used for the activity of chrome plating to calculate air emissions for the use (0.575 kg/year).

The release factor then was applied to the estimate the environmental concentration and exposure of man via the environment with EUSES model. The resulting local PEC is equal to 4.38×10^{-7} mg/m³ while the PEC regional air is considered equal to 0 (zero) by the applicant.

Water

The applicant used EUSES to calculate the concentration into water compartment. Despite measured data of Cr(VI) concentration in wastewater not present in the CSR, the applicant has provided the requested information in the table in Annex I in the response to RAC's questions.

Local and regional concentration are estimated with EUSES, using as input values the daily amounts used at site, the release factor into water and the working/production days.

As explained in response to RAC's request, when calculating the "Daily use amount at site", the applicant used the default assumption of 20 working days associated to a specific tonnage band (< 20 tonnes/day). RAC agrees with the applicant that this leads to a calculated local release rate (1.72×10^{-4} kg CrVI / day) which is a more conservative estimate (around one order of magnitude greater) than the release calculated with the actual number of working days (250). Based on these assumptions, the total regional release per year is calculated multiplying the daily release rate for the default working days, resulting in a value of 3.45×10^{-3} kg/year.

Soil

The applicant stated that there are no emissions to soil from the use applied for.

Table 5: Summary of releases to the environment

Release route	**Release factor**	**Release per year** [kilograms of Cr(VI)]	**Release estimation method and details**
Air	5×10^{-3} %	0.575	Based on measured data
Water	3×10^{-5} %	3.45×10^{-3}	Based on measured data
Soil	-	No releases	-

For the assessment of indirect exposure of the general population the applicants considered two exposure routes inhalation and oral intake (ingestion of drinking water and food) as reported in the Table 6.

Table 6: Summary of exposure to the environment and humans via the environment

Parameter	Local	Regional
PEC in air (mg Cr(VI)/m^3)	4.38×10^{-7}	0
PEC water (mg/L)	N/A	Not relevant
Human via Environment - Inhalation mg/m^3	4.38×10^{-7}	0
Daily dose via oral route (mg/kg bw/d)	Not relevant	6.16×10^{-10}

2.5. RAC's evaluation of the exposure assessment

Workers exposure

RAC notes that the inhalation exposure assessment is based on a qualitative assessment for WCS 1, on measurements (personal and static) for WCS 2 and on modelling using ART 1.5 for WCSs 3-7.

The applicant's assessment for WCS 1 is zero inhalation exposure, considering that there is no potential for exposure due to closed storage area and sealed solid CrO_3 drums.

RAC agrees with the use of 90th percentile of the measured data (15 measurements presented by the applicant) for the risk characterisation in case of WCS 2 "manual plating process". As a worst case, the applicant has assumed that operators work 8 hours near the chromium baths where the static measurements have been conducted. Nevertheless, of the 8 hours, at least 2 hours are spent for assembling and masking of parts, as well as loading and unloading of jigs.

RAC also agrees with the use of 90th percentile of the modelled data corrected for frequency and effectiveness of the RPE in case of the risk characterisation for WCSs 3-7.

RAC notes that modelled data are currently not supported by measured data as presented by the applicant, but internal and external monitoring programmes are in place, including measurements for short or less frequent tasks such as sampling, maintenance, and cleaning, as well as additional measurement points, implemented under their role as a downstream user in the CTAC supply chain. Measurements according to this programme have been performed in April 2021 (while the authorisation CSR was performed in March 2021), so is to be reported to ECHA as required under authorisation decision made for CTAC. RAC notes that personal and/or static exposure measurements for specific tasks are preferred to modelled data for exposure estimation.

The exposure values presented in bold in Table 4 were considered for risk characterisation.

Combined exposures:

RAC agrees that the combined exposure described by the applicant can be considered as a realistic worst-case.

Taking into account the exposure assessment performed by the applicant as well as all the information provided on RMMs and OCs, RAC considers the shortcomings mentioned above to be of minor significance for the purpose of exposure and further risk assessment.

RAC notes that biomonitoring values above 12 µg/L for chromium in urine (exposure equivalent for carcinogenic substances - EKA value) were measured by the company's occupational health laboratory in 2016 (> 25 µg/L) and 2018.

RAC also notes that, according to the applicant, contextual information on the biomonitoring data cannot be provided, since the biomonitoring and exposure measurements were not performed on the same time and person. The chromium biomonitoring does not differentiate between exposure to Cr(VI) or other forms of chromium.

RAC takes note of the applicant's response that detailed information on the background exposure to chromium are necessary to use the biomonitoring data in a reliable manner in the risk assessment, as it is also mentioned in the literature.

Although the applicant has implemented annual biomonitoring campaigns, the biomonitoring data were not available for use in the exposure assessment. However, RAC takes note that the applicant does not have any objection to continue their annual occupational monitoring during the review period. RAC considers that the data obtained or the general statement from the occupational physician that chromium values are below the limit values should be included in the review report. However, since the applicant did not use biomonitoring to estimate or support the exposure assessment, there are no uncertainties identified by RAC related to the biomonitoring data that would affect the exposure assessment.

Environment and Humans via the environment

Since direct and indirect release to the soil is excluded due to adequate technical and organisational measures, only the oral route (by drinking water and fish, at regional level)) and exposure via air (direct inhalation at local level) are considered to be relevant by the applicant.

RAC notes that the frequency of monitoring (every three years) is not adequate to intercept potential fluctuations in the releases of Cr(VI), the applicant explained that it was decided that the emission control would take place annually in the future.

2.6. RAC's conclusions on the exposure assessment

RAC considers that the data provided in the CSR and the applicant's answers to RAC's requests is sufficient to conclude on the reliability of the exposure assessment (for workers and HvE).
RAC considers that the proposal to continue the monitoring programme, as presented in section 8, will address the identified shortcomings due to the lack of measured data for short or less frequent tasks as well as the relatively low frequency for the monitoring of the air emissions to the environment.

RAC recommends the applicant in Section 8 to continue annual biomonitoring programme for the workers potentially exposed to Cr(VI).

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

3. Risk characterisation

To calculate the Excess Lifetime Risk (ELR) for lung and intestinal cancers, the applicant used the dose-response relationship derived by RAC for the carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1, agreed at RAC 27)[14].

3.1. Workers

The applicant conservatively assumed that all inhaled chromium trioxide particles are in the respirable range and contribute to lung cancer risk. Thus, an excess life-time lung cancer risk of 4×10^{-3} per µg Cr(VI)/m^3 for 40 years of exposure (8 h/day, 5 d/week) for workers was considered for the risk assessment.

In Table 8 the excess cancer risk estimation for workers is presented based on the exposure data in Table 4.

