Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Use of Chromium Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP)

Submitting applicant

Tata Steel IJmuiden BV

ECHA/RAC/SEAC: AFA-O-0000006906-64-01/F

Consolidated version

Date: 28/12/2020

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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to the following application for authorisation:

Applicants	**Tata Steel IJmuiden BV** (position in supply chain: downstream) **Tata Steel UK Ltd.** (position in supply chain: downstream)
Substance ID EC No CAS No **Substance ID** EC No CAS No	**Chromium trioxide** 215-607-8 1333-82-0 **Sodium dichromate** 234-190-3; 10588-01-9; 7789-12-0
Intrinsic properties referred to in Annex XIV	☒Carcinogenic (Article 57(a)) ☒Mutagenic (Article 57(b)) ☒Toxic to reproduction (Article 57(c)) ☐Persistent, bioaccumulative and toxic (Article 57(d)) ☐Very persistent and very bioaccumulative (Article 57(e)) ☐Other properties in accordance with Article 57(f) -
Use title	**Use of Chromium Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP)**
	Other connected uses: Use of sodium dichromate for the electrolytic passivation of tin-plated steel for the packaging industry. Authorisation Number: REACH/20/5/8 (Authorisation holder: AD International BV, Markweg Zuid 27 4794 SN Heijningen Noord-Brabant Netherlands).
	Same uses applied for: -

Use performed by	☒ Applicants ☐ Downstream User(s) of the applicants
Use ID (ECHA website)	0211-01 0211-02
Reference number	11-2120842586-46-0001 11-2120842586-46-0002 11-2120842586-46-0003 11-2120842586-46-0004
RAC Rapporteur	KAPELARI Sonja
SEAC Rapporteur SEAC Co-rapporteur	ALEXANDRE João CAVALIERI Luisa
ECHA Secretariat	MAZZEGA SBOVATA Silvia (until 31 July 2020) SIHVONEN Kirsi (from 1 August 2020) NURMI Väinö Ilmari LIOPA Elīna

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	03/12/2019
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	29/04/2020
Application has been submitted by the Latest Application Date for the substance and applicants can benefit from the transitional arrangements described in Article 58(1)(c)(ii).	☐Yes ☒No
Consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	13/05/2020 - 08/07/2020
Comments received	☒Yes ☐No Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/25633/del/200/col/synonymDynamicField_302/type/asc/pre/2/view https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/25634/del/200/col/synonymDynamicField_302/type/asc/pre/2/view
Request for additional information in accordance with Article 64(3)	On 15/06/2020, 20/07/2020, 22/07/2020 and 05/11/2020 Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/25633/del/200/col/synonymDynamicField_302/type/asc/pre/2/view https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/25634/del/200/col/synonymDynamicField_302/type/asc/pre/2/view
Trialogue meeting	Not held – no new information submitted in consultation.

Extension of the time limit set in Article 64(1) for the sending of the draft opinions to the applicants	☐Yes ☒No
The application included all the necessary information specified in Article 62 that is relevant to the Committees' remit.	☒Yes ☐No Comment:
Date of agreement of the draft opinion in accordance with Article 64(4)(a) and (b)	RAC: 10/12/2020, agreed by consensus.
	SEAC: 10/12/2020, agreed by consensus.
Date of sending of the draft opinion to applicants	16/12/2020
Date of decision of the applicants not to comment on the draft opinion, in accordance with Article 64(5)	28/12/2020
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: 28/12/2020, adopted by consensus.
	SEAC: 28/12/2020, adopted by consensus.
Minority positions	RAC: ☒N/A
	SEAC: ☒N/A

THE OPINION OF RAC

RAC has formulated its opinion on:

- the risks arising from the use applied for,
- the appropriateness and effectiveness of the risk management measures described,
- as well as
- other available information.

RAC concluded that it was not possible to determine DNELs for the carcinogenic properties of the substances in accordance with Annex I of the REACH Regulation.

SEAC concluded that currently there are no technically and economically feasible alternatives available for the applicants with the same function and similar level of performance. 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 monitoring arrangements for the authorisation are expected to provide information on the trends in exposure over the authorisation period. The information should also be included in the review report.

The exposure to workers was estimated to be at maximum:

- inhalation (µg Cr(VI)/m^3): 0.220 (Trostre and IJmuiden) (highest exposure estimate)
- dermal (µg Cr(VI)/kg bw/d): 25.4 (Trostre), 28.0 (IJmuiden) (highest exposure estimates).

For reference, as of January 2020, the binding occupational exposure limit (BOEL) for inhalation for Cr(VI) is 10 µg Cr(VI)/m^3 (transitional value of until 17 January 2025, after which 5 µg Cr(VI)/m^3 applies).

The exposure to the general population was estimated to be:

- inhalation, local (µg Cr(VI)/m^3): 8.12×10^{-4} (Trostre), 6.61×10^{-3} (IJmuiden)
- oral: local (µg Cr(VI)/kg bw/d): 3.66×10^{-5} (Trostre), 2.73×10^{-4} (IJmuiden).

The excess lifetime cancer risk for workers (40 years of exposure):

- directly exposed is estimated to be at maximum:
  - inhalation: 8.8×10^{-4} (Trostre and IJmuiden)
  - RCR dermal (reproductive toxicity): 0.59 (Trostre), 0.65 (IJmuiden),
- indirectly exposed is estimated to be at maximum:
  - inhalation: 3.25×10^{-6} (Trostre), 2.92×10^{-5} (IJmuiden)
  - oral: 7.31×10^{-9} (Trostre), 5.45×10^{-8} (IJmuiden).

The excess lifetime cancer risk for the general population (70 years of exposure) is calculated to be:

- inhalation: 2.35×10^{-5} (Trostre), 1.92×10^{-4} (IJmuiden),
- oral: 2.92×10^{-8} (Trostre), 2.18×10^{-7} (IJmuiden)
- combined: 2.36×10^{-5} (Trostre), 1.93×10^{-4} (IJmuiden).

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 substances as documented in the application, taking into account the information submitted by interested third parties, as well as
- other available information.

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

The following alternatives have been assessed: Chromium-Free Passivation Alternative (See Section 4 of the Justifications).

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

- By the time of adoption of this opinion, there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicants.
- The substitution plan was credible and consistent with the analysis of alternatives and the socio-economic analysis.

SEAC concluded on the socio-economic analysis that:

- The expected socio-economic benefits of continued use are up to €23 million per year and additional benefits to society have been assessed qualitatively but have not been monetized.
- Considering:
    - the endpoint relevant for listing the substance in Annex XIV of REACH;
    - the less than 400 directly exposed workers, less than 4 000 indirectly exposed workers;
    - the general population exposed at local scale up to 1 000 persons
    - the risk of continued use as assessed by RAC may result in less than 3.35×10^{-2} additional cases of cancer per year
    - the monetised risk of continued use is up to €14 550 per year.
- Risks to human health of shortlisted alternatives have not been quantified. There may therefore be a risk arising due to the use of an alternative should the authorisation not be granted.

SEAC has no substantial reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the monetised risks to human health associated with the continued use of the substance.

SEAC considered that if an authorisation was refused, the use of the substance could:

- be taken up by market actors using the same substance (having an authorisation) operating inside the EU
- be taken up by market actors operating outside the EU

SEAC considered that, if an authorisation was refused, it was likely that in the European

Union:[1]

- less than 750 jobs would be lost

PROPOSED CONDITIONS AND MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

No conditions for the authorisation for the authorisation are proposed.

Additional monitoring arrangements for the authorisation are proposed. These are listed in section 8 of the justification to this opinion.

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

REVIEW PERIOD

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

[1] Wherever reference is made to the European Union, this shall apply also to EEA countries.

SUMMARY OF THE USE APPLIED FOR

Role of the applicants in the supply chain	Upstream ☐ [group of] manufacturer[s] ☐ [group of] importer[s] ☐ [group of] only representative[s] ☐ [group of] formulator[s] Downstream ☒ group of downstream users
Number and location of sites covered	Two sites, in Trostre (UK) and IJmuiden (NL).
Annual tonnage of Annex XIV substance used per site (or total for all sites)	29.3 tonnes of sodium dichromate and chromium trioxide/year, expressed as Cr(VI)[2]. At the Trostre site, 5-15 tonnes of Cr(VI) and at the IJmuiden site (the tonnage provided covers already the potential future increase in IJmuiden's production capacity), 10-40 tonnes of Cr(VI) are used.
Function(s) of the Annex XIV substance.	The primary function of Cr(VI) in the production of ETP as packaging material is to form a stable oxide layer on the product and as such to ensure corrosion resistance and food safety.
Type of products (e.g. articles or mixtures) made with Annex XIV substance and their market sectors	Tin-plated sheets are primarily used among customers in the food packaging and processing sectors. Major focus for the use of tin-plate is food contact materials and non-food contact materials.
Shortlisted alternatives discussed in the application	Alternative substances considered: Cr(III); Zirconium oxides / Zr-Ti /organic Zirconates Alternative technologies considered: CFPA (Chromium-Free Passivation Alternative)
Annex XIV substance present in concentrations above 0.1 % in the products (e.g. articles) made	☐Yes ☒No ☐Unclear ☐Not relevant
Number of workers exposed per site (or total for all sites)	Directly: < 400 (< 300 in IJmuiden and < 100 in Trostre) Indirectly: < 4 000 (< 2 000 IJmuiden; < 2 000

[2] Based on the molecular weights of chromium trioxide (99.99 g/mol), sodium dichromate (261.97 g/mL for the anhydride) and chromium (51.9961 g/mol) a factor of 0.52 and 0.40 was used to calculate the amount of Cr(VI) resulting from the amount of chromium trioxide or sodium dichromate used, respectively.

