Version 4.1

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Draft Final Opinion

on an Application for Authorisation for the Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP)

Submitting applicant
LIBERTY GALATI SA

ECHA/RAC/SEAC: AFA-O-0000007369-63-01/F

Consolidated version

Date: 01/12/2023

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]	**LIBERTY GALATI SA**
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	**Chromium trioxide** EC No: 215-607-8 CAS No: 1333-82-0 **Sodium dichromate** EC No: 234-190-3 CAS No: 10588-01-9
Intrinsic properties referred to in Annex XIV	☒Carcinogenic (Article 57(a)) ☒Mutagenic (Article 57(b)) ☒Toxic to reproduction (Article 57(c)) only for sodium dichromate ☐Persistent, bioaccumulative and toxic (Article 57(d)) ☐Very persistent and very bioaccumulative (Article 57(e))

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

	☐Other properties in accordance with Article 57(f)
Use title	**Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP)**
	Other connected uses:
	Similar uses applied for: 0274-01, 0274-02, 0304-01
Indicative number and location of sites covered	1 site in Belgium
Annual tonnage of the Annex XIV substance used per site	10-40 tonnes per annum (sodium dichromate and chromium trioxide expressed as Cr(VI) equivalent)
Function(s) of the Annex XIV substance	Stabilising agent for food packaging material to ensure corrosion resistance and food safety
Type of products (e.g. articles or mixtures) made with the Annex XIV substance and their market sectors	Tin-plated steel for food packaging material, primarily cans
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)	Until the end of 2027
Use ID (ECHA website)	0301-01
Reference number	11-2120936155-56-0001

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	24/08/2022
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	13/02/2023
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	15/02/2023-12/04/2023
Were comments received in the consultation?	☒Yes ☐No Link: https://echa.europa.eu/documents/10162/17229/0301-01_comments_public_en.zip/413f9017-ac01-6fc7-76ba-a15860213086?t=1682065607164&download=true
Request for additional information in accordance with Article 64(3)	On 30/03/2023 and 26/05/2023 Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/72405/del/200/col/synonymDynamicField_1512/type/asc/pre/3/view
Trialogue meeting	Not held – reason, e.g. no new information submitted in consultation, no need for additional information/discussion on any technical or scientific issues related to the 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: 14/09/2023, agreed by consensus
	SEAC: 12/09/2023, agreed by consensus
Date of sending of the draft opinions to the applicant	27/10/2023
Date of decision of the applicant not to comment on the draft opinions, in accordance with Article 64(5)	01/12/2023
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: 01/12/2023, adopted by consensus
	SEAC: 01/12/2023, adopted by consensus
Minority positions	RAC: No minority positions
	SEAC: No minority positions
RAC Rapporteur	Malcolm DOAK
SEAC Rapporteur SEAC Co-rapporteur	Jonathan SPITERI Dorota DOMINIAK
ECHA Secretariat	Monique PILLET Mateusz WILK Mikael HIRN

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
ES	Exposure scenario
ECS	Environmental contributing scenario
LAD	Latest application date
LEV	Local exhaust ventilation
OC	Operational condition
PBT	Persistent, bioaccumulative and toxic
PEC	Predicted environmental concentration
PNEC	Predicted no-effect concentration
PPE	Personal protective equipment
RAC	Committee for Risk Assessment
REACH	European Union regulation on registration, evaluation, authorisation and restriction of chemicals
RMM	Risk management measure
RP	Review period
RPE	Respiratory protective equipment
RR	Review report
SDS	Safety data sheet
SEA	Socio-economic analysis
SEAC	Committee for Socio-economic Analysis
SP	Substitution plan
SSD	Sunset date
vPvB	Very persistent and very bioaccumulative
WCS	Worker contributing scenario
WWTP	Wastewater treatment plant

This document provides the opinions of the Committees for Risk Assessment and for Socio-economic Analysis based on their scientific assessment of the 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,
- other available information.

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

RAC concluded that it was not possible to determine DNEL(s) for the carcinogenic and mutagenic properties of chromium trioxide and sodium dichromate in accordance with Annex I of the REACH Regulation.

Regarding the exposure to Cr(VI) associated with use of chromium trioxide and sodium dichromate, RAC concluded that the **operational conditions and risk management measures described in the 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.

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

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

The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently.

The exposure of workers and the general population to the substance is estimated to be as described in section 2 of the justification to this opinion.

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

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.

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 the Commission's Better Regulation guidance, the guidance documents on applications for authorisation and socio-economic analysis as well as specific guidance related to how SEAC evaluates the applications (e.g. dose response functions, values of health endpoints).

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

SEAC has assessed the availability, 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:

1. Chromium Free Passivation Alternative (CFPA) (a Zirconium/Titanium Fluoride liquid solution system).

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

- The applicant has demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the applicant by the date of adoption of this opinion.
- There is information available in the application for authorisation and in the comments submitted by interested third parties indicating that there are alternatives available that are technically and economically feasible in the EU. However, RAC is unable to conclude on whether these alternatives are safer.
- The applicant submitted a substitution plan. The substitution plan is credible for the review period recommended.

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 are estimated to be up to €23 million per year over the requested review period and consist of foregone profits both for the applicant as well as upstream suppliers of raw materials, higher costs for European can-makers, social costs related to job losses and environmental damages from higher CO_2 emissions. Additional societal impacts of not granting an authorisation have been assessed but have not been monetised and consist of the impact on internal demand for HRC, indirect job losses and loss of competitiveness across European steel mills.

The risks arising from granting an authorisation, which consider:

- the endpoint relevant for listing the substance in Annex XIV of REACH;
- The 1 000-1 500 directly and indirectly exposed workers;
- the general population exposed at local scale up to 10 000 people;
- that the risk of continued use as assessed by RAC may result in approximately 8.4×10^{-3} expected additional cases of cancer over the requested review period;
- the value of these expected additional cases has been monetised based on the willingness-to-pay methodology and corresponds to an estimate of up to €10 000 per year over the requested review period.

Risks to human health of alternatives have not been assessed.

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

PROPOSED CONDITIONS, MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

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

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

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

REVIEW PERIOD

Taking into account the information provided in the application for authorisation submitted by the applicant and the comments received in the consultation, a review period until **the end of 2027** is recommended for this use.

JUSTIFICATIONS

0. Short description of use

The applicant LIBERTY GALATI SA is a downstream user of chromium trioxide and sodium dichromate at one site in Belgium (Liège).

The applicant is requesting an authorisation for the continued use of chromium trioxide (CT) and sodium dichromate (SD) for the passivation of Electrolytic Tinplate (ETP) with subsequent use as food packaging, at a site where the number of workers engaged in the ETP process is < 70, at one electroplating line (tinning line).

The applicant foresees a maximum use of 10-40 tonnes/year of chromium trioxide and/or sodium dichromate (expressed as Cr(VI)) until the end of 2027.

The use is currently covered by Authorisations No. REACH/20/5/6-8 (use of sodium dichromate)[2] and REACH/20/18/28-34 (use of chromium trioxide)[3] [4].

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

During the ETP process, the surface of tin-plated steel is passivated in a cathodic process in the presence of chromium (VI) salts by covering the tin-plated steel with an inert layer of metallic chromium and chromium (III) oxide. The site uses both chromium trioxide and sodium dichromate as a source of chromate ions in the electrolyte and/or for pH control and they are handled and used under similar processes.

The steel to be passivated is delivered in large spooled steel coils. These steel coils are unwound at the beginning of the line in the entry section and passed through several consecutive cells. First, the steel strip is pre-treated to prepare the surface, then it is plated with tin followed by passivation in the chemical treatment section. During the passage of the steel through the passivation bath, Cr(VI) is reduced in a cathodic driven process and deposited on the steel as a mixed layer of metallic chromium (Cr(0)) and chromium (III) oxide (Cr_2O_3) on both sides of the steel. After passivation, the steel strip is rinsed, dried and then treated in the oiling unit before it is wound up again in the exit section.

Passivation of tin-plated steel is a continuous process and the passivation itself is as a one step in a series of different treatment steps which are performed consecutively. The passivation bath has a 25 m^3 volume and 2 m^2 surface area, while the rinsing passivation, including Rinsing 1, 2 and 3, totals 35 m^3 in volume and 6 m^2 in surface area.

The applicant has presented one environmental contributing scenario (ECS) and 9 worker contributing scenarios (WCS), as part of the one downstream CSR which has been prepared for the member companies of the Association of European Producers of steel for packaging (APEAL) AfA consortium. APEAL member companies are currently running 10 sites in 8 European countries for which the one site at Liege, is a member. Site specific data for Liege

[2] https://ec.europa.eu/docsroom/documents/40845/attachments/1/translations/en/renditions/native.
[3] https://ec.europa.eu/docsroom/documents/44374/attachments/1/translations/en/renditions/native.
[4] Please note that the Court has annulled the Commission Implementing Decision C(2020) 8797 of 18 December 2020 for uses of chromium trioxide (Uses 2, 4, and 5 as well as Use 1 in relation to the formulation of mixtures of these uses). CURIA - Documents

starts at page 94 in the CSR.

The nine common APEAL WCS's are outlined in Table 1, together with a short description. The worker contributing scenarios (WCS) are also referred to as Tasks (T). The tasks that extend over a longer duration are T9, relating to activities close to the line but not directly handling Cr(VI) powders or solutions and T10, activities in the segregated control room. Line operator-based tasks with potential Cr(VI) exposure are: T1, changing out large containers of chromate solution (all sites use liquid CT/SD solution for Use 1); T2, sampling of the tanks; T5, cleaning. Support tasks are T3 to T6 relating to maintenance, cleaning and waste. Most workers undertake a combination of these tasks.

Table 1: Contributing scenarios presented in the use

Contributing scenario	Name of the contributing scenario	Elaboration
ECS 1	Use of chromium trioxide and sodium dichromate for the passivation of Electrolytic Tinplate (ETP)	Exposed population: Local: < 5000 (indirectly exposed workers) and < 5000 (general population)
WCS 1 (T1)	Changing intermediate bulk containers (IBC)	Once connected, the addition takes place in a fully automated manner in a closed system. Exposure potential exists only when connecting and disconnecting pipes/hoses or valves.
WCS 2 (T2)	Sampling of passivation tank	Manual sampling is done at a dedicated point in the tinning line cellar
WCS 3 (T3)	Sampling of Wastewater	Wastewater samples are taken after the reduction step prior to final discharge. The discharge point at Meuse River is monitored and controlled by local authorities.
WCS 4 (T4)	Maintenance	Highly variable, planned and unplanned maintenance as required. Undertaken by a combination of operators, internal and external maintenance workers. Contaminated equipment is flushed before handling and may be dipped in reducing agent.
WCS 5 (T5)	Cleaning	Often undertaken in combination with maintenance. Often with use of water hose. Conducted by external workers under a work permit system issued by site.
WCS 6 (T6)	Sludge removal	No filter press. Settled waste sludge in the circulation tank and the sump pit is pumped out by vacuum truck (by means of an authorised and approved company) once a year.
WCS 7 (T7)	Addition of solid CT	Not Applicable to this Site
WCS 8 (T8)	Dissolution of solid CT/SD	Not Applicable to this Site
WCS 9 (T9)	Activities close to the ETP line without handling of Cr(VI) containing solutions	For example, sanding or changing of rolls, forklift driving.
WCS 10 (T10)	Control-Room activities	Operators spend time in control room when not required on the line. Although air supply is from shop floor.

Tasks 7 and 8 are <u>not</u> performed at the applicant's site and will therefore not be further considered in this opinion.

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

The applicant uses the substance(s) for passivation of electrolytic tinplate (ETP).

Chromium trioxide and/or sodium dichromate are used to stabilise the product and ensure corrosion resistance and food safety. The applicant indicates nine requirements that will be met:

1. Tin oxide growth resistance
2. Lacquer adhesion
3. Readiness for decorative printing and welding
4. Compliance with food contact material (FCM) regulations
5. Sulphide staining resistance
6. Market acceptance
7. Suitability and compatibility with the can making process
8. Chemical resistance (against canned products)
9. Machinability: surface tension, sliding properties.

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

The applicant is producing electrolytic tinplate (ETP) which is used for food packaging material, primarily cans.

1. Operational Conditions and Risk Management Measures

The information below on OCs and RMMs was provided in the CSR and in response to questions during the opinion formation.