Table 7: Combined exposure and risk characterisation (for lung cancer risk)

Contributing scenario	**Exposed population**	**Route**	**Exposure value corrected for PPE and frequency (µg Cr(VI)/m^3)**	**Excess risk***
WCS 1 Delivery & storage	2	Inhalation	No potential exposure	0
WCS 2 Manual plating process	23	Inhalation	0.60	2.40×10^{-3}
WCS 3 Sampling	1	Inhalation	0.0016	0.64×10^{-5}
WCS 4 Conc. adjustment	2	Inhalation	0.010	0.4×10^{-4}
WCS 5 Maintenance & cleaning by surface treatment team	3	Inhalation	0.02	0.8×10^{-4}
WCS 6 Maintenance & repair by maintenance staff	3	Inhalation	0.009	0.36×10^{-4}
WCS 7 Waste and wastewater management	1	Inhalation	0.00036	1.44×10^{-6}
Maximum combined exposure for 8 hours WCS2 + WCS3 + WCS4 + WCS5	27	**Inhalation**	**0.63**	**2.53×10^{-3}**

* Estimated individual risk resulting from exposure

[14] For workers: excess life-time lung cancer risk of 4×10^{-3} per µg Cr(VI)/m^3 for 40 years of exposure (8 h/day, 5 d/week). For general population: excess lifetime lung cancer mortality risk of 2.9×10^{-2} per µg Cr(VI)/m^3 for 70 years (24 hours/day, 7 days/week).

3.2. Humans via the environment

The applicant takes into account two distinct exposure routes for the assessment of indirect human exposure to the environment with EUSES 2.1.2. The first is the inhalation of Cr(VI) airborne residues (at local scale) and the second is the oral ingestion of contaminated food sources and drinking water (at regional scale). In both the cases, the RCR is considered as not relevant by the applicant.

Table 8: Exposure and risk to humans via the environment – local and regional scale

Parameter	Local		Regional	
	Exposed population:		Exposed population:	
	Exposure	Excess risk*	Exposure	Excess risk*
Humans via the environment – Inhalation	4.38×10^{-7} (mg Cr(VI)/m^3)	1.27×10^{-5}	not relevant	-
Humans via the environment – Oral	Not relevant	-	6.16×10^{-10} (mg/kg bw/d)	5.28×10^{-9}
Humans via the environment - Combined	Not applicable	-	Not applicable	-

* Estimated individual risk resulting from exposure.

3.3. Environment

Since the Cr(VI) is a carcinogenic and mutagenic substance with potential hazards for human health, the evaluation of any potential hazards to the environment is not required within the framework of this authorisation. Based on this, RAC notes that the RCR for the different environmental compartments is not relevant for the assessment of risk characterization.

3.4. RAC's evaluation of the risk characterisation

For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). In Germany, the evaluation standard is 1 µg Cr(VI)/m^3.

RAC notes that the shortcomings related to the absence of measured data for short and less frequent tasks and which have been discussed and addressed in the relevant sections above, are minor and are not likely to affect the risk characterisation significantly. The related shortcomings remedied by appropriately conservative assumptions do not undermine the reliability of the risk characterisation.

3.5. RAC's conclusions on the risk characterisation

RAC considers that the application includes all relevant tasks and routes of exposure as well as endpoints and populations.
RAC notes that the highest calculated excess risk estimate for worker's combined exposure is 2.53×10^{-3}. The excess cancer risk calculated for humans via the environment, is 1.27×10^{-5} (lung cancer) and 5.28×10^{-9} (intestinal cancer) for the general population.
There are no significant uncertainties in the characterisation of risks.
The identified shortcomings have been remedied by appropriately conservative assumptions in the calculation of the individual excess risk values.

RAC considers that the estimates of excess cancer risk for workers and for indirect exposure of humans (workers and general population) via the environment calculated by the applicant allow a health impact assessment.

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

The applicant is a downstream user, and alternatives are assessed from the perspective of the applicant, with some information presented on the perspective of the customers of the applicant. The AoA provided by the applicant considers both the etching and plating steps. As described in section 0.1, the etching and chrome plating steps currently take place in the same chromium trioxide-containing plating bath. In response to SEAC's request, the applicant clarified that in the future the etching step would no longer be performed in the same bath if using the alternative described hereafter for plating. The applicant has searched for and tested alternatives to Cr(VI) and has contacted manufacturers and distributors of potential alternative technologies and tested some of their products. Since 2016, the applicant has worked with alternatives providers AtoTech, Coventya, and Savroc Oy, and also participated in collective projects or surveys of alternatives (ChromGruen survey and consultations within the CTAC consortium). The applicant also carried out a survey among 47 of its customers in 2020. The results were used to assess which were the most promising alternatives from the point of view of the customers.

To assess the alternatives the applicant has defined a set of core criteria (Microcracking, Hardness, Wear resistance, Corrosion resistance), and a set of customer-specific criteria. If one of the core criteria is not satisfied and no improvements can be made, the alternative is discarded. Customer-specific requirements can vary in terms of performance requirements but are commonly expressed in terms of: layer thickness, heat resistance, roughness, expansion coefficient, ductility, friction resistance (friction coefficient), tensile strength, adhesive properties, safety requirements. The applicant has provided some examples and qualitative descriptions of sector- and article-specific requirements.

The applicant originally identified eight technologies that could potentially substitute Cr(VI) in some of their applications.

After this step, the applicant further narrowed the potential alternatives to four shortlisted ones, namely: Trivalent chrome and nickel electroplating, High velocity oxygen fuel spray (HVOF), Electroless nickel dispersion deposition, and BALITHERMTM PPD. The other originally

identified technologies were rejected due to technical and/or economical limitations[15].

Among these four technologies, the most promising alternative is trivalent chrome (Cr(III)) electroplating, eventually in combination with nickel coatings. This alternative is currently being tested. Although the applicant has started the project to switch most of its production to this alternative, they consider it to not yet be a mature enough technology to substitute Cr(VI) currently in any of its applications. The applicant is conducting further R&D to develop suitable Cr(III) electrolytes, Cr(III) specific anodes, and Cr(III) process optimization for functional chrome plating. For around 30 % of the applicant's applications, Cr(III)-based electroplating with nickel coatings might not be a suitable alternative. The share of 30 % comes from an analysis of the potential applicability of Cr(III) across the 17 typical use areas identified by the applicant, given his knowledge and experience so far. Given promising results already obtained with Cr(III), other shortlisted alternatives (High velocity oxygen fuel spray (HVOF), Electroless nickel dispersion deposition, and BALITHERMTM PPD) have not yet been assessed. The applicant states it will start research on them and on their implementation in the future (by 2024) to achieve near-full substitution of its product portfolio (the applicant considers that some applications in the aerospace industry would nonetheless continue requiring Cr(VI), but the information provided in the application does not include any evidence of this in terms of regulatory requirements or specific information from the relevant customers.