	Trostre)
Number of humans exposed via the environment	Local scale: 1 000 (0 IJmuiden; 1 000 Trostre) Regional scale: 14.99 million (10 million IJmuiden; 4.99 million Trostre)
Releases to the environmental compartments	☒Air ☒Water
The applicants have used the Dose response relationship recommended by RAC	☒Yes – Application for Authorisation: Establishing a Reference Dose Response Relationship for Carcinogenicity of Hexavalent Chromium. Helsinki, 4 December 2013. RAC/27/2013/06 Rev.1[3] ☐No – [alternative values used] ☐Not relevant
All endpoints listed in Annex XIV were addressed in the assessment	☒Yes ☐No if 'No' – which endpoints are not addressed
All relevant routes of exposure were considered	☒Yes
Adequate control demonstrated by applicants for the relevant endpoints	☐Yes ☐No ☒Not Applicable – non-threshold substances
Level of (combined, daily / shift-long) exposure/release used by applicants for risk characterisation	Workers: - inhalation (µg Cr(VI)/m^3): max. 0.220 (Trostre and IJmuiden) - dermal (µg Cr(VI)/kg bw/d): 25.4 (Trostre), 28.0 (IJmuiden) Humans via environment: - inhalation, local (µg (Cr(VI)/m^3): 8.12×10^{-4} (Trostre), 6.61×10^{-3} (IJmuiden) - oral: local (µg Cr(VI)/kg bw/d): 3.66×10^{-5} (Trostre), 2.73×10^{-4} (IJmuiden)
Risk Characterisation	Directly exposed workers (at maximum), excess life risk (40 years): - inhalation: 8.8×10^{-4} (Trostre and IJmuiden) - RCR dermal (reproductive toxicity): 0.59 (Trostre), 0.65 (IJmuiden)

[3] http://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf

	Indirectly exposed workers (at maximum), excess life risk (40 years): - Inhalation: 3.25×10^{-6} (Trostre), 2.92×10^{-5} (IJmuiden) - oral 7.31×10^{-9} (Trostre), 5.45×10^{-8} (IJmuiden) Humans via environment, excess life risk (70 years): - inhalation: 2.35×10^{-5} (Trostre), 1.92×10^{-4} (IJmuiden) - oral: 2.92×10^{-8} (Trostre), 2.18×10^{-7} (IJmuiden) - combined: 2.36×10^{-5} (Trostre), 1.93×10^{-4} (IJmuiden)
Applicants are seeking authorisation for the period of time needed to finalise substitution ('*bridging application*')	☒Yes ☐No ☐Unclear
Review period argued for by the applicants (length)	Until the end of 2027.
Most likely Non-Use scenario	ETP passivated with CFPA will be accepted by the can-makers for 35-55 % of the current use of passivated ETP (passivated ETP currently accounts for 65-90 % of total ETP) from 2021 onwards. For the remaining share of the use, can-makers start partially accepting CFPA at 2023. For more problematic applications or where new internal coating are needed, can-makers accept CFPA only at the end of 2026.
Applicants conclude that benefits of continued use outweigh the risks of continued use	☒Yes ☐No ☐Not Applicable – threshold substance with adequate control
Applicants' benefits of continued use	For the review period argued: less than €50 million euros
Society's benefits of continued use	For the review period argued: less than €274 million euros
Monetised health impact on workers	For the review period argued: Trostre: €4 965 IJmuiden: €49 589 Both sites: €54 554
Distributional impacts if authorisation is not granted	NA

Job loss impacts if authorisation is not granted	Less than 750 direct job losses

SUMMARY OF RAC AND SEAC CONCLUSIONS[4]

1. Operational Conditions and Risk Management Measures

1.1. Conclusions of RAC

Conclusion for workers

RAC concludes that the RMMs and OCs presented by the applicants are appropriate and effective in limiting the risks for workers, provided that they are adhered to.

RAC notes that WCS 8 “Dissolution of solid Chromium Trioxide (CT)/Sodium Dichromate (SD)” will be implemented if there is a lack of liquid CT/SD, therefore, there are some minor uncertainties related to this task which will be addressed via monitoring arrangements.

Are the OCs/RMMs in the Exposure Scenario appropriate and effective in limiting the risk?

☒Yes ☐No

Conclusion for Humans via environment (HvE)

RAC concludes that the RMMs and OCs presented by the applicants are appropriate and effective in limiting the risks for workers, provided that they are adhered to.

Are the OCs/RMMs in the Exposure Scenario appropriate and effective in limiting the risk?

☒Yes ☐No

Does RAC propose additional conditions related to the operational conditions and risk management measures for the authorisation?

☐Yes ☒No

Does RAC propose monitoring arrangements related to the operational conditions and risk management measures for the authorisation?

☒Yes ☐No

Does RAC make recommendations related to the operational conditions and risk

[4] The numbering of the sections below corresponds to the numbers of the relevant sections in the Justifications.

management measures for the review report?

☒Yes ☐No

2. Exposure Assessment

Exposure level used by RAC for risk characterisation:

Workers: highest level of individual, shift-long exposure[5]

Inhalation: Trostre: 0.220 µg Cr(VI)/m^3 (at max. for Trostre and IJmuiden)
Dermal: Trostre: 25.4 µg Cr(VI)/kg bw/d and IJmuiden: 28.0 µg Cr(VI)/kg bw/d

Humans via environment (local)

Inhalation: Trostre: 8.12 × 10^{-4} µg Cr(VI)/m^3 and IJmuiden: 6.61 × 10^{-3} µg Cr(VI)/m^3
Oral: Trostre: 3.66 × 10^{-5} µg Cr(VI)/kg bw/d and IJmuiden: 2.73 × 10^{-4} µg Cr(VI)/kg bw/d

Releases to the environmental compartments

Air:
Trostre: 1.01 kg Cr(VI)/year (mean: 2016-2018) and IJmuiden: 6.68 kg Cr(VI)/year (2018)
Water:
Trostre: 0.72 kg Cr(VI)/year (mean: 2016-2018) and IJmuiden: 0.91 kg Cr(VI)/year (2018/2019)
Soil:
Both sites: 0

Conclusions of RAC

RAC notes that the applicants´ CSR provides generic information on the tasks undertaken and the associated OCs and RMMs for the both sites at Trostre and IJmuiden. However, more detailed information was provided on RAC´s request for further information. Therefore, RAC considers that the description of the use provided in the CSR and in the applicant´s answers to RAC´s request is sufficient to conclude on the reliability of the exposure assessment for workers and humans via the environment.

The exposure assessment for workers is principally based on modelled data but the applicants took some effort to underpin these data with monitoring data from their sites and with pooled data from the APEAL consortium and the German MEGA database.

However, RAC is of the opinion that baseline exposure estimates should primarily be based on measured data from the respective site (linked to the tasks performed on the WCSs – if possible) to ensure their representativeness. According to information provided on RAC´s request, the applicants are aware of this shortcoming. They stated that the monitoring programmes at the IJmuiden site will be expanded and that at the Trostre site monitoring programmes had already been initiated for the manufacturing of ETP.

The exposure assessment of humans via the environment (including indirectly exposed workers) can be considered as a worst case estimate since measurements on total chromium at the two sites were used for the estimate of emissions and since these measurements results as well as the results for Cr(VI) concentration in waste water are below the respective

[5] For details on exposure levels see section 2 of the Justifications.

LoD (limit of detection). However, as already pointed out to the applicants, measurements of Cr(VI) emissions to air should be performed to strengthen the emission estimate.

Shortcomings are mainly related to the small number of measured data (for workers and humans via the environment) provided from each site. This leads to monitoring arrangements for the authorisation which are presented in section 8.

Does RAC propose additional conditions[6] related to exposure assessment for the authorisation?

☐Yes ☒No

Does RAC propose monitoring arrangements[7] related to exposure assessment for the authorisation?

☒Yes ☐No

Does RAC make recommendations related to exposure assessment for the review report?

☒Yes ☐No

3. Risk Characterisation

Risk level used for health impact assessment calculated by RAC:

Workers:

Directly exposed workers (at maximum) over 40 years:

- inhalation: 8.8×10^{-4} (Trostre and IJmuiden)
- RCR dermal (reproductive toxicity): 0.59 (Trostre), 0.65 (IJmuiden)

Indirectly exposed workers (at maximum) over 40 years:

- inhalation: 3.25×10^{-6} (Trostre), 2.92×10^{-5} (IJmuiden)
- oral: 7.31×10^{-9} (Trostre), 5.45×10^{-8} (IJmuiden)

Humans via environment (over 70 years):

- inhalation: 2.35×10^{-5} (Trostre), 1.92×10^{-4} (IJmuiden)
- oral: 2.92×10^{-8} (Trostre), 2.18×10^{-7} (IJmuiden)
- combined: 2.36×10^{-5} (Trostre), 1.93×10^{-4} (IJmuiden)

Conclusions of RAC

The current exposure of workers and the exposure of man via the environment reported in this application are below the DNELs for reproductive toxicity (RAC/35/2015/09, discussed at RAC-35) for all relevant exposure routes, therefore the risk of reproductive effects is considered to be adequately controlled. Such exposures still may cause a risk of lung or intestinal cancer. Taking that into account, the assessment of carcinogenic risk is central to the risk-benefits analyses for authorisation purposes, given that for the estimated exposure

[6] Conditions can be proposed where RCR is > 1, OCs and RMMs are not appropriate and effective, risk is not adequately controlled, minimisation of emissions is not demonstrated.
[7] Monitoring arrangements can be recommended where RCR is < 1, OCs and RMMs are appropriate and effective, risk is adequately controlled, minimisation of emissions is demonstrated – but minor concerns were identified.

levels the reproductive toxicity would not contribute to the total ill-health risk.

The characterisation of cancer risk might be an overestimate since workers not engaged in any specific tasks related to Cr(VI) exposure are included in the highest risk. RAC is of the opinion that for the other types of workers, the risk should be based on the respective exposure estimate. However, this shortcoming will be addressed with monitoring arrangements for the authorisation since more measurements would clarify the exposure for this type of workers.

Summing up, the tendency to overestimate the risk does not impede the risk characterisation.

RAC considers that the estimates of excess cancer risk for workers and for indirect exposure of humans via the environment (including indirectly exposed workers) calculated by the applicants allow for a health impact assessment.

4. Analysis of alternatives and substitution plan[8]

What is the amount of substance that the applicants use per year for the use applied for?

29.3 tonnes of Cr(VI)

Are there alternatives with the same function and similar level of performance that are technically and economically feasible to the applicants before the adoption of this opinion?

☐Yes ☒No

Have the applicants submitted a substitution plan?

☒Yes ☐No

If yes, is the substitution plan credible and consistent with the analysis of alternatives and the socio-economic analysis?

☒Yes ☐No

Conclusions of SEAC

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

[8] The judgment of the ECJ Case T-837/16 Sweden v Commission stated that the applicant has to submit a substitution plan if alternatives are available in general. The Commission is currently preparing the criteria, derived from the judgment for establishing when an alternative is available in general. Once these are prepared this opinion format will be amended accordingly. The European Commission informed the REACH Committee in 9-10 July 2019 of its preliminary views on the criteria. In that note the Commission considered that the criteria defining a 'suitable alternative' would imply that it was i) *safer* and ii) *suitable*. Suitability would not mean it to be *"in abstracto"* or "*in laboratory or exceptional conditions*" but it should be "*technically and economically feasible in the EU*" and "*available, from the point of view of production capacities of the substance or feasibility of the technology, and legal and factual conditions for placing on the market*".

- By the time of adoption of this opinion there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicants.
- The substitution plan was credible and consistent with the analysis of alternatives and socio-economic analysis.

Does SEAC propose any additional conditions related to the assessment of alternatives for the authorisation?

