Version 4.1

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Use of Chromium (VI) Trioxide for Electrolytic Chromium Coating of Steel (ECCS); also known as Tin Free Steel (TFS)

Submitting applicant:

ArcelorMittal France, ArcelorMittal España S.A.

ECHA/RAC/SEAC: AFA-O-0000007266-71-01/F

Consolidated version

Date: 12/05/2023

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]	**ArcelorMittal France,** **ArcelorMittal España S.A.**
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[s]
Use performed by	☒Applicant ☐Downstream user(s) of the applicant
Substance ID	**Chromium trioxide** CAS No: 1333-82-0 EC No: 215-607-8
Intrinsic properties referred to in Annex XIV	☒Carcinogenic (Article 57(a)) ☒Mutagenic (Article 57(b)) ☐Toxic to reproduction (Article 57(c)) ☐Persistent, bioaccumulative and toxic (Article 57(d)) ☐Very persistent and very bioaccumulative (Article 57(e)) ☐Other properties in accordance with Article 57(f)

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

Use title	**Use of Chromium (VI) Trioxide for Electrolytic Chromium Coating of Steel (ECCS); also known as Tin Free Steel (TFS)**
	Other connected uses: Use 1: Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP)
	Similar uses applied for: other applications for authorisation for the use of Chromium (VI) Trioxide for Electrolytic Chromium Coating of Steel (ECCS)
Number and location of sites covered	2 sites (Etxebarri, Spain; Basse-Indre, France)
Annual tonnage of the Annex XIV substance used per site	< 52 tonnnes per year per site, expressed as Cr(VI) equivalent
Function(s) of the Annex XIV substance	Stabiliser 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	Food packaging (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	until the end of 2028
Use ID (ECHA website)	0274-03
Reference number	CT, ARCELORMITTAL ESPAÑA S.A., 11-2120920978-40-0002 CT, ArcelorMittal France, 11-2120920978-40-0005

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	20/05/2022
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	03/08/2022
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	17/08/2022-12/10/2022
Were comments received in the consultation?	☒Yes ☐No Link: Adopted opinions and previous consultations on applications for authorisation - ECHA (europa.eu)
Request for additional information in accordance with Article 64(3)	On 25/08/2022 and 14/10/2022 Link: Adopted opinions and previous consultations on applications for authorisation - ECHA (europa.eu)
Trialogue meeting	Not held – no need for additional information/discussion on any technical or scientific issues related to the application from the rapporteurs
Was the time limit set in Article 64(1) for the sending of the draft opinions to the applicantextended?	☐Yes ☒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: 16/03/2023, agreed by consensus
	SEAC: 15/03/2023, agreed by consensus
Date of sending of the draft opinions to the applicant	08/05/2023

Date of decision of the applicant not to comment on the draft opinions, in accordance with Article 64(5)	12/05/2023
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: 12/05/2023, adopted by consensus
	SEAC: 12/05/2023, adopted by consensus
Minority positions	RAC: No minority positions
	SEAC: No minority positions
RAC Rapporteur	Bridget GINNITY
SEAC Rapporteur SEAC Co-rapporteur	Jonathan SPITERI Dorota DOMINIAK
ECHA Secretariat	Morgane THIERRY-MIEG Mateusz WILK Simone GERVASUTTI

LIST OF ACRONYMS

ACH	Air change per hour
AfA	Application for authorisation
AoA	Analysis of alternatives
APF	Assigned protection factor
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
ECCS	Electrolytic Chromium Coating of Steel
ETP	Electrolytic Tinplate
IBC	Intermediate bulk container
LAD	Latest application date
LEV	Local exhaust ventilation
LoD	Limit of detection
LoQ	Limit of quantification
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 not possible to determine DNEL(s) for the carcinogenic and mutagenic properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC concluded that there are no technically and/or economically feasible alternatives available for the applicant with the same function and similar level of performance by the date of adoption of this opinion. Therefore, RAC did not evaluate the potential risk of alternatives.

RAC concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion.

The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented 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 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.

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. Low Tin Steel (LTS) with CFPA passivation

2. Trivalent Chromium Coating Technology (TCCT)

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

- The applicant has demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the applicant by the date of adoption of this opinion.
- There is information available in the application for authorisation indicating that there are alternatives available that are technically and economically feasible in the EU.
- The applicant submitted a substitution plan. The substitution plan is consistent with the analysis of alternatives and the socio-economic analysis. The substitution plan is credible for the review period requested.

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

The expected societal costs of not granting an authorisation, which are estimated to be approximately €40.5-100 million over the requested review period, consisting 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 100-500 directly exposed workers;
- the general population exposed at local scale (less than 7 000 people);
- that the risk of continued use as assessed by RAC may result in approximately 1.44×10^{-1} 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 approximately €393 709 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 2028 is recommended for this use.

JUSTIFICATIONS

0. Short description of use

The applicant, ArcelorMittal France and ArcelorMittal España S.A. (further referred to as ArcelorMittal) is a downstream user of chromium trioxide in two sites, located in France (Basse-Indre) and in Spain (Etxebarri).

The applicant is requesting an authorisation for the continued use of chromium trioxide for the Electrolytic Chromium Coating of Steel (ECCS), also known as Tin Free Steel (TFS) with subsequent use as food packaging.

The current use per site is in the range 26-52 tonnes/year per site of chromium trioxide (expressed as Cr(VI)).

The use is currently covered by Authorisations No. REACH/20/18/21-27 (use of chromium trioxide)[2].

The applicant is also requesting an authorisation for the continued use of chromium trioxide and sodium dichromate for the passivation of Electrolytic Tinplate (ETP) (Use 1) in the same production area at both sites, addressed in a separate Opinion.

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

The surface of steel is coated in a cathodic process in the presence of chromium (VI) salts by covering it with an inert layer of metallic chromium (0) and chromium (III) oxide.

Manufacturing of ECCS is a continuous process and the chrome plating itself is only one step in a series of different treatment steps which are performed consecutively.

The steel to be plated to form Tin Free Steel is delivered in large, spooled steel coils. These 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 for coating in the chrome plating bath. After plating, the steel strip is rinsed, dried and then treated in the oiling unit before it is wound up again in the exit section.

In Basse-Indre, the ECCS line is currently operated with < 25 workers per shift in several shifts[3]. In Etxebarri, the ECCS line is operated with a total of < 75 workers in several shifts. Production volume and employment levels are anticipated to increase at both sites. The tonnage applied for takes into account this intended increase; up to < 100 workers plus 1-50 external maintenance workers are intended to work in the sites.

The applicant has presented one environmental contributing scenario (ECS) and 9 worker contributing scenarios (WCS). These are outlined in Table 1, together with a short description. The worker contributing scenarios (WCS) are also referred to as Tasks (T). The procedures at both sites are similar with the exception of how chromium trioxide is added. At Basse-Indre, it is added in liquid form while in Etxebarri it is added in sold form (flakes).

At both sites, one task extends over a longer duration: T9, relating to activities close to the line but not directly handling Cr(VI) powders or solutions. Line operator-based tasks with potential Cr(VI) exposure are: T1, changing out large containers of chromate solution (only at

[2] https://ec.europa.eu/docsroom/documents/44374/attachments/1/translations/en/renditions/native.
[3] The number of shifts in each site is claimed confidential by the applicant but known to committees.

Basse-Indre site); T2, sampling of the tanks; T6, cleaning; and T7, adding flakes of chromium trioxide to make-up the chrome-electroplating bath solution (only at Etxebarri site). Support tasks are T3 to T6 relating to maintenance, cleaning and waste. Most workers undertake a combination of these tasks. The applicant included a task T8, dissolution of solid CT, which is not undertaken at present in Basse-Indre but could theoretically be undertaken in the future in all sites, should supply chain issue arise. It is similar to T7, undertaken currently at Etxebarri.

Table 1: Contributing scenarios presented in the use (ECCS- Use 2)

Contributing scenario	Name of the contributing scenario	Elaboration
ECS 1	Use of chromium trioxide for the Electrolytic Chromium Coating of Steel (ECCS), also known as Tin Free Steel (TFS)	Exposed population: Local: < 2 000 (indirectly exposed workers) and < 5 000 (general population)
WCS 1 (T1)	Changing intermediate bulk containers (IBC)	Basse-Indre only. 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 electroplating tank/IBC	Undertaken at dedicated sampling points (valves). Sampling of IBC (monthly) undertaken at Basse-Indre only.
WCS 3 (T3)	Sampling of Wastewater	Wastewater samples are taken after the reduction step to check if the final Cr(VI) concentration and exposure potential is negligible.
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.
WCS 6 (T6)	Filter press /Sludge removal	Sludge is suspended in solution and removed by vacuum. Filter press is not associated with electroplating baths but is used at wastewater treatment.
WCS 7 (T7)	Addition of solid CT	Etxebarri only. A complete drum is dispensed through tundish (funnel) under negative pressure into mixing tank below.
WCS 8 (T8)	Dissolution of solid CT	Theoretical scenario, applies to Basse-Indre only. Not planned but included in case of supply difficulties for liquid chromates in IBCs. Charging of solid chromates through tundish (funnel) into mixing tank on floor below.
WCS 9 (T9)	Activities close to the ETP line without handling of Cr(VI) containing solutions (e.g. sanding or changing of rolls)	For example, sanding or changing of rolls, forklift driver, inspector.

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 for electrolytic chromium coating of steel (ECCS), also known as Tin Free Steel (TFS).

Chromium trioxide is used in the production of the packaging material to ensure corrosion resistance, coating adhesion and food safety. The applicant indicates seven requirements that must be met:

1. Corrosion protection of the steel plate
2. A suitable surface for coating
3. Chemical resistance to the contents of the can
4. Compatibility with the can-making process
5. Conforming with food contact material (FCM) regulations
6. Acceptable aesthetic properties
7. A robust process capable of industrial level of production

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 chromium coated steel (ECCS), which is used for food packaging material, primarily cans. ECCS has a lower corrosion resistance than tinplated steel and therefore some limitations in use; e.g. ECCS it is not appropriate for acidic food (pH < 4) and not suitable for welding or soldering. Chromium coated steel was developed as an economic alternative to tin plated steel.

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

<u>Operational Conditions</u>

- Cr(VI) concentration:
  - IBC: 19.5 %.
  - CrO_3 flakes: 52 %.
  - electroplating baths: 6 %.
  - filter press/sludge: 5 %.
- Operating temperature 45-60 °C.
- Duration and frequency of tasks are shown in Table 2.