During the consultation, a company called MetalCoating S.R.L. submitted a comment containing patent-related technical information on coating of Nickel Phosphorus with Boron Carbide nanoparticles added. According to the comment, the alternative has a very good energy efficiency and less toxic fumes compared to chromium, resulting in a reduction of energy costs. The applicant responded that electroless nickel is among the alternatives they intend to further investigate in the future, and they described potential technical difficulties that will need to be overcome. Furthermore, the applicant stated it has approached MetalCoating S.R.L. (July 2021, without success) to investigate possibilities for future collaboration. Currently, the applicant seeks an exchange with any companies offering similar coating systems. As a response to question from SEAC, the applicant informed that the information in the comment would not affect their request for the (length of the) review period.

The applicant has provided a substitution plan. The substitution plan describes parallel R&D, process adaptation and stepwise conversion and extension of the electroplating facilities to Cr(III) until 2034. This is the date when up to (the maximum) 70 % of the substitution would have taken place, according to the applicant's expectations regarding customer acceptance of the Cr(III) alternative. The applicant explained that due to financial and human resource constraints, other alternatives cannot be tested and implemented while the process to move to Cr(III) is ongoing, but the research and implementation of other alternatives will start after 2024. The applicant already foresees they would submit a review report at the end of the requested review period (of 14 years), since only the substitution carried out with Cr(III) will have been completed at this date.

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

Considering all the elements above, SEAC considers that the applicant has screened and analysed the possible alternatives thoroughly. SEAC also finds that the functional requirements used to assess alternatives appear to be valid. However this assessment cannot be considered

[15] The discarded technologies were: PVD – Physical Vapor Deposition, EHLA - Extreme High-speed Laser Material Deposition -, High alloy steel with high Cr content, Cast aluminium instead of coated cast steel.

as complete since, as noted above, some of the shortlisted alternatives will be assessed at a later stage (after 2024). Even if the activity reported by the applicant appeared to start relatively recently (2016), SEAC considers that the applicant demonstrated an active information search and collaboration with alternatives providers and their customers. SEAC notes that the applicant convincingly addressed the comment provided in the public consultation.

SEAC agrees with the applicant that since not all tests have been carried out, technical feasibility is not totally ensured in all applications, as well as acceptance of Cr(III) by downstream supply chains. The actual achievement of the 70 % substitution target in 2034 cannot be known with certainty; however, it does not impact significantly SEAC's evaluation of the AoA and the SP. The uncertainty is higher regarding the perspective to substitute the remaining 30 % of current applications of Cr(VI) since research and tests have not started yet. Future technological progress in the alternative technologies (including Cr(III)) during the RP may also still change the picture before 2034, leaving some uncertainties remaining in the substitution timeline.

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

Has the applicant demonstrated that there are no alternatives with the same function and similar level of performance that are technically and/or economically feasible for the applicant before the date of adoption of this opinion?

☒Yes ☐No

Is there information available in the application for authorisation 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

During the initial screening of potential alternatives, the applicant rapidly discarded four of them: PVD, Extreme High-speed Laser Material Deposition (EHLA), High alloy steel with high Chromium content, Cast aluminium instead of coated cast steel. In brief, these alternatives were discarded due to low performance and inability to coat for complex geometries (PVD and EHLA), lack of anti-abrasion and antiadhesive properties (high alloy steel with high Cr content), and components breaking during use (cast aluminium).

The technical basis and data used which caused these alternatives to be discarded at this stage were not explained in the application. However, in an answer to a SEAC question, the applicant explained and further justified that these alternatives were not thoroughly assessed as it is unlikely that the applicant would be able to switch to a completely different technology such as vapour deposition processes (CVD, PVD), spray process (HVOF) or welding technologies (EHLA), given their lower application spectrum compared to Cr(III)-based technology.

SEAC understands that the applicant, given their knowledge of alternatives (and the survey of the customers) had enough information to decide that Cr(III) was the most preferred option identified, with the broadest coverage in terms of their applications. The applicant stated there are no suitable alternatives in the EU in general, but nevertheless submitted a substitution

plan.

The applicant has chosen Cr(III) to be the alternative for the main part of their products (70 % of the revenue), and therefore their R&D work has concentrated on Cr(III). This explains why a detailed technical assessment of the other short-listed alternatives (High velocity oxygen fuel spray (HVOF), Electroless nickel dispersion deposition, and BALITHERMTM PPD) was not provided by the applicant. However, advantages as well as obstacles to their implementation by the applicant were described.

The applicant evaluated the technical feasibility of Cr(III)-based coatings based on technical assessments within different frameworks (research projects, REACH consortia) and the first promising results of still ongoing tests undertaken together with their partners (COVENTYA). Overall the applicant concludes that this technology is expected to become technically and economically feasible, however stressing that there still remain technical issues to be resolved in the future. The applicant explained that they have started the substitution to Cr(III) and they are in the process of discussing financing of required investment through bank loans.

In response to a request from SEAC, the applicant explained in the application and further justified the main remaining technical (and economic) issue for the Cr(III) alternative – macrocracking. Cr(III) presents macrocracking at the surface rather than microcracking, this being a cause for insufficient corrosion resistance. The existing technical solution of adding a first Nickel coating is considered to be economically non-feasible (the applicant provided a representative example in which the combined use of Ni + Cr(III) is three times more expensive than the use of Cr(III) alone). Currently, the applicant is still conducting R&D on another identified approach (details are confidential but known to SEAC) to influence cracks structure and increase corrosion resistance up to the level required by customers.

Another economic issue that was clarified by the applicant at the request of SEAC, is that the mixed metal (MMO) anodes required by the Cr(III) technology are significantly more expensive that the currently used lead anodes (10 times more expensive according to the applicant for simple geometries). Therefore, the applicant is working on finding an alternative to its current lead anodes and to the MMO anodes. The applicant also mentioned that the sensitivity of current Cr(III) electrolytes to contaminants is still another issue that needs to be resolved.

In terms of economic challenges, in an answer to a question by SEAC, the applicant explained that an idea of cost sharing (i.e. that the applicant and its customers could share R&D costs to improve economic acceptability for the applicant) was not realistic, especially as it would require multiple actors (potentially competitors or actors from completely different industry sector) working together. SEAC regrets to note that collaboration between applicants and its customers, and/or between other actors, potentially a key factor for an improved and accelerated substitution, is not more developed. However, SEAC recognises it is out if its competence to try address this point further.

Regarding the Cr(III)-based technology, the applicant also explained that the technical challenges relate to reaching the required performance of the plating step. Even if the plating step is the one which generates a technical feasibility issue (requiring the search for alternative chemicals to chromium trioxide), the preliminary etching step represents the main part of the economic investment (because of the need of new bath (with already identified chemicals) and with technical equipment).

As mentioned above, the one comment received in the consultation raised the question of another alternative, and the applicant explained they intend to investigate this further in the future.

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

Given the above, SEAC has no major reservations on the applicant's assessment of the technical and economic feasibility of the alternatives and agrees that there are no technically and economically feasible alternatives for the applicant. SEAC also finds that the functional requirements used to assess alternatives appear to be valid. However, the assessment of alternatives cannot be considered as fully completed since, as noted above, some of the shortlisted alternatives will be further tested at a later stage (after 2024).