☐Yes ☒No

Does SEAC make any recommendations to the applicants related to the content of the potential review report?

☐Yes ☒No

5. Benefits and risks of continued use

Have the applicants adequately assessed the benefits and the monetised risks of continued use?

Conclusions of SEAC:

☒Yes ☐No

SEAC has no reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the monetised risks to human health associated with the continued use of the substance. This conclusion is made on the basis of:

- The application for authorisation,
- SEAC's assessment of the benefits of continued use,
- SEAC's assessment of the comments received in the public consultation,

Any additional information provided by the applicants or its downstream users.

6. Proposed review period for the use

☐ 4 years

☐ 7 years

☐ 12 years

☒ Other – Until the end of 2027.

7. Proposed additional conditions for the authorisation

RAC

Additional conditions:

For workers	☐Yes	☒No
For Humans via Environment	☐Yes	☒No
For consumers	☐Yes	☐No
For the environment	☐Yes	☐No

SEAC

Additional conditions: ☐Yes ☒No

8. Proposed monitoring arrangements for the authorisation

RAC

Monitoring arrangements:

For workers ☒Yes ☐No

For Humans via Environment ☒Yes ☐No

SEAC

Monitoring arrangements ☐Yes ☒No

9. Recommendations for the review report

RAC

For workers ☒Yes ☐No

For humans via environment ☒Yes ☐No

SEAC

AoA ☐Yes ☒No

SP ☐Yes ☒No

SEA ☐Yes ☒No

10. Applicants comments on the draft opinion

Have the applicants commented the draft opinion?

☐Yes ☒No

Has action been taken resulting from the analysis of the applicants' comments?

☐Yes ☒No

JUSTIFICATIONS

0. Short description of use

The use applied for covers the continued use of chromium trioxide (CT – CrO_3) and sodium dichromate (SD – $Na_2Cr_2O_7 \times 2H_2O$) for the passivation of tinplated steel (ETP), used for the production of tin cans for food and metal packaging in general. The ETP process is performed in a comparable manner across two sites in IJmuiden (NL) and Trostre (UK).

Both substances are used by the applicants as Cr(VI) sources in highly automated and partially contained installations for the passivation of tinplated steel (ETP). In the IJmuiden plant, the chromium trioxide is also used by the applicants for pH control of the electrolytic bath to reduce the formation of black dust, but in Trostre site only sodium dichromate is used.

Passivation is one stage of a continuous electrolytic production process in which low carbon steel rolls, hot rolled coil (HRC), are unwound and passed through several consecutive different surface treatment baths (cleaning and pickling, tinning, passivation).

There are four production lines at which passivation takes place at the IJmuiden plant, and one in the Trostre plant. The process is identical for all five lines, the set-up, however, may differ slightly among the lines due to practical reasons specific for each line.

The amounts of CT and SD are expressed as Cr(VI) equivalents.

According to the applicants, the passivated tinplate steel produced in both sites is found to be Cr(VI) free.

The applicants have applied for authorisation for the ETP process using chromium trioxide and sodium dichromate as part of the CTAC and CCST submission consortia under the application numbers 0032-06 and 0043-03 respectively. The use of sodium dichromate for electrolytic passivation of tinplated steel for the packaging industry has been granted by the Commission for AD International BV (No. REACH/20/5/8) (part of the CCST consortia). The relevant Commission decision is C(2020)2084.

0.1. Description of the process in which Annex XIV substances are used

Table 1: Contributing Scenarios presented in the Use, Trostre and IJmuiden site

Contributing# scenario	ERC / PROC	Name of the contributing scenario	Size of the exposed population##
ECS1	ERC 5	Industrial use resulting in inclusion into or onto a matrix	Regional – not relevant Local – Trostre: < 2 000 workers 1 000 residents Local – IJmuiden: < 2 000 workers No residents
WCS 1	PROC 8b	Changing IBC containers	No of operators: at Trostre: ≤ 10 at JJmuiden: ≤ 60
WCS 2	PROC 9	Sampling of passivation tank	No of operators: at Trostre: ≤ 10 at JJmuiden: ≤ 60
WCS 3	PROC 9	Sampling of wastewater	No of operators: at Trostre: ≤ 5 at JJmuiden: ≤ 20
WCS 4	PROC 28	Maintenance	No of operators: at Trostre: ≤ 60 at JJmuiden: ≤ 190
WCS 5	PROC 28	Cleaning	No of operators: at Trostre: ≤ 10 at JJmuiden: ≤ 80
WCS 6	PROC 28	Filter press/sludge removal	No of operators: at Trostre: ≤ 10 at JJmuiden: ≤ 5
WCS 8*	PROC 5	Dissolution of solid CT/SD – theoretical scenario, not yet in place	No of operators: at Trostre: 4 at IJmuiden: 20
WCS 9	PROC 4	Activities close to the ETP line without handling of Cr(VI) containing solution (e.g. sanding or changing of rolls)	No of operators: at Trostre: ≤ 60 at JJmuiden: ≤ 300
WCS 10	No PROC assigned	Control-room activities	No of operators: at Trostre: ≤ 60 at JJmuiden: ≤ 300

* Theoretical scenario – not yet in place but will be in place in case there is no supply of the liquid form of CT and/or SD (see further explanation below and in Table no 2, footnote no 10).

There is no information on WCS 7 (“Addition of solid CT”) since this WCS is not relevant neither for the Trostre nor for the IJmuiden site. At both sites only liquid solution of CT/SD is used.

Exact numbers of the workers per task are claimed confidential by the applicants but known to RAC. The total number of workers directly exposed is: < 300 in IJmuiden and < 100 in Trostre.

According to the applicants, the Exposure Scenarios (which are the same for both sites) include all relevant processes and tasks associated with the use of CT and SD that could result in either exposure to workers or to humans via the environment.

Cr(VI) is used in a highly automated and partially contained installation. Passivation is one stage of a continuous process in which steel rolls are unwound and passed through several consecutive different surface treatment baths (pre-treatment, tinning, passivation). During the passivation of tin-plated steel in a cathodic process multi-layered steel is produced in the presence of Cr(VI) salts by covering the tin-plated steel with an inert layer of metallic chromium and chromium(III) oxide. The raw material for the production of tin plate consists of rolled coils of low carbon steel supplied by other Tata Steel group companies.

Operators are involved in connecting IBC containers (containing liquid CT and/or SD concentrate) to the process installation (WCS 1), sampling of Cr(VI) passivation tank (WCS 2) or waste water (WCS 3) via dedicated sampling systems, maintenance (WCS 4) and cleaning (WCS 5) activities, filter press/sludge removal (WCS 6) from passivation tanks, activities close to the ETP line without handling of Cr(VI) containing solutions (WCS 9), and control-room activities (WCS 10).

WCS 8 (Dissolution of solid CT and/or SD) is not yet in place but in case the liquid form of CT/SD will not be available, the applicants will use the solid form of these substances. That means that WCS 8 is included in the AfA for both sites.

Although the ETP process is performed in a comparable manner at the two sites in Trostre and IJmuiden, there are some differences, particularly with regard to the storage of the IBC containers (dedicated locations inside or outside the production hall, filling of Cr(VI) solutions in a storage tank or the passivation bath or a separate tank to prepare the passivation electrolyte). However, once the IBC containers are connected, the addition of the Cr(VI) solution takes place in a fully automated manner in closed pipes.

At the Trostre site, there is one ETP line whereas at the site in IJmuiden, four ETP lines are in place.

According to the applicants, the Cr(VI) concentration on the surface of the tin-plate steel is below the reported detection limit (LoD) of 0.05 mg/m^2 and therefore found to be Cr(VI) free. This statement is based on a measurement performed in 2018 by an external laboratory which confirmed via a migration test that no Cr(VI) was detectable, using a detection method according to DIN 38 405-D24.

Therefore, there are no consumer, downstream user or article service-life Exposure Scenarios relevant to the use applied for.

The applicants claim that the use applied for is currently covered by the authorisation number REACH/20/5/8 granted to AD International BV for the use of sodium dichromate for electrolytic passivation of tin-plated steel for the packaging industry. The relevant Commission decision is C(2020)2084[9].

0.2. Key functions and properties provided by the Annex XIV substance

The production of passivated ETP occurs in integrated multi-step process lines. Steel strips are electrolytically coated on both sides by a layer of tin before the passivation with chrome deposition, in a continuous process.

The exposition to the air of the chromium top layer will convert the chromium into chromium oxide. Therefore, the passivated ETP is a material where both surfaces are constituted by a stable protective layer which is composed of tin oxides, Cr(III) oxides and metallic chromium.

[9] https://eur-lex.europa.eu/legal-content/IT/TXT/PDF/?uri=CELEX:52020XC0421(03)&from=EN

The primary function of the passivation is to stabilise the material preventing the corrosion as well as other chemical reactions, with this, contribute for food safety requirements.

For some demanded applications, the passivated ETP still needs to be coated with an anti-corrosive organic coating. When an organic coating is applied, the chromium layer has a double function: to protect the tinplated steel and to provide a surface with improved adhesion properties for the organic coating.

Although the temperature resistance and the tinplate process speed are relevant requirements, the six overarching requirements for a suitable alternative for the use of Cr(VI) are:

1. Tin oxide growth resistance
2. Lacquer adhesion
3. Suitability and compatibility with the can making process
4. Sulphide staining resistance
5. Market acceptance
6. Compliance with the Food Contact Material Regulations

0.3. Types of products made with Annex XIV substance and market sectors likely to be affected by the authorisation

The type of material (tinplated steel plates and coils) produced is used mainly for the production of tin cans for food, and for metal packaging in various non-food applications as aerosols, cans for paints or tins for confectionery and for dry products. The foodstuff segment represents almost 50 % of the total consumption of ETP. Until 2017, less than 5 % of the produced tinplated steel is used in non-packaging applications.

The sheets are cut into a variety of formats according to the packaging to be produced: coils, narrow strip, straight-cut sheets and scroll-cut sheets.

1. Operational Conditions and Risk Management Measures

Workers	☒Yes	☐No
Humans via Environment	☒Yes	☐No

1.1. Workers

The production process is highly automated, however, other auxiliary processes such as pH adjustment, filter press activities, maintenance and cleaning activities include manual tasks.