Technical RMMs

- Local exhaust ventilation (LEV) hoods above baths, close to bath surface and almost covering the bath.
- Control rooms on both lines. All are supplied with internal air (supplied from the working area), with the exception of one of the six control rooms in the production area at Basse Indre, which is supplied with air from outside.
- No mist suppressants are used.
- Cr(VI) added to tanks in liquid form at Basse-Indre, with closed transfer.
- Cr(VI) added to tanks in solid form at Etxebarri. CrO_3 flakes are charged to a tank in the basement via a tundish/funnel under negative pressure.
- Samples are taken using dedicated sampling points at electroplating tanks and reduction plant.
- A containment basin is used to collect spills and washings.
- During tank clean, sludge is suspended in water and vacuumed.

Note: there is no mechanical room ventilation, only natural ventilation.

Organisational RMMs

- The effectiveness of risk management measures and operating conditions are regularly reviewed and, where appropriate, measures are introduced to further reduce exposure and emissions.
- The ventilation flowrate for LEV is monitored continuously and a decrease in the flowrate triggers the shutdown of the line.
- LEV systems are inspected and maintained on a regular basis.
- Standard procedures are in place for the use and maintenance of respiratory protective equipment (RPE) (including initial fit testing and pre-use seal testing).
- A programme of PPE management is implemented on site, including the selection of PPE, training on the correct wearing/removal of PPE, storage of PPE, cleaning or renewal and distribution of PPE, and communication about workplace signage and workplace instructions.
- The provision of PPE to workers is organised by a designated responsible person and the condition of the PPE is checked regularly.
- Chemical risk training is provided regularly for workers who handle chemicals. Safety data sheets and instructions for handling hazardous chemicals are available.
- Workplace training is conducted regularly and work instructions are available on how to perform specific tasks using standard operating procedures.
- Cleaning of uniforms provided by the company is organised by the site, or soiled clothing is replaced.
- Work clothes and private clothes are kept either in separate or segregated lockers.
- All staff have annual occupational health checks.
- All waste with Cr(VI) is disposed of by a licenced waste company.

In response to questions, the applicant provided a detailed description of OC/RMMs that are intended to be implemented for the theoretical scenario T8 (Dissolution of solid CT). These are similar to the T7 (addition of solid CT) at Etxebarri and include:

- A drum lift will be used to increase the distance between the operator and the source, which will reduce the exposure of the operator.
- A local exhaust ventilation system or an air extraction system will be installed to reduce dust generation.
- Access to the area will be restricted.
- The activity will only be carried out by trained operators.
- Exposure of the operators will be checked by biomonitoring and air monitoring.
- PPE including RPE (respiratory full mask with P3) will be worn.

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

Contributing scenario	**Duration and frequency of exposure**	**Engineering controls** (e.g. containment, segregation, automation, LEV)	**PPE** (RPE and Skin protection used)	**Organisational controls** (access control, procedures, training)
T1 Changing IBC containers Basse-Indre only (PROC 8b)	Duration: 15 min Frequency: 72 days per year	Closed IBC containers stored at dedicated places, Natural ventilation	Chemical resistant clothing[1] RPE [2] Gloves[3] Safety glasses/face shield	Specific activity training for dedicated operators careful transport of closed containers to dedicated place
T2 Sampling of electroplating tank (both sites) / IBC (Basse-Indre) (PROC 9)	Tanks: Duration: 15 min Frequency: daily IBC: Duration: < 5 min Frequency: 10 times per year	Dedicated sampling points Baths with high level of containment LEV with scrubber in Basse-Indre (Eff. not specified) Natural ventilation	Chemical resistant clothing[1] Gloves[3] Safety glasses/face shield	As T1 Annual LEV system verification
T3 Sampling of Wastewater (PROC 9)	Duration: 5 min Frequency: daily	Dedicated sampling points Natural ventilation	Chemical resistant clothing[1] Gloves[3] Safety glasses/face shield	As T1
T4 Maintenance (PROC 28)	Duration: 60 min Frequency: 48 days per year	Natural ventilation	Protective clothing or chemical resistant clothing[1] RPE [2] Gloves[3]	As T1. Before major maintenance activities Cr(VI) baths are emptied; contaminated objects are emptied and rinsed before maintenance
T5 Cleaning (PROC 28)	Duration: 15 min Frequency: daily	Natural ventilation	Chemical resistant clothing[1] RPE [2] Gloves[3]	As T1
T6 Filter Press/Sludge removal (PROC 28)	Duration: 15 min Frequency: 48 days per year	Natural ventilation	Protective clothing or chemical resistant clothing[1] RPE during sludge removal from tank [2] Gloves[3]	As T1
T7 Addition of Solid CT (PROC 8b) Etxebarri only	Duration: 5 min Frequency: daily	Tundish under negative pressure (50 % eff.)	-	Specific activity training

T8 Dissolution of solid CT (PROC 5) (theoretical)	Duration: 30 min Frequency: daily	Not specified	-	As T7
T9 Activities close to the ECCS line without handling Cr(VI) (e.g. Changing rolls) (PROC 4)	Duration: up to 480 min/day Frequency: daily	No direct contact to Cr(VI) Natural ventilation	Standard PPE set: protective clothing, safety glasses, protective helmet, ear protection and safety shoes	As T7

[1] Chemical resistant clothing type 6 acc. to EN13034, chemically resistant gloves (tested to EN374)
[2] RPE (half mask or full mask with P3 filter (APF 20 and APF 40 respectively) or full mask with P3 combination filter (APF 20). Typically used: Moldex Half Mask with Moldex 9030 A1B1E1K1 P3R combination filter. (APF = Assigned Protection Factor)
[3] Chemical resistant gloves, AlphaTec 58-535W; Nylon-Nitril gloves according to EN 374 breakthrough time ≥ 8 h for aqueous CT solutions (10 % CT):

1.2. Environment /Humans via the environment

Air

Exhaust air from the ECCS process is released via stacks. The air is passed through scrubbers prior to release at Basse-Indre.

Water

The waste solution of the electroplating tank as well as other Cr(VI) containing wastewater is collected in a dedicated drain and directed to the wastewater reduction/neutralisation facility where the water is processed in a two-step procedure.

First, Cr(VI) is reduced to Cr(III) by the addition of sodium bisulfite in excess. After reduction, the wastewater is neutralized so that Cr(III) is precipitated and removed through a filtering process in an automated filter press. After checking the Cr(VI) content of the reduced wastewater, the wastewater is mixed (diluted) with Cr(VI)-free wastewater and sent to an on-site or off-site wastewater treatment plant from where it is discharged to the receiving water (river).

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 electroplating baths and wastewater treatment process is not applied to agricultural soil but is sent to a landfill or incinerated.

Waste (other than wastewater)

In addition to sludges and filter cakes which are disposed of by a specialised waste company, Cr(VI) contaminated solid waste such as filters (e.g. from filtering the process baths), contaminated PPE and other consumables and dirty wipes is generated. These are stored in closed containers prior to disposal by a specialised waste company.

Additional information on soil and waste RMMs incorporated in the sections above was provided during the opinion formation.

Table 3: Environmental RMMs – summary

Compartment	RMM	Stated effectiveness
Air	Wet scrubbers at Basse-Indre	Not stated
Water	Reduction to Cr(III) and precipitation following neutralisation	Not stated (concentration in wastewater < 0.1 %)
Soil	Collection tanks, concrete or antiacid tiles, secondary containment, incineration/landfilling of sludge	100 %

1.3. RAC's evaluation on the OCs and RMMs

Worker OCs and RMMs

T1: Changing IBC containers (Basse-Indre only)

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 electroplating bath

Dedicated sampling points are used and a photograph provided during opinion formation shows an open tap arrangement. Although preferable to direct sampling, the tap could be a more effective RMM if adapted to maximise containment and minimise liquid disturbance.

This task also includes the sampling of the Cr(VI) concentrate from the IBC (Basse-Indre only) with a pipette or small container on an extension stick. Although the concentration is higher, the duration and frequency is much lower than sampling of tanks.

The RMM for electroplating bath sampling could potentially be improved. This leads to a condition in section 7.1 of the opinion.

T3: Sampling of wastewater

The Cr(VI) in the wastewater is reduced before sampling and the concentration is well below 0.1 %. The exposure potential is negligible and further RMMs would not be required.

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

Cleaning of the electroplating bath area is undertaken and also as a preliminary step before maintenance. It often involves the use of a 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 7.1 of the opinion.

T6: Filter Press/Sludge removal

Vacuuming of the sludge to remove it from the tank is an effective RMM as manual intervention is expected to be less than with manual removal.

The description of this task includes "filter press" for the passivation/electroplating bath. However a filter press does not seem to be installed in the baths in the two sites that form part of this application.

There are filter presses in the WWTPs. Removal of the filter cake is automated, with no potential for exposure. In Etxtbarri, workers have to scrape off residue on occasion which could potentially give rise to exposure if dry, but it is described as being "clearly wet" which would effectively minimise exposure. Also, the Cr(VI) content is likely to be minimal due to the reduction step earlier in the process.

The OCs and RMMs are adequate.

T7: Addition of solid CT (Etxebarri only)

In Etxebarri, solid CT flakes are used to make up the chrome-electroplating bath solution of the ECCS line. Several RMMs are likely to reduce worker exposure: the use of flakes rather than powder; the addition of a full drum (not requiring dispensing); negative pressure at the tundish ducting. The specified LEV effectiveness of 50 % is conservative.

In the CSR, the applicant stated that liquid addition was not feasible due to potential for distortion of the specification of the electrolytic bath. In response to RAC's question, the applicant further explained that liquid addition has not been implemented due to space constraints and that the cost of adapting the area is not justifiable due to the limited amount of time remaining for this use.

Although RAC acknowledges the challenges of substituting to the liquid form, this task is the major contributor to worker exposure. Consequently RAC recommends that the OCs and RMMs for this task be improved. This leads to a condition in section 7.1 of the opinion.

T8: Dissolution of solid CT – theoretical, Basse-Indre only

In the CSR, no technical RMMs such as LEV are assumed for this theoretical task. In response to RAC question, the applicant the applicant indicated that implementing additional RMMs is necessary to reduce the estimated exposure, such as a drum lift and LEV.

These RMMs would be required if this task becomes a normal part of production.

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

Workers such as forklift drivers, roll changing and inspectors are in the vicinity of the ECCS line and have the potential for exposure. They are reliant on effective natural ventilation, as well as effective local exhaust ventilation of the line. RAC takes note that there is no mechanical general air extraction system installed at the facility.

The emissions from the plating baths are captured with exhaust hoods. From photos provided in response to questions, the proximity to the surface of the baths and the extent of the coverage indicates that performance is likely to be good.