1.1. Workers

Operational Conditions

- Cr(VI) concentration:
  - IBC (as liquid): 32 %
  - passivation baths: 1 %
  - filter press/sludge: 5 %
  - waste water: 0.37 %
- Operating temperature: 45-60 °C
- Duration and frequency of tasks are shown in Table 2. These vary between sites reported in the CSR for the collective 'APEAL' consortium (table 28 in CSR) and worst-case assumptions are presented in the table.

Technical RMMs

- No mist suppressants are used.
- Mechanical ventilation system on the roof of the hall covering the tinning line and also a mechanical ventilation in the cellar of the line. There is no automatic control.

- Operator controlled LEV based on switch in the control room with manual control whether the line is stopped or not.
- Ventilation systems are included in the maintenance plan of the line. Upgrades to include check points for the correct suction of the passivation hood (measurement of the air speed near the hood).
- Accidental leaks in the passivation area are directed via gutters to a sump, with wastewater sent for treatment.
- Acid-resistant resin coats holding tanks and pipes to prevent ground seepage

Organisational RMMs

- All waste with Cr(VI) is disposed of by a licensed waste company.
- Internal procedures for testing and inspection of respiratory protective equipment are followed.
- The work clothes are periodically cleaned by a specialised company.
- Chemical risk prevention training emphasises the aspect of good hand hygiene. A cleaning company ensures that hand washing consumables are always available to staff.
- Chromium reagent storage includes spill containment, with operators trained in spill response and equipped with necessary gear.
- A management system is defined for provision of RPE (disposable masks, self-contained breathing apparatus).
- Induction for new workers where the risks are specified and workplace training for specific risks are conducted.
- Occupational health department manages health checks according to the periodicity in the legislation. Staff exposure measurements are planned on an annual basis (portable measurement devices, urine biomonitoring).

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

NOTE: T7 and T8 are not tabled here or discussed further, since neither WCS exists at Liege

Contributing scenario	**Duration and frequency of exposure**[1]	**Engineering controls** (e.g. containment, segregation, automation, LEV)[2]	**PPE** (RPE and Skin protection used)[3]	**Organisational controls** (access control, procedures, training)
T1 Changing IBC containers (PROC 8b)	Duration: 15 min Frequency: 48 days/y	Closed transfer either directly into bath or into storage tank Mechanical ventilation	Chemical resistant clothing. RPE Gloves. Safety glasses/face shield	Specific activity training for dedicated operators. Careful transport of closed containers to dedicated place
T2 Sampling of passivation tank (PROC 9)	Duration: 15 min Frequency: daily	Manual sampling is done at a dedicated point in the tinning line cellar. LEV above electroplating bath (Eff. not specified) Mechanical ventilation	Chemical resistant clothing. Gloves. Safety glasses/face shield. No RPE used.	As T1 Annual LEV system verification
T3 Sampling of Wastewater (PROC 9)	Duration: 15 min Frequency: 240 days/y	Dedicated sampling points Natural ventilation	Chemical resistant clothing. Gloves. Safety glasses/face shield	As T1
T4 Maintenance (PROC 28)	Duration: 60 min Frequency: 48 days/y	Mechanical ventilation	Protective clothing or chemical resistant clothing. RPE Gloves.	As T1. Before major maintenance activities Cr(VI) [by external workers] baths are emptied; contaminated objects are emptied and rinsed before maintenance. External workers attend a safety meeting to outline protective measures and acquire necessary work permits.
T5 Cleaning (PROC 28)	Duration: 15 min Frequency: daily	Mechanical ventilation	Chemical resistant clothing. RPE Gloves.	As T1

T6 Sludge removal (PROC 28)	Filter Press: Duration: 15 min; Frequency: 48 days per year Sludge Removal: Duration: 4 hours; Frequency: annually	The accumulated waste sludge in the circulation tank and sump pit is removed annually, by an approved vacuum truck service. Mechanical ventilation	Protective clothing or chemical resistant clothing. RPE during sludge removal from tank. Gloves	As T1
T9 Activities close to the ETP line without handling Cr(VI) (e.g. Changing rolls, forklift operation) (PROC 4)	Duration: up to 480 min/day Frequency: daily	No direct contact to Cr(VI) Mechanical ventilation	Standard PPE set: protective clothing, safety glasses, protective helmet, ear protection and safety shoes	Specific activity training
T10 Control Room	Duration: up to 480 min/day Frequency: daily	Control rooms are strategically placed at a safe distance from passivation facilities along the line. They lack external fresh air supply, instead utilizing air from the hall environment for ventilation.	Standard PPE set: protective clothing, safety glasses, protective helmet, ear protection and safety shoes	-

[1] Worst case assumptions are presented
[2] ACH3 assumed for mechanical ventilation
[3] PPE details were provided for each site. RPE is typically full or half mask with ABEK2P3 combination filter, with an assigned protection factor (APF) of 20.

1.2. Consumers

Not applicable.

1.3. Environment/Humans via the environment

Air

Air and aerosols that accumulate over the bath in the passivation and rinsing cells are trapped by a hood, which is linked to a washing and mechanical ventilation mechanism. This air is then expelled through a chimney. Local authorities monitor a designated measurement point on the chimney. The passivation section has a scrubber and ventilation system, though the wet scrubbing installation is decommissioned due to its oversized capacity for passivation vent capture.

Water

Cr containing wastewater is pumped from the tinning line to the wastewater treatment facility. There is a dedicated installation to treat chromium wastewater where Cr(VI) is reduced to Cr(III) in a reactor by adding sodium bisulphite. The treatment is carried out according to a redox measurement with an adapted pH regulation. The treated water is neutralised with lime slurry, mixed (diluted) with Cr(VI)-free wastewater and discharged to the receiving water (Meuse River). This discharge point is monitored and controlled by the local authorities.

Soil

Accidental release to soil is mainly prevented by a secondary containment pit around the treatment baths.

In addition, indoor and outdoor surfaces where chemicals are handled are constructed in a way to prevent the chemicals from entering the soil (concrete or antiacid tiles).

Sludge from the passivation baths and wastewater treatment process is not applied to agricultural soil but is sent to a landfill or incinerated.

Waste (other than wastewater)

The waste sludge is pumped out by vacuum truck by an authorised and approved company at most once a year.

In addition, other wastes contaminated by Cr(VI) are mainly maintenance consumables and used PPE. After use, they are put in chemical waste bins and collected by a specialised and authorised contractor.

Table 3: Environmental RMMs – summary

Compartment	RMM	Stated effectiveness
Air	Capturing hood linked to a washing mechanism. The wet scrubbing installation is unused as it is oversized for capturing into the passivation vents.	Not stated. All official measurement campaigns at the passivation section's stack are compliant.
Water	Reduction to Cr(III) and precipitation following neutralisation	Measuring effectiveness is challenging. However, the water treatment plant is equipped with automated controls to

		detect anomalies before discharge, and buffer storage is in place should the treatment capacity be exceeded. (concentration in final wastewater < 0.1 %)
Soil	Operators are equipped with spill containment equipment and are trained in spill response procedures. Any leaks in the passivation area are channelled via gutters to a collection sump, and the resulting wastewater is sent for specialised treatment.	100 %

1.4. RAC's evaluation on the OCs and RMMs

Worker OCs and RMMs

T1: Changing IBC containers

Closed liquid transfer removes the potential for exposure to Cr(VI) dust and there is low potential for dermal exposure during connection/disconnection. The OCs and RMMs are adequate.

T2: Sampling of passivation baths

RAC notes that manual operations are performed for sampling tasks. A solitary sampling point is situated at level -1 in the tinning line cellar. Samples are obtained using a specialised sampling valve fitted on the manifold of the passivation circuit. The applicant is currently exploring the potential of installing a manual closed sampling system to prevent any risk of coming into contact with the passivation bath. No RPE is used.

As explained in section 2, the static measurements from this cellar location show Cr(VI) concentrations ranging from 0.9 to 1.3 µg/m³ which are orders of magnitude higher than the TWA 0.003 µg Cr(VI)/m^3 based on other APEAL sites and used by the applicant for the assessment. RAC finds this discrepancy indicates that the OCs and RMMs are not optimised to minimize exposure for activities taking place in the cellar, even when the LEV is operational.

As the source of Cr(VI) in the cellar is unclear, RAC recommends that the applicant enforce the use of RPE during activities conducted in the cellar (including T2 sampling of passivation bath), as long as the exposure measured in the cellar is higher than the value used for the exposure assessment of the sampling task.

This leads to a condition in section **Error! Reference source not found.** of the opinion.

T3: Sampling of wastewater

The Cr(VI) in the wastewater is reduced before sampling (only at site boundary emission point) and the concentration is well below 0.1 %. The exposure potential is negligible and there is no need for RMMs.

T4: Maintenance

Maintenance is generally conducted on cleaned equipment and so exposure potential is generally low. However, maintenance activity may be undertaken in vicinity of a Cr(VI) process that is in operation, with potential for indirect exposure. The OCs and RMMs are adequate.

T5: Cleaning

External workers are tasked with chromium passivation installations' maintenance and cleaning. Prior to work, they attend a safety meeting or risk analysis to outline protective measures based on chromium safety data sheets, and secure necessary permits for tasks like pipe and confined space work. Cleaning is undertaken of the passivation bath area and as a preliminary step before maintenance. It often involves the use of water hose, which can result in generation of aerosols. The measures taken to remove the contaminant before hosing include flushing the parts and dipping the parts in a reducing agent prior to handling. RAC considers that additional measures such as pre-wiping surfaces and optimising the technique used in hosing can reduce the exposure. RPE is worn.

The OCs and RMMs are adequate, although there may be potential for improvement. This is minor however and does not lead to a condition in section **Error! Reference source not found.** of the opinion.

T6: Sludge removal

An authorised company annually vacuums out the settled sludge from the circulation tank and sump pit using a truck, under site work permits.

RAC considers that vacuuming of the sludge to remove it from the tank is an effective RMM as manual intervention is expected to be less.

T9: Activities close to the ETP line without handling of Cr(VI) containing solutions

Workers such as forklift drivers, roll changing and inspectors are in the vicinity of the ETP line and have the potential for exposure. There is a mechanical ventilation system on the roof of the hall covering the tinning line and there is mechanical ventilation in the cellar of the line. There is no automatic control. In addition, the emissions from the passivation baths are captured with exhaust hoods.

T10: Control Room

Control rooms are positioned along the line, at a safe distance from passivation facilities, and are ventilated with air from the hall environment. A specific fresh air supply was deemed unnecessary by the applicant due to the occupational medicine department's exposure measurements, which revealed no Cr(VI) presence in any control rooms' atmosphere. Control rooms are an effective risk management measure to separate workers from the production lines when the intake air is uncontaminated fresh air.

Environmental OCs and RMMs

RAC notes that mist suppressant is not used and that the operating temperature of the passivation bath is 45-60 °C, both factors which would be likely to increase emissions to air in the absence of air scrubbers in the air extract stack.

However, RAC acknowledges that the applicant has implemented a number of technical measures to reduce the environmental emissions of Cr(VI):

- The passivation section is equipped with a scrubber and ventilation system, but the wet scrubbing installation has been decommissioned because its capacity for capturing passivation vents is excessively large. The wastewater is treated in a reduction system prior to wastewater treatment and discharge;
- there is no potential for release to soil due to spill containment equipment available to operators on the line. All accidental leaks in the passivation area are collected to a network of gutters to a collection sump. The waste water of this sump is sent to specific waste water treatment.

- all hazardous waste is disposed of by a licenced contractor.

These RMMs significantly reduce the potential for release of Cr(VI) to the environment and are considered by RAC to be good practice.

1.5. RAC's conclusions on the OCs and RMMs

Overall conclusion

Are the operational conditions and risk management measures appropriate and effective[5] in limiting the risks?

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

RAC considers that the OCs and RMMs implemented for workers' protection and humans via environment (HvE) are generally appropriate and effective in limiting the risk to workers.

RAC has moderate concerns outlined below. Consequently, additional conditions for the authorisation are proposed in section 7 of this opinion to further reduce the potential for exposure to workers.

- sampling of bath concentration is manual and open at dedicated sampling points;
- it is not clear if the workers perform a 'fit check' of the seal of their RPE before taking on relevant tasks.

2. Exposure assessment

Introduction

The CSR accompanying this application was prepared initially for the six member companies of the Association of European Producers of steel for packaging (APEAL) to be used for the application for authorisation (AfA) for 10 sites for the Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP).

The ETP process is performed in a comparable manner at all sites. A joint exposure assessment was performed using production information and monitoring data for the 10 sites

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

provided by the individual companies.