The OCs, technical RMMs and PPE implemented in each WCS, with their effectiveness as described by the applicants are summarised in Table 2. In addition, the following RMMs are in place:

Technical Risk Management Measures:

- Automated closed transfer systems of Cr(VI) containing solutions throughout the plant;
- Installation of a coverage and a LEV above the passivation tanks which are not completely closed in order to ensure that the steel strips are able to move along the production line;
- Installation of valves at the dedicated sampling points;
- Automated process control to ensure the effective removal of Cr(VI);
- Process control at all lines (the process line is stopped in case the LEV does not run);
- Installation of dedicated sampling stations;

Organisational Risk Management Measures:

- Aqueous solutions (rather than the neat solid substance) of CT and SD are used as sources for chromium (VI);
- For the theoretical WCS 8, which will be applicable in case that the supply chains might become interrupted and no liquid CT or SD concentrates will be available, isolation of the hazard will be performed by separating this activity from the ETP line and performing the dissolution at a dedicated place;
- Interruption of line(s) in case interventions are needed; During interruption of the line(s), the LEV runs. In case of the yearly maintenance, there is a complete shutdown (ETP lines inclusive LEV). In case there are interruptions of LEV, the line cannot run;
- Measurement of air flow (LEV) and wash water (scrubber) are prerequisite for running the tinning lines;
- LEV flow measurements are inspected, checked and calibrated at least every two months;
- LEV, gas scrubbers and wastewater treatment are inspected, cleaned and serviced as part of the annual maintenance programme;
- Cleaning of the equipment (e.g. valves, pumps) with a water hose before maintenance activities take place;
- Training of workers on health and safety issues concerning Cr(VI) and on the use of PPE;
- Work procedures (e.g. cleaning procedure, maintenance procedure) are in place;
    - Work procedures are in compliance with the following Health and Safety and Environmental related standards:

        - ISO 9001:2008 (Trostre and IJmuiden)
        - ISO 14001:2015 (Trostre and IJmuiden)
        - OHSAS 18001:2007 (IJmuiden)
    - Occupational practices follow the Tata Steel 15 principles and satisfy the requirements of the Health Safety Executive (HSE – the UK competent authority for occupational regulations) (Trostre).

- Subcontracted professional users (e.g. outsourced maintenance and waste management subcontractor workers) are informed about health and safety issues related to Cr(VI), respectively CT and SD;
- Supervision and internal audit system are implemented.

Personal protective equipment (PPE):

The PPE is determined based on the actual activity and the time during which the activity is carried out. The set of applicable PPE (for standard and potentially elevated Cr(VI) situations) is described in work instructions.

Table 2: Operational Conditions and Risk Management Measures (sub-set of Succinct Summary of RMMs and OCs) for the Trostre and the IJmuiden site

Contributing scenario	Concentration of the substance	Duration and frequency** of exposure	Engineering controls effectiveness as stated by the applicants	PPE + effectiveness as stated by the applicants	Organisational controls
WCS 1 PROC 8b Changing IBC containers	32 % Cr(VI) at max.	Duration: 15 min Frequency: 48 days/year ###	Closed IBC containers stored at dedicated places Careful transport of closed containers to dedicated place Natural ventilation Empty IBC containers are sent back to supplier	Protective apron or chemical resistant overall Chemically resistant gloves (Nitrile gloves 0.38 mm (Alpha Tec® Solvex® 37-675) tested to EN374 (APF 20)) Respiratory protective equipment (RPE) (at Trostre: Full face mask with P3 Filter** (APF 20); at IJmuiden: 3M P3 masks Type 8835 (APF 20))	Specific activity training for dedicated operators
WCS 2 PROC 9 Sampling of passivation tank	1 % Cr(VI) ≤ 500 mL per sample Bath is heated (temperature range is confidential)	Duration: 15 min Frequency: 240 days/year (daily activity)	Dedicated sampling points Baths with high level of containment LEV with scrubber installed above passivation bath Natural ventilation	Protective clothing Chemically resistant gloves (Nitrile gloves 0.38 mm (Alpha Tec® Solvex® 37-675) tested to EN374 (APF 20)) RPE (at Trostre: Full face mask with P3 Filter** (APF 20); at IJmuiden: 3M P3 masks Type 8835 (APF 20)) Safety googles or face shield	Specific activity training for dedicated operators
WCS 3 PROC 9 Sampling of wastewater	0.37 % Cr(VI)#	Duration: 15 min Frequency: 240 days/year (daily activity)	Dedicated sampling points Natural ventilation	Protective clothing Chemically resistant gloves (at Trostre: Nitrile gloves (LD 854 CAT 3) tested to EN374 (APF 20); at IJmuiden: Nitrile gloves 0.38 mm (Alpha Tec® Solvex® 37-675) tested to EN374 (APF 20)) RPE (at Trostre: not applicable; at IJmuiden: 3M P3 masks Type 8835 (APF 20)) Safety googles or face shield	Specific activity training for dedicated operators

WCS 4 PROC 28 Maintenance	1 % Cr(VI)##	Duration: 60 min Frequency: 48 days/year	Natural ventilation	Protective clothing or chemically resistant overall (depending on the place of activity) Chemically resistant gloves (Nitrile gloves 0.38 mm (Alpha Tec® Solvex® 37-675) tested to EN374 (APF 20)) RPE (at Trostre: Full face mask with P3 Filter** (APF 20); at IJmuiden: 3M P3 masks Type 8835; 3M airstream helmet - indicated in specific work permits for maintenance activity (APF 20)	Specific activity training for dedicated operators
WCS 5** PROC 28 Cleaning	1 % Cr(VI)##	Duration: 15 min Frequency: 240 days/year	Natural ventilation	Tight long apron and boots or suitable chemical protection suit Chemically resistant gloves (Nitrile gloves 0.38 mm (Alpha Tec® Solvex® 37-675) tested to EN374 (APF 20)) RPE (at Trostre: Full face mask with P3 Filter** (APF 20); at IJmuiden: 3M P3 masks Type 8835 (APF 20))	Specific activity training for dedicated operators
WCS 6 PROC 28 Filter press/sludge removal	5 % Cr(VI)	Duration: 15 min Frequency: 48 days/year	Natural ventilation	Protective clothing or chemically resistant overall (depending on the place of activity) Chemically resistant gloves (tested to EN374 (APF 20)) RPE (at Trostre: Full face mask with P3 Filter** (APF 20); at IJmuiden: 3M P3 masks Type 8835; 3M airstream helmet (APF 20))	Specific activity training for dedicated operators
WCS 8* (PROC 5) Dissolution of solid CT/SD	Cr(VI) concentration not provided – pure substance (flakes)	Duration: 20 min Frequency: 240 days/year (daily activity)	Delivery of substance in clip-top drums Careful transport of closed containers to dedicated place LEV (90 % effectiveness) Natural ventilation	Chemically resistant overall Chemically resistant gloves (tested to EN374 (APF 20)) and RPE (half mask with P3 filter or full mask with P3 filter or P3 combination filter (APF 20)) will be used if the theoretical scenario will become relevant.	Specific activity training for dedicated operators

WCS 9 (PROC 4) Activities close to the ETP line without handling of Cr(VI) containing solutions	No direct contact to Cr(VI)	Duration: up to 480 min Frequency: 240 days/year (daily activity)	Basic, general ventilation (1-3 ACH)	Standard PPE set: protective clothing, safety glasses, protective helmet, ear protection and safety shoes	Specific activity training for dedicated operators
WCS 10 (no PROC assigned) Control room activities	No direct contact to Cr(VI)	Duration: up to 480 min Frequency: 240 days/year (daily activity)	Separate room on the shop floor	Standard PPE set: protective clothing and safety shoes	

Worst case assumption for sampling before wastewater reduction. According to the applicants, the Cr(VI) concentration in the waste water at Trostre is below 0.1 %. RAC notes that at the Trostre and the IJmuiden site the wastewater is sampled after the reduction step.

Worst case assumption in case that no cleaning of the equipment has been performed before the maintenance.

Frequency depends on whether the Cr(VI) containing solution is directly filled from the IBC container into the process (lower frequency) or filled in a storage tank from where it is fed into the process.

* Theoretical scenario[10] – not yet in place but will be in place in case there is no supply of the liquid form of CT and/or SD. LEV with an effectiveness of 90 % will be installed.

** Duration and frequency of exposure is not specific to both sites at Trostre and IJmuiden. These parameters cover the situation for all APEAL sites.

[10] The applicants stated on RAC´s request for further information that the dissolution of the solid substance will be performed at a dedicated place where a tundish is installed which is connected to a dissolution tank located in the subjacent floor. Besides the tundish a lifting device will be installed, which grips the open drums, lifts them up and tips them to drain the flakes slowly into the tundish from where the solid is transported by gravity into the dissolution tank. The tasks will be supervised by trained operators wearing chemical resistant overalls, gloves and respiratory full mask with P3 filter.

There is no information on WCS 7 (Addition of solid CT, where solid CT pellets are added to the ETP process manually to adjust the pH value of the passivation bath on demand) since this scenario is not relevant for both sites (but is used in some other APEAL sites). Besides WCS 8 (Dissolution of solid CT and/or SD) is only theoretical by the time since in general the applicants use liquid CT or SD concentrate as a principle of RMM. However, in case that there might be an interruption of the supply chains and no liquid CT or SD concentration will be available, the substances will be used in their solid form by the applicants.

On RAC´s request, the applicants clearly state that the hierarchy of control principle is followed for all tasks.

1.2. Humans via Environment

Operational Conditions and Risk Management Measures in place for control of emissions to:

Air:

All air extracted from the Cr(VI) containing installations (e.g. from the process baths (see section 1.1. “workers”)) is treated by wet scrubber systems for removal of Cr(VI) before the air streams are emitted to outside air. Scrubber water is directed to the reduction/neutralisation unit.

Water:

At both sites, the generated Cr(VI) containing effluents from all processes (e.g. from the scrubbers, the liquid waste from the baths, waste water from cleaning and maintenance activities) are collected by the wastewater network and directed to the on-site wastewater treatment facility, where a reduction/neutralisation of Cr(VI) – overstoichiometrical addition of ferrous chloride (IJmuiden) or ferrous sulphate/ferrous chloride (Trostre) - takes place fully automated. At the site in IJmuiden, a part of the rinsing water is regenerated and re-used in the plant before it is released after adequate treatment.

The effectiveness of the reduction/neutralisation process is daily checked by measurements of Cr(VI) in order to confirm that the final Cr(VI) concentration is within the permitted limit. At the Trostre site, all daily measurements since 2016 were below the LoD of 0.001 mg Cr(VI)/L. At the IJmuiden site, all weekly measurements have been below the LoD of 0.01 mg Cr(VI)/L.

Soil:

There are no direct emissions of Cr(VI) to soil.

Waste:

Solid waste occurs as sludge from the ETP process including removed filter cake from the chromium baths. It is stored in sealed barrels, located in a segregated area, ready for off-site disposal via a specialised waste company.

Empty drums are cleaned at dedicated places with a water hose. The wash water is collected in the wastewater drain from where it enters the wastewater treatment plant. Empty drums are recycled or disposed as solid waste.