Although not included as a worker contributing scenario, line operators spend time in control rooms adjacent to the lines. The control rooms are not supplied with external air, with the exception of one of the 6 control rooms at Basse-Indre. In reply to questions, the applicant emphasised that the lines are located in large industrial halls and the bay doors are regularly open so that fresh air is constantly supplied. Furthermore, due to the size of the warehouse, installation of external ventilation to the control rooms would take considerable technical effort.

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 the applicant has implemented a number of technical measures to reduce the environmental emissions of Cr(VI):

- a wet scrubber is installed to remove Cr(VI) before release to air at the Basse-Indre site;
- the wastewater is treated in a reduction system prior to wastewater treatment and discharge;

- there is no potential for release to soil due to collection basins/shut-off walls/non-permeable floor coating;
- all hazardous waste is disposed of by a licenced contractor.

With the exception of the site where there is no treatment of the air emissions, these RMMs significantly reduce the potential for release of Cr(VI) to the environment and are considered by RAC to be good practice.

RAC notes that mist suppressant is not used and that the operating temperature 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.

Air emissions results from Etxebarri indicate that the release of Cr(VI) into the atmosphere through the ECCS production line exhaust is 13 times lower in Etxebarri than in Basse-Indre, although no air scrubber is used at Extebarri in contrast to Basse-Indre (see section 2.3). Consequently, installation of an air scrubber is not included as a condition of authorisation for Etxebarri. Verification through measurement is recommended (see section 8.1 of this opinion).

1.4. RAC's conclusions on the OCs and RMMs

Overall conclusion

Are the operational conditions and risk management measures appropriate and effective[4] 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 the environment (HvE) are generally appropriate and effective and follow the hierarchy of control principles.

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. RAC acknowledges that use of a tap reduce exposure compared with dipping directly into the bath;
- Chromium trioxide is added in the solid form (flakes) at Etxebarri. RAC acknowledges that the applicant has provided a number of reasons as to why liquid form is not feasible;
- Risk management measures are not specified for the theoretical Task 8 (Dissolution of

[4] '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.

solid CT). RAC acknowledges that the intention to implement RMMs was indicated by the applicant during the opinion formation

RAC has the minor concerns outlined below. These minor concerns, are not seen as significant enough to warrant a decisive element in a future Commission Decision. Therefore, they do not lead to conditions for authorisation in section 7 of this opinion.

- Only natural ventilation is available;
- Air supply to the control rooms is internal (from within the hall) and not external in most cases;
- RMMs are not installed on the air exhaust on the Etxebarri site.

2. Exposure assessment

2.1. Inhalation exposure

Monitoring

Basse-Indre

Extensive personal exposure monitoring data at the ECCS line was provided for the years 2017-2021 and information on the methodology was provided. A combination of operator-based and task-based measurements were undertaken. Information on activities undertaken during monitoring was limited.

Sampling durations were classified as long term (> 120 min, typically 300-500 min) and short term (< 120 min). The limit of quantification (LoQ) differed between sampling campaigns and ranged from 2 ng/filter and 50 ng/filter (about 0.07-0.11 µg Cr(VI)/m^3). For values that were below the LoQ, half of the LoQ (LoQ/2) was used for the calculation.

Individual data points were provided, plus range, mean, median and 90th percentile.

Etxebarri

Exposure monitoring data was provided for the years 2016-2021 at the ECCS line and information on the methodology was provided. Each year, single personal measurements were taken at three operator positions and one static measurement position close to the chrome plating section. Information on the activities undertaken by the operators on the day of measurement was not provided.

Sampling duration varied between 73-279 minutes. The LoQ differed between the years in a range of 13 ng/filter to 100 ng/filter (about 0.07-0.45 µg Cr(VI)/m^3). Values below the LoQ were treated as LoQ/2.

Table 4: Overview of measured exposure – inhalation

Worker / Task	Type of measurement[1]	No of samples	Number of samples < LoQ	Range Cr(VI) µg/m³	Measured concentration 90th percentile[2] Cr(VI) µg/m³
Basse-Indre					
Chemist operator	Long term	24	3	0.028-2.80	1.2
Inspector	Long term	13	0	0.031-0.370	**0.19**
Maintenance worker (internal)	Long term	5	0	0.02-27.9[3]	**17.1**
Quality operator	Long term	3	3	< 0.05	n/a
T1 Changing IBC containers	Short term	5	0	0.052-3.37	**3.2**
	Long term	10	0	0.057-2.80	0.92
T2 Sampling baths	Short term	7	0	1.12-10.0	**6.0**
	Long term	8	0	0.060-1.31	1.2
T4 Maintenance	Long term	2	0	0.660-1.94	n/a
T5 Cleaning	Short term	6	0	1.12-4.00	**3.7**
	Long term	10	1	0.057-2.05	1.2
Etxebarri					
Basement operator	Long term	6	3	< 0.1-0.189	n/a
Team leader/ deputy	Long term	6	4	< 0.06-1.00	n/a
Maintenance worker	Long term	4	1	< 0.1-2.8	n/a
Static	-	5	3	< 0.06-0.29	n/a

[1] Sampling duration varied, measurements < 120 min were regarded as short-term measurements, whereas measurements with a duration ≥ 120 min were regarded as long-term measurements.

[2] Value is not provided when the number of valid samples is low. This excludes the effect of the RPE worn during tasks with high potential exposure and may be an overestimate.

[3] Range excluding elevated result from 2021 was 0.02-0.66 µg/m³ . Monitoring report identified elevated result as "exceptional inspection time"

Modelling

The Advanced Reach Tool (ART) Version 1.5 was used to perform the assessment of inhalation exposure to Cr(VI) for all worker contributing scenarios. 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) and T9 (activities close to the line). 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 ACH1 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 applicant pooled the measured data from the individual sites. The values brought forward for the risk characterisation are presented in bold in Table 5.

For Maintenance, T4, the pooled data of 9 measuement points gave a 90th percentile exposure (before correction for RPE and frequency) of 7.8 µg/m^3. The exposure was 1.7 µg/m^3 when the elevated value was excluded and this is the value that was carried forward by the applicant in the risk characterisation. The exposure value corrected for RPE and frequency was 0.078 ug/m^3 and 0.017 ug/m^3 including and excluding the elevated value respectively.

For a number of tasks where measured and modelled estimates were available, the more conservative estimate was generally selected. This was not the case for T2 (sampling) where the modelled value was selected even though it was a factor of ten lower. The reasoning presented by the applicant was a number of other tasks were carried out during the measurement period in addition to sampling, leading to high uncertainty in measured results

Most workers have combined exposure and this is assessed in section 3, together with the potential impact of the second production line in the same area.

Table 5: Overview of long term exposure values used for inhalation risk characterisation – Basse-Indre and Etxebarri

WCS	Method of assessment	Concentration Cr(VI) µg/m^3	8h TWA exposure value (µ of Cr(VI)/m^3)	Exposure value corrected for frequency (ug of Cr(VI)/m^3)	Exposure value corrected for RPE and frequency (µg of Cr(VI)/m^3)
T 1 Changing IBC containers Basse-Indre only	Modelling	0.680	0.021	0.006	**< 0.001**
	Measurement	3.17	0.099	0.030	0.002
T2 Sampling tank/IBC	Modelling	0.540	0.017	0.017	**0.017**
	Measurement	6.02	0.188	0.188	0.19
T3 Sampling Wastewater	Modelling	< 0.001	< 0.001	< 0.001	**< 0.001**
T4 Maintenance	Modelling	0.600	0.075	0.015	< 0.001

WCS	Method of assessment	Concentration Cr(VI) µg/m³	8h TWA exposure value (µ of Cr(VI)/m³)	Exposure value corrected for frequency (ug of Cr(VI)/m³)	Exposure value corrected for RPE and frequency (µg of Cr(VI)/m³)
	Monitoring	1.686	1.686	0.337	**0.017**[1]
T5 Cleaning	Monitoring	3.686	0.115	0.115	**0.006**
T6 Filter Press/Sludge removal	Modelling	11.00	0.344	0.069	**0.003**
T7 Addition of solid CT Etxebarri only	Modelling	280.0	5.83	5.83	**0.29**[2]
	Monitoring	0.595	0.021	20.8	0.001
T8 Dissolution of solid CT Theoretical scenario	Modelling	310	19.4	19.4	**0.97**[3]
T9 Activities close to the ECCS line without handling of Cr(VI) containing solutions	Monitoring	0.189	0.189	0.189	**0.19**

[1] Excludes elevated sample. The exposure is 0.078 µg/m³ when the elevated result is included.

[2] Assumes LEV 50 % effective.

[3] Only corrected for frequency; does not incorporate RMMs.

Exposure contribution from adjacent production lines

RAC notes that at both sites an adjacent Electrolytic Tinplate (ETP, Use 1) line operates that uses both chromium trioxide and sodium dichromate, both potential indirect sources of Cr(VI). Information on the proximity and potential for exposure from adjacent production lines was provided in response to questions.

The distance between the lines in Basse-Indre is 30m with partial separation and in Etxebarri is 10 m with no separation. The applicant considers that in Basse-Indre the exposure estimate is not affected by the adjacent line. In Etxebarri, operators could change between lines on a day to day basis, with a slightly higher exposure on the ETP line of 0.22 µg Cr(VI)/m³ than on the ECCS line, where it is 0.19 µg Cr(VI)/m³.

2.2. Biomonitoring

Biomonitoring data from 2017-2022 was provided for the Etxebarri site. Only post shift levels were monitored. In 2017-2019, the LoQ was 0.2 µg Cr/L urine and the mean of 86 samples was 0.75 µg Cr/L with a maxiumum of 4.6 µg Cr/L. For 2020-2021, the LoQ was 10 times higher at 2 µg Cr/L and 42 of the 49 samples in Etxebarri 2020 and 2021 were below the LoQ. The maximum value was 4.8 µg Cr/L.

The applicant explained that biomonitoring values for the operators in Basse-Indre have also been recorded, but they are kept by the occupational health officers and are not available to the applicant.

2.3. Environmental releases

Monitoring data for Cr(VI) releases to water and air are available for the sites Basse-Indre and Etxebarri as required by national legislation.

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) of human exposure via the environment, to establish environmental concentrations and risks for HvE. Release to soil was assessed qualitatively.

Both the Limit of Quantification (LoQ) and Limit of Detection (LoD) were used as the reporting limit, as shown in Table 6. When the measured emission was below the LoQ(D), LoQ(D)/2 was used for calculating the emission values. The applicant provided the LoQ/LoD but claimed them as confidential. They vary between sites and sometimes between years for a given site. RAC has confirmed that they are sufficiently low to provide a valid result for the exposure emission.