In particular, SEAC has no reservations regarding the rationale provided by the applicant to justify that Cr(III) plating is the most promising alternative in its particular situation.

SEAC finds the applicant's assessment that there are no suitable alternatives in the EU in general very brief, and SEAC was not able to conclude whether there are available technically and economically feasible alternatives in the EU based on the information provided in the application. A consultation comment received offered information about a potential alternative; however, based on the comment, SEAC cannot judge whether that would be applicable to the use in this application and whether the alternative would be readily available. However, SEAC notes that the applicant is planning to substitute 70 % (by revenue) of their use by the end of 2034. As a result, SEAC concludes that there is no indication in the AoA nor in comments received in the consultation that there would be technically and economically feasible alternatives available in the EU. Furthermore, SEAC (and RAC) could not conclude as to whether the use of these alternatives are safer than the use applied for in this application.

There were several unclarities in the technical and economic assessment of alternatives in the application, but most of the issues raised by SEAC during two rounds of questions and answers with the applicant were solved. A few minor issues remain. For instance, it was not finally always clear whether some of the mentioned technical difficulties such as sensitivity of bath contamination could not be overcome with the planned changes in process management (bath cleaning) and the reconfiguration of the plant (bath extension). However, the latter consideration, and more generally the uncertainty regarding the actual confirmation of the feasibility of Cr(III) plating mentioned above are not regarded to challenge SEAC's conclusions.

A way to accelerate and ease substitution can be in certain cases to reassess performance requirements. In an answer to a SEAC question on this issue, the applicant explained that they are not in the position to negotiate component specifications with their customers, and furthermore, the customers themselves are often contract manufacturers who cannot define the performance requirements. SEAC notes it cannot assess the consumer and producer surplus losses associated with adapting performance requirements, because this information is not available to the applicant.

SEAC notes the consultation comment providing information on a potential alternative. As a response to SEAC's question, the applicant stated and justified, that the alternative would require significant research and that therefore the information does not modify applicant's assessment of the alternatives, nor the requested review period.

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 above 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 activities/plan

Did the applicant submit a substitution plan?

☒Yes ☐No

Is the substitution plan credible for the review period requested and consistent with the analysis of alternatives and the socio-economic analysis?

☒Yes (as regards the consistency of the SP with the AoA and the SEA)

☒No (as regards the credibility of the SP for the RP requested)

The applicant provided a SP that is fully consistent with the AoA, and is based on the following main conclusions from the AoA:

- Only 70 % of applications can be substituted within the requested RP of 14 years
- Cr(III) coating is suitable as an alternative process for these 70 % of applications; however, other alternatives are thought to be preferred for the rest (30 %) of the alternatives.
- R&D on alternatives for the remaining 30 % of products will not be achieved before the maximum implementation of Cr(III) plating has been achieved, because the applicant does not have the human and financial resources to implement several substitution projects at the same time. It follows that implementation of those other alternative would occur only after the end of the present substitution plan.

The SP also describes in accordance with the AoA the main factors that can affect the substitution timeline:

- Outcome of the ongoing R&D to improve corrosion resistance of Cr(III) coatings (macrocracking), and eventually to avoid the need for expensive nickel undercoating under some applications, and therefore reduce the cost of and time needed to implement associated process equipment. However the SP includes the enlargement of the current nickel facilities, since nickel will likely be still required for some applications.
- Validation of the performance of the new Cr(III) based coating by customers from the different application sectors
- Development of a technically and economically feasible anode technology for Cr(III) plating baths
- Improving bath stability to avoid complex and expensive reconfiguration of the process

Besides aforementioned constraints in terms of human and financial resources, the applicant explains that they also have constraints in space availability.

From the considerations and constraints above, the following substitution timeline is presented by the applicant:

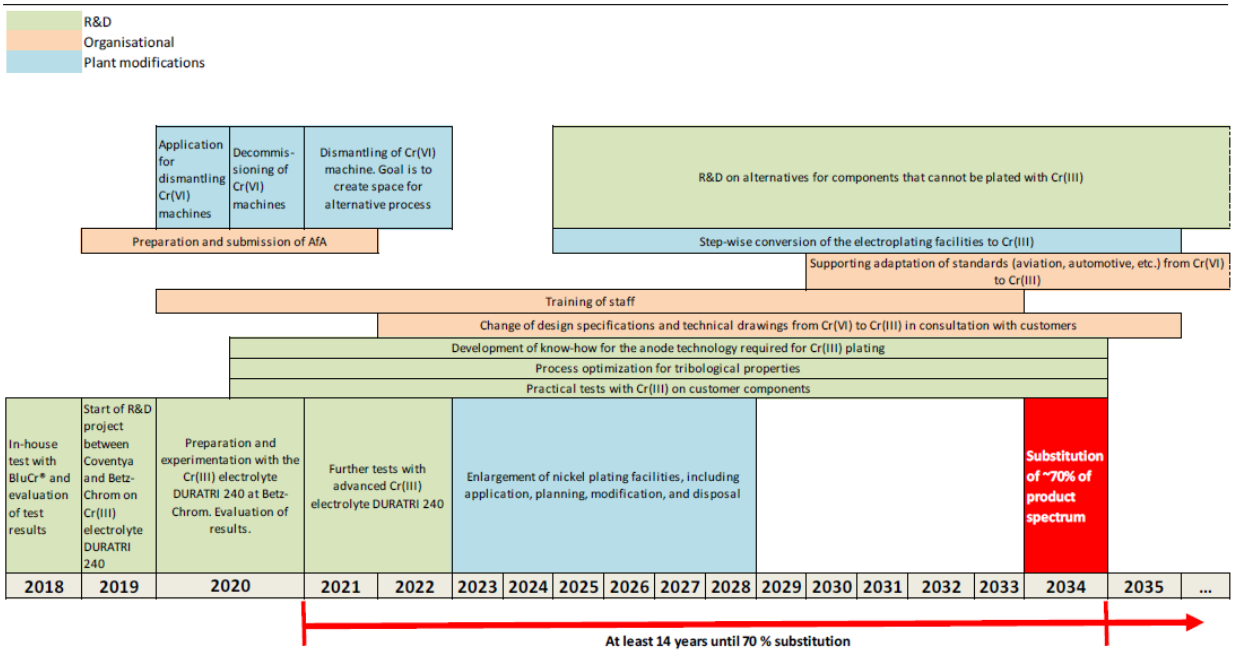

Figure 2: Substitution timeline

A monitoring plan has also been submitted by the applicant with specification of monitoring goals, frequency, measures, and responsible teams for each main tasks of the SP.

In answer to a question by SEAC, the applicant explained it was currently not possible to provide specific and more accurate substitution timelines for each of the main sectors served. The applicant clarified that at this stage they have not enough technical and scientific information to predict how the complexity of substitution with Cr(III) technology would vary between different industry sectors or article types.