Table 3: Environmental RMMs – summary for both sites

Compartment	RMM	Stated Effectiveness
Air	LEV and wet scrubbers	90 %* (according to process engineers).
Water	On-site reduction-neutralisation	No effectiveness stated.
Soil	-	No effectiveness stated.

* On RAC´s request the applicants provided information on the effectiveness of the LEV of the ETP lines and the scrubbers but did not underpin it with e.g. measured data.

1.3. Discussion on OCs and RMMs and relevant shortcomings or uncertainties

The information in the CSR about the RMMs in place for workers for both sites could have been provided in more detail (e.g. information on general ventilation, further details on engineering controls, on storage of PPE or fit testing before use of filter masks, details on standard operating procedures and internal audit systems). However, further information was provided on RAC´s request but information on the effectiveness of the LEV of the ETP lines and the scrubbers was not underpinned by measured data or any other data which might confirm the stated effectiveness.

RAC notes that minor shortcomings are related to the effectiveness of the LEV of the ETP lines and the scrubbers as well as to WCS 8 which will be only implemented in case of a lack of liquid CT/SD. RAC also took note that the natural ventilation is not described.

Overall conclusion: RAC concludes that the RMMs and OCs implemented in both sites are appropriate and effective in limiting the risk, provided that they are adhered to.

Are the operational conditions and risk management measures appropriate[11] and effective[12] in limiting the risk for workers, consumers, humans via environment and / or environment?

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

Monitoring arrangements for the authorisation as presented in section 8 should address the shortcomings with regard to WCS 8.

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

2. Exposure assessment

For the inhalation exposure assessment, the applicants used a combination of air monitoring data (static and personal monitoring) and modelled data (ART, version 1.5).

2.1. Inhalation exposure

Monitoring

According to the applicants, personal monitoring was the best method related to the exposure situation in the companies of the consortium (see Table 4). Although these monitoring data which are presented in an anonymised form comprise values for total chromium and Cr(VI), only the latter are relevant for the exposure assessment. They were used to compare with the results of the modelled data of the individual tasks. Besides, the applicants presented an evaluation of static monitoring data on Cr(VI) of the German MEGA database (from 2000 to 2009) for comparison. According to this, the 90th percentile on aggregated Cr(VI) exposure concentration for all WCSs of 806 sites, including 1 837 measurements with an LoQ of 0.1 µg/m^3 is 3.66 µg/m^3, the arithmetic mean is 2.93 µg/m^3 and the median is < LoQ of 0.1 µg/m^3. These results, comprising exposure levels in the metal processing industries, show that there is a high variation between the single measured results.

Site specific data for the site at Trostre and IJmuiden are also included in the CSR:

- For Troste, only measurements for total chromium are available. Static monitoring values are available for the years 2014 (LoQ: 1 µg/m^3), 2016 (LoQ: 1 µg/m^3), 2017 (LoQ: 0.1 µg/m^3) and 2018 (LoQ: 0.1 µg/m^3) but the data from 2017 and 2018 are included in the data pool of the APEAL consortium. Personal sampling results are available for the years 2014 (LoQ: 1 µg/m^3) and 2016 (LoQ: 5 µg/m^3).
- For the IJmuiden site, the LoD for the personal and static monitoring data obtained from 2017 to the present is 0.1 µg/m^3 for Cr(VI) or total chromium. The personal monitoring data on Cr(VI) for 2017 and the static monitoring data for 2019 on Cr(VI) are included in the data pool of the APEAL consortium.

On RAC´s request, clarification on the measured data reported in the CSR was provided in addition to personal (from 25 to 28 November 2019) and static monitoring (November/December 2019) data from the IJmuiden site. According to these data (N=26), all personal monitoring results for Cr(VI) were below the respective LoD of 0.1 µg/m^3. The static measurements for WCS 3 (N = 8), WCS 9 (N = 8) and WCS 10 (N = 4) are also mainly below the LoQ of 0.1 µg/m^3 (for static monitoring) Only for WCS 9 higher concentrations (0.16, 0.29 and 0.40 µg Cr(VI)/m^3) were obtained, the rest of the measurements for WCS 9 (N = 5) were also below the LoQ of 0.1 µg (Cr(VI)/m^3).

Besides, the applicants explained that they do not have yet enough monitoring data (personal and static) to base their exposure assessment on monitoring data from each of the sites in Trostre and IJmuiden. Therefore, they used aggregated data from the APEAL consortium for each WCS and compared them with the modelled data.

In Table 5, the results of the personal measurements of the APEAL consortium are presented. The static and personal measurements are provided in Annex 2, CSR p. 115-117 (Table 70) and in information provided on RAC´s request.

For the exposure estimate of WCS 4 (Maintenance), WCS 5 (Cleaning) and WCS 9 (Activities close to the ETP line without handling of Cr(VI) containing solutions), the 90th percentile of personal monitoring data was used.

For the exposure estimate of WCS 2 (Sampling of passivation tank) and WCS 3 (Sampling of wastewater) the applicants used modelled data although measured data of the APEAL consortium showed higher exposure levels. The applicants explained their approach by the fact that a part of the limited monitoring results was below the LoQ. This means that the results of the measured data were influenced by the respective LoQ. RAC notes that in WCS 1 (Changing IBC containers), WCS 4 and WCS 5 also more than half of the air monitoring results were below the respective LoQ.

In addition, RAC points out that while the applicants did not correct the modelled data in WCS 2, WCS 3 and WCS 5 for the use of PPE, RAC corrected the data for PPE (see Table 5 below, corrected data are flagged in grey).

Modelling

The applicants based their inhalation exposure assessment for WCS 1, WCS 2, WCS 3, WCS 6 and WCS 8 on the upper interquartile confidence interval of 75th percentile of ART (version 1.5). They explained that their approach follows the recommendations of the developers of the tool. Table 4 provides an overview of the results of workers´ exposure modelling data comparing the 90th percentile (incl. lower and upper interquartile confidence interval) and the upper interquartile confidence interval of the 75th percentile.

The input data are provided in the CSR, Table 28, p. 57-60. They are largely based on a survey conducted by the consultants performing the exposure assessment for the APEAL consortium. The modelling results are reproducible, the ART report is provided in Annex 5, CSR, p. 134-142. In Table 5, the results of the modelling are presented. RAC notes that the ART modelling tool does not use PROCs for exposure modelling. With the exemption of WCS 1, the modelling was performed on SD (and not on CT).

Table 4: Results of workers´ task-based exposure modelling data via ART

WCS	Modelling data µg Cr(VI) / m³			
	90th percentile	**Lower interquartile confidence interval of 90th percentile**	**Upper interquartile confidence interval of 90th percentile**	**Upper interquartile confidence interval of 75th percentile**
WCS 1	0.940	0.430	2.200	**1.100**
WCS 2	0.088	0.040	0.200	**0.100**
WCS 3	0.053	0.024	0.120	**0.060**
WCS 4	0.089	0.040	0.200	**0.100**
WCS 5	Outside the applicability domain of ART			
WCS 6	7.400	3.700	15.000	**7.600**
WCS 8	260.000	130.000	550.000	**270.000**
WCS 9	Outside the applicability domain of ART			
WCS 10	Outside the applicability domain of ART			

RAC points out that measurements are the best way to estimate workers´ exposure. Therefore, RAC would have appreciated if the applicants would have based the exposure assessment for the inhalation route on the available dataset on measured workplace air concentrations and underpinned it by the measured data available from other sites (including the biomonitoring data from the site) and by modelled data.

RAC notes that in any review the exposure assessment should be based on measured data from the respective site representative for the range of tasks undertaken where exposure to Cr(VI) is possible, including tasks involving maintenance workers, the OCs and RMMs typical for each of these tasks and the number of workers potentially exposed.

2.2. Dermal exposure

Dermal exposure should be estimated for all activities which are related to a possible Cr(VI) exposure due to the use of SD in order to check whether there is any risk for reproductive toxicity. That means that dermal exposure might be relevant for all WCSs but not for WCS 9 (Activities close to the ETP line without handling of Cr(VI) containing solutions) and WCS 10 (Control room activities).

In a conservative manner, the dermal exposure assessment does not distinguish between Cr(VI) exposure due to CT and exposure to SD. That means the estimate is based on the total amount of Cr(VI) used.

Modelling

The dermal exposure estimates are based on modelled data, using the 90th percentile of RISKOFDERM model, version 2.1. Since, there is only an adequate module for tasks included in WCS 2, WCS 3 and WCS 8 a second (generic) modelling approach – using a default dermal load of 0.1 mg/cm^2/day according to EU RAR for SD for non-disperse uses – was followed to calculate dermal exposure. RAC noted that the applicants used the highest calculated exposure value for the risk assessment in case there was more than one exposure estimate. Table 5 provides dermal exposure values received from modelling.

The input data are provided in the CSR, p. 106 – 108 and Annex 6, CSR, p. 144 and 145.

Monitoring

Measured data on dermal exposure were not presented in the CSR. Wipe samples or any monitoring data of similar approaches not available.

Table 5: Exposure – inhalation and dermal[13] by RAC

Contributing scenario (WCS PROC##)	Route of exposure	Method of assessment	Exposure value (8h TWA)	Exposure value corrected for duration, PPE and frequency#
WCS 1 PROC 8b Changing IBC containers	Inhalation (µg/m³)	ART modelling (75th percentile)	0.0344	**0.00034**
		Personal sampling (90th percentile) (four sites; N=22; < LoQ)	0.050 (LoQ/2)	0.00002
	Dermal (µg/kg bw/d)	Generic modelling (hands)	11.0	**2.19**
WCS 2 PROC 9 Sampling of passivation tank	Inhalation (µg/m³)	ART modelling (75th percentile)	0.100	**0.00016**
		Personal sampling (90th percentile) (five sites; N=24 < LoQ – 7.550 µg/m³)###	0.140	0.00022
	Dermal (µg/kg bw/d)	RISKOFDERM	0.49	**0.49**
		Generic modelling (hands)	0.34	0.34
WCS 3 PROC 9 Sampling of waste water	Inhalation (µg/m³)	ART modelling (75th percentile)	0.060	**0.00009**
		Personal sampling (90th percentile) (four sites; N=8; < LoQ – 0.710 µg/m³)	0.260	0.00041
	Dermal (µg/kg bw/d)	RISKOFDERM	0.18	**0.18**
		Generic modelling (hands)	0.13	0.13
WCS 4* PROC 28 Maintenance	Inhalation (µg/m³)	ART modelling (75th percentile)	100	0.13
		Personal sampling (90th percentile) (four sites; N=9; < LoQ – 12.250 µg/m³), total chromium	1.160	**0.116**
	Dermal (µg/kg bw/d)	Generic modelling (hands)	0.34	**0.069**
WCS 5 PROC 28 Cleaning	Inhalation (µg/m³)	ART modelling	This task is outside the domain of ART.	
		Personal sampling (90th percentile) (five sites; N=17; < LoQ – 0.290 µg/m³)	0.140	**0.00035**

[13] Values for measured inhalation exposure are from the APEAL consortium. All exposure values are for Cr(VI).