Comprehensive information on the methodology and the measurement results are given in Annex 6 of the CSR and is entirely claimed as confidential, but known to committees.

Table 6: Summary of releases to the environment

Production Site	**Release route**	**Reporting Limit Air: mg/Nm³ Water mg/L** (order of magnitude)	**Release factor[1]**	**Release per year[2]** [kilograms Cr(VI)]	**Release estimation method and details**
Basse-Indre	Air	LoQ: 10^{-3}	1.0×10^{-4} to 1.0×10^{-3}	17.5	Measured data/Annex 6a
	Water	LoQ: 10^{-2}	1.0×10^{-5} to 1.0×10^{-4}	2.5	Measured data/Annex 6a
	Soil	n/a	0	0	Qualitative
Etxebarri	Air	LoD: 10^{-3}	1.0×10^{-5} to 1.0×10^{-4}	1.3	Measured data/Annex 6b
	Water	LoQ: 10^{-3}	1.0×10^{-3} to 1.0×10^{-2}	68.4	Measured data/Annex 6b
	Soil	n/a	0	0	Qualitative

[1] Exact values claimed confidential but known to committees. Values scaled for ECCS release only based on production volumes.

[2] Projected emissions from 2022 onward for ECCS line only (excludes ETP related emissions).

Table 7: Summary of modelled exposure for humans via the environment

Production Site	**Parameter**	**Local[1]**
Basse-Indre	PEC in air (µg Cr(VI)/m³)	1.3×10^{-2}
	Daily dose via oral route (µg Cr(VI)/kg bw/d) [2]	1.7×10^{-3}

Production Site	Parameter	Local[1]
Etxebarri	PEC in air (µg Cr(VI)/m^3)	1.0×10^{-3}
	Daily dose via oral route (µg Cr(VI)/kg bw/d) [2]	1.2×10^{-3}

[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).

2.4. RAC's evaluation of the exposure assessment

Workers exposure

The applicant used standard methodology for measuring and estimating the exposure. The inhalation monitoring information provided for Basse-Indre was comprehensive and appears to be representative of the exposure. The applicant identified uncertainties in the activities undertaken for some samples, and the difficulty in isolating short term activities.

The monitoring data provided for Etxebarri was less comprehensive. It was consistent with the data provided for Basse-Indre.

The applicant assumes the exposure to be the same in both sites and pooled the measurement data where applicable. There are differences in the production layout between sites but the process is sufficiently similar so that it is a reasonable assumption.

For the measured exposure estimates, the 90th percentile values were used. In general, the 90th percentile value represents a reasonable worst-case exposure level of a distribution within a generally suitable dataset (ECHA, R14).

For modelled estimates, the conditions of use and effectiveness of the RMMs are broadly consistent with the description provided. Where LEV systems are in place, the assumed effectiveness of 50% is conservative.

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.

Both measured and modelled estimates were provided where possible. When both estimates were provided, the applicant identified the estimate they considered most representative (in bold in Table 5) and justified the selection. RAC generally concurred with the reasoning. An exception was for T4 (maintenance), when the applicant excluded an elevated result. RAC considers that the exposure during maintenance can vary widely and that it is generally not justifiable to exclude elevated results. Nevertheless, the daily exposure value is relatively low and the difference does not have a significant impact on the risk characterisation.

For tasks currently undertaken, the highest estimated exposure is 0.3 µg Cr(VI)/m^3 for T7 (addition of solid CT), based on modelling and conservative inputs. Substitution with liquid chromate could potentially reduce the exposure.

The modelled exposure estimate for the theoretical scenario T8 (Dissolution of solid CT) is relatively high at 1 µg Cr(VI)/m^3. RAC notes that RMMs described during the opinion formation (notably LEV) are not included in the estimation and considers that exposures similar to T7 could be achieved in practice.

Regarding the influence of adjacent production lines on the exposure, RAC concurs with the conclusion of the applicant that the impact in Basse-Indre is likely to be relatively small. RAC considers that for T9 (activities close to the line), this exposure is based on measurement that will have included the impact of the adjacent line.

In the case of Etxebarri, the applicant considers that interchange with the ETP line would lead to a slight underestimate, as the T9 exposure on the ETP line is 0.22 µg Cr(VI)/m^3 compared with 0.19 µg Cr(VI)/m^3 on the ECCS line. RAC concurs and considers that the difference is not sufficient to warrant amendment of the applicant's exposure estimate.

The biomonitoring data provided is for one site only and is limited to post shift. Consequently, it is difficult to attribute any elevated level to workplace exposure or lifestyle. Post shift levels were low however, indicating that significant workplace exposure did not occur in the days prior to sampling.

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

RAC concludes that the applicant has provided a reliable exposure estimate. Taking the uncertainties identified here into consideration, RAC considers that the estimates are generally realistic.

Humans via the environment

RAC notes that the applicant performs measurements of the air and wastewater releases in accordance with standard procedures. 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 has concerns about the absence of risk management measures in the exhaust air such as wet scrubber at Etxebarri, particularly as mist suppressant is not used and the operating temperature is above ambient. However, RAC notes that the measured emissions are not elevated at Etxebarri.

There is however an inconsistency in the air emission estimates between sites. The annual air release is 13 times greater in Basse-Indre than in Etxebarri, although production quantities are similar and RMMs (wet scrubbers) are installed in Basse-Indre only. RAC is concerned about this elevated releases to air at Basse-Indre and notes that the reasons are not identified in the application.

The emissions to water at Etxebarri are 27 times greater than at Basse-Indre, although production quantities are similar. This was explained by the applicant to be due to a combination of high tonnage, flow rate and that measurement takes place before treatment by the off-site WWTP where there is further reduction by 90 % according to the information claimed by this external WWTP (not provided by the applicant). RAC notes that the off-site WWTP treatment brings the effective release at Etxebarri to about 3 times greater than at Basse-Indre.

RAC notes the observation by the applicant that the application of LoQ/2 to values below the

LoQ leads to a highly conservative estimate with regard to wastewater emission. RAC also notes that at Etxebarri, measured levels of Cr(VI) in wastewater exceeded the LoQ by up to factor was 10. In addition, at Basse-Indre, over half the measured values provided exceeded the LoQ (893 of 1637 over 5 years). Consequently, RAC does not concur that the estimate is highly conservative.

RAC notes that the applicant calculated the release factors by taking into account the average releases and consumptions of the previous years, and that they are therefore not worst-case. The applicant estimated the releases by combining these average release factors with projected tonnages for the review period.

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[5] 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 Draft Opinion.

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

RAC considers that it is relevant to include the Cr(VI) emissions from ETP (Use 1) in the risk characterisation.

2.5. 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;
- the workplace exposure and air emission monitoring provided is sufficient at both sites although the low number of measurements at Etxebarri is a shortcoming in the exposure assessment;
- the modelled exposure estimates are plausible and conservative;
- the measured air releases at Etxebarri and Basse-Indre do not correlate with the presence or absence of air scrubbers at the sites (elevated releases at Basse-Indre where an air scrubber is installed, lower releases at Etxebarri where no air scrubber is installed);
- the estimates of exposure for workers and for humans via the environment provide a reasonable basis for the assessment.

RAC proposes additional conditions in Section 7 due to the elevated air emission at Basse-Indre. Due to the insufficiency of measured data in some instances and the inconsistencies in some of the measured emissions, RAC proposes monitoring arrangements for the authorisation where applicable (see section 8) and recommendations for the review report (see section 9) to address these shortcomings.

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

3. Risk characterisation

For risk characterisation, the exposure estimates are compared with the exposure-risk relationships derived by ECHA (RAC 27/2013/06 Rev. 1, agreed at RAC 27) as follows:

Inhalation: ambient exposure concentration of 1 µg Cr(VI)/m^3 corresponds to an excess lung cancer risk of 4×10^{-3} for workers and 2.9×10^{-2} for the general population.

Oral (drinking water and fish): A constant average oral daily dose of 1 µg Cr(VI)/kg bw/day corresponds to an excess small intestine cancer risk of 8×10^{-4} for the general population.

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[6], taking into account also that the excess lifetime risk for intestinal cancer is one order of magnitude lower than that for lung cancer.

3.1. Workers

Similar tasks are undertaken at both sites but the operator titles and combinations of tasks differ. The applicant identified the operator types at each site and the associated typical task combinations.

The applicant summed the task exposures from measured or modelled estimates (Table 5) to establish the long term aggregated exposure for each operator type, as shown in Table 8 for Basse-Indre and Table 9 for Etxebarri. Unit operators typically spend parts of the shift in the control room, visually controlling and adjusting the operation of the processes. This is not included in Table 8 and Table 9.

For operators spending much of their shift on the line, their exposure is established by summing the task exposures (with RPE where applicable) with the exposure of 0.19 µg Cr(VI)/m^3 for Task 9 (activities performed along the line without handling of Cr(VI)). Many of the task combinations involving line operation have a calculated aggregated exposure of 0.21 µg Cr(VI)/m^3. The highest combined exposure is 0.34 µg Cr(VI)/m^3 for the basement operator in Etxebarri, due to the inclusion of Task 7 (Addition of solid CT). It is reported that this operator does not undertake Task 9.

The aggregated exposure and corresponding risk characterisation for the theoretical scenario T8 (dissolution of solid) was not provided by the applicant.

The full shift excess risk for each operator type was determined by applying the excess lung cancer risk (ECHA2013) to the aggregated exposure. The applicant concluded that the upper-end excess risk was 7.6×10^{-4}, corresponding to an indirect exposure level of 0.19 µg Cr(VI)/m^3. This is not the highest estimated value; the highest values are reported in the following tables.

[6] 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."