The main body of the CSR accompanying this application in 2018 is for the 10 sites APEAL consortium, with minor amendments. Individual information for this one site at Liege, that has applied here for authorisation is provided in the succinct summary of OCs/RMMs and in the confidential annexes. The site-specific information in the annexes was updated where available, and consequently there is some variation with data presented in the main body of the CSR.

In the main body of the CSR, the individual, anonymised, data and/or pooled values for the 10 sites of the APEAL consortium are presented. The monitoring data for the applicant's site are presented in Annex 3 for worker exposure (only 4 measurements) and Annex 7/8 for environmental exposure.

The applicant states that in preparation of the CSR, data evaluation was performed in close contact with the sites, including a site visit by the consultant.

2.1. Inhalation exposure

Monitoring

The applicant pooled the exposure monitoring data from all 10 sites and considered that it was representative of all sites. The applicant identified the following challenges in collating the data:

- the analyte measured was either total chromium or chromium(VI);
- the limit of quantification varied over 2-3 orders of magnitude;
- the number of samples varied from single measurements up to a full set of personal and static samples;
- data was a combination of short-term/task based and long-term/operator type based;
- the description of activities undertaken varied between companies from very limited to relatively detailed.

Personal and/or static task-related measurement values for T1-10, were included in the annex in an anonymised form.

An overview of the data reported is presented in Table 4. Task-based personal exposure data for the various tasks is presented in Table 5. Long term personal exposure data for various line operators was provided in the annexes and is compiled in Table 6.

Information on activities undertaken during measurement was not available.

Details on measurement methodology were not included. Regarding data analysis, the 90th percentile value was used for risk characterisation. The Limit of Quantification (LoQ) varied between sites and measurement campaigns, and the range is shown in Table 4. For values that were below the limit of quantification (LoQ), half of the LoQ (LoQ/2) was used for the calculation. In instances where all samples were below the LoQ, the maximum LoQ/2 was taken.

When a substantial proportion of samples were below the LoQ, the wide range in LoQ influenced the exposure estimate, particularly when a large number of non-detect samples had

a high LoQ. The applicant presented the exposure estimate both with and without high LoQ values. The estimates with excluded values were carried forward by the applicant in the risk assessment.

An exposure estimate that has a significant influence on the risk characterisation for line operators is the estimate for Task 9 (activities close to the line without performing any Cr(VI) related activities). It corresponds to an indirect or far-field exposure as the operators are not directly involved with the plating activities. For Task 9, personal and static measurements are available.

A total of 88 personal measurements from 10 sites were available: 52 with short durations and high LoQ were excluded and the remaining 36 values (8 of which were < LoQ) were considered in the assessment by the applicant. The median of these 36 values is 0.09 µg Cr(VI)/m^3 and the 90th percentile is 0.22 µg Cr(VI)/m^3. The applicant added the value of 0.22 µg Cr(VI)/m^3 to task-specific exposures to determine the aggregated exposure of operators on the ETP lines (see 3.1).

A total of 56 static measurements from 10 sites were available: Almost half of the 56 values were above the LoQ and the 90th percentile was 3.1 µg Cr(VI)/m^3. This is over ten times the measured personal exposure of 0.22 µg Cr(VI)/m^3. The influence of the LoQ was not described. Static results for Task 9 were the highest of static results for all tasks 1-10, typically by more than a factor of 10. The applicant considered that stationary monitoring values "do not necessarily provide a realistic estimate for the different operator subgroups, because the documentation of these values is often not sufficient to clearly indicate for which type of operators they might be representative".

For Task 10, all 17 static measured values were below the LoQ. The corresponding 90th percentile was 0.05 µg/m^3.

Regarding all 177 static measurements, the applicant compared the measured values with the mean, median and 90th percentile of 1 837 values from the German MEGA database for stationary sampling at 806 workplaces between 2000 and 2009. The pooled data from the 10 sites was below the MEGA values.

The highest personal exposure from measurement data is 0.6 µg/m^3 (Table 4, basement operator, 90th percentile, excludes RPE).

Table 4: Overview of measurement data reported

Measurement type	Site	Years	Number of personal samples	Number of static samples	Comment
Task related	All 10 sites	-	196	177	Includes data from at least two sites of this application for all scenarios (personal and/or static)
Operator related	Liege	2018	2	2	SEE results below for Liege

	Personal monitoring values		Stationary monitoring values	
	Operator 1 (ground floor)	Operator 2 (basement)	Close to passivation	Cellar

Soluble Cr(VI) µg/m^3	< 0.6	< 0.6	< 0.7	1.3
Insoluble Cr(VI) µg/m^3	< 0.6	< 0.6	< 0.7	0.9

The static monitoring results in Table 4 show Cr(VI) concentrations in the cellar which are orders of magnitude higher than the TWA 0.003 µg Cr(VI)/m^3 based on other APEAL sites and used by the applicant for the assessment for T2 - Sampling of passivation bath (Table 6). The source of Cr(VI) in the cellar is unclear to RAC.

Table 5: Overview of task based personal measurement data (up to 10 sites)

Task	**Number of sites**	**Number of Cr(VI) samples**	**Cr(VI) measure-ments <LoQ Cr(VI)[2]**	**Air monitoring results[1]: Cr(VI) µg/m^3**		
				AM	**Median**	**90th P**
T1 - Changing IBC containers	4	22	100 %	0.03	0.03	0.05
T2 - Sampling of passivation bath	6	26	84.6 %	0.40	0.03	0.5
T3 - Sampling of wastewater	4	8	75 %	0.13	0.05	0.26
T4 – Maintenance	5	9	66.7 %	0.44	0.06	1.16
T5 – Cleaning	5	17	47 %	0.07	0.05	0.14
T6 - Sludge removal	1	2	100 %			
T9[3,4] **-** Activities close to the ETP line without handling of Cr(VI) containing solutions	5	88	75 %	0.49	0.75	0.75
T10[4] - Control-Room	2	19	100 %	0.29	0.03	0.03

[1] AM: arithmetic mean; 90 P: 90th percentile

[2] Values below the limit of quantification were taken as LoQ/2.

[3] For task 9, 52 of the personal measurements < LoQ were short duration and high LoQ. Excluding those gave 36 values with median of 0.09 µg/m^3 and 90th percentile of 0.22 µg/m^3. For comparison, almost half of the 56 measured stationary values were above the LoQ and the 90th percentile was 3.1 µg/m^3.

[4] There are inconsistencies in the values for personal exposure presented by the applicant for T9 and T10, as the median and 90th percentile are the same value. Annex 2 shows T10 90th percentile exposure to be 0.75 µg/m^3. For T10, 17 static results are available, and all were below the LoQ of between 0.01-0.05 µg Cr(VI)/m^3 although this pooled data includes none of the sites of this application.

Modelling

The Advanced Reach Tool (ART) Version 1.5 was used to perform the assessment of inhalation exposure to Cr(VI) for all tasks. The applicant considered that the exposure scenarios within this assessment were within the applicability domain of the ART-tool with the exception of T5, cleaning (water hose/aerosol generation) T9 (activities close to the line) and T10 (Control room). The input parameters were provided in the CSR for each task.

The following approach was taken:

- Exposure was modelled as "near field exposure" (< 1 m)
- The upper inter-quartile confidence interval of the 75th percentile is used as the exposure estimate.
- For task-based concentration, an exposure duration of 480 min was assumed and then converted outside the tool to time-weighted average (TWA)
- The critical input parameters for each task were established by questionnaires and a site visit. These include concentration, temperature, transfer rate, duration, frequency, room volume as applicable. The range, the median and the maximum values are provided and the value (median or maximum) used in the ART model for each parameter was justified.
- An air change rate of ACH3 was used to represent the extent of natural ventilation based on open windows and doors.

Inhalation exposure estimates brought forward for risk characterisation

For each worker contributing scenario, the applicant addressed the uncertainties in the measured and modelled exposure estimates and justified the selection of the value to be used for further risk analysis. The values brought forward for the risk characterisation are presented in Table 6.

The exposure estimate carried forward for risk characterisation was the modelled exposure in the majority of cases. T5 (cleaning), and T10 (control room) were based on measurement as modelling is not possible.

For T2 (sampling), there was good agreement. The modelled value was slightly lower than the measured value. The applicant brought forward the modelled value due to large number of samples below the LoQ.

For T4 (maintenance), there was a 100-fold discrepancy between measured and modelled values. The higher estimate from measurement was used as additional exposure could potentially occur during maintenance than encompassed by the model.

Table 6: Overview of long-term exposure values used for risk characterisation

Task	Frequency days/year	RPE APF	Long-term TWA µg Cr(VI) /m^3 [1]	Comments
T1 - Changing IBC containers	48	20	< 0.001	Based on modelling. Personal monitoring: 4 sites, 22 samples, all < LoQ
T2 - Sampling of passivation bath	240	1 (no RPE)	0.003	Based on modelling. Personal monitoring: 5 sites, 24 valid samples, 20 < LoQ, long term 90th percentile = 0.004µg/m^3.
T3 - Sampling of wastewater	240	1 (no RPE)	0.002	Based on modelling
T4 – Maintenance	48	20	0.012	Personal monitoring: 4 sites, 9 valid samples, 6 < LoQ, 90th percentile = 20 × median value. Exceeds modelled value × 100.

T5 – Cleaning	240	20	0.007	Personal monitoring: 5 sites, 17 valid samples, 8 < LoQ, 90th percentile = 5 × median value. RPE with APF 20 worn but not included. No modelling performed
T6 - Sludge removal	48	20	0.002	Based on modelling. One personal sample < LoQ
T9 - Activities close to the ETP line without handling of Cr(VI) containing solutions	240	1 (no RPE)	0.220	Personal monitoring: 4 sites, 36 valid samples, 8 < LoQ, 90th percentile = 2.5 × median value. No modelling performed.
T10 - Control-Room activities	-	-	-	Applicant considers time spent in control room does not contribute to Cr(VI) exposure. Qualitative

[1] This was derived by correcting 8hour Time Weighted Average exposure for frequency (no. of days/240) and Assigned Protection Factor (APF) of RPE when applied.

2.2. Dermal exposure

A quantitative dermal exposure assessment was undertaken with respect to effects on reproduction due to sodium dichromate exposure.

Modelling

Two models were used, Riskofderm and a generic model.

The applicant used Riskofderm (v.2.1) to estimate exposure for those tasks within the scope of that tool, namely T2, and T3. These were modelled as filling tasks. The conditions of use and results for realistic and conservative inputs were also provided. The 90th percentile exposure estimate was used.

A second (generic) modelling approach using a default dermal load of 0.1 mg/cm^2/d (EU RAR for SD for non-dispersive uses) was also undertaken for each task and the results compared where possible.

The results are presented in Table 7, based on realistic inputs. There was good agreement in estimated exposure between both models. When two modelling estimates were available, the higher value was brought forward for risk characterisation.

Table 7: Exposure concentrations for workers (dermal exposure)

Task	Frequency (d/y)	Model	Exposure (uncorrected) µg Cr(VI)/kg bw/d	Exposure (frequency corrected) µg Cr(VI)/kg bw/d
T1 - Changing IBC containers	48	Generic	11.0	2.19
T2 - Sampling of passivation bath	240	Riskofderm	0.49	0.49
		Generic	0.34	0.34
T3 - Sampling of wastewater	240	Riskofderm	0.18	0.18
		Generic	0.13	0.13
T4 – Maintenance	48	Generic	0.34	0.07
T5 – Cleaning	240	generic, hands	0.34	0.34
		generic, body	25.0	25.0
		generic, hands and body	25.3	25.3
T6 - Sludge removal	48	Generic	0.34	0.07

2.3. Biomonitoring

The applicant conducts annual biomonitoring. However, this data was not used for the exposure assessment.

2.4. Environmental releases

Monitoring data for Cr(VI) releases to water and air are available in the Annexes to the CSR.

Release factors for the releases of Cr(VI) to water and air were derived from the measured emission data per site and the tonnage used per site. The release factors were used as input for the EUSES modelling (v.2.1.2) to establish environmental concentrations and risks for exposure to humans via the environment (HvE). Release to soil was assessed qualitatively.

Ranges and/or anonymised data for the 10 sites of the APEAL consortium is provided in the main body of the CSR. The data for the applicants' site is included in the annex (data is confidential but available to committees). As a result, the data from both the CSR and the annex is presented in Table 8.