	Dermal (µg/kg bw/d)	Generic modelling (hands & body)	25.3	**25.3**
WCS 6 PROC 28 Filter press/sludge removal	Inhalation (µg/m³)	ART modelling (75th percentile)	0.238	**0.00238**
		Personal sampling (90th percentile) (one site; N=1; < LoQ (0.030 µg/m³))	0.030 (LoQ/2)	0.00001
	Dermal (µg/kg bw/d)	Generic modelling (hands)	0.34	**0.069**
WCS 8 PROC 5 Dissolution of solid CT/SD	Inhalation (µg/m³)	ART modelling (75th percentile)	270	**0.5625** (without considering LEV)
		Personal sampling	No air monitoring was available.	
	Dermal (µg/kg bw/d)	RISKOFDERM	7.63	**7.63**
		Generic modelling (hands)	13.7	**13.7**
WCS 9 PROC 4 Activities close to the ETP line without handling of Cr(VI) containing solutions	Inhalation (µg/m³)	Since the workers do not handle any Cr(VI) containing liquids/subjects, no modelling was performed.		
		Personal sampling (90th percentile) (four sites; N = 36; < LoQ – 0.00051 µg/m³)###	0.220	**0.220**
	Dermal	Since the workers do not handle any Cr(VI) containing liquids/subjects, no modelling was performed.		
WCS 10 (No PROC assigned) Control room activities	Inhalation (µg/m³)	Since the workers do not handle any Cr(VI) containing liquids/subjects, no modelling was performed.		
		Personal sampling (90th percentile) (two sites; N = 19; < LoQ: 1.500 and 0.060 µg/m³)	< 0.060 (N = 12)	< 0.060 (N = 12)**
	Dermal	Since the workers do not handle any Cr(VI) containing liquids/subjects, no modelling was performed.		

The exposure levels in bold were taken forward for the risk characterisation.

N=number of measurements

The modelled dermal data are adjusted for frequency and use of PPE but not for duration.

The applicants calculated the inhalation exposure values for 240 days of exposure.

Measurements from the site with the highest LoQ and/or with only 1.5 h measurement duration are excluded.

* Only near field exposure estimates were considered. Far field exposure estimates are lower (near field: 0.0125 µg/m³ compared to far field ones: 0.00575 µg/m³).

** According to the applicants the exposure concentration on Cr(VI) in the control room can be considered as irrelevant due to fact that all measurements were below the respective LoQ of 1.500 (N = 7) and 0.060 (N = 12) µg/m³.

*** The applicants did not correct the exposure estimates for task duration since they assumed that

exposure during sampling as well as maintenance/cleaning mainly contributes to the overall exposure.

2.3. Biomonitoring

There are no biomonitoring data on total chromium or on Cr(VI) for the Trostre site whereas at the IJmuiden site biomonitoring based on total chromium is performed on a regular basis. On RAC´s request, it was explained that in 2018 and 2019 chromium biomonitoring has been performed in parallel to air monitoring activities before the first early shift and after the second afternoon shift. The sampling period comprised therefore a total of four working days. The amount of chromium in the urine is expressed in µg chromium/g creatinine[14].

183 of 276 workers (66 %) submitted urine samples pre- and post-shift in 2019. In 15 of these the amount of total chromium in the urine was higher than the LoD of the analytical method (1 µg/L). The results of the biomonitoring campaign in 2018 were not provided.

In order to explain why biomonitoring on Cr(VI) would not be useful for the exposure assessment, the applicants made the following assumptions: Taking into account a creatinine content of 1.5 g/L urine, background values of 0.2 – 1.0 µg/g creatinine correspond to 0.3 – 1.5 µg chromium/L. Based on the correlation between chromium content in urine and Cr(VI) concentration in air presented by the German MAK Commission (12 µg chromium/L correspond to 0.03 mg CT/m^3), the molecular weight for CT (ca. 99.99 g/mol) and chromium (ca. 52 g/mol) and assuming that a linear correlation is also applicable for lower concentrations, the Dutch background concentration of 0.3 – 1.5 µg chromium/L would correspond to an air Cr(VI) concentration of 0.4 – 1.9 µg/m^3 which is well above the air concentrations measured during workplace monitoring.

RAC agrees that measurements of total chromium in the urine (U-Cr) may not be sensitive enough at very low exposure levels because of the background U-Cr levels in the general population. U-Cr 5th percentile levels in the general population are usually at the level of 0.5-1 µg/L. When the inhalation exposure is below 0.5 µg/m^3, this might not increase the U-Cr levels clearly above the general population 95th percentile level. However, in this case there was a clear increase in U-Cr levels during the working week with average levels above the general population range in the Netherlands. This might suggest higher exposure than estimated on the basis of air measurements and modelling although it is not possible to draw firm conclusions on the exact air levels based on the biomonitoring data. High dermal contamination may also contribute to the results.

On the other hand, based on biomonitoring data, it is possible to conclude that dermal modelled exposure estimates are highly conservative. U-Cr reflects exposure via all routes of exposure, including dermal and hand-to-mouth behaviour. Using dermal models, it had been estimated that dermal exposure at both sites at Trostre and IJmuiden is between 25 µg/kg bw/day and 28 µg/kg bw/day. Using RAC dermal absorption fraction of 4 %, this means systemic exposure of about 1 µg/kg bw/day. Since systemically absorbed Cr(VI) is rapidly and almost completely excreted into the urine, it can be calculated that this kind of systemic exposure is likely to result in a steady state urine level of more than 30 µg/L, which are one order of magnitude higher than levels measured in the biomonitoring campaign.

RAC agrees with the applicants that it might not be possible to base the exposure assessment on biomonitoring data. However, RAC points out that a thorough analysis of biomonitoring data collected according an appropriate sampling strategy, and recorded with contextual information on date and hour of sampling, OCs and RMMs in place, and tasks performed by

[14] According to the applicants, the average concentration of chromium in urine of non-professionally exposed persons is 0.2 to 1.0 µg chromium/g creatinine in the Netherlands.

the worker before sampling, could be used to underpin the exposure assessment.

The applicants confirmed on RAC´s request for further information that in a biomonitoring campaign in 2017[15] at IJmuiden, the average chromium concentration of the samples before the first early shift was 0.73 µg/g creatinine whereas after the second afternoon shift a concentration of 1.54 µg/g creatinine was measured. According to the applicants, a further analysis of these results revealed that a cross contamination during handling of the samples could not be excluded. Therefore, the workers were instructed accordingly and the more recent biomonitoring results did not show a relevant uptake on chromium. RAC notes that well instructed workers about safety and health issues related to Cr(VI) should also have a sufficient knowledge on cross contamination and how to avoid it.

2.4. Environmental exposure

The applicants considered that "ECR 5 – Use at industrial site leading to inclusion into/onto article" is the most appropriate Environmental Contributing Scenario (ECS).

The assessment of human exposure via the environment at local and regional scale is based on EUSES modelling, version 2.12, using monitoring data as input data. The input data for EUSES are provided in the CSR. The data presented by the applicants for each compartment are summarised below.

For oral human exposure via the environment, exposure via drinking water and fish was taken into account.

Release factors for the release of Cr(VI) to water and air were derived from the measured emission data per site and the tonnage used per site.

Water

At Trostre, the Cr(VI) containing waste water is collected in a single sump and pumped into a dedicated tank at the on-site Effluent Treatment Plant. Rinse water undergoes the same process. At the Effluent Treatment Plant, reduction of the Cr(VI) containing waste waters takes place batch-wise 3×/week using ferrous sulphate/ferric chloride solutions. Only after analytical analyses, these waste waters are mixed with other chromium free waste waters for pH adjustment.

After neutralisation, all waste waters are combined in a settlement tank. The Cr(VI) concentration in total waste water is sampled and analysed daily. Since 2016 these analyses were below the LoD of 0.001 mg Cr(VI)/L.

In 2018, a total chromium concentration of 5.600 µg/L was measured at the borehole relevant for the ETP-related operation, which indicates that the total chromium in the groundwater is very low.

At the IJmuiden site, Cr(VI) containing rinsing water together with reflow quench water is regenerated via a set of cation/anion exchangers. The concentrated waste water, however, of which part is Cr(VI) containing waste water (from the exchange of the chromium bath, part of the rinsing water, cation/anion exchangers and cleaning processes prior to maintenance as well as water from the scrubbers) is collected in several tanks before it is treated in two on-site Wastewater Treatment Plants (WWTPs). There, detoxification with overstoichiometrical addition of ferrous chloride followed by neutralisation and dewatering takes place. The Cr(IV) concentration in the treated waste water is measured daily with an indicative colorimetric

[15] 154 workers of a total of 223 workers (69 %) submitted urine samples.

method[16]. At least once per month, 24 h samples are taken consisting of 50 mL wastewater collected from every 2 000 L wastewater produced. Since 2018, all of these measurements (spectrometric method) show Cr(VI) concentrations below the LoD of 0.01 mg/L.

The applicants pointed out that the reductive wastewater treatment is highly effective. They consider the release of Cr(VI) to be negligible.

Air

All air extracted from the Cr(VI) containing installations (e.g. from the process baths) is treated by wet scrubber systems for removal of Cr(VI) before the air streams are emitted to outside air. Scrubber water is directed to the reduction/neutralisation unit in the Effluent Treatment Plant respectively in the WWTPs.

At the Trostre site, air emissions of total chromium or Cr(VI) are measured at least annually. In 2016 0.0018 µg Cr(VI)/m^3 (one measurement for 90 minutes on one day) was measured while in 2017 and 2018 only measurements for 120 minutes on total chromium were conducted: 0.0075 and 0.0034 µg/m^3 (2017) and 0.004 µg/m^3 (2018).

At the IJmuiden site, emissions of total chromium from the ETP process are measured once every three years. All measurements on total chromium as a surrogate for Cr(VI) are below the respective LoD of 0.01 mg/m^3. The measurements from seven different emission sources (the LoD of these measurements was taken forward for the calculation) related to the ETP process were used to calculate the air emission for 2018 (6.68 kg Cr(VI)/year). This information was provided on RAC´s request for further clarification.

Soil

According to information in the CSR, there is no release to soil.

[16] Colour change indicates presence and rough amount of chromium but not the precise concentration.