Table 8: Combined exposure and risk characterisation, Basse-Indre

Operator Type	Combination of Cr(VI) related tasks	Aggregated inhalation exposure [µg/m³]	Risk –Operator type [1]
Team leader	T4 + T5 + T9	**0.21**	8.5×10^{-4}
Team leader deputy	T4 + T9	**0.21**	8.2×10^{-4}
Entry operator	T4 + T9	**0.21**	8.2×10^{-4}
Exit operator	T4 + T9	**0.21**	8.2×10^{-4}
Chemist operator	T1 + T2 + T4 + T5	**0.04**	1.6×10^{-4}
Inspector	T9	**0.19**	7.6×10^{-4}
Forklift driver	T9	**0.19**	7.6×10^{-4}
Quality operator	T2 + T9	**0.21**	8.2×10^{-4}

[1] Estimated individual risk resulting from exposure. The applicant proposes an upper end risk estimate of 7.6×10^{-4}

Table 9: Combined exposure and risk characterisation, Etxebarri

Operator Type	Combination of Cr(VI) related tasks	Aggregated inhalation exposure [µg/m³]	Risk –Operator type [1]
Team leader	T9	**0.19**	7.6×10^{-4}
Team leader deputy	T4 + T5 + T9	**0.21**	8.5×10^{-4}
Entry operator	T4 + T5 + T9	**0.21**	8.5×10^{-4}
Exit operator	T4 + T5 + T9	**0.21**	8.5×10^{-4}
Basement operator	T2 + T3 + T4+ T5 + T6 + T7	**0.34**	1.3×10^{-3}
Inspector	T4 + T5 + T9	**0.21**	8.5×10^{-4}
Expeditor	T9	**0.19**	7.6×10^{-4}
External and Internal maintenance/cleaning	T4 + T5	**0.02**	9.1×10^{-5}

[1] Estimated individual risk resulting from exposure. The applicant proposes an upper end risk estimate of 7.6×10^{-4}

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. The estimated exposure and individual excess risk over 70 years is shown in Table 10.

Regarding inhalation exposure and risk, the applicant considers that the estimates presented are conservative due to over-conservative default settings in EUSES.

Regarding oral exposure and risk, the applicant considers that the estimates are based on very conservative assumptions, taking wastewater Cr(VI) values that are below the LoQ to be LoQ/2 and that reduction to Cr(III) is likely to be complete. Also, 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 applicant also provided an assessment of the regional risk but it is not considered further here due to the low risk. An aggregated risk estimate was provided but not considered further by RAC as inhalation and oral risks relate to different endpoints.

Table 10: Exposure and risk to humans via the environment – local scale

Exposure route / Site	**Local**	
	Exposed population: up to 7 000	
Humans via the environment – Inhalation	**Exposure Cr(VI) µg/m³**	**excess risk (Cr(VI))**
Basse-Indre	1.3×10^{-2}	3.9×10^{-4}
Etxebarri	1.0×10^{-3}	3.0×10^{-5}
Humans via the environment – Oral	**Exposure Cr(VI) µg/kg/d**	**excess risk (Cr(VI))**
Basse-Indre	1.7×10^{-3}	2.8×10^{-7}
Etxebarri	1.2×10^{-3}	2.3×10^{-7}

Releases of Cr(VI) also occur from another use, Electrolytic Tinplating ETP (Use 1), at both sites and RAC considers that it is relevant to note that the emissions from both uses contribute to the overall exposure via environment. In Basse-Indre, the combined release is about 1.4 times higher than the release from the ECCS line only, with a corresponding excess risk of 5.3×10^{-4}. In Etxebarri, the combined release is about 1.2 times higher than the release from the ECCS line only, with a corresponding excess risk of 3.5×10^{-5}.

3.3. RAC's evaluation of the risk characterisation

Workers

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

For information, the current binding Occupational Exposure Limit (BOEL) for Cr(VI) as of 17 January 2020 is 5 µg/m³, with a transitional value of 10 µg/m³ until 17 January 2025.

RAC notes that the applicant takes forward an upper end risk estimate of 7.6×10^{-4} for all operators. The determined risk estimate exceeded this for several operator types, typically by about 10 %. Although a more conservative approach is to take the actual or higher risk estimate, RAC acknowledges that the difference is not significant with the exception of the basement operator in Etxebarri.

The excess risk estimate determined by the applicant for the basement operator in Etxebarri (taking into account RPE when relevant) is 1.3×10^{-3}. This corresponds to a combined exposure estimate of 0.34 µg Cr(VI)/m³ and is consistent with the measured personal exposure of the

basement operator of 0.6 µg/m^3 (90th percentile, excludes RPE). RAC considers that the risk estimate of 1.3×10^{-3} for the basement operator is a more representative and conservative reflection of the risk than 7.6×10^{-4} considered by the applicant and proposes that this value be used in assessing the health impact.

The risk characterisation was not provided by the applicant for combined exposure that includes the theoretical scenario T8 (dissolution of solid), if that task is implemented in the future. RAC recognises that no RMM was taken into account for this scenario and considers that inclusion of additional RMMs would be required to reduce the risk. Upon request from RAC, the applicant has indicated that RMMs (which are not listed in the CSR) would be implemented. These RMMs are expected to reduce the risk.

The potential exposure in the control rooms was not included in the risk characterisation and exposure data was not provided to support the applicant's assumption that the exposure was negligible. RAC has minor concerns about the potential for exposure during the cold season when doors may be closed.

The potential influence of the adjacent ETP production line on the worker exposure was not addressed initially by the applicant, as described in 2.4 and further detail was provided during opinion formation. Due to distance and separation, this would not increase the risk at Basse-Indre.

At Etxebarri, the ETP and ECCS lines are located within 10 m and the operators can work on one or the other line, changing from day to day. The upper end risk estimate considered by the applicant for the ETP line (see opinion for Use 1), at 8.8×10^{-4}, is slightly higher than the value considered by the applicant for Use 2 at 7.6×10^{-4}. RAC considers that the impact of the adjacent ETP line on the exposure estimate is relatively small, taking into account the variability and uncertainty associated with the exposure measurements and estimation. Furthermore, the excess risk for these workers has been addressed in the draft opinion for ETP (Use 1).

RAC acknowledges uncertainties that give rise to over- and under-estimates and considers that overall, the risk characterisation regarding workers is realistic, with the exception of the basement operator at Etxebarri, as described above.

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 this 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.

As mentioned earlier, the reason for the elevated emissions at Basse-Indre was not identified, although RMMs are in place that are absent at Etxebarri.

RAC notes that Cr(VI) emissions also arise from operation of an ETP production line in the same facility (covered in the opinion for Use 1) and that the combined risk (that is, the sum of the excess risks from Use 1 and Use 2 for these 2 sites) was presented by the applicant. The higher individual and combined excess risk was at Basse-Indre, with an inhalation risk of 3.9×10^{-4} for Use 2 and 5.3×10^{-4} combined with Use 1.

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 of excess cancer risk for workers allow a health impact assessment. RAC accepts the risk characterisation for workers presented by the applicant with the exception of the basement operator in Etxebarri. RAC considers that the risk estimate of 1.3×10^{-3} for the basement operator is a more representative and conservative reflection of the risk than 7.6×10^{-4} proposed by the applicant.

RAC concludes that the estimates of excess cancer risk for humans via the environment allow a health impact assessment. RAC has concerns about the air emissions from Basse-Indre, which are higher than expected compared with Etxebarri, and considers that measures should be applied for risk reduction.

RAC notes 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 provided a detailed description of the process required to replace chromium trioxide for the manufacture of Electrolytic Chromium Coating of Steel (ECCS), also known as Tin Free Steel (TFS).
They have described the key functional requirements (detailed in section 0.2) of the substance which the alternative substance(s) must meet.
Additionally, ECCS as a global product has to comply with a broad range of legal requirements, including on food safety and standards, and its alternative will also have to meet them.
In search for available alternatives, the applicant considered the regulatory requirements for products safety, namely: sterilisations, resistance to corrosion and damaging effects, sealed ends from contamination, durability of coating in long shelf-life storage conditions.
Food cans made of ECCS are always used with protection layers added to the can. New surface treatments or coating system (alternative) have to be complied with the food contact legislation around the world.
Regarding non-food sectors an alternative must ensure proper lacquer adhesion.

The applicant took part in the IPSA project (RFSR-CT-2008-2017) and the approach of the IPSA project was to replace the chromium coating of ECCS by a combination of between 1 and 3 different surface treatments or coatings.
The applicant conducted screening tests on all different surfaces targeting the following market

segments:

- Food – vegetable, fruits, meet, fish, soup, milk, oils, pet food, etc.
- Personal care, household products
- Paint, oil, syrups, decorative, confectionary, dray product, unlacquered applications
- Aerosol for food and non-food
- Technical applications
- Closures – crown cork and caps (single use, re-usable).

Results from screening tests were compared to ECCS. The surfaces were then coated by different lacquers and PET films reflecting the broad applications of ECCS in the European market.
Some of these potential alternative were different Low Tin Steel (LTS) alternatives produced. As part of the process, different surface treatments were used to generate thin oxide-films on LTS. In order to scale-up testing phase, a pilot line was prepared for industrial testing of two variants (reflown/non-reflown). The ecological and economical risks were evaluated in parallel. Nine different systems were prepared onto LTS. All samples were investigated with and without organic coatings following a test-program.
After selecting the potential alternative for following tests and first industrial trials, two production lines were adapted by the applicant in order to produce the alternative tinplate without Cr(VI) (LTS with CFPA passivation) for following pack testing with customers. Regarding the development of CFPA-passivated tinplate, regular follow-ups are organised with those customers.

In addition to the screening tests, a study was made on Cr(III) baths for chromic coating production, however Cr(III) bath did not meet the technical requirements.

Considering that all steel used as packaging has to be qualified by the can-makers and their customers, the can-fillers, several customers have received test products made with LTS with CFPA passivation. The process of sampling and pack testing with customers started in 2019.

Qualifications of steel specifications supplied by EU-based tin mills were conducted by can-makers and their customers, through consultations as part of ongoing regular follow-ups.
Based on the current results of the applicant's R&D, LTS will not be accepted by can-makers for all applications until the end of 2027. After that, an additional time is needed for market acceptance and line conversions. A shorter review period than until the end of 2028 would result in a significant loss of market share and profits for the applicant.

Three comments were received during the third-party consultation: from APEAL (Association of European Producers of Steel for Packaging), MPE (Metal Packaging Europe) both of whom are trade associations and ChemSec (International Chemical Secretariat), a non-governmental organisation.
APEAL and MPE supported the application and the requested review period, stating that at present there are no suitable alternatives to the ECCS process.
According to ChemSec, alternatives should be considered in terms of specific requirements for specific products, to take a broader perspective and rethink the need for each functionality.

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

SEAC notes that the applicant has conducted a detailed R&D activities taking into account a

wide range of different alternatives for chromium trioxide. Furthermore, they have collaborated with other members of the APEAL consortium, which shows commitment to find a Cr(VI)-free solution across the industry.

Additionally, they have conducted their own data searches and R&D both within and outside of the IPSA project. They have regular contact with customers and suppliers of alternatives, who were included in testing and sampling of potential alternatives. Their research also covered different substrate materials.

SEAC finds the applicant's approach to analysis of alternatives clear and transparent. Their activities are detailed and well thought out.