Both the Limit of Quantification (LoQ) and Limit of Detection (LoD) were used as the reporting limit, as shown in Table 8. When the measured emission was below the LoQ(D), LoQ(D)/2 was used for calculating the emission values. The exposure estimate was generally based on the year of highest release and was determined for projected production volumes.

All Cr(VI) containing solid waste is collected by an external service provider so no release of Cr(VI) to soil is possible.

Table 8: Summary of releases to the environment

Release route	Reporting Limit Air: mg/Nm³ Water mg/L (order of magnitude)	Release factor	Release per year kilograms Cr(VI)	Release estimation method and details
Air	LoD: 10^{-3} to 10^{-4}	6.65×10^{-10} to 7.88×10^{-4}	0.0214	Measured data/Annex 7
Water	LoQ: 10^{-4}	1.09×10^{-5}- 1.37×10^{-3}	28.49	Measured data/Annex 7
Soil	n/a	0	0	Qualitative

Table 9: Summary of modelled exposure for humans via the environment

Parameter	Local[1]
PEC in air (µg Cr(VI)/m³)	1.63×10^{-5}
Daily dose via oral route (µg Cr(VI)/kg bw/d)[2]	9.867×10^{-4}

[1] Regional exposure was reported by the applicant but is not included here due to low levels. Values are typically two or more orders of magnitude lower than local exposure.

[2] For oral human exposure via the environment, only exposure via drinking water and fish is taken into account in accordance with EU Risk Assessment Report for hexavalent chromium (ECB, 2005) and supported by the data reported by EFSA (2014).

2.5. RAC's evaluation of the exposure assessment

Workers exposure

Measured inhalation exposure

RAC acknowledges that pooling task-related exposure data offers the benefit of a large data set. However, this approach also has a downside as it includes information from other sites not part of this application, thereby affecting the exposure assessment. The applicant states that the sites are similar. Due to the anonymised nature of the data provided, it is not possible to evaluate the difference in measured task-related exposure between sites. Measurement methodology was not described. RAC considers that sufficient measurement data was provided to evaluate the exposure, although it was limited by clarity on activities undertaken during measurement and the anonymisation of data.

The data handling approach was clearly described. The 90th percentile was used, which gives a reasonable worst-case estimate. The applicant excluded results below the LoQ when the LoQ was elevated. RAC considers this to be reasonable due to the large number of samples below the high LoQ at some sites. The estimated exposure was typically a factor of 4 lower when these data points were excluded.

The sufficient measurement of data provided by the pooling of data is not so effective for this site, given the paucity of actual data that was provided for the Liege site. Only two static and two personal monitoring results were provided for 2018, and are of limited meaning since they were taken using a high LoD (0.6 µg/m³ Cr(VI)).

For Task 9 (activities close to the line without performing any Cr(VI) related activities), a substantial number of personal and static measurement results were provided, but for the 10 sites. The applicant considered the static measurement results to be non-representative.

RAC notes that the static measurement results were 10 times higher than the personal exposure results.

RAC considers that stationary measurements can be representative of the personal exposure for tasks such as Task 9 that do not have direct activity related exposure. However, their representativeness depends on the sampling location and proximity to the line. In the absence of such information, RAC accepts the statement of the applicant that the results are non-representative but notes they are elevated compared to personal results.

Modelled inhalation exposure

In ART, the applicant used the upper inter-quartile confidence interval of the 75th percentile as the exposure estimate. RAC considers this to be a reasonable approach. Although the 90th percentile is often used, the values are generally similar and this approach follows the recommendations of the tool developers.

The input parameters for the model were clearly identified and the selections justified. Where there was a range of conditions between sites, a worst-case assumption was generally taken. The input parameters were consistent with the task descriptions.

For tasks such as maintenance (T4) where there is a high degree of uncertainty due to the nature of the works, the applicant provided additional information on the sensitivity of the outcome to the assumptions. Furthermore, the applicant used the measured values as these were higher.

For T6 (filter press/sludge), the modelling was based on filter cake removal. However, the CSR states that sludge removal is undertaken at most of the 10 sites of the consortium rather than a filter press. There is reference to sludge removal by vacuum once a year at Liege, but no filter cake is handled since the site has no filter press. Consequently, the modelled exposure may not be representative of the task.

Overall, RAC considers that the applicant provided a representative estimate of the modelled exposure, taking into account the uncertainties referred to here.

Inhalation exposure estimates brought forward for risk characterisation

The applicant presented both measured and modelled data where possible. In many tasks, comparison between the measured and the modelled values showed good agreement, particularly when values with high LoQ were disregarded.

The applicant identified the exposure value they considered representative and justified the decision. Due to the uncertainty inherent in the monitoring data because of aspects such as their dependence on the LoQ, and uncertainties such as distance and the exact activities undertaken during monitoring, the applicant generally selected modelled values for further risk estimates, even when the modelled value was slightly lower, such as with T2 (sampling) Although this is not the most conservative approach, RAC considers that it is reasonable. For T4 (maintenance), the measured value was 100 times greater than the modelled value and the applicant chose to bring the higher value forward due to the potential for additional exposure from handling contaminated objects. RAC concurs with this approach.

RAC notes that the main contributor to the combined exposure and risk characterisation of most workers is T9 (activities close to the line) and this is based on personal exposure of 0.22 µg Cr(VI)/m^3 from measured data.

The applicant converted exposures (measured and modelled) to 8 hour time-weighted average (TWA) as appropriate and determined the long term exposure based on the number of days per year (240 days is a full year) and the effectiveness of any RPE worn.

Dermal exposure

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

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

The highest estimated exposure by the dermal route was for T5, cleaning, where it was assumed that one half of the body was exposed. RAC agrees that this is a worst-case assumption and considers that it is likely to be an overestimate in an industrial setting.

Biomonitoring exposure

Biomonitoring was not used for the exposure assessment.

Humans via the environment

RAC notes that the applicant performs measurements of the air and wastewater releases at least annually and in accordance with standard procedures. RAC also notes that the frequency and number of measurements is sufficient to enable an assessment to be made of the environmental emissions.

The applicant states that as Cr(VI) rapidly reduces to Cr(III) in many environmental compartments, the releases based on Cr(VI) can significantly overestimate the human exposure via the environment. The applicant adds that the calculated partition coefficients used in modelling are not applicable to inorganic substances such as Cr(VI). RAC concurs that these considerations lead to conservative estimates.

RAC notes the observation by the applicant that the assumption of using LoQ/2 (when the measured values are below the LoQ) leads to a highly conservative estimate with regard to wastewater emission. RAC also notes however that typically half the data points exceeded the LoQ, and that the exceedance was up to ten times the LoQ. Consequently, RAC does not concur that the estimate is highly conservative.

The applicant also provided an assessment of exposure at the regional scale. RAC notes that the EU risk assessment report (RAR) for Cr(VI) substances[6] states that "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". Therefore, RAC is of the opinion that the regional exposure is not particularly relevant and did not include it in this Opinion.

RAC considers that the release estimates are generally realistic and can be brought forward for risk characterisation.

2.6. RAC's conclusions on the exposure assessment

Having regard to the evaluation of the exposure assessment, RAC concludes that:

- all relevant health effects and routes of exposure were considered;

[6] https://echa.europa.eu/documents/10162/3be377f2-cb05-455f-b620-af3cbe2d570b

- the inhalation exposure estimates, both measured and modelled, are derived in a transparent and well-founded manner and are representative of the exposure;
- the dermal exposure estimates are soundly based and conservative;
- the measured environmental releases provide a reliable basis for determination of the exposure,

RAC considers that although the exposure estimates used to characterise the risk are plausible, the exposure assessment contains moderate shortcomings due to the small amount of measured exposure data at the applicant's site plus limited contextual information, and use of a high LoD (0.6 µg/m^3 Cr(VI)) for the monitoring results provided for 2018. Consequently, 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.

3. Risk characterisation

The applicant addressed all endpoints listed in Annex XIV for chromium trioxide and sodium dichromate in the assessment.

The applicant used the dose response relationship for lung and intestinal cancer risk associated with Cr(VI) exposure recommended by RAC (RAC 27/2013/06 Rev. 1, agreed at RAC 27).

The applicant has conservatively assumed that all inhaled chromium trioxide particles are in respirable range and contribute to the lung cancer risk and therefore no exposure via the oral route (mucociliary clearance and swallowing of non-respirable fractions) needs to be considered[7], taking into account also that the excess lifetime risk for intestinal cancer is one order of magnitude lower than that for lung cancer.

The applicant used the DNELs for reproductive risk associated with sodium dichromate recommended by RAC (RAC/35/2015/09, agreed at RAC 35).

3.1. Workers

Inhalation exposure to Cr(VI)

The applicant summed the task exposures (from measured or modelled estimates as shown in Table 6) to establish the long-term aggregated exposure for each operator type. The reduction provided by RPE is included where applicable.

RAC compiled this information in Table 10. In this table, the operator types are grouped based on information contained in the CSR (Table 60). The main contributor is the exposure of 0.22 µg Cr(VI)/m^3 for Task 9, activities performed along the line without handling of Cr(VI).

The task-based risk estimates are in the range of 1.38×10^{-6} to 8.8×10^{-4}.

[7] In document RAC/27/2013/06 Rev.1 states that "in cases where the applicant only provides data for the exposure to the inhalable particulate fraction, as a default, it will be assumed that all particles were in the respirable size range."

Applying this excess lung cancer risk to the indirect exposure level of 0.22 µg/m^3, the applicant concluded that the upper-end excess risk was 8.8 × 10^{-4}.

Table 10: Combined exposure and risk characterisation (inhalation)

Operator Type	Cr(VI) related tasks	Number of workers	Long-term TWA Cr(VI) based on calculation for individual tasks µg/m^3	Upper end Excess risk[1]
Polyvalent operator Forklift driver (day worker)	T1	< 5	0.0003-0.22	8.8 × 10^{-4}
Maintenance operator (Internal & External)	T4	< 20	0.0116	8.8 × 10^{-4}
External cleaning operator	T5, T6	< 5	0.007	8.8 × 10^{-4}
Entry/Anodes/ Polyvalent Operator Inspector	T2, T9	< 10	0.22	8.8 × 10^{-4}
Total number of workers		< 70		

[1] Estimated individual risk resulting from exposure. The applicant identified an upper end excess risk associated with 0.22 µg/m^3 for all operators likely to spend the majority of shift on the line.

Exposure to sodium dichromate

The risk characterisation ratios for dermal and inhalation exposure of workers are based on the DNELs derived by RAC for effects on fertility (ECHA, 2015):

- dermal DNEL systemic long-term: 43 µg Cr(VI)/kg bw/d
- inhalation DNEL systemic long-term: 43 µg Cr(VI)/m^3

The RCR for the inhalation exposure (Table 6) was combined with the RCR for the dermal exposure (Table 7) for each task in Table 11. The combined RCR with respect to reproductive toxicity is below 1 for all tasks. The dermal route contributes over 95 % to the exposure.

The highest task RCR is 0.59 for T5 (cleaning). The aggregated RCR for tasks 1-6 is 0.66.

Table 11: Risk characterisation – sodium dichromate

Task	Combined RCR
T1 - Changing IBC containers	0.05
T2 - Sampling of passivation bath	0.01
T3 - Sampling of wastewater	< 0.01
T4 – Maintenance	< 0.01
T5 – Cleaning	0.59
T6 - Sludge removal	< 0.01
Sum, T1-T6	0.66

3.2. Humans via the environment

The risk assessment for humans exposed to Cr(VI) via the environment addresses both the

inhalation of airborne residues and the oral intake via the food chain at the local level, with health effects of lung cancer and intestinal cancer respectively. In addition, the reproductive risk from exposure to sodium dichromate is also assessed. The exposure and individual excess risk/risk characterisation ratio (RCR) is shown in Table 6.

The excess risk for the general population associated with Cr(VI) exposure was determined using the exposure-risk relationship established by RAC (2013). According to this, inhalation exposure to 1 µg Cr(VI)/m^3 is associated with an excess lung cancer risk of 2.9×10^{-2} and oral exposure to 1 µg Cr(VI)/kg bw/day is associated with an excess small intestine cancer of 8×10^{-4}.

When determining the risk from drinking water, the applicant reduced the local Cr(VI) concentration by a factor of 5, due to a number of factors in the EUSES model that lead to overestimation, as justified in section 9.1.1 in the CSR.