There are uncertainties in the SP that are related to the outcome of the R&D and to customer acceptance, as mentioned above. In particular, it is not known to the applicant at this stage whether and to what extent Nickel undercoating will be needed to improve corrosion resistance performance of the Cr(III) coating.

SEAC's evaluation of the substitution activities/plan

SEAC finds that the SP provided by the applicant is credible to support a review period of 12 years (see the justification for the duration of the RP recommended by SEAC in section 6). The applicant has demonstrated past and future engagement to find and implement alternative technologies, working in close collaboration with several alternative providers. The applicant also engaged in direct communication with his customers and more generally communicates around the substitution to Cr(III) proactively (articles in specialised technical publications, webinars) in order to get more users to test and possibly adopt this alternative in the future.

SEAC finds the arguments put forward by the applicant regarding the steps, tasks, and related time needed to achieve substitution credible. The factors that can influence substitution are clearly identified and justified. SEAC understands the uncertainty surrounding the pace of the substitution given that R&D is still ongoing and since tests with most customers still need to be carried out and all outcomes cannot be predicted at this stage. SEAC however notes that the actual substitution may require more or less time i.e. to happen faster or slower than currently estimated. SEAC finds that the applicant does not fully take into account that possible

future technological progress, its own learning-by-doing process, or new insights from collaborations with customers and the relevant industrial community could lead to faster and less expensive implementation of the Cr(III) alternative. The applicant recognized that there are alternatives they did not study at this stage. The outcome of their forthcoming study could lead to significant changes in the substitution process (whether accelerating or slowing it down). Finally, the longer the timeframe of a substitution plan, the higher is the probability that some unforeseen event in the applicant or in its multiple and complex supply chains could impact the substitution plan previsions. While SEAC agrees that the Substitution Plan is credible for the duration of a long review period (12 years), SEAC finds for the above reasons that uncertainties beyond 12 years become too important to qualify the substitution plan as credible for 14 years.

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 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 no information available in the application for authorisation 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 by the date of adoption of this opinion.
- The applicant submitted a substitution plan. The substitution plan was credible for a review period of 12 years and consistent with the analysis of alternatives and the socio-economic analysis, but not credible for the requested review period of 14 years.

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 applicant 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)

5.1. Human health and environmental impacts of continued use

The applicant provided quantitative estimates of human health impacts stemming from the remaining risk associated with the continued use of chromium trioxide. The assessment of human exposure to chromium trioxide differentiates between directly exposed workers at the production facilities (Gräfelfing, Germany) and the people potentially exposed in the direct neighbourhood, hence, human via the environment.

Based on the applicant's exposure assessment and the reference dose-response function established by RAC for carcinogenicity of hexavalent chromium, the excess lifetime risk was

derived for each identified endpoint and group of potentially exposed people. In accordance with the CSR, the risk assessment for directly exposed workers was restricted to inhalation of airborne chromium trioxide (the corresponding endpoint is lung cancer). For the potentially exposed local population, inhalation and oral uptake were taken into account (lung and small intestinal cancer considered as endpoints). The applicant reported that the total number of potentially directly exposed workers is 27 employees. The applicant assumed the maximum number of people exposed via the environment, i.e. people exposed in proximity of the production site, to be 10 000 (the applicant stated this figure to be based on a cautious standard estimate).

Non-confidential values of excess cancer risks for directly and indirectly exposed workers as well as the general population were provided.

The applicant used the excess lifetime cancer risk, adjusted by the review period, and the number of exposed people per WCS to calculate the number of statistical cancer cases to provide a magnitude of the impact on human health.

For the monetization of human health impacts, the applicant used a value of a statistical life of EUR 3.5 to 5 million in 2012-prices and a value of cancer morbidity of EUR 0.41 million in 2012-prices as estimated by ECHA. The applicant also took into account in their calculations the disease latency and fatality rates, as well as inflation adjustment and discount rates between 2 % (upper bound) and 4 % (lower bound).

The applicant provided public ranges of the monetised excess risk over the requested period of 14 years at €48 299-80 418 for directly exposed workers and €74 469-123 991 for the local population and indirectly exposed workers, which sum up in total to €0.12-0.20 million. The applicant stated that the reported values are considered worst-case, scenarios. SEAC notes that RAC agrees that the combined exposure described by the applicant can be considered as a realistic worst-case.

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

SEAC agrees with the methodology used by the applicant and with the corresponding estimates provided by the applicant. However, SEAC recalculated the estimated statistical cancer cases and monetised excess risk to adjust the estimates to the recommended review period of 12 years. The adjusted figures from SEAC are presented in Tables 9a and 9b below.

Overall, SEAC estimates that the present value of monetised excess risk is approximately €0.11-0.18 million over 12 years (including both fatal and non-fatal cancer cases for workers and the general population). This corresponds to a rough approximation of annualised value of €9 000-15 000 i.e., when dividing the monetised excess risk by the length of the recommended review period, 12 years.

Table 9a: Summary of additional statistical fatal cancer cases

	Excess lifetime <endpoint> risk[1]	**Number of exposed people**	**Estimated statistical <endpoint> cases**	**Value per statistical <endpoint> case (lower and upper bound)**	**Monetised excess risk over 12 years**
Workers					

Directly exposed workers[2]	2.17×10^{-3}	27	1.65×10^{-2}	2 835 896-4 764 776	**€41 399-68 930**
Indirectly exposed workers[3]	1.27×10^{-5} Lung cancer 5.28×10^{-9} Intestinal cancer	10 000	2.54×10^{-2} Lung cancer 4.75×10^{-7} Intestinal cancer	2 835 896-4 764 776 1 514 108-3 470 881	**€63 830-106 276** **€0.72-1.65**
Total		Approx. 10 000			**€105 230-175 206**
Latency (years)	10 year for lung cancer 26 years for intestinal cancer				

Table 9b: Summary of additional statistical non-fatal cancer cases

	Excess lifetime <endpoint> risk[1]	**Number of exposed people**	**Estimated statistical <endpoint> cases**	**Value per statistical <endpoint> case(lower and upper bound)**	**Monetised excess over 12 years**
Workers					
Directly exposed workers[2]	6.96×10^{-4}	27	5.29×10^{-3}	297 370-361 101	**€1 572-1 910**
Indirectly exposed workers[3]	4.08×10^{-6} Lung cancer 2.55×10^{-10} Intestinal cancer	10 000	8.15×10^{-3} Lung cancer 5.11×10^{-7} Intestinal cancer	297 370-361 101 158 768-263 043	**€2 424-2 944** **€0.08-0.13**
Total		Approx. 10 000			**€3 997-4 853**
Latency (years)	10 year for lung cancer 26 years for 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.
5. Derived from the lifetime risk of 40/70 years.