In their application, they have provided a detailed rationale to move from a long list of potential alternatives to a short list by comparing potential alternatives to the critical criteria (detailed in section 0.2) in order to select the most suitable alternative(s). This resulted in a short list of two alternative that was taken forward for further consideration:

1. Low Tin Steel (LTS) + CFPA passivation
2. Trivalent Chromium Coating Technology (TCCT)

Applicant has also provided a detailed assessment of the potential alternatives in terms of suitability for their operations.

SEAC notes that the development of the LTS product is partly dependent on CFPA (Use 1) works, with the substitution plan requiring one year longer than for ETP passivation (CFPA), due to required market acceptance for all customers after a successful implementation of the alternative. SEAC accepts that the additional year is needed to ensure market acceptance for LTS and line conversion. Shortening of the requested review period may result in a significant loss of market share and profits for the applicant.

During that period, the applicant will gradually convert their lines to the use of the preferred alternative. The applicant will also finalise the R&D work, while can-makers complete their qualification protocols.

SEAC also notes that qualification pack-testing timeframes can take up to 5 years. The applicant highlights, that in the event that testing needs to be repeated (e.g. reformulation of lacquer) not all customers would finish their tests in the requested review period. However, the substitution plan seems to be consistent and aligned with the one for CFPA (Use 1).

SEAC agrees with the applicant's approach for shortlisted alternatives. The assessment presented by the applicant, allows SEAC to agree with the rationale as to why these alternatives were chosen.

The substitution plan encompasses both ETP passivation and ECCS, which two uses concern products that are closely linked to each other, and therefore cannot be separated.

Nevertheless, the substitution plan contains sufficient detail to allow SEAC a conclusion on the length of the recommended review period.

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 or the comments submitted by interested third parties in the consultation indicating that there are alternatives available that are technically and economically feasible in the EU?

☒Yes ☐No

The applicant was involved in a number of research activities to replace the ECCS. One of these was the IPSA project, which had the following essential criteria for an alternative substance:

- Enhanced adhesion to organic coatings allowing deforming processes like deep draw and draw-redraw
- Excellent corrosion resistance
- Cost-effective solution
- Extensive food-contact testing required (long shelf-life).

For can-makers the coatings must also fulfil some of the key requirements:

• adhere well to metal, coatings and end sealants
• be flexible
• have a high resistance to food components
• be resistant at temperatures up to 130 °C
• have good organoleptic properties
• be inert with low/safe/no migration

Can-makers produce a whole range of diverse products, with different internal conditions based on the filling (of which there are many, even within segments e.g. different food products). Each can-maker may have their own pack-test qualification protocols based on the products they manufacture and the fillings that their customers will put into the can. This has been confirmed through surveys of can-makers. In addition, the end products must meet specific standards and legal regulations for relevant sectors and countries.

The objective of the IPSA project was to develop and evaluate an innovative packaging steel with enhanced adhesion to organic coatings allowing deforming processes and leading to excellent corrosion resistance. Screening tests were conducted on all different surfaces in applied studies and compared to ECCS. The surfaces were then coated by different lacquers and PET films. The final 2 potential alternatives, e.g. LTS and an interlinked mixture, will be used simultaneously. These alternatives were forwarded for further pack tests.
Additionally, a study was made on Cr(III) baths for chromic coating production. However, this potential alternative was rejected due to difficulties and inflexibility of technology as well non-comparability to standard ECCS of product's porosity and adhesion.

Based on their activities the applicant came up with a shortlist of 2 potential alternatives, which were compared to the following criteria:

1. Corrosion protection of the steel plate

2. A suitable surface for coating
3. Chemical resistance to the contents of the can
4. Compatibility with the can-making process
5. Conforming with food contact material (FCM) regulations
6. Acceptable aesthetic properties
7. A robust process capable of industrial level of production

Alternative 1: Low Tin Steel (LTS) with CFPA passivation

Technical feasibility

The applicant confirmed that the LTS alternative and the CFPA alternative (Use 1) are both based on the same chemistry, which means that issues identified for one will also be applicable to the other.
During development of this alternative the applicant has encountered two challenges (confidential but known to SEAC) that could affect the viability of this alternative, which makes it currently not yet technically feasible.

The Low Tin Steel (LTS) system is coated with a Bonderite M-NT 1456 layer (not-reflown tin). Initial trials had already been carried out on an industrial line, and applicant confirms that this process is compatible with an existing ETP-line.
The applicant seems confident that with further development, reformulations and testing these challenges can be overcome, which should make this alternative technically feasible in the near future.

Economic feasiblity

Expected cost of LTS alternative is equivalent to the raw material cost of the current raw materials used in the ECCS process. Energy, human resource and other ancillary costs would also be equivalent. Nevertheless, adaptation of the lines will require considerable engineering works and capital investment. This will financially constrain the timeframe especially considering that the applicant has to also do the full implementation of CFPA (Use 1).
In addition, it is possible that some lacquers will require re-formulation or development. This would mean that both coatings providers and can makers will 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 may have significant economic impact on the downstream supply chains of the applicant.

Availability

The applicant has confirmed that LTS would be available in the quantity and quality required to be able to manufacture their products to the current level.
However, this is not yet possible, as only two lines have been converted so far. This means, that at present the applicant does not have enough capacity to fulfil their demand.
Consequently, the current availability of the LTS output is at significantly reduced tonnages to that of the traditional Cr(VI) ECCS, until the capacity is increased in order to allow for qualification pack-tests.

Based on the issues listed above the applicant cannot conclude whether this alternative is suitable for them at this stage, as it is not yet technically feasible for them.

Alternative 2: Trivalent chromium Coating Technology (TCCT)

Technical feasibility

Electro-deposition process based on Cr(III) coating on black plate was developed as a proprietary technology by Tata Steel, which has been licensed to ThyssenKrupp. The layer achieved with this technology is comparable to current the ECCS material, albeit with a diffuse layer including chromium carbide. Though comparable to the Cr(VI) process, there are major differences related to the chemical composition of the electrolytes, the additives required in the process, the operating parameters and the anode. Consequently, this process would require significant modifications of the production line.
Based on the analysis with some promising results at lab-scale, work still needs to be undertaken in order for the material produced at pilot scale to perform as expected. However, at present the applicant cannot consider Cr(III) as a technically feasible alternative to the current Cr(VI) process.

Economic feasibility

The raw material costs, energy, human resource and other ancillary costs would be equivalent. Nevertheless, adaptation of the lines will require considerable engineering works and financial resources. As the applicant has invested more heavily in the development of LTS over the Cr(III) alternative, these costs would also need to be taken into consideration, as a lost investment already made in LTS.

Availability

Although substances used in the Cr(III) process are available to the applicant, the technology and know-how is patented by Tata Steel. Consequently, the applicant would need to engage in negotiations to obtain a license for this technology.
Furthermore, even if a license was obtained, the applicant has little knowledge of operating this process and would require significant time to develop the process for their specific needs, in addition to the time required to adapt their production lines.
The applicant has evaluated the feasibility of such choice and concluded that it would not allow him to substitute Cr(VI) faster than the pursuit of the Alternative 1 (Low Tin Steel). This would also entail a much higher level of uncertainty regarding the success and duration of implementing Alternative 1.

Based on the issues listed above the applicant states that the Alternative does not yet meet their technical requirements. Therefore, they cannot conclude whether this alternative is suitable for them at this stage.

The applicant compared both potential alternative and stated that their preferred alternative is Alternative 1.

Comments in the third-party consultation

Three comments were received in the consultation from APEAL (Association of European Producers of Steel for Packaging), MPE (Metal Packaging Europe) and ChemSec (International Chemical Secretariat). APEAL and MPE support the application and the requested review period, stating that at present there are no suitable alternatives to the ECCS process.
According to ChemSec, alternatives should be considered in terms of specific requirements for specific products, to take a broader perspective and rethink the need for each functionality. ChemSec is suggesting that each review period should not be longer than 4 years for chromium trioxide.

In their response the applicant reiterated that their requested review period corresponds to the time required for them to be able to replace the SVHC substance fully, whilst maintaining customers satisfaction and all safety aspects. They also added that the effort to find a suitable alternative for this use has been a joint one, with other companies across the sector, with many activities dedicated to finding the best solution.
They added that although they referred to the Marketplace website mentioned in the comment, they found it to be mainly dedicated to hard chrome plating applications, which have much different technical requirements than metallic packaging sector. Furthermore, according to the applicant's response, the introduction of a new alternative would require 4 years for adaptation of technology to a level of industrial capability, followed by a further 5 years of qualification by their value chain.
Additionally, the applicant reiterated in their response, that metal packaging used in food contact applications requires strict controls to ensure a high level of consumer safety. For the above reasons, the applicant stated that this would result in the need for an extended review period for the use of hexavalent chromium, far in excess of the current request.

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

SEAC agrees with the applicant's analysis of alternatives in terms of their technical and economic feasibility and finds it clear and well documented. Considering a detailed progress into the replacement of Cr(VI) shows a clear commitment from the applicant to replace the SVHC substance with an alternative.

Based on the applicant's analysis, Alternative 1 (LTS) will be able to fulfil the technical requirements within the requested review period, while Alternative 2 (Cr(III) based) is excluded from further testing.

Although the applicant confirms that the formulation used for LTS is generally available, not all production lines have been converted and consequently the LTS material is available at reduced tonnages. More time is needed to achieve the quantity and quality required by applicant to continue their manufacturing to the same level as today.
SEAC agrees that the applicant's operations would require further development and investment to support the current level of production.
SEAC accepts the applicant's justification for an additional year of review period for this use, considering the applicant's ongoing R&D activities, which require the following:

1. Completion of pack-testing (as detailed in section 4.1)
2. Resolution of challenges detailed in section 4.2
3. Acceptance of CFPA alternative by the can-makers, which cannot be made successfully by the end of 2027.
4. Additional time needed for line conversions and further market acceptance of LTS

SEAC accepts, that it is possible that some lacquers may require re-formulation or further development. This would mean that coating providers and can makers will be required to undertake expensive qualification rounds to ensure safety of the new lacquer in terms of food contact, but this is not yet known at this stage.

In summary, SEAC agrees with the analysis of alternatives conducted by the applicant. They have clearly shown their research activities and how the short list of alternatives was developed from the long list. SEAC notes that although LTS shows the most promise to replace Cr(VI), still some time is needed to fully develop it and to complete the substitution.

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 consistent with the analysis of alternatives and the socio-economic analysis?

☒Yes ☐No

Is the substitution plan credible for the review period requested?