The risk characterisation for reproductive effects due to sodium dichromate via the environment is based on the DNEL derived by RAC for effects on fertility (ECHA, 2015) for oral and inhalation exposure of humans. The inhalation DNEL (systemic long-term) is 11 µg Cr(VI)/m^3 and the oral DNEL (systemic long-term) is 17 µg Cr(VI)/kg bw/d.

The applicant also provided an assessment of the regional risk but it is not considered further here due to the low risk.

Table 12: Exposure and risk to humans via the environment – local scale

Parameter	**Local**		
	Exposed population: up to 10 000		
	Exposure	**excess risk**	**RCR (sodium dichromate)**
Humans via the environment – Inhalation	0.163×10^{-4} µg Cr(VI)/m^3	4.73×10^{-7}	1.48×10^{-6}
Humans via the environment – Oral	0.9867×10^{-3} µg Cr(VI)/kg/d	1.49×10^{-7}	5.8×10^{-5}

3.3. RAC's evaluation of the risk characterisation

Workers

The applicant has addressed all endpoints listed in Annex XIV for chromium trioxide and sodium dichromate in the assessment.

RAC notes that the worst-case combined exposure estimated by the applicant is 0.22 µg Cr(VI)/m^3 (taking into account RPE when relevant) corresponding to an excess risk of 8.8×10^{-4}.

RAC acknowledges that a conservative approach was generally taken by the applicant when establishing the exposure and risk characterisation and overall accepts the risk characterisation provided by the applicant.

Regarding exposure to sodium dichromate and associated reproductive risk, the applicant has derived a conservative estimate of the exposure and used the DNELs recommended by RAC.

RAC considers that the conclusion of aggregated RCR of 0.66 for reproductive effects is an

overestimate due to worst-case assumptions on exposed body area.

Overall, RAC acknowledges that there are uncertainties regarding the exposure estimates and the task combinations for various workers. Nevertheless, RAC concludes that these uncertainties do not prevent the derivation of a representative risk characterisation.

Humans via Environment

RAC acknowledges the conservative default assumptions in EUSES and considers that this leads to an overestimation of exposure and risk. RAC accepts the reduction factor of 5 applied to the calculation of risks from drinking water and considers that is conservative. Furthermore, RAC notes that the reduction of Cr(VI) to Cr(III) in air was not included in the risk characterisation, again leading to a conservative conclusion. However, RAC does not accept the applicant's assertion that application of a factor of LoQ/2 when dealing with values below the LoQ is highly conservative.

RAC notes that the risks associated with sodium dichromate exposure are based on total Cr(VI) emitted from both chromium trioxide and sodium dichromate and this consequently leads to an overestimate.

3.4. RAC's conclusions on the risk characterisation

RAC is of the opinion that the application includes all relevant tasks and routes of exposure as well as endpoints and populations in the risk assessment.

RAC concludes that the estimates for workers of excess cancer risk associated with Cr(VI) exposure and RCR for reproductive risk associated with exposure to sodium dichromate allow a health impact assessment.

RAC concludes that the estimates of excess cancer risk and reproductive risk for humans via the environment associated with Cr(VI) exposure allow a health impact assessment.

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

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

4. Analysis of alternatives and substitution plan

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

The applicant is an end-user of the Cr(VI) substances which are used for passivation of packaging steel to produce mainly food cans.

In 2000 the applicant began search for a suitable alternative substance, and later they started

a collaboration with the International Tin Research Institute (ITRI) on a research project (the Global Chromium-free Passivation Project) established in 2006.

In their search for alternatives, the applicant was also involved in the Chromium Free Passivation Alternative (CFPA) Research and Development Working Group established in October 2017 (CFPA R&D WG), as a joint collaboration between all the parties. This WG sought to scale-up the potential alternative system to mill-product trials with verification of the system through trial programs.

In 2018, trials of the new material were initiated for critical applications, which previously had weaknesses. Long term pack tests only started in late 2018 for a subset of products. The applicant has already started switching to the new Cr(VI) free technology, whilst continuing the R&D process, and conducting ongoing preliminary testing of material for can-making. Two production lines were adapted to CFPA by the applicant to accommodate the transition.

During their search for alternatives the applicant took into consideration a wide range of known alternatives for packaging of end-products (like plastics, aluminium, glass etc), concluding that tinplate packaging has the most suitable characteristics.

The applicant, working collectively with other European tinplate manufacturers, have chosen CFPA as one of the better performing alternatives to further develop, because the passivation performance was superior to other possible alternative systems. It was aimed to be suitable for use with the majority of currently used lacquers in the shortest period of time, after the sunset date for Cr(VI) substances.

In their application, they provided a detailed list of 24 potential alternatives with their short description obtained from the ITRI project and reasons for their unsuitability.

These alternatives were compared with the following required properties:

a. technical performances (detailed in section 4.2)
b. manufacturing process feasibility
c. compliance with food contact legislation
d. reduction in workers exposure

In the end, only one alternative substance (CFPA) was selected and taken forward, while other 23 were rejected.

In their application the applicant has provided a substitution plan from Arcelor Mittal's (AM) application for authorisation. This is due to their plant in Belgium, at the time, being part of the AM Group where the implementation of the Chrome Free solution was being implemented. During questions to the applicant, they have confirmed that they intend to use and follow the AM's substitution plan with only minor deviations.

The applicant's plan is divided into four phases and the length of each timeline has been provided.

The applicant has drawn up a substitution plan and has identified a number of steps involved the substitution process. Based on the information provided, the applicant expects that the substitution process will be completed by the end of 2027, in line with the rest of the companies involved in the CFPA working group.

Two comments were received during the third-party consultation: from APEAL (Association of European Producers of Steel for Packaging) and MPE (Metal Packaging Europe) both of whom are trade associations. They supported the application and the requested review period, stating that at present there are no suitable alternatives to the passivated ETP material.

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

The applicant has presented detailed activities, covering global level collaboration with other members of the APEAL consortium. These include consultations with can-makers, including on their subsequent R&D activities, market qualification process and ongoing testing.

SEAC finds the applicant's analysis of alternatives clear and transparent. Their activities are detailed and include alternative substances as well as alternative substrates used for packaging material.

It is clear that their scope is to find an alternative, which characteristics will closely resemble those of the Cr(VI) based material.

SEAC finds that the applicant's approach to only shortlist one alternative is sufficiently justified. Additionally, a joint effort by the whole APEAL consortium shows a clear commitment to switching to CFPA. Their presented assessment allows SEAC to conclude on the suitability of their preferred alternative.

The substitution plan provided by the applicant and responses to SEAC questions contain sufficient level of detail to allow SEAC a conclusion on the length of the recommended review period. Despite the temporary closure of facilities, the applicant is expected to complete the substitution within the requested review period, by using an accelerated operations process detailed below (section 4.4).

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 by the date of adoption of this opinion?

☒Yes ☐No

Is there information available in the application for authorisation that there are alternatives available that are technically and economically feasible in the EU?

☒Yes ☐No

The applicant points out that tinplate packaging allows hermetic closing and protects the product from oxygen, light, contaminants, allows pasteurization, while ensuring the nutritional value of food products. Such packaging is non-corrosive, easy to transport and store, and protects the product from deformation. Other packaging, e.g. plastic, aluminium, paper, glass, etc. is less capable of preserving food for such long shelf lives (up to 5 years) than cans. In addition, tinplated steel is easy separated from other waste and highly recyclable, without degradation of its properties.

Material used for food contact must pass tests for migration of harmful substances into food and comply with legal requirements in accordance with global standards.

The applicant shows four main end products and alternatives for its packaging:

- Food/Pet food: aluminium, composite carbon, glass, plastic and pouch

- Beverages: aluminium, composite carbon, glass and plastic
- Chemical-technical products: plastic and steel
- Aerosols: aluminium, plastic and steel

According to the applicant, among other packaging, steel is the best option for a variety of reasons: costs (although plastic is cheaper, but it does not have the same technical properties), food preservation (glass and aluminium have comparable properties), heat resistance (glass and aluminium have comparable properties), recyclability, strength, weight (only glass is heavier).

Even though there are a number of alternative packaging materials available on the market for some applications, such as glass, steel for packaging is the only technically feasible material that can be used for most products as food containers. The properties of steel for packaging result in continued demand, even where possible alternative materials are available.

The list below gives details of the requirements as described by the applicant that a potential alternative must meet:

Key **critical** technical requirements:

- Tin Oxide Growth Resistance
- Lacquer Adhesion
- Suitability and Compatibility with the can making process
- Sulphide Staining Resistance
- Market Acceptance
- Compliance with FCM Regulations
- Ability of the Applicants to implement

Key **important** technical requirements:

- Temperature Resistance
- Tinplate Process Speed Compatibility

Tin oxide growth must be controlled otherwise it will result either in an adverse outcome (confidential, exact issue known to SEAC) for the can or loss of adhesion of the lacquer. Lacquer adhesion and compatibility with lacquers is critical to ensure chemical resistance of the tinplated can.

Alternative 1: Chrome-Free Passivation Alternative (CFPA)

Although the alternative has been identified, further testing on end products with CFPA packaging is still required. Each can-maker may have their own pack-test qualification based on the products (fillings) they manufacture. In addition, the end products must meet standards and legal regulations for relevant sectors and countries.

CFPA was chosen as the preferred alternative because it is an alternative with which the applicant has the most experience and it has the shortest industrialisation timeframe in Europe. In addition, CFPA was the superior alternative tested under the ITRI project for tin oxide growth resistance, which is a key critical parameter for European tinplate manufacturers and can makers.

Technical feasibility

According to the applicant the preferred alternative (CFPA) seems to meet all critical parameters required for substitution. Nevertheless, further finalisation of R&D and market acceptance following qualification pack-testing are still required (more advanced shelf-life testing in real-time for other products categories and in different ambient conditions to fulfil necessary legal and qualitative requirements), hence CFPA cannot currently be considered a

technically feasible alternative to Cr(VI)-based ETP, according to the applicant. The applicant demonstrated that there are no technical possibilities for substitution Cr(VI)-based process as of yet.

Availability

According to the applicant, CFPA is already commercially available (as BONDERITE® M-NT 1456) in the quantity and quality required, to allow the applicant to maintain their current manufacturing level.

However, as currently the applicant has not yet converted all their lines to CFPA, the availability for them is significantly reduced in comparison to the current level of production with Cr(VI) substances. According to the applicant the production capacity of CFPA needs to be gradually built up to meet the current demand.

Economic feasibility

Cost of CFPA formulation is similar to the cost of current raw materials used in the ETP process. Energy, human resource and other ancillary costs would also be equivalent. Nevertheless, adaptation of the lines will require considerable engineering works and additional capital investment. This will financially constrain the timeframe for the full implementation of CFPA.

In addition, it is possible that some lacquers will require re-formulation or further development. This would mean that both coating providers and can makers may be required to undertake expensive qualification rounds to ensure safety of use in terms of food contact. Necessity of development or re-formulation of lacquer has significant economic impact on the downstream supply chains of the applicant.

Comments in the third-party consultation

Two comments were received in the third-party consultation: from APEAL (Association of European Producers of Steel for Packaging) and MPE (Metal Packaging Europe) for this use.

APEAL and MPE support the application and the requested review period, stating that at present there are no suitable alternatives to the passivated ETP material.

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

SEAC agrees that the applicant's analysis of alternatives in terms of their technical and economic feasibility is clear and well justified. Considering a detailed progress into the replacement of Cr(VI) shows a clear commitment from the applicant to replace the SVHC substances with CFPA.

The requirements criteria used by the applicant when selecting alternatives are clear and sufficiently detailed. They have also considered compliance with strict global food contact legislation for potential alternatives.

SEAC accepts that the applicant has developed the preferred alternative in collaboration with other manufacturers and that the CFPA was chosen as the preferred alternative for the other European tinplate industry and can makers. SEAC acknowledges that qualification pack testing for CFPA are still ongoing, meaning that at present it is not possible to replace Cr(VI)-based ETP with CFPA in all of the applicant's food packaging applications. The selected alternative (CFPA) requires more advanced level testing in order to ensure product safety and quality.

CFPA as commercial product is available in quantities as today. However, the applicant

confirms that the quantities of CFPA will not be sufficient until all required production lines are converted and the customers have completed their qualification activities. This suggests that further development is required in order for the industry to be able to reach sufficient production capacity.