5.2. Societal costs of not granting an authorisation

Non-use scenario

In case of a rejected application for authorisation, the applicant envisaged three possible non-use scenarios (NUS):

1. NUS A: Outsourcing of affected production activities outside the EEA,

2. NUS B: Relocation of production activities outside the EEA,

3. NUS C: Permanent shutdown of the affected production in the EEA.

4. NUS D - Others: Non-use scenario dependent on their customers

Under NUS A - Outsourcing of affected production activities outside the EEA - an initial screening of the best suited supplier(s) in terms of geographical position, available production capacity, technical feasibility and knowledge, quality standards and subsequent lead times is necessary. According to the applicant such a process requires at least 5 years. Furthermore, under this scenario the cost will increase due to the need to pay the third party platers to take over chromium trioxide dependent production processes. Depending on the availability and feasibility of production capacity at the potential supplier's, this could potentially imply interrupted production of their affected article(s) and delivery lags in the EEA. Therefore, the applicant considers NUS A not plausible.

According to the applicant, the NUS B, - relocation of the production activities outside the EEA - in order to continue chrome-plating activities, also requires an initial screening phase of 2 years including site inspections. Furthermore, in case of the relocation of the production outside the EEA, a new production facility with quality standards conforming to local regulations outside the EEA needs to be established in the area. The applicant estimated that the relocation process will require an additional investment of approximately €9-16 million for constructing a new site. This is not considered economically feasible by the applicant due to low profitability and the absence of another business segment to ensure continuous cash flow while production related to chromium trioxide is being relocated outside the EEA. Therefore, the applicant does not consider NUS B plausible.

Under NUS C the applicant considers to permanently shut down all affected activities in the EEA. Since a significant part of the applicant's sales depend on the use of chromium trioxide products and because the applicant's departments are interconnected, its entire business would come to a standstill as a result. The applicant explained that temporarily shutting down its business until an alternative is available is not an option for Betz-Chrom, as development and implementation of the new alternative is expected to take at least 14 years for 70 percent of the impacted products and it risks leading the firm towards insolvency. Therefore, only a permanent shutdown of Betz-Chrom's activities as a non-use scenario is considered by the applicant.

Under NUS D the applicant surveyed responses from their customers that stated their non-use scenarios in case Betz-Chrom is refused an authorisation for hard chrome plating. For some customers, deriving a potential scenario due to a refused authorisation to Betz-Chrom is difficult especially when they do not have any contact with the end customer and completely depend on their own customers' specifications. To develop and implement an alternative, they need to be aware of the necessities at several points for several actors across the whole supply chain. In industries with a complex supply chain, it can be a challenge to find the right balance between benefits and the efforts/costs in terms of re-organising and convincing such a supply chain of a new process in the non-use scenario. The applicant considers that it is not possible to derive a NUS based on the results of the survey made to their customers.

Based on the information provided by the applicant, SEAC concurs with the presentation of the potential non-use scenarios. SEAC notes that NUS D is not really a self-standing alternative NUS but rather complementary information about what would happen under the most likely NUS C. As such it can be seen to be a part of NUS C and it does not affect the conclusions about the most appropriate NUS.

The applicant selected NUS C as the most likely scenario in case of non-granting authorisation. SEAC has no substantial reservations on the justification of NUS C as the most likely NUS.

Economic impacts of non-use

The applicant estimated the economic impacts of continued use based on the most likely NUS C, i.e. permanent shutdown of all activities of Betz Chrom. Economic impacts provided by the applicant included loss in profits and additional costs of site/plant closure, decommissioning and cleaning. All monetised impacts are calculated as present values over the requested period of 14 year, discounted to the same base year (2020) at a 4 % discount rate, in line with ECHA's guidance. The applicant also provided the annual values. As mentioned above, for the comparison, SEAC adjusted the 14-year figures to recommended 12-year review period.

Foregone profit

The applicant considered profit losses to be a relevant economic impact under NUS C. Based on the forecasted turnover until the end of the review period requested and a minimum profit margin (both claimed confidential), the applicant estimated the annual value of avoided foregone profits to be in the range of €0.01-0.1 million per year (public range, provided in response to SEAC's request for additional information, question 8, Table 6).

Closure costs

Additional dismantling costs

The applicant provided the additional costs such as costs of cleaning, dismantling and disposal at the production site in Gräfelfing and the production finishing site at Maisach that they would incur due to the closure process. These cost estimates are based on Betz-Chrom's previous experience. The exact values of these costs are provided (but claimed confidential), and the applicant provided a public range for these costs at €5-10 million (present value, 2020, 4 % social discount rate) for the requested review period of 14 years. As a response to SEAC's request, the applicant also provided a public range for the avoided dismantling costs of €0.1-1 million calculated per year. SEAC notes that in their estimates the applicant did not consider the revenues from selling the current equipment because most of the machines are adapted to the specific requirements of the company and cannot be transferred easily, and, secondly, as most of the machines are already fully depreciated.

Additional cost due to permanent shut down

Under NUS C additional costs of contract termination with Betz-Chrom's suppliers, service providers including credit and leasing institutions and DUs will accrue. The applicant explained that currently it is not possible to fully assess these costs, and some elements such as mortgages are provided but claimed confidential. The applicant stated that these costs will be substantial and that in case of insolvency due to permanent shutdown of all production activities, Betz-Chrom would be unable to pay these mortgage payments besides other economic impacts stated above. SEAC notes the potential costs but considers those to be rather distributional in nature and as such not to be calculated as part of the closure costs here.

Impacts on Betz-Chrom's customers

The applicant also provided qualitative information about the potential impact for the customers under all NUS scenarios such as increasing investment costs, increased competition, potential additional regulations for quality assurance in the countries where plating is sourced by customers. According to the applicant, the absence of quantification of these impacts will lead to substantial underestimation of the benefits of continued use.

Social impacts

The following social impacts are considered:

The applicant estimates that about 67 employees will be dismissed in the beginning of 2021 if no authorisation is granted. Following the approach endorsed by SEAC , the cost of job losses is based on average gross annual earnings in German's manufacturing and services sector in 2018 amounting to €123 260 (present value, 2020, 4 % social discount rate)/ per a job lost (retrieved from Eurostat). As a result, the applicant estimates the monetary value of 67 job losses at €8.3 million over the requested review period (present value, 2020, 4 % social discount rate).

Other not quantified social impacts

The applicant also provided some qualitative information related to the social activities at Betz-Chrom such as support for refugees and other social organisations, Biodiversity support which will stop under NUS C.

Social impacts to the customers

The applicant did not provide, quantitative estimates but considered that NUS C will have a negative impact on the employment rates of the customers.