☒Yes ☐No

The applicant is applying for two uses to replace the hexavalent chromium compounds, and although the two uses are separate from each other, the proposed alternative(s) are linked together, which is reflected in the substitution plan.

The substitution plan is a culmination of many years of R&D, discussions with customers and suppliers, testing and development. The applicant has been working for many years on the development of an alternative for ECCS with their supply chains, which are in the process of testing and qualifying the alternative.

In the development of an alternative for ECCS, the applicant pursued the development of the alternative that was deemed the most promising at the end of another research project (RFCS), in association with three other main European manufacturers of ECCS.
However, as the preferred alternative for ECCS is based on the formulation also used in CFPA, the development works on LTS and CFPA are run in parallel by the applicant, with information gained on CFPA feeding into the development of LTS. The development of CFPA has taken the priority, with ETP being a more important market, therefore implementation of LTS takes longer.
The applicant is in regular contact with its customers in order to gain feedback on preliminary pack-testing and identification of further research and developments activities.

In particular, the applicant with other interested parties took part in the research project IPSA (RFSR-CT-2008-00017). The screening tests have shown 13 different substances/adhesion system, which have been subsequently narrowed to the top 5 and then to final top 2 of potential alternatives. The most promising alternative has been forwarded to implementation.

The preferred alternative (LTS + CFPA) seems to fulfil the critical parameters required for substitution. Several key steps in its implementation are required, including finalisation of R&D as well as market acceptance following qualification pack-testing, which is a key step to ensure product and food safety.

In their substitution plan, the applicant listed the following milestones:

1. Completion of Research and Development (build-up of production experience by the tinplate manufacturers, can-makers and lacquer suppliers). **End of 2019**
2. Completion of preliminary testing of material for can-making and R&D work. **Beginning of 2020**
3. Feedback on preliminary pack testing from the can-makers and identification of further research and development activities. The applicant is in constant communication with their supply chain which means they are able to quickly receive information on any major issues. **End of 2020**
4. Reformulation of lacquers, if required. **Between end of 2020 and end of 2025**
5. Other issues related to CFPA material for can manufacture. **Between end of 2020 and end of 2025**
6. Qualification of the production material, ensuring that it maintains the high levels of safety required and that it is in compliance with relevant food contact regulations. **Between end of 2020 and end of 2025**
7. Re-engineer and adaptation of tinplate manufacturer lines planning. **Mid 2025**
8. Re-engineering works implementation and new line commissioning. **Beginning of 2026**
9. LTS production increase. **Mid 2026**
10. Complete replacement of ECCS with LTS. **End of 2027**
11. Development and testing of lines, qualification by can-makers (if required). **Until end of 2028**

As opposed to Use 1 (ETP) in the case of LTS, the R&D on the product and process programmes are done entirely internally. The testing programme is organised through collaborations with the applicant’s leading customers and progress on customer tests is measured monthly.

Dashboards following the progress of pack tests are updated accordingly.

Commercial deliveries of LTS are expected to start before the end of 2022. The applicant's conversions are staged progressively. Substitution will occur gradually until the end of 2028. Complete replacement with LTS is conditional on the successful completion of qualification pack-tests, market acceptance and global regulatory approvals, to ensure all markets currently accessible for material manufactured using the current ECCS products are accessible for LTS.

The applicant asked for a review period of approximately 6 years (until the end of 2028).
It is a year later than the one for ETP passivation (end of 2027), because further market acceptance and line conversion development may be required after the full implementation of the CFPA.
This review period requested by the applicant includes the finalisation of R&D work, conversion of production lines and allows for the time required by can-makers to complete their qualification protocols to ensure the continued high levels of consumer safety that are required of materials intended to be used in food contact applications.

SEAC's evaluation of the substitution plan/activities

SEAC's view is 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) with one of the shortlisted alternatives (LTS).

Several key steps in its implementation are required for substitution, i.e. finalisation of R&D, market acceptance, following qualification pack-testing. The production capacity needs to be adjusted to LTS based on customers' feedback. Customers' products have to be verified in pack-tests in order to check of fulfilling all technical and legislative requirements.

SEAC understands that due to these complex operations, a complete replacement with LTS is also conditional on the successful completion of the CFPA alternative (Use 1). In other words, both uses are closely linked and one use cannot succeed without the other use.

SEAC accepts that the review period includes the finalisation of R&D work and allows for the completion of qualification protocols and to ensure the continued high levels of consumer safety that are required of materials intended to be used in food contact.

The uncertainty is that not all customers can make it in the same time frame and during requested review period. If the requirements are not met, the formulation have to be changed, resulting in another series of tests and postponing the use of an alternative further.

In SEAC's view the applicant has presented a substitution plan which clearly demonstrates their willingness to substitute and detailed activities contained in the plan justify the review period they requested. The plan is also consistent with the information provided in the analysis of alternatives.

SEAC agrees with the applicant's assessment that the preferred alternative will become technically feasible within the requested review period.

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 indicating that there are alternatives available that are technically and economically feasible in the EU.
- The applicant submitted a substitution plan. The substitution plan is credible for the review period requested and consistent with the analysis of alternatives and the socio-economic analysis.

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 less than 250 tonnes of Cr(VI) equivalent per year (exact number claimed confidential but known to SEAC) for two uses, across two manufacturing sites, with Cr(VI) resulting from the use of chromium trioxide.

Chromium trioxide was included under Annex XIV due to its carcinogenic and mutagenic properties. 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 100-500 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 < 7 000 people from the local population are at risk of exposure across both sites (exact figure is confidential, but known to SEAC).

The applicant has estimated the additional statistical cancer cases associated with the use of chromium trioxide on the basis of the exposure levels, duration of the exposure, 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 applicant has incorrectly-applied the dose-response function when calculating the number of excess cancer cases resulting in an underestimation of both fatal and non-fatal cases for both cancers.

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 2021 prices using GDP deflators for the EU-27 to account for annual inflation (figures shown below).

Table 11: Willingness-to-Pay values for monetised health impacts

WTP Values	2012	2022
Value of Statistical Life (VSL)	€3 500 000	€3 920 000
Value of Cancer Morbidity (VCM)	€410 000	€460 000

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 mortality rates in each case for 2020 across both sites (France and Spain) as provided by the World Health Organisation's Cancer Today database (IARC, 2020)[7], which are 79.5 % and 83.7 % in France and Spain respectively for lung cancer, and 42.5 % and 44.9 % for colorectal (intestinal) cancer in France and Spain respectively.

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 2021 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 €16 808 and €14 415 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, 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 and regional population.

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

Table 12 below summarises the excess cancer cases and associated monetised costs, broken down by workers and general population. The applicant's total monetised excess cancer risk from continued use (comprising both lung and intestinal cancer) is estimated at €393 709 over the entire review period, with the annualised monetised risk valued at €65 595.

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.

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

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. Nonetheless, as mentioned above the applicant has underestimated the number of fatal and non-fatal cancer cases in their assessment since the dose-response function has not been applied correctly in the calculation of excess cancer cases, which in turn has led to an underestimated monetised excess cancer risk from continued use. Nonetheless, these figures have not been recalculated by SEAC since any updates to the values would not have a material impact on the conclusions derived from the socioeconomic analysis.

SEAC also 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 monetisation calculations, and has assumed a constant level of exposure to Cr(VI) 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 (LTS), thus constituting a conservative approach to the monetisation of health impacts.
SEAC therefore accepts the applicant's monetised health impacts, while noting the methodological issues[8] highlighted earlier which led to both an underestimation and overestimation of monetised health impacts, 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 also 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 12: Summary of additional statistical cancer cases

	Excess lifetime cancer risk	**Number of exposed people**	**Estimated statistical cancer cases (over the requested RP)**	**Value per statistical cancer case**	**Monetised excess risk (over the requested RP)**
Workers					
Directly exposed workers	2.3×10^{-5}-1.4×10^{-3}	100-500	1.45×10^{-2} (fatal + non-fatal lung cancer)	€4.41 million (fatal + non-fatal lung cancer)	€40 849 (fatal + non-fatal lung cancer)
Indirectly exposed workers	Included above				

[8] Neither of these methodological issues would materially impact the conclusions of the subsequent SEA.

Sub-total					€40 849
General population					
Local	2.05×10^{-16}-3.86×10^{-4} (inhalation) 1.81×10^{-10}-1.74×10^{-8} (oral)	< 7 000	1.24×10^{-1} (fatal + non-fatal lung cancer) 5.5×10^{-3} (fatal + non-fatal intestinal cancer)	€4.41 million (fatal + non-fatal lung cancer) €4.46 million (fatal + non-fatal intestinal cancer)	€343 301 (fatal + non-fatal lung cancer) €9 559 (fatal + non-fatal intestinal cancer)
Regional	Not relevant				
Sub-total					€352 860
Total			**1.44×10^{-1}**		**€393 709**
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 solution to the substitution of Cr(VI)-based ECCS that meets the requirements of can-makers within the EEA. To this end, LTS has been identified as the alternative of choice by the applicant, and which will be fully integrated into production once the relevant can tests have been completed. Nonetheless, as stated by the applicant the identification and development of the alternative has taken longer than expected, meaning that authorisation refusal would have a significant impact on the applicant as well as the EU steel industry in general and EU-based can-makers.

On this basis, the following non-use scenarios have been developed by the applicant.

Main non-use scenario

Under the most-likely non-use scenario, the applicant has assumed that they would lose the entirety of their passivated ECCS exports to non-EU competitors as from the end of 2024, since they are covered by a CTAC until September 2024. This loss in exports mainly stems from the fact that non-EU customers would not be willing to accept an alternative that may not satisfy their performance requirements, particularly since they are not subject to REACH. Furthermore, given the current state of testing for LTS, the applicant has assumed that less than 50 % (confidential, but known to SEAC) of current sales within the EU would be served by LTS from 2025, with the remaining proportion not expected to recover until the end of 2026 or 2027, particularly for more complex applications of ECCS or where new internal coatings are required. This would lead to the closure of some of the applicant's production lines for passivated ECCS, while can-makers in the EU would shift to non-EU imports or potentially move their operations outside the EU, based on feedback received from consultations carried out with EU can-makers. In addition, the applicant has mentioned that upstream suppliers of chromium trioxide, steel and other raw materials and services would be negatively impacted

by authorisation refusal under this NUS due to lower revenues.