Furthermore, the availability of the CFPA passivated tinplate is currently significantly lower in terms of manufactured tonnages when compared to that of the hexavalent chromium passivated ETP. This means that should the hexavalent chromium-based process cease, there would not yet be enough capacity to fulfil demand, assuming a 1:1 switch to CFPA at that point (which is not currently possible given the need for qualification pack tests).

However, should there be any delay in the development process, the applicant could submit a review report to request additional time.

According to the applicant, CFPA is economically feasible comparing the costs of raw materials. However, technical adaptation of the production lines will require considerable financial resources. This will financially constrain the timeframe for the full implementation of CFPA. In addition, there are potential technical challenges that could result in further financial costs for the supply chain.

In conclusion, SEAC agrees with the applicant that although the alternative is generally available in the EU, it is not yet technically and/or economically feasible for the applicant.

SEAC accepts that the applicant's assessment on technical and economic feasibility, as well as the availability of the shortlisted alternative is sufficiently detailed and allows SEAC to agree with the conclusions of the applicant in terms of suitability of the chosen alternative.

Furthermore, based on the information provided by the applicant, a feasible alternative will not be readily available in the near term. SEAC accepts that more time is needed to fully replace Cr(VI) with an alternative substance.

4.3. Risk reduction capacity of the alternatives

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

☐Yes ☐No ☒Not applicable

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

Regarding available alternatives that are technically and economically feasible in general, RAC is unable to conclude on whether such alternatives are safer since the operational conditions are not known and no assessment of the risks of these alternatives has been submitted in the application or by interested third parties beyond what is discussed on the risk of the shortlisted alternatives above.

4.4. Substitution plan/activities

Did the applicant submit a substitution plan?

☒Yes ☐No

Is the substitution plan credible for the review period recommended?

☒Yes ☐No

The Applicant provided the following elements of the substitution plan[8], with the timetable for complete implementation of CFPA:

- Phase I: Early-stage R&D – testing of candidate alternatives – selection of potential alternatives (started in 2022 and now completed).
- Phase II: Qualification of preferred alternative – fully established and accepted alternative process (start in 2024 and max. 24 months)
- Phase III: Commercialisation / Industrialisation of suitable alternative(s) (start approximately 2026 and max. 24 months)
- Phase IV: Phase-out of chromium (VI) / ramp-up of the CFPA production to 100 % capacity (12-24 months) - overlap with previous phase of 12 months.

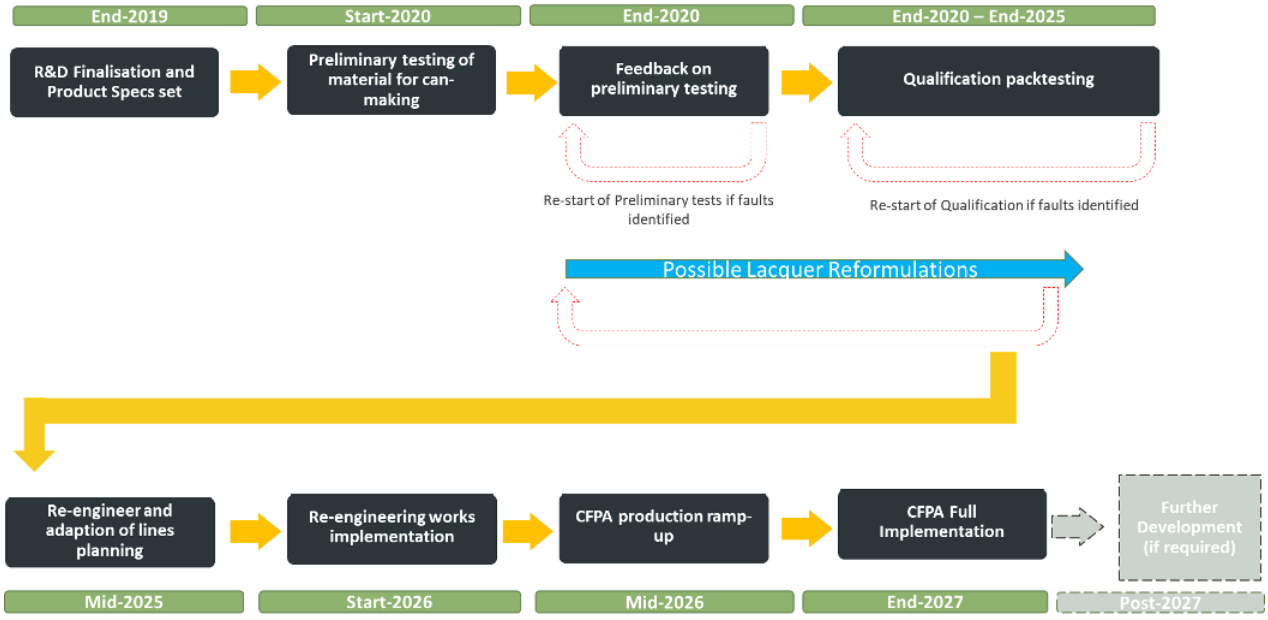

Figure 1. Detailed substitution plan

In answers to SEAC's questions, the applicant stated that due to unexpected events after preparation for phases II and III, the facilities were shut down in August 2022. However, they expect the production to resume from Q1 2024.

In order to accelerate work in phases II and III, they planned to increase flexibility of the production facilities (i.e. through "reversible hybrid" – the original or the chrome free

[8] Please note, as explained in detail in section 4.1 this substitution plan is that of Arcelor-Mittal and therefore some elements of it may have slightly different timelines.

installation) in testing phases, as well as the introduction of production process shiftability (up to 3 shifts) to complete both phases by the end of 2027. In a worst-case scenario, the applicant assumes that year 2028 could be the end of final stage at the latest.

The applicant has already invested in the conversion of two production lines dedicated to the alternative. To ensure a gradual transition that follows the completion of pack-tests by customers and expected growth of market demand for CFPA, the planned conversion of further lines is during the requested review period. Production sections will not only need to be converted to new passivation, but they need additional engineering works.

The applicant will have to meet the market requirements, including new ones that may arise. They will have to increase the scale of testing for large scale sampling and homologations for future commercial orders. The substitution to the alternative will be done progressively. Feedback from can-makers/fillers based on their requirements in this area is an ongoing process.

As mentioned above in the substitution plan, the qualification pack-testing for products/lacquers are provided by the applicant's customers and may continue until the end of 2028, which is longer than the requested review period. However, this step can be done without the use of Cr(VI) substance(s).

Qualification pack-testing timeframes can take up to 5 years. Analysis of the packaging occurs at intervals of for example 3, 6 and 12 months etc. for the entire 5 years. At any point up to and including the final opening at 5 years, a packaging may fail, necessitating investigations into the reasons for the failure, which would put a pressure on the timeframe and add a risk of additional financial costs.

Furthermore, in order to monitor all activities and to ensure the implementation of the substitution plan across all members of the APEAL consortium, the applicant was involved in the activity of the Chromium Free Passivation Alternative Research and Development Working Group (CFPA R&D Working Group). The WG was established in 2017 as a joint collaboration between the interested parties and coordinated by the APEAL Secretariat. The task of the WG was to scale-up the potential alternative system to mill-product trials with verification.

Additionally, the WG worked on the development of the best industrial practices for the CFPA process, to provide a forum to exchange information on experiments with members' respective products, and to ensure regulatory food contact approvals (EU, USA, Mercosur, China, etc).

The WG monitors all the developments of CFPA and liaises with interested parties in order to implement the alternative in the most efficient and practical way. B2B interactions of the applicant with his customers allow for product and process development (pack tests, feedback on the applicant's product). Additionally, testing is ongoing in parallel across many sectors.

In addition to the WG activities, the applicant has internal procedures (claimed confidential but known to SEAC) and dedicated teams that are set up for the development and monitoring of the progress through meetings and discussions with their customers and liaison with the WG.

SEAC's evaluation of the substitution plan/activities

SEAC notes that the substitution plan provided by the applicant is credible and sufficiently detailed. It contains action points, timelines and steps that are required to successfully replace Cr(VI) substances with their chosen alternative (CFPA).

Several key steps in its implementation are required for substitution, including market acceptance and qualification pack-testing, however these indicate a clear commitment to

substitution. Additionally, a detailed progress and investment already made into the alternative also support this view.

SEAC notes that the review period includes the completion of qualification protocols and ensures the continued high levels of consumer safety that are required of materials intended to be used in food contact.

Based on the application, it could be estimated that full implementation of CFPA could be completed by the end of the requested review period at the end of 2027. Any significant issues with qualification pack-tests for food fillings that may occur later in the qualification process and may result in the need to restart the process, were not included in the substitution plan.

However, taking into account the temporary shutdown of facilities from 2022 to 2024, it is unclear whether the substitution will be completed in the requested review period. Should that be the case, the applicant can always apply for a review period to extend the time to use the substance.

SEAC accepts that the applicant's substitution plan clearly demonstrates their willingness to substitute and detailed activities contained in the plan justify the review period they have requested. The plan is also consistent with the information provided in the analysis of alternatives.

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 information available in the application for authorisation and in the comments submitted by interested third parties in the consultation indicating that there are alternatives available that are technically and economically feasible in the EU. However, RAC is unable to conclude on whether these alternatives are safer.
- The applicant submitted a substitution plan. The substitution plan is credible for the review period recommended.

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 intends to use 10-40 tonnes of Cr(VI) equivalent per year (exact number claimed confidential but known to SEAC), at its manufacturing site in Belgium, with Cr(VI) resulting

from both the use of chromium trioxide and sodium dichromate.

Both chromium trioxide and sodium dichromate were included under Annex XIV due to their carcinogenic and mutagenic properties, with sodium dichromate also being toxic to reproduction. The main exposure routes for Cr(VI) are inhalation and oral. Inhalation is associated with lung cancer risk, while oral exposure is associated with intestinal cancer. The applicant assumes that a total of 1 000-1 500 workers are at risk of potential exposure to Cr(VI) via inhalation (the exact figure is confidential, but known to SEAC). In addition, the applicant estimates that < 10 000 people from the local population are at risk of exposure (confidential, but known to SEAC). In response to SEAC's questions, the applicant has stated that they have used a lower default value for the number of people exposed from the local population than that recommended by ECHA[9] since this would represent a gross overestimation of the resident population living within the vicinity of their manufacturing plant.

The applicant has estimated the additional statistical cancer cases associated with the use of chromium trioxide and sodium dichromate on the basis of the exposure levels and the number of people exposed, using RAC's reference dose response relationships for both substances. Both fatal and non-fatal lung and intestinal cancers have been estimated by the applicant, although it is important to note that SEAC has identified an error in the calculations pertaining to these estimates since the dose-response function has been incorrectly applied when calculating the number of excess cancer cases, resulting in an underestimation of both fatal and non-fatal cases for both cancers. However, SEAC did not recalculate these values, as they would not materially impact the assessment of costs and benefits.

The health impacts have been monetised by the applicant applying ECHA lower bound WTP values for the value of statistical life (VSL) of €3.5 million, and value of cancer morbidity of €0.41 million. These in turn have been uprated from 2012 to 2019 prices using GDP deflators for the EU to account for annual inflation (figures shown below).

Table 13: Willingness-to-Pay values for monetised health impacts

WTP Values	2012	2019
Value of Statistical Life (VSL)	€3 500 000	€3 800 000
Value of Cancer Morbidity (VCM)	€410 000	€440 000

The applicant has utilised these values to derive the value of an additional fatal and non-fatal cancer case, for both lung and intestinal cancer.

The applicant has assumed no latency periods for both lung and intestinal cancer, which constitutes a more conservative approach than that recommended in ECHA's 2016 report on valuing selected health impacts of chemicals. A discount rate of 4 % has been applied to the monetised values, which is at the upper end of ECHA's SEA guidance on the use of discount rates over time for environmental and health impacts. The applicant has also sought to calculate morbidity costs for non-fatal cancer cases. In this regard, the applicant has used the

[9] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

average mortality rates in each case for 2019 across the EU-28 as provided by the World Health Organisation's Cancer Today database (IARC, 2019)[10], which are 83 % for lung cancer and 49 % for colorectal (intestinal) cancer.

In addition, the applicant has also provided monetary estimates for the medical treatment costs associated with both types of cancer, using annual data on cancer-specific costs across several peer-reviewed studies, adjusted to 2019 values using a GDP deflator to account for annual inflation. Thus, the annual medical treatment costs for lung and intestinal cancer have been estimated at €16 810 and €14 420 respectively. These values have been used by the applicant to estimate total medical treatment costs for both lung and intestinal cancer over the requested review period of approximately 5 years (until the end of 2027), in conjunction with survival rates for both types of cancer after 1, 5 and 10 years of diagnosis as provided by Cancer Research UK as well as the total number of additional non-fatal cancer cases for both cancer types across workers and the local population.