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

SEAC notes that the applicant used operation profit for the year 2018 as a starting point and agrees with its arguments to not take into account the negative operating profit in 2019 and 2020 as they do not represent Betz-Chrom's business as usual (because of the impact of the COVID 19 pandemic). SEAC considers that the methodology used to calculate foregone profits was appropriate and provides a good indication of the scale of the potential impacts of non-authorisation. Foregone profits are most appropriate to monetising the welfare implications of non-use. However, changes in profits made by the applicant do not necessarily reflect net changes in economic surplus across the EU economy. SEAC notes that considering the profit losses of the applicant over several years might overstate the impacts. The applicant itself had used the one year profit to describe the amount of foregone profits for the whole review period requested. SEAC accepted the applicant's approach as a lower bound for foregone profits. The applicant provided a public range value for the foregone profits for the review period requested in the original application. In response to SEAC's request, the applicant provided public ranges for the foregone profits €0.1-1 million for the review period, and €0.01-0.1 million per year (Question 8, Table 6 in applicant's response to SEAC's I information request). SEAC adopted the latter per-year public range of the profit loss and used it when calculating the economic impact of the NUS (see Table 11 below).

Concerning the closure costs, SEAC agrees that the estimates provided by the applicant represent the lower bound of the closure costs as they do not cover all possible cost elements.

SEAC notes that the applicant did not consider in their estimates the revenues from selling the current equipment due to the low value of the current equipment. While it is not possible for SEAC in detail to assess the magnitude of the revenues from selling the current equipment,

SEAC considers that they should have been included as they represent a negative cost, and thus incremental benefit, in NUS C that might reduce the closure cost. However, SEAC also notes that most of the machines are adapted to the specific requirements of the company and as such cannot be transferred easily. In its calculations, SEAC takes forward the public range for the closure cost of €0.1-1 million per year as provided by the applicant as a response to the SEAC's I request for additional information. (see Table 11 below).

SEAC agrees with the approach used by the applicants to monetise the welfare loss associated with the unemployment of their workers, and the calculation of the social cost of unemployment at €8.3 million for the review period or on average €0.7 million per year. In response to a SEAC request, the applicant explained that due to the COVID 19 crisis the rate of the employment decreased over the last year and therefore the provided estimates correspond to the upper bound of the social unemployment impacts. SEAC takes forward the values provided by the applicant adjusted to the proposed review period resulting in €0.7 million per average year.

In total, the benefits of continued use derived by SEAC amount to €0.8-1.8 million, expressed as annual costs per year considering the recommended review period of 12 years

Following a clarification request from SEAC, the applicant explained that they are a member of the Chromium Trioxide Authorisation Consortium (CTAC) and that in case of a refused authorisation, the applicant would not immediately stop activities (due to CTAC coverage until 2024). However, similar impacts would occur, just at a different point in time (in 2024 instead of when this single application is decided). SEAC notes the applicant's clarification and the benefit estimations provided and considers that they do not materially affect its conclusions).

SEAC took note on the described additional social costs related to the social activities at Betz-Chrom as assessed by the applicant.

SEAC also agrees with the applicant that social impact on the customers i.e., job losses if authorisation is not granted, are possible.

SEAC acknowledges that the provided estimates associated with the non-use take only a one-year profit loss to describe the losses for the whole review period, and they do not include all costs and impacts e.g., some closure cost elements (revenues from selling the current equipment impacts, etc.). However, taking into account the magnitude of shut-down costs and the fact that they correspond to the lower bound of the possible impact of non-granting authorisation, SEAC concludes that as such the provided estimates tend to represent the realistic costs.

Table 10: Societal costs of non-use

Description of major impacts	Monetised/quantitatively assessed/qualitatively assessed impacts
1. Monetised impacts	**Millions € annualized value per year[1]**
Economic impacts due to investment and/or additional production costs related to the adoption of an alternative	Not applicable
Producer surplus loss due to ceasing the use applied for	0.01-0.1
Relocation or closure costs	0.1-1
Loss of residual value of capital	n.a.[2]

Other costs (e.g. additional costs for transportation or quality testing)	n.a.[2]
Social cost of unemployment	0.7
Spill-over impact on surplus of alternative producers	
Other monetised impacts (please specify)	
Sum of monetised impacts	0.81-1.8
2. Additional quantitatively assessed impacts	**[Per year]**
Number of patients treated	Not applicable
Avoided CO2 emissions	Not applicable
Other quantitatively assessed impacts (please specify)	
3. Additional qualitatively assessed impacts	
Consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity)	DUs impacts profit losses social cost of unemployment
Other qualitatively assessed impacts (please specify)	

Notes:

1. Per average year during the time horizon used in the analysis.
2. Not available.

SEAC's evaluation of the combined assessment of impacts

Based on information provided by the applicant and the suggested review period of 12 years, SEAC estimated the benefits of continued use to be €0.8-1.8 million per year and €9.6-21.6 million over the 12-year review period and human health risk approximately €0.009-0.015 million per year and €0.11-0.17 million over the 12-year review period.

Table 11: Societal costs of non-use and risks of continued use

Societal costs of non-use		**Risks of continued use**	
Monetised impacts in Million € (per year[1])	Avoided profit loss 0.01-0.1 Avoided closure cost 0.1-1 Avoided unemployment social costs 0.7	Monetised excess risks to directly and workers (Million € per year[2])	0.004-0.007
Additional quantitatively assessed impacts (per year)	Foregone profits along the upstream and downstream supply chain of the applicants	Monetised excess risks to the general population (Million € per year[2])	0.005-0.008

Additional qualitatively assessed impacts (per year)	Avoided economic loses for DUs	Additional qualitatively assessed risks (per year)	N.A
Summary of societal costs of non-use	**€0.8-1.8 million**	**Summary of risks of continued use**	**€0.009-0.015 million**

Notes:

1. Annualised to a typical year based on the time horizon used in the analysis.
2. Per average year during the time horizon used in the analysis.

The applicant provides a detailed and transparent description of the methodology used to calculate the different impacts, which allows SEAC to understand the assumptions behind the calculations and to conclude on their reliability.

SEAC agrees that the non-use scenario C would likely result in an increase of unemployment at the applicant's facility. The approach to monetise the related impacts follows SEAC's note on the social cost of unemployment. SEAC notes that this impact would present a significant welfare cost and can be considered as a significant benefit of continued use.

5.3. 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,
- any 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, in that sense, any remaining uncertainties are considered negligible.

6. Proposed review period

☐Normal (7 years)

☒Long (12 years)

☐Short (4 years)

☐Other: … years

☐No review period recommended

The applicant considers that their AoA and SP provide sufficient justification for more than 12-year review period.

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

- The criteria set in the CARACAL document CA/101/2017 for a longer than 12 year review period are not fulfilled. 1) the lifetime excess risk for workers threshold of 1×10^{-5} is exceeded, and 2) it cannot be stated that it is highly unlikely that suitable alternatives will be available and can be implemented for the use concerned within 14 years, given that there are possibilities that the substitution process could be either longer or faster, as explained above in section 4.
- The applicant has reviewed potential alternative substances and concluded that there are no alternatives available with the same function and similar level of performance that are safer and technically and economically feasible. SEAC, assessing the issues for the time of adoption of this opinion, concurs with the applicant's assessment on the technical and economic feasibility.
- Due to the time needed for the research and development and implementation and the regulatory approval process of alternatives, SEAC finds it credible that it would not be possible for the applicant to substitute within a normal (seven year) review period.
- SEAC considers that the substitution plan (activities and timelines) proposed by the applicant is credible for and justify a 12-year review period, but that uncertainties beyond this duration become very significant.
- SEAC has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the risks to human health associated with the continued use of the substance. The applicant's impact assessment was considered by SEAC to provide robust conclusions in this respect.