Worst-case scenario

As part of the worst-case scenario, apart from the complete loss in passivated ECCS exports as described in the previous NUS, LTS as proposed by the applicant would not be accepted by over 65 % of can-makers (confidential, but known to SEAC) for current uses of ECCS, with a significant drop in sales revenues. Once again, the applicant would close down some of their production lines for ECCS, while can-makers would pivot towards imported ECCS from outside the EEA, with some producers opting to relocate to non-EEA locations in order to fulfil their demand. Similarly, upstream suppliers would also be impacted as described above, albeit to a greater extent for suppliers of steel, raw materials and services due to the higher drop in the applicant's turnover.

Overly-optimistic scenario

The applicant has also included a best-case scenario, whereby LTS is accepted by can-makers for less than 50 % of current use of passivated ECCS from 2025 (confidential, but known to SEAC), with this proportion gradually increasing year-on-year until almost-full recovery is achieved by the end of 2028. Under this NUS, no closures of ECCS production lines are foreseen, although they would remain inactive at a cost of < €300 000 per year (confidential, but known to SEAC) until full conversion to LTS. Can-makers would still likely shift to non-EU imports or potential relocation outside the EU in order to meet the remainder of their ECCS requirements, but will gradually revert back to the applicant over the requested review period. Once again, upstream suppliers of chromium trioxide would experience negative impacts on their sales, similar to those described under the most-likely NUS, while for other suppliers these would initially be identical, although these impacts would dissipate gradually as the applicant recovers their market share.

In response to SEAC's questions, the applicant has stated that given that this is essentially a bridging application, 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 agrees with the applicant's conclusion that under the most-likely non-use scenario, LTS is only accepted for immediate use (i.e. as from 2025) by can-makers for less than 50 % of current use of passivated ECCS, with the remaining uses only accepted towards the end of 2027 or 2028.

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 the applicant over the requested review period, with the Net Present Value (NPV) in 2022 calculated using a discount rate of 4 %. The applicant has quantified foregone profits, line conversion costs, losses accruable to suppliers of raw materials and other services, 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 ECCS production by < 50 % (exact range is confidential, but known to SEAC) under the most-likely NUS. An EBITDA of 12 % has been assumed annually, based on the industry-average EBITDA of 10.5-14 % recorded in 2017. The applicant has estimated the discounted value of profit losses accruing over the whole requested review period, with both a lower and upper bound value for profit losses provided, in line with the confidential range for the estimated losses in ECCS production under the most-likely NUS.

SEAC notes the applicant's approach to estimating foregone profits, while also noting that the decision to include their 7-years' worth of profit losses is in direct conflict with ECHA's guidance on assessing changes in producer surplus for SAGA cases[9]. Therefore, SEAC has recalculated the profit losses accruable to the applicant under the most-likely NUS, which are now valued at €16-30 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.

Line conversion costs

The applicant has also sought to quantify the costs related to converting some of its ECCS production lines in order to ramp-up production using the non-chromate alternative (LTS). The applicant has stated that under continued use, these costs would actually be higher than under the most-likely NUS, for confidential reasons, meaning that under authorisation refusal the applicant would get cost savings of €4-20 million (the exact figure is confidential, but known to SEAC).

SEAC notes the applicant's points regarding the conversion costs under both the most-likely NUS and continued use. SEAC questions the inclusion of these costs, particularly in light of the applicant's own admission regarding the uncertainty surrounding the actual conversion process and related costs. Nonetheless, SEAC has accepted this value and has included it in the analysis, since it represents a more conservative approach to estimating the costs of authorisation refusal.

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 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 to reflect the range of potential losses in ECCS sales following authorisation refusal under the most-likely NUS, as described earlier.

Profit losses for its suppliers have been estimated by the applicant over the same 7-year period as that used initially for its own profit losses. 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 €4-8 million NPV (the exact range is confidential, but known to SEAC). These values have been carried forward in the analysis.

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

Impacts on can-makers

The applicant has included predicted 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 500 kt per year of passivated ECCS on average from outside the EU over the requested review period. This is consistent with the need to replace the < 50 % of passivated ECCS sourced from within the EU and which would be lost since this proportion could not be served using the non-chromate alternative (LTS). 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 LTS. Therefore, the applicant has assumed that the additional imports of ECCS 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 higher 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 ECCS (confidential), over the requested review period. 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 higher costs to can-makers valued at €4-20 million NPV (the exact range 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 ECCS. Under the most-likely NUS, the applicant has assumed that internal demand for HRC will drop by < 80 % (the exact range is confidential, but known to SEAC). Overall, the profit losses accruable to the applicant due to lost internal HRC demand are estimated at less than €20 million per year over the 7-year period. 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 < 2 000 jobs would be lost if no authorisation is granted under the most likely non-use scenarios (the exact value is confidential, but known to SEAC). This includes both workers directly employed by the applicant as well as those employed by external service providers that carry out various tasks like cleaning and driving.

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)[10]. The approach

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

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 industrial workers at 2021 prices across the applicant's two production sites via Eurostat, with these salaries weighted by the number of direct employees in each country, resulting in an average weighted annual salary of €40 773. Based on this approach, the applicant has estimated total job losses valued at €20-60 million (the exact range 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 industrial workers across both countries. 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 ECCS from Asia over the period September 2024 to end of 2028, 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 8.4 g CO_2 per tonne-km (Cefic, 2018)[11], and a value of €50 per tonne as the economic cost per tonne of CO_2 emissions (Defra, 2007)[12]. The applicant has estimated the monetised environmental cost from increased CO_2 emissions at €0.5-2 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[13]. 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 €1.5 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

[11] 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

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

[13] 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

from authorisation refusal under the most-likely NUS, mainly in relation to the European steel manufacturing sector. As mentioned earlier, the partial ceasing of ECCS 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 ECCS 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 agrees with the non-use scenario and has included monetised impacts of foregone profits accruing to both the applicant and suppliers of raw materials, line conversion costs, 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 until 2028. Therefore, SEAC has recalculated all annualised values on this basis. SEAC's assessment, based on the applicant's information, is set out below, with results provided in NPVs in congruence with the applicant's approach.

Table 113: Societal costs of non-use

Description of major impacts	Monetised/quantitatively assessed/qualitatively assessed impacts
1. Monetised impacts	**€ over requested RP and per year**
Producer surplus loss due to ceasing the use applied for	€16-30 million Annualised: €2-8 million
Line conversion costs (savings)	-€4-20 million Annualised: -€0.7-3.3 million
Foregone profits for upstream suppliers of raw materials and services	€4-8 million Annualised: €0.7-1.3 million
Higher costs for European can-makers	€4-20 million Annualised: €0.7-3.3 million
Social cost of unemployment	€20-60 million Annualised: €3.3-10 million
Environmental damages from higher CO_2 emissions due to transportation	€0.5-2 million Annualised: €0.1-0.3 million
Sum of monetised impacts	**€40.5-100 million** **Annualised: €6.8-16.7 million**
2. Additional quantitatively assessed impacts	**€ over requested RP and per year**

Impact on internal demand for HRC	< €80 million Annualised: < €13.3 million
Indirect job losses	< €1.5 billion Annualised: < €250 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 and differ in terms of the period of assessment, 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 €40.5-100 million over the requested review period, annualised at €6.8-16.7 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 requested review period (until 2028) as well as in annualised terms. Based on the analysis conducted below, the estimated net societal benefits from continued use range between €40.5-100 million over the review period, with the benefits-to-costs ratio ranging between 103:1 and 254:1. 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 12: Societal costs of non-use and risks of continued use

Societal costs of non-use		**Risks of continued use**	
Monetised impacts (€ over the requested RP) (per year)	€40.5-100 million NPV Annualised: €6.8-16.7 million	Monetised excess risks to directly and indirectly exposed workers (€ over the requested RP) (per year)	€40 849 NPV Annualised: €6 806
Additional quantitatively assessed impacts (€ over the requested RP)		Monetised excess risks to the general population (€ over the requested RP) (per year)	€352 860 NPV Annualised: €58 789

(per year)			
Additional qualitatively assessed impacts (€ over the requested RP) (per year)		Additional qualitatively assessed risks (€ over the requested RP) (per year)	
Summary of societal costs of non-use	**€40.5-100 million NPV** **Annualised: €6.8-16.7 million**	**Summary of risks of continued use**	**€393 709 NPV** **Annualised: €65 595**

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 2028)

☐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 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).
- The applicant submitted a substitution plan. The substitution plan is consistent with the analysis of alternatives and the socio-economic analysis. The substitution plan is credible for the review period requested.
- 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 benefits of continued use for Use 2 are higher than the risks by a considerable degree (103-254 times).

Taking into account all of the above points, a review period until the end of 2028 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. In the event that T8 (Dissolution of solid CT) is undertaken in Basse-Indre, during the review period, the applicant shall implement appropriate OC/RMMs to reduce workplace exposure to Cr(VI) in addition to those proposed in the CSR. As a minimum, the following RMMs shall be implemented:
   - Install a local exhaust ventilation system or an air extraction system to reduce dust generation.
   - Restrict access to the area where the dissolution will take place.
   - Ensure operators that carry out the activity are trained in how to minimise exposure.
   - Monitor exposure of the operators by air monitoring and biomonitoring.

   The potential for exposure shall be brought to as low a level as technically and practically feasible prior to commencement of the activity.
2. The applicant shall carry out and document a detailed feasibility study on:
   a. the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE, in both sites.
   b. the substitution of solid CrO_3 flakes by liquid solutions of CrO_3, or if not feasible, measures that minimise dust generation during charging, to further limit exposure in Etxebarri.

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.

3. The applicant shall conduct a root cause analysis for the elevated release factor to air at Basse-Indre within three months of the granting of an authorisation for this use. Following this analysis, the applicant shall implement immediately appropriate actions to improve the efficiency of the applied OCs and RMMs at the site for air release control, implementing additional RMMs if required.

   Control measurements shall be conducted to confirm the impact of any action. The "control measurement – analysis – action" cycle shall be continued to reduce these releases to as low a level as technically and practically feasible.

7.2. Justification

RAC

RAC is of the opinion that the operational conditions and risk management measures are generally appropriate and effective in limiting the risk, provided that they are adhered to.

For T8, which is currently presented as a theoretical task, the applicant has indicated that additional RMMs should be implemented, should this task become active during the review period. These RMMs are necessary to ensure that exposure of workers is minimised, as the exposure estimation provided in the application based on theoretical considerations show elevated exposure.

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

RAC observes that the air emissions from Basse-Indre are higher than expected compared with the other site, and considers that measures should be applied for risk reduction.

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 and/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 small amount of measured exposure data in Etxebarri;
- limited contextual information at both sites;
- lack of monitoring data on background levels in the production halls and control rooms;
- the elevated air emissions at Basse-Indre despite the installed RMM.

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 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