In response to questions, the applicant provided SEAC with spreadsheets including all relevant calculations pertinent to the human health impacts.

Table 14 below summarises the excess cancer cases and associated monetised costs, broken down by workers and general population. These have been included in SEAC's assessment. The applicant's total monetised excess cancer risk from continued use (comprising both lung and intestinal cancer) is estimated at < €50 000 over the entire requested review period, with the annualised monetised risk valued at < €10 000 (both values are confidential, but known to SEAC). Note that these values have been recalculated by SEAC on the basis of the 5-year review period requested by the applicant, together with minor revisions presented by the applicant in response to SEAC's questions.

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

SEAC notes the applicant's methodological approach and assumptions. SEAC also notes the applicant has used ECHA's 2016 report on valuing selected health impacts of chemicals and has uprated the values from 2012 prices to 2021 using the GDP deflator.

SEAC considers that the applicant's estimated economic burden broadly reflects the welfare loss in the continued use scenario due to increased mortality and morbidity from both lung cancer and intestinal cancer, although as mentioned above the applicant has underestimated the number of fatal and non-fatal cancer cases in their assessment since they have incorrectly-applied the dose-response function when calculating the number of excess cancer cases. This in turn has led to an underestimated monetised excess cancer risk from continued use, although this error does not materially impact the conclusions derived from the socioeconomic analysis. Similarly, SEAC notes that the applicant has opted to utilise a lower value for local population exposure than that recommended by ECHA on the basis of population numbers and density within the manufacturing plant's surrounding area, which also leads to a slight underestimation of the monetised excess cancer risk, although this would have no impact on the conclusions derived from the SEA.

On the other hand, SEAC notes that the applicant has included monetised costs of medical treatment for both cancers, reflecting the burden on the healthcare system, although the WTP values do not incorporate other types of indirect costs (such as decreased labour productivity) associated with cancer. Furthermore, the applicant has assumed no latency period in the

[10] https://gco.iarc.fr/today/home

monetisation calculations, and has assumed a constant level of exposure to Cr(VI) substances for both workers and the general population over the review period, even though, as explained by the applicant, they will gradually reduce the amount of Cr(VI) consumed as they transition towards more widespread use of the alternative substance (CFPA), thus constituting a conservative approach to the monetisation of health impacts. SEAC therefore broadly accepts the applicant's monetised health impacts, while noting the underestimation of both fatal and no-fatal cancer cases as well as the fact that additional costs (in terms of productivity loss) could be expected in the continued use scenario and have not been covered in the applicant's socio-economic analysis.

SEAC notes that the applicant's estimated costs have been discounted as per ECHA SEA guidance. SEAC also notes that the monetisation approach employed by the applicant includes morbidity costs for both fatal and non-fatal cancer cases (for both types of cancer), in order to capture a more complete picture of the morbidity costs involved. The mortality rates used are appropriate and the calculations are reasonable.

Overall, SEAC concludes that the applicant's figures provide a reasonable estimate of the monetised human health costs.

Table 14: Summary of additional statistical cancer cases

	Excess lifetime cancer risk	**Number of exposed people**	**Estimated statistical cancer cases (over 5 years)**	**Value per statistical cancer case**	**Monetised excess risk (over 5 years)**
Workers					
Directly and indirectly exposed workers	1.4×10^{-6}-8.8×10^{-4}	1 000-1 500	3.2×10^{-3} (fatal + non-fatal lung cancer)	€4.41 million (fatal + non-fatal lung cancer)	< €15 000 (fatal + non-fatal lung cancer)
Sub-total					< €15 000
General population					
Local	4.7×10^{-7} (inhalation) 1.9×10^{-7} (oral)	< 10 000	1.4×10^{-4} (fatal + non-fatal lung cancer) 5.1×10^{-3} (fatal + non-fatal intestinal cancer)	€4.41 million (fatal + non-fatal lung cancer) €4.46 million (fatal + non-fatal intestinal cancer)	< €1 000 (fatal + non-fatal lung cancer) < €34 000 (fatal + non-fatal intestinal cancer)
Regional	Not relevant				
Sub-total	6.6×10^{-7}				< €35 000
Total	**8.8×10^{-4}**	**11 000-11 500**	**8.4×10^{-3}**		**< €50 000**
Latency (years)	No latency period has been assumed for either lung or intestinal cancer				

5.2. Societal costs of not granting an authorisation

Non-use scenario

The applicant has emphasised the importance of finding a common solution to the substitution of Cr(VI)-passivated ETP that meets the requirements of can-makers within the EEA. To this end, CFPA has already been selected as the alternative of choice for the entire sector, although in case of authorisation refusal the applicant has stated that at present only 35-55 % of the existing EU passivated ETP market would be catered for using CFPA.

The applicant, as part of the APEAL consortium, has undertaken a detailed consultation with can-makers in order to understand the impact of a refused authorisation on the supply chain. Based on these consultations, the following non-use scenarios have been developed by the applicant.

Worst-case scenario

Under the worst-case scenario, can-makers would not accept CFPA-passivated ETP within the next 4-5 years as the industry awaits the results of the ongoing packing tests. During this time, can-makers would pivot towards imported ETP from outside the EEA, with some producers opting to relocate to non-EEA locations in order to fulfil their demand, based on feedback received from consultations carried out with EU can-makers. As a result, ETP production within the EEA would cease from 2024, which would have a severe negative impact on the applicant in terms of turnover losses related to ETP and potential job losses due to site closures. This would also have ancillary impacts on steel suppliers, since they would lose the entirety of their hot rolled coils (HRC) sales used in the production of passivated ETP, while can-makers would also be negatively impacted since the switch towards imported ETP would imply higher costs and potentially-longer lead times. Finally, retailers and consumers alike would also be impacted in terms of higher potential prices for finished goods due to higher can costs and shipping.

Main non-use scenario

The most-likely non-use scenario would envisage a situation whereby CFPA-passivated ETP is accepted for immediate use (i.e. as from 2024) by can-makers for 35-55 % of current use of passivated ETP, with the remaining uses only accepted towards the end of 2025-2026. The likely ramifications are qualitatively very similar to those described under the worst-case scenario, albeit to a lesser extent since under this scenario passivated ETP production within the EU would not cease entirely, but rather drop by 45-65 %. Furthermore, it is assumed that under this scenario EU can-makers will continue to import passivated ETP from non-EEA countries for a proportion of their uses beyond 2025, although EU-based passivated ETP suppliers would gradually recover 75 % of their existing market share by the end of 2025 with a further 15-20 % recouped by 2032, meaning that 5-10 % of current market share would be lost permanently to non-EEA imports.

Overly-optimistic scenario

The applicant has also included a best-case scenario, whereby CFPA-passivated ETP is accepted for immediate use by can-makers for 55-80 % of current use of passivated ETP, with the remaining uses only accepted towards the end of 2025-2026. Once again, the likely impacts on the entire supply chain are qualitatively similar to those described earlier, although once again these would be less severe that in the previous two scenarios, with EU passivated ETP suppliers expected to recover their market share more rapidly, with close to full recovery by

the end of 2027.

In response to SEAC's questions, the applicant has stated that given that this is a bridging application with a review period of only approximately 5 years (until the end of 2027), it would not make sense for them to contemplate alternative non-use scenarios such as relocation, particularly given the cost and timelines involved in building new production plants.

Based on the information provided, SEAC considers that the applicant's choice of the most-likely non-use scenario is justified, with CFPA-passivated ETP accepted for immediate use (i.e. as from 2024) by can-makers for 35-55 % of current use of passivated ETP, with the remaining uses only accepted towards the end of 2025-2026.

Economic impacts of non-use

The applicant has listed a number of economic benefits resulting from continued use, and thus the avoidance of the most likely non-use scenario. The monetised impacts have been considered by SEAC over the 5-year requested review period, with the Net Present Value (NPV) in 2022 calculated using a discount rate of 4 %. The applicant has quantified foregone profits, losses accruable to suppliers of raw materials, losses to can-makers due to higher costs, lost internal demand for HRC, environmental impacts, and social costs of direct job losses under the most-likely NUS. The applicant has also provided a qualitative description of wider impacts on the steel manufacturing industry and indirect job losses. In response to SEAC's request, the applicant has provided SEAC with spreadsheets including all relevant calculations pertinent to the monetisation of socioeconomic impacts.

Foregone profits

The applicant has provided an estimate of foregone profits resulting from the partial closure of passivated ETP production by 45-65 % under the most-likely non-use scenario, with production picking up only gradually in subsequent years. The applicant has assumed an EBITDA of 12 % annually, based on the industry-average EBITDA of 10.5-14 % recorded in 2017. The applicant has provided both a lower and upper bound value for profit losses, in line with the range of 45-65 % for the estimated losses in ETP production. In response to SEAC's questions, the applicant has stated that although the requested review period is approximately 5 years (until the end of 2027), they have opted to include profit losses for 9 years since this represents the expected time that it would take for the EU market for ETP to somewhat recover once CFPA-passivated ETP has been approved by can-makers, and therefore the profit losses accrued over this adjustment period.

SEAC notes the applicant's justification for including foregone profits over the 9-year adjustment period, while also noting that this is in direct conflict with ECHA's guidance on assessing changes in producer surplus for SAGA cases[11]. Therefore, SEAC has recalculated the profit losses accruable to the applicant under the most-likely NUS, which are now valued at < €50 million NPV over a two-year period (the exact range is confidential, but known to SEAC). These values have been included in SEAC's assessment.

Impacts on suppliers of raw materials

The applicant has also estimated the profit losses accrued by its upstream suppliers of raw materials and ancillary services, including tin for ETP, other coating materials, chromates, maintenance, cleaning services and transportation. The applicant has assumed a profit margin of 12 % for suppliers of raw materials and services, and has provided both upper and lower bound estimates.

[11] https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138.

Profit losses for its suppliers have been estimated by the applicant over the same 9-year period as that used initially for its own profit losses, i.e. 2024-2032. Once again, in line with ECHA's guidance on assessing changes in producer surplus, these values have been recalculated over a two-year period, with profit losses to suppliers now valued at < €15 million NPV (the exact range is confidential, but known to SEAC). These values have been carried forward in the analysis.

Impacts on can-makers

The applicant has included losses incurred by European can-makers under the most-likely NUS. According to the applicant, authorisation refusal would result in the importation of less than 3 000 thousand of tonnes per year of passivated ETP on average from outside the EU over the period 2024-2032 (the exact range is confidential, but known to SEAC). This is consistent with the need to replace the 45-65 % of passivated ETP sourced from within the EU and which would be lost under the most-likely NUS since this proportion could not be served using CFPA, with the proportion gradually falling over time as the European market recovers. The applicant has emphasised that based on their discussions with can-makers, steel originating from Japan or Korea is of better quality than steel from China or the USA, and would thus be used to substitute for those uses which cannot be catered for by CFPA technology, with less demanding uses likely covered by Chinese steel, which currently accounts for 10-50 % of ETP imported within the EU. Therefore, the applicant has assumed that the additional imports of ETP will be sourced from either Japan or Korea, with each country accounting for half of these imports. This would entail higher costs to can-makers in terms of shipping costs, assumed to be €51 per tonne, and furthermore it is assumed that the overall cost of non-EU imported steel will increase by 3 % following authorisation refusal, bridging the current gap between the FOB price of Korean and Japanese steel and EU-made steel. These costs do not include other likely costs including longer lead times, storage costs and increased production complexity. In addition, the applicant has assumed that all of these impacts will be borne by the can-makers due to concerns related to competition, following consultations with can-makers.

The applicant has estimated the higher costs to can-makers using the lower-bound value for the replacement of EU-produced ETP (45 %), over the 9-year period from 2024 to 2032. Once again, in line with ECHA's guidance on assessing changes in producer surplus, these values have been recalculated over a two-year period, estimated at < €15 million NPV (the exact value is confidential, but known to SEAC). This value has been carried forward in the analysis.