Taking into account these points, SEAC recommends a **12**-year review period, i.e. until 15/02/2033 (the date of submission of the application, 15/02/2021, as a starting date).

7. Proposed additional conditions for the authorisation

Were additional conditions proposed for the authorisation?

☒Yes ☐ No

7.1. Description

RAC

The applicant shall continue the efforts to minimize the workers' exposure to Cr(VI) by implementing state of the art RMMs as result of their ongoing research projects (such as LEGOLAS).

The applicant shall investigate the feasibility, and implement the findings, with regard to the selection and wearing of respiratory protective equipment (RPE) for the tasks with potential exposure to Cr(VI) (e.g. "plating (manual)", "sampling" (manual), "weekly maintenance by surface treatment staff", "maintenance & cleaning involving maintenance staff"), considering

the comfort of the workers during the use.

SEAC

None

7.2. Justification

Although RAC is of the opinion that the risk management measures and operational conditions as proposed in the application are generally appropriate and effective in limiting the risk to workers, humans via the environment and the general population, provided they are adhered to, an additional condition for the authorisation was proposed to minimise the exposure to Cr(VI) in the production hall and consider RPE selection for manual tasks. The proposal is in line with the applicant commitment to minimise the exposure to Cr(VI) by continuously improving of the OCs and RMMs in place.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements proposed for the authorisation?

☒ Yes ☐No

8.1. Description

RAC

1. The applicant shall continue to implement the following programmes for Cr(VI):
   - (a) Occupational inhalation exposure monitoring programmes, which shall:
     - (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI);
     - (ii) be based on relevant standard methodologies or protocols;
     - (iii) comprise personal sampling for the workers involved in plating, sampling, concentration adjustment and maintenance activities (WCSs 2, 3, 4, 5 and 6) and static inhalation exposure sampling;
     - (iv) be representative of:
       - a. the full range of tasks undertaken where exposure to Cr(VI) is possible;
       - b. the OCs and RMMs typical for each of these tasks;
       - c. the number of workers potentially exposed;
     - (v) include contextual information about the tasks performed during sampling.
   - (b) Environmental releases:
     - (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater;
     - (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process;
     - (iii) the monitoring programmes for wastewater and air emissions shall:
       - a. be based on relevant standard methodologies or protocols; and
       - b. be representative of the OCs and RMMs used at the applicant's site.

.

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible.

3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.

4. The applicant shall continue to conduct their bi-annual biomonitoring programme for the workers potentially exposed to Cr(VI)

8.2. Justification

Although RAC considers the OCs and RMMs described in the application in relation to both workers and humans via the environment to be appropriate and effective in limiting the risk resulting from exposure through inhalation and oral route, the exposure assessment (for workers and humans via the environment) contains some shortcomings due to the absence of workplace air measurements for specific tasks (such as sampling, concentration adjustment, maintenance) and to the limited number air emissions data.

RAC considers that clarification of these shortcomings would not be expected to lead to significantly higher exposure estimates compared to those considered for the risk characterisation, but the applicant should nevertheless address these shortcomings by obtaining representative measurements for workers' exposure and environmental releases.

RAC notes that the proposed monitoring arrangements for the authorisation are in line with the applicant’s commitment to implement elaborated monitoring programmes of the potential emissions of Cr(VI) in the workplace and environmental compartments (Betz Chrom performs four occupational exposure measurement campaigns per year plus biomonitoring twice a year in Gräfelfing).

9. Recommendations for the review report

Were recommendations for the review report made?

☒ Yes ☐No

9.1. Description

RAC

The results of the measurements referred to in sections 8 paragraphs 1 and 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8

paragraph 2, should be documented and included in any subsequent review report.

SEAC

Alternatives that have been shortlisted but not tested further so far will need to be assessed and their eventual rejection justified in any review report. This concerns the following alternatives: High velocity oxygen fuel spray (HVOF), Electroless nickel dispersion deposition, and BALITHERMTM PPD.

The review report should describe and justify any significant deviation in case the 70 % target share of Cr(III) conversion is not to be reached. The review report should take account of the technological progress since the initial application for authorisation and assess whether the technological progress would allow conversion beyond the 70 % target, or to acceleration of substitution in any other way. In particular, any progress towards substitution in the R&D on other alternatives since 2025 should be described.

The applicant should carefully clarify and justify if the use of Cr(VI) is still necessary in applications for aerospace industry at the time of preparing the potential review report.

9.2. Justification

RAC

Provision of the representative monitoring results would allow the air measurements to be corroborated and a better evaluation of the actual and future situation at the applicant's site. RAC notes the absence of biomonitoring data for 2020.

SEAC

In case the review report is submitted, SEAC will need the aforementioned requested information to assess substitution efforts made. Namely, as discussed in section 4, the substitution plan provided describes the planned substitution activities until 2034 which the applicant expected to be the date when up to 70 % of the substitution would have taken place. A description and reasoning of the substitution activities in the review report would help SEAC to gain better understanding of the substitution work undertaken since the present application for authorisation. This is important as SEAC in section 4.2 above finds that the assessment of alternatives cannot yet be considered as fully completed since some of the shortlisted alternatives are planned to be further tested only after 2024.

10. Applicant's comments on the draft opinion

Did the applicant comment the draft opinion?

☐Yes ☒No

10.1. Comments of the applicant

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

☐Yes ☐No ☒Not applicable – the applicant did not comment

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

Not relevant.

10.3. Reasons for not introducing changes

Not relevant.

Annex I

Table 12: Concentration of Cr(VI) the wastewater in mg/L

Parameter (limit value)		Cr(VI) (limit value 0.1 mg / L)
January	Mean	< 0.01
	Highest	< 0.01
February	Mean	0.01
	Highest	0.06
March	Mean	< 0.01
	Highest	< 0.01
April	Mean	< 0.01
	Highest	0.01
May	Mean	< 0.01
	Highest	< 0.01
June	Mean	< 0.01
	Highest	< 0.01
July	Mean	< 0.01
	Highest	< 0.01
August	Mean	< 0.01
	Highest	< 0.01
September	Mean	< 0.01
	Highest	< 0.01
October	Mean	< 0.01
	Highest	< 0.01
November	Mean	< 0.01
	Highest	< 0.01
December	Mean	< 0.01
	Highest	< 0.01
Annual mean		< 0.01
Annual high		0.06
Number of measured values		73
Number of limit exceedance		0