Table 6: Summary of environmental emissions

Release route	Release factor	Release per year (kilograms Cr(VI))	Release estimation method and details
Water	Trostre: 8.94×10^{-5} IJmuiden: 5.59×10^{-5}	Trostre: 0.72 (mean: 2016-2018) IJmuiden: 0.91 (2018/2019)	For calculating the waste water emission for the both sites, LoD/2 was multiplied with the total waste water discharge volume of the plant.
Air	Trostre: 1.32×10^{-4} IJmuiden: 4.09×10^{-4}	Trostre: 1.01 (mean: 2016-2018) IJmuiden: 6.68 (2018)	For the calculation of the release, the average emission on total chromium as surrogate for Cr(VI) for the years 2016-2018 (Troste) / the emission of 2018 (IJmuiden) and the corresponding production volume was taken into account.
Soil	0	0	0

Table 7: Summary of indirect exposure to the environment and humans via the environment for the Trostre site

Parameter	Local	Regional
PEC in air (µg Cr(VI)/m^3)	8.12×10^{-4}	7.97×10^{-15}
Daily dose via oral route (µg Cr(VI)/kg bw/d)*	3.66×10^{-5}	4.84×10^{-7}

Table 8: Summary of indirect exposure to the environment and humans via the environment for the IJmuiden site

Parameter	Local	Regional
PEC in air (µg Cr(VI)/m^3)	6.61×10^{-3}	6.48×10^{-14}
Daily dose via oral route (µg Cr(VI)/kg bw/d)*	2.73×10^{-4}	3.76×10^{-6}

* Oral intake from drinking water and fish consumption.

2.5. Discussion of the information provided and any relevant shortcomings or uncertainties related to exposure assessment

Worker exposure

The applicants based their exposure assessment mainly on modelled data, using ART, version 1.5. However, they provided also a small set of measured data from the applicants' sites in Troste and IJmuiden and for comparison a pool of data from the APEAL consortium and the German MEGA database.

Detailed information on the input parameters of the ART model are presented in the CSR. RAC does not note any shortcomings related to these input parameters but recognises that the considered effectiveness of 90 % of the LEV could not be underpinned by measurements. However, RAC notes that the applicants used the upper interquartile of the 75th percentile instead the 90th percentile. According to the applicants, the upper interquartile confidence interval of 75th percentile better accounts for uncertainty and variability in the underlying data than the e.g. 90th percentile. In order to show the difference between the applicants´ approach and the 90th percentile, RAC presents the data in Table 4 above. RAC further notes that the point estimate of the particular percentile of the exposure distribution may either shift to higher or lower values due to the Bayesian update, depending on the particular scenario and the distribution of the calculated data.

The exposure assessment for WCS 4 (Maintenance), WCS 5 (Cleaning) and WCS 9 (Activities close to the ETP line without handling of Cr(VI) containing solutions) is based on monitoring data since there is no domain in ART for WCS 5 and WCS 9 while for WCS 4 the personal samples show the highest exposure values compared to static measurements and ART modelled data.

The 90th percentile of the data of the German MEGA database shows for WCS 1 to WCS 4 and WCS 9 much higher exposure values than the personal samplings of the pooled data of the APEAL consortium or the modelled data do. Only for WCS 6 the MEGA database exposure data are lower compared to the modelled data. However, it is not clear if these data represent an 8h TWA. Summing up, the data from the MEGA database are not helpful for underpinning the exposure assessment by the applicants.

According to the monitoring data provided by the applicants from their sites (although their number is rather limited, particularly from the Trostre site) and according to the monitoring data of the APEAL consortium, the exposure estimates for workers might be worst case estimates although for WCS 2 (Sampling of passivation tank) and WCS 3 (Sampling of waste water) the modelled exposure concentrations were taken forward for the risk characterisation which were two orders of magnitude lower than the measured concentrations on Cr(VI). However, the applicants explained that most of the monitoring results (about 80 %) revealed exposure concentrations below the LoQ, which means that the LoQ of the underlying method mainly influenced the result instead of the real exposure. Therefore, the uncertainty resulting from the monitoring values could not be quantified and for this reason the applicants decided to base the exposure assessment on modelled data instead. In addition, the outcome of measured data for WCS 9 (see Table 55 on page 93 of the CSR), could suggest that the measurements assigned to this WCS might also include activities related to direct handling of Cr(VI) which shall not be assigned to this specific WCS (WCS 9 - Activities close to the ETP line without handling of Cr(VI) containing solutions) and which further supports a worst case estimate.

On RAC´s request, the applicants provided more detailed information on the PPE used which clarified that for WCS 1, WCS 2, WCS 4, WCS 5 and WCS 6 RPE is mandatory. RAC corrected the exposure estimates for the use of RPE for the WCS 2, WCS 3 and WCS 5 since the applicants presented the data without considering the use of RPE which is mandatory also for these WCSs according to the CSR and the information provided on RAC´s request.

The applicants also clarified that the input parameters in Table 2 above (e.g. on duration and frequency) are not site specific. They might be different at both sites. RAC acknowledges that in case the tasks take longer or are performed more often at one or both of these sites, the workers´ exposure must not exceed the estimates provided.

RAC agrees with the applicants that the task duration on maintenance may be substantially

longer than exposure duration to Cr(VI), since repair might mostly start only after cleaning. Besides, during cleaning, the Cr(VI) concentration will rapidly decline due to dilution with water. Therefore, a maximum of 1 h is assumed for contact with contaminated objects as an upper end or even worst-case estimate for the applicants´ sites.

The dermal modelling results are considered by the applicants to be rather conservative since the workers are instructed to wear protective clothing and gloves to avoid skin contact and therefore exposure to SD might be rather unlikely. Besides, RAC notes that the dermal exposure assessment includes the total amount of Cr(VI) used and not only the one resulting from the use of SD.

RAC points out that measurements are the best way to estimate workers´ exposure. Therefore, an exposure assessment for the inhalation route based on measured workplace air concentrations and underpinned it by the measured data available from other sites (including the biomonitoring data from the site) and by modelled data would be preferable. There is a number of site-specific measured workplace concentrations available, particularly for the site at IJmuiden.

According to information provided on RAC´s request, the applicants are aware that measured data should be primarily used for the exposure assessment. They stated that the monitoring programmes at the IJmuiden site will be expanded and that at the Trostre site monitoring programmes had already been initiated for the manufacturing of ETP. RAC notes that the applicants did not provide information on the standards used for workplace air monitoring. This shortcoming will be addressed in the monitoring arrangements in section 8.

RAC further notes that there is some uncertainty with regard to WCS 8. Since this is a theoretical scenario as long as there is sufficient liquid supply of CT and SD, this WCS does not take place and therefore only modelled data are available for this WCS.

In the ART modelling, three air changes per hour were considered for WCS 1, WCS 2, WCS 3 and WCS 6 while in the summary of RMMs natural ventilation is considered with no information on the air exchange rate. This leads to some shortcomings on the modelled data.

Biomonitoring data are only available for the IJmuiden site. RAC notes that the LoD of 1 µg total chromium/L urine used for the measurements was relatively high.

Based on the biomonitoring data provided, RAC can confirm that the dermal estimates are conservative.

Humans via the environment

RAC notes that the exposure assessment for humans via the environment (including indirectly exposed workers) at the local and regional scale was based on EUSES modelling, version 2.12, using monitoring data as input data from the respective site. The applicants considered two exposure routes – inhalation and oral intake (consumption of drinking water and fish) for exposure of general population at the local and regional scale. In addition, at local level, a total of less than 4 000 (< 2 000 at each site) (public range provided at SEAC's request) workers in an area within a radius of 1 km from the plants are indirectly exposed. At local level, according to the applicants' estimate, none is exposed in the area surrounding IJmuiden, while 1 000 (public range provided at SEAC's request) people living in an area with a radius of 1 km around Trostre are indirectly exposed.

The measured concentration - average concentration of total chromium (three measurements) and Cr(VI) (one measurement) for three years at the Trostre site and seven measurements of total chromium from different sources of the ETP process in 2018 at the IJmuiden site -

multiplied by average mass flow, extrapolated to the amount of Cr(VI) used in the respective years were used to calculate the release to air. The applicants considered the estimates of air emission to be conservative because they are mainly based on total chromium.

Based on the fact that addition of reductive substances is performed overstoichiometrically to ensure complete reduction of Cr(VI) in the waste water, the applicants considered that the release of Cr(VI) to waste water is likely negligible. They are also of the opinion that Cr(VI) release to air is an overestimate due to the fact that total chromium was measured for the release estimate and not Cr(VI).

The applicants assessed oral exposure to Cr(VI) in principle according to the EU RAR. However, the applicants used in addition a general reduction of the local Cr(VI) concentration in drinking water, calculated in EUSES, by a factor of 5. They justified their approach as followed:

- EUSES modelling does not consider the reduction on Cr(VI) to Cr(III). The starting concentrations, based on the monitoring values for Cr(VI) are not corrected for the average amount of Cr(VI) to be reduced to Cr(III) in the environment.
- The majority of measurements in wastewater showed Cr(VI) concentrations below the LoQ. Although the LoQ/2 was used for the exposure calculation, this might still be an overestimate due to the fact that the addition of reducing agents may lead to negligible Cr(VI) concentrations in the released wastewater.
- For inorganic substances no “purification factor” is specified which accounts for removal processes from surface water (e.g. adsorption to suspended particles) in deriving the concentration in drinking water. Although these effects are difficult to quantify, the value of 50 % for adsorption to sewage sludge as applied in the EU RAR is considered by the applicants as an indicator for the amount of Cr(VI) eliminated from water due to adsorption to sewage sludge.
- Drinking water as it is delivered to consumers is not identical to the water in the mixing zone for which the PEC is calculated. Water from other sources is added and contributes to further dilution.

With regard to the factor of 5 the applicants stated that the factor is a default factor which cannot be completely justified but taking into account a factor of 2 for the adsorption to sewage sludge and in addition a factor of 2.5 for the conservatism of the remaining influences as outlined above, seems to be appropriate.

RAC acknowledges that Cr(VI) will transform rapidly in the environment to Cr(III) under most environmental conditions. This has been previously discussed in the EU RAR for chromate substances (EU RAR 2005), and will reduce the potential for indirect exposure to humans to Cr(VI) via the environment, particularly from the oral route of exposure but notes that the factor of 5 has not yet been agreed on EU level and therefore the applicants are recommended not to change default assumptions in EUSES.

However, RAC notes that inhalation represents 99.9 % of the combined risks. Therefore, the factor 5 used by the applicants does not have any significant impact on the combined risks for humans via the environment in this case.

In addition, RAC notes that the default assumptions in EUSES for local assessment estimate $PEC_{local,air}$ is relevant within 100 m from a point source. This, in general, is likely to overestimate exposure for workers considered in the vicinity of the site.