Impact on internal demand for hot rolled coil (HRC)

The applicant has also provided an estimate for the drop in internal HRC demand due to the reduced production of passivated ETP. Under the most-likely NUS, the applicant has assumed that this demand will drop by less than 3 000 thousand of tonnes per year on average (the exact range is confidential, but known to SEAC). The applicant has stated that it will be difficult to find alternative, external customers to take on these quantities of HRC, since market demand may not adjust accordingly, with such demand typically originating internally. Overall, the profit losses accruable to the applicant are estimated at < €100 million over the 9-year period from 2024 to 2032 (the exact range is confidential, but known to SEAC). Nonetheless, the applicant has opted not to include this value in the analysis to avoid potential double-counting stemming from the inclusion of the applicant's profit losses. SEAC notes these calculations, and agrees with the decision to exclude this estimate from the analysis.

Social impacts related to job losses

The applicant has stated that < 500 jobs at its production site in Belgium would be lost if no authorisation is granted under the most likely non-use scenarios (the exact value is

confidential, but known to SEAC).

The applicant has used a simple assessment for calculating the social cost of these job losses in line with SEAC's note on the social cost of unemployment (Dubourg, 2016)[12]. The approach uses a welfare cost factor value of 2.7 to estimate the social value of the lost jobs, with data on wages obtained using average salaries of operators across the applicant's four production sites via Eurostat. Based on this approach, the applicant has estimated total job losses valued at < €35 million (the exact value is confidential, but known to SEAC). This value has been carried forward by the applicant in the socio-economic analysis.

SEAC notes that the applicant has followed the methodology for valuing the social cost of unemployment endorsed by SEAC and has updated the values for wages based on gross earnings for the workers concerned. On this basis, SEAC considers the monetised estimates for job losses under the NUS provided by the applicant to be reasonable and has included them in its assessment.

Environmental impacts

The applicant has included an estimate of the monetised environmental costs related to higher levels of imported ETP from Asia over the 9-year period 2024-2032, specifically in terms of higher carbon dioxide (CO_2) emissions from transportation. The applicant has used a CO_2 factor for deep sea shipping of 8.4g CO_2 per tonne-km (Cefic, 2018)[13], and a value of €50 per tonne as the economic cost per tonne of CO_2 emissions (Defra, 2007)[14]. The applicant has estimated the monetised environmental cost from increased CO_2 emissions at <€1 million per year (exact value is confidential, but known to SEAC). This value, pertaining to a single year, has been carried forward by SEAC in the analysis.

Indirect job losses

The applicant has also included an estimate of the monetised impacts of indirect job losses across various economic sectors as a result of the most-likely NUS. The applicant has cited a study by Oxford Economics in order to assess the overall contribution of the steel industry to the EU economy[15]. Based on the findings in this report, the applicant has estimated that under the most-likely NUS, the value of these job losses is less than €2 billion (this range is confidential, but known to SEAC). This value has not been included in the final analysis by the applicant. SEAC notes these calculations and agrees with the applicant's decision to omit them from the analysis.

Wider economic impacts

The applicant has also provided a qualitative description of wider economic impacts emanating from authorisation refusal under the most-likely NUS, mainly in relation to the European steel

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

[13] McKinnon, A, Piecyk, M, 2018, "Measuring and Managing CO_2 Emissions of European Chemical Transport", Available at: https://cefic.org/app/uploads/2018/12/MeasuringAndManagingCO2EmissionOfEuropeanTransport-McKinnon-24.01.2011-REPORT_TRANSPORT_AND_LOGISTICS.pdf

[14] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/243825/background.pdf.

[15] Oxford Economics (2018) The impact of the European steel industry on the EU economy; [Online] Available at: https://d2rpq8wtqka5kg.cloudfront.net/431604/open20180502033000.pdf?Expires=1571993003&Signature=I-KDXP7IR~oFuOQQKe97My0WfBu48aRSUqkFAimUCHO~5SR6Jn5azXnzwfe9LPf67M61PlhNbJS-yDtRX~9k8dbnUW9HWBQPAWA2CKOHrVy0WK7~eZShxSiu8Y61Vr-5-LNeYIsTugNkROD3YLF-gnaYyMZds2

manufacturing sector. As mentioned earlier, the partial ceasing of ETP manufacturing would have a significant impact on internal demand for HRC, which would necessitate the pursuance of new external markets for steel material, which may push global prices downwards. In addition, as mentioned earlier authorisation refusal would enable non-EU manufacturers to enter the market, some with inferior quality steel products relative to the EU. Furthermore, according to the applicant this may also jeopardise the development of a global, technically feasible solution to chromium trioxide usage across steel manufacturers, since non-EU producers could capture the EU market for passivated ETP using existing CR(VI)-based production technology. The applicant has also presented a discussion on the advantages and disadvantages of steel packaging. SEAC notes these qualitative remarks.

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

SEAC's specific, detailed views regarding both the non-use scenarios and the individual economic and social impacts are explained above. SEAC considers the choice of non-use scenario to be reasonable and has included monetised impacts of foregone profits accruing to both the applicant and suppliers of raw materials, higher costs for European can-makers, and social costs from direct job losses and environmental damages in the impact assessment.

SEAC notes the applicant's comments regarding the wider economic impacts resulting from authorisation refusal.

SEAC notes the applicant's request for a review period of approximately 5 years (until the end of 2027). SEAC's assessment, based on the applicant's information, is set out below, with results provided in NPVs.

Table 15: Societal costs of non-use

Description of major impacts	Monetised/quantitatively assessed/qualitatively assessed impacts
1. Monetised impacts	**€ over 5 years and per year**
Producer surplus loss due to ceasing the use applied for	< €50 million Annualised: < €10 million
Foregone profits for upstream suppliers of raw materials and services	< €15 million Annualised: < €3 million
Higher costs for European can-makers	< €15 million Annualised: < €3 million
Social cost of unemployment	< €35 million Annualised: < €7 million
Environmental damages from higher CO_2 emissions due to transportation	< €1 million Annualised: < €0.2 million
Sum of monetised impacts	**< €116 million** **Annualised: < €23 million**
2. Additional quantitatively assessed impacts	**€ over 5 years and per year**
Impact on internal demand for HRC	< €100 million Annualised: <€25 million
Indirect job losses	< €2 billion

	Annualised: < €500 million
3. Additional qualitatively assessed impacts	
Wider economic impacts	Loss of competitiveness of European steel mills

The monetised values have in most cases been recalculated, as detailed above for each element, with the sole exception of social impacts from job losses, which are identical to those estimated by the applicant.

Based on the above, SEAC has estimated the socio-economic benefits of authorisation at < €116 million over the proposed review period, annualised at < €23 million.

5.3. Combined assessment of impacts

SEAC's evaluation of the combined assessment of impacts

The table below summarises the monetised values included in SEAC's assessment of the socio-economic benefits and costs associated with continued use by the applicant, expressed both in aggregate terms over the proposed review period of approximately 5 years (until the end of 2027) as well as in annualised terms. Based on the analysis conducted below, the estimated net societal benefits from continued use are <€116 million over the review period, with the benefits-to-costs ratio at around 2 320:1. The applicant has also presented an assessment of uncertainties which may affect the overall outcome of the socioeconomic analysis (SEA). Based on this assessment, the applicant has concluded that even under the overly optimistic scenario, the change in assumptions would not materially impact the conclusions of the SEA. SEAC notes this uncertainty analysis and based on the information presented agrees with the conclusions derived by the applicant.

Table 16: Societal costs of non-use and risks of continued use

Societal costs of non-use		**Risks of continued use**	
Monetised impacts (€ over 5 years) (per year)	< €116 million NPV Annualised: < €23 million	Monetised excess risks to directly and indirectly exposed workers (€ over 5 years) (per year)	< €15 000 NPV Annualised: < €3 000
Additional quantitatively assessed impacts (€ over 5 years) (per year)		Monetised excess risks to the general population (€ over 5 years) (per year)	< €35 000 NPV Annualised: < €7 000
Additional qualitatively assessed impacts (€ over 5 years)		Additional qualitatively assessed risks (€ over 5 years)	

(per year)		(per year)	
Summary of societal costs of non-use	**< €116 million NPV** **Annualised: < €23 million**	**Summary of risks of continued use**	**< €50 000 NPV** **Annualised: < €10 000**

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

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

This conclusion of SEAC is made on the basis of:

- the application for authorisation,
- SEAC's assessment of the societal costs of non-use,
- SEAC's assessment of the availability, technical and economic feasibility of alternatives,
- SEAC's assessment of the information submitted by interested third parties,
- additional information provided by the applicant, and
- RAC's assessment of the risks to human health.

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

6. Proposed review period

☐Normal (7 years)

☐Long (12 years)

☐Short (4 years)

☒Other: until the end of 2027

☐No review period recommended

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

- The applicant considers that their AoA and substitution plan provides sufficient justification for the requested review period. SEAC agrees with the applicant.
- SEAC reviewed the analysis of alternatives and concluded that by the time of adoption of this opinion there are no alternatives available for the applicant with the same function and similar level of performance that are safer and technically and economically feasible.
- The applicant has provided evidence of their on-going engagement with customers and alternative suppliers to phase out Cr(VI) substances.

- 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.
- The applicant submitted a substitution plan. The substitution plan is credible for the review period recommended.
- The benefits of continued use are higher than the risks by a considerable degree.

Taking into account all of the above points, a 5-year review period until the end of 2027 is recommended for this use.

7. Proposed additional conditions for the authorisation

Were additional conditions proposed for the authorisation?

☒Yes ☐No

7.1. Description

RAC

1. The applicant shall ensure that workers select an appropriate RPE using a fit test, that workers always perform a fit check of the seal of their RPE before taking on relevant tasks, and that workers are trained to do these fit checks and fit tests adequately..
2. The applicant shall ensure that for any task conducted in the cellar (including bath sampling) appropriate RPE is worn, as long as the exposure measured in the cellar are higher than the value used for the exposure assessment of the sampling task (T2).
3. The applicant shall carry out and document a detailed feasibility study on the implementation of an automated system to perform passivation tank sampling tasks, where exposure to Cr(VI) is foreseen. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

7.2. Justification

RAC

Although RAC is of the opinion that the RMMs and OCs as proposed in the application are generally appropriate and effective in limiting the risk to workers and humans via the environment, provided they are adhered to, additional conditions for the authorisation are proposed to minimise the exposure to Cr(VI).

The mandatory use of RPE for tasks conducted in the cellar should ensure that the workers are adequately protected e.g., during the bath sampling tasks (15 min/day).

The feasibility study will provide the necessary data to allow a decision on the potential improvement of the bath sampling operation. The applicant is exploring a closed sampling system to avoid exposure to the passivation bath.

RAC is of the opinion that the implementation of the measures identified above and those measures resulting from the feasibility study requested will contribute to the continued improvement of the RMMs with the aim of minimising exposure of the workers to Cr(VI).

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements proposed for the authorisation?

☒Yes ☐No

8.1. Description

RAC

The applicant shall implement or continue to implement as applicable the following monitoring 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) ensure a sufficiently low limit of quantification;

(iv) comprise personal or static inhalation exposure sampling;

(v) be representative of:

a. the full range and duration 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;

(vi) include contextual information about the tasks performed during sampling.

(b) Environmental releases:

(i) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process;

(ii) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater;

(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.

c. ensure a sufficiently low limit of quantification.

2. The information gathered via the measurements referred to in paragraph 1 and related

contextual information shall be used annually 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. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.

3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.
4. 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.
5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of workers and humans via environment has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. Measurements should however be conducted at least annually.
6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers and humans via the environment at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues and humans via the environment to be reduced to as low a level as technically and practically possible
7. The applicant shall continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI).

8.2. Justification

RAC considers that although the exposure estimates used to characterise the risk are plausible, the exposure assessment contains moderate shortcomings due to:

- the actual small number of measured worker exposure data at the applicant's site;
- limited contextual information at the site;
- use of a high LoD for the monitoring results provided for 2018.

Biomonitoring can be used as a complementary exposure assessment tool to confirm the effectiveness of the RMMs and OCs in place and can contribute to identifying other exposure routes besides inhalation.

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

9. Recommendations for the review report

Were recommendations for the review report made?

☒Yes ☐No

9.1. Description

RAC

The results of the feasibility studies mentioned in section 7 and the measurements referred to in section 8.1, should be documented and included in any subsequent authorisation review report. The conclusions based on these results and any actions taken should also be included

9.2. Justification

RAC

Provision of the results of the feasibility study and the representative monitoring results would allow for a better evaluation of the actual and future situation at the applicant sites and corroborate the appropriateness and effectiveness of RMMs and OCs as described in the application.

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

10.3. Reasons for not introducing changes