Overall, RAC acknowledges the approach by the applicants to reduce the local Cr(VI) concentration in drinking water by a factor of 5 in EUSES modelling but points out that this approach has not been agreed at the EU level. It introduces some minor uncertainties concerning potential underestimation of exposure via the oral route for humans via the

environment. The applicants are recommended not to change the default assumptions in EUSES unless they are well justified. However, RAC notes that the excess risk for combined exposure remains the same at the local scale since the inhalation route contributes about 99.9 % to the combined risk.

2.6. Conclusions on exposure assessment

RAC notes that the applicant´s CSR provides generic information on the tasks undertaken and associated OCs and RMMs for the both sites at Trostre and IJmuiden. However, more detailed information was provided on RAC´s request.

The exposure assessment for workers is principally based on modelled data but the applicants took some effort to underpin these data with monitoring data from their sites but also pooled data from the APEAL consortium and the German MEGA database.

The exposure assessment on air emissions can be considered as a worst-case estimate since measurements on total chromium were in principle used for the estimates at both sites. However, as already pointed out by the applicants, measurements for Cr(VI) to air should be performed to strengthen the emission estimate.

Summing up, RAC is of the opinion that the exposure estimate includes some shortcomings due to the small dataset on Cr(VI) measurements for the site in Trostre and due to the small number of measured data on Cr(VI) for emissions to air for both sites. RAC notes that the exposure assessment should be based on site-specific data for workers and humans via the environment.

Monitoring arrangements for the authorisation for workers and for air emissions should address the minor shortcomings for both sites. Since there will be a considerable increase of the amount of substance used in IJmuiden[17], monitoring should also be regularly performed in IJmuiden to ensure the effectiveness of the RMMs and OCs in place for the higher amount used. In addition, RAC is of the opinion that the exposure assessment for WCS 8 should be underpinned by measured data as soon as it takes place. The applicants have already confirmed that they will improve the dataset on measured data.

Therefore, RAC considers that the description of the use provided in the CSR and in the applicant´s answers to RAC´s request is sufficient to conclude on the reliability of the exposure assessment for workers and humans via the environment.

[17] The applicant stated in the AoA and SEA report that the ranges (including consumption of chromates) take into account the potential future increase in IJmuiden's production capacity. The increase is estimated to be between 10 % - 40 %, exact figure is claimed confidential. The tonnage provided in this opinion thus covers the potential increase of the production capacity.

3. Risk characterisation

The applicants have estimated cancer risk according to the RAC reference dose response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1, agreed at RAC 27).

There are no data to indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans, but it might present a risk for reprotoxic effects.

RAC has proposed reference DNELs for the reprotoxic properties of some Cr(VI) compounds, including sodium dichromate (RAC/35/2015/09, discussed at RAC-35).

In the socio-economic analysis (SEA) the remaining human health risks are evaluated based on the dose-response relationship for carcinogenicity of hexavalent chromium (RAC/27/2013/06 Rev.1, Agreed at RAC-27).

3.1. Workers

Based on exposure for 40 years (8 hours/day, 5 days/week), the excess lifetime lung cancer mortality risk according to the RAC reference dose response relationship is 4×10^{-3} per µg Cr(VI)/m^3.

The exposure assessment for workers is mainly based on modelled data, using ART (version 1.5) for the inhalation route and RISKOFDERM, version 2.1 as well as a generic modelling approach according to EU RAR for SD for non-disperse uses for the dermal route.

The applicants calculated the excess cancer risk (inhalation route) and the risk characterisation ratio for reproductive toxicity (dermal route) for the combined (aggregated) exposure based on the tasks performed by the different types of operators and the long-term TWA on Cr(VI) concentration assigned to the different tasks.

Since RAC took forward the exposure estimates for WCS 2, WCS 3 and WCS 5, which do not take into account the use of RPE, the exposure for these WCS might be overestimated.

The number of workers performing the different tasks is confidential for both sites. The total number of directly exposed workers is less than 400 (< 100 (Trostre) and < 300 (IJmuiden)).

Table 9: Combined exposure and excess lifetime risk characterisation for the Trostre site (risk values per exposed worker)

Workers	Contributing Scenarios	Route	Exposure value (Cr(VI)) corrected for PPE, duration and frequency	Combined RCR or Excess cancer risk	
				Excess lung cancer risk	RCR for reproductive toxicity
Team leader	WCS 4, WCS 5	Inhalation	0.0186 µg/m^3	7.44 × 10^{-5}	
		Dermal	25.37 µg/kg bw/d		0.59
Team leader deputy	WCS 4	Inhalation	0.0116 µg/m^3	4.64 × 10^{-5}	
		Dermal	0.069 µg/kg bw/d		0.002
Entry operator	WCS 4	Inhalation	0.0116 µg/m^3	4.64 × 10^{-5}	
		Dermal	0.069 µg/kg bw/d		0.002
Exit operator	WCS 4	Inhalation	0.011.6 µg/m^3	4.64 × 10^{-5}	
		Dermal	0.069 µg/kg bw/d		0.002
Anode operator Type 1	WCS 1, WCS 4	Inhalation	0.01194 µg/m^3	4.76 × 10^{-5}	
		Dermal	2.26 µg/kg bw/d		0.053
Anode operator Type 2	WCS 2	Inhalation	0.00313 µg/m^3	1.25 × 10^{-5}	
		Dermal	0.49 µg/kg bw/d		0.011
Inspector*		Inhalation	0.220 µg/m^3	8.8 × 10^{-4}	
		Dermal	-		-
Expeditor*		Inhalation	0.220 µg/m^3	8.8 × 10^{-4}	
		Dermal	-		-
Forklift driver*		Inhalation	0.220 µg/m^3	8.8 × 10^{-4}	
		Dermal	-		-
External maintenance worker	WCS 4	Inhalation	0.0116 µg/m^3	4.64 × 10^{-5}	
		Dermal	0.069 µg/kg bw/d		0.002
Contract worker (cleaning)	WCS 5, WCS 6	Inhalation	0.0094 µg/m^3	3.76 × 10^{-5}	
		Dermal	25.37 µg/kg bw/d		0.59
External contractor for WWTP	WCS 3	Inhalation	0.00188 µg/m^3	7.52 × 10^{-6}	
		Dermal	0.18 µg/kg bw/d		0.004

Table 10: Combined exposure and excess lifetime risk characterisation for the IJmuiden site (risk values per exposed worker)

Workers	Contributing Scenarios	Route	Exposure value (Cr(VI)) corrected for PPE, duration and frequency	Combined RCR or Excess cancer risk	
				Excess lung cancer risk	RCR for reproductive toxicity
Team leader*		Inhalation	0.220 µg/m^3	8.8 × 10^{-4}	
		Dermal	-		-
Process operator	(WCS 1, WCS 2, WCS 4, WCS 5)/2 + 45 min WCS 9	Inhalation	0.03166 µg/m^3	1.27 × 10^{-5}	
		Dermal	28.05 µg/kg bw/d		0.652
Entry operator	WCS 4	Inhalation	0.0116 µg/m^3	4.64 × 10^{-5}	
		Dermal	0.069 µg/kg bw/d		0.002
Exit operator*		Inhalation	0.220 µg/m^3	8.8 × 10^{-4}	
		Dermal			-
Anode operator*		Inhalation	0.220 µg/m^3	8.8 × 10^{-4}	
		Dermal			-
Inspector*		Inhalation	0.220 µg/m^3	8.8 × 10^{-4}	
		Dermal			-
Process operator wastewater stream	WCS 3 + 105 minutes WCS 9	Inhalation	0.050 µg/m^3	2.0 × 10^{-4}	
		Dermal	0.18 µg/kg bw/d		0.004
Shift maintenance operators	WCS 4	Inhalation	0.0116 µg/m^3	4.64 × 10^{-5}	
		Dermal	0.069 µg/kg bw/d		0.002
Maintenance day shift	WCS 4	Inhalation	0.0116 µg/m^3	4.64 × 10^{-5}	
		Dermal	0.069 µg/kg bw/d		0.002
Contract maintenance worker	WCS 4, WCS 5	Inhalation	0.0186 µg/m^3	7.44 × 10^{-5}	
		Dermal	25.37 µg/kg bw/d		0.59
Contract worker	WCS 6	Inhalation	0.002375 µg/m^3	9.5 × 10^{-6}	
		Dermal	0.069 µg/kg bw/d		0.002

* These types of operators are not engaged in any specific tasks related to Cr(VI) exposure.

The applicants also considered a task-independent upper end exposure estimate of 0.220 µg/m^3 for exit operators, anode operators and for inspectors (IJmuiden) and for inspectors, expeditors and for forklift drivers (Trostre), in order to take possible exposure during non-Cr(VI) related activities into account. The applicants explained that a task related exposure estimate might underestimate the real exposure if it is taken into consideration that

operators also stay for different times in the area along the ETP line performing also other non-Cr(VI) related tasks. RAC agrees with this approach but does not take into account the upper end-estimate of 8.8×10^{-4} for all different types of workers. On RAC´s request, the applicants confirmed that their approach might have been too conservative for both sites. Stationary monitoring results as presented in Annex 3, CSR indicate that the Cr(VI) concentration is below the LoQ of 0.1 µg/m³ at most measuring points.

With respect to dermal exposure, the applicants pointed out that the modelling results might be conservative since dermal exposure is unlikely to occur due to the corrosive effects of the substance. In addition, the applicants did not differentiate between the use of CT and SD for calculating RCRs.

RAC notes that the applicants did not include the risk for the theoretical scenario WCS 8 which is currently not in place. The exposure estimate for this task is 0.5625 µg/m³ (much higher than the estimate of 0.220 µg/m³ for some workers). The applicants stated that this is a conservative estimate based on the assumption that no local exhaust ventilation or any containments are in place, only PPE. On RAC´s request, the applicants provided information on the RMMs considered for this task (see footnote 10).

3.2. Humans via Environment

According to RACs reference dose response relationship for carcinogenicity of Cr(VI) the following will be used to calculate the excess cancer risk for the indirectly exposed workers.

Based on exposure for 40 year working life (8 h/day, 5 days/week), the excess lifetime lung cancer mortality risk is 4×10^{-3} per µg Cr(VI)/m³, the excess lifetime intestinal cancer risk is 2.0×10^{-4} per µg Cr(VI)/kg bw/day.

The number of indirectly exposed workers is < 4 000 (< 2 000 (Trostre) and < 2 000 (IJmuiden)).

Table 11: Exposure and excess lifetime risk to indirectly exposed workers (risk values per worker)

Parameter	Indirectly exposed workers			
	Trostre site		IJmuiden site	
	Exposure	Excess risk	Exposure	Excess risk
Inhalation	8.12×10^{-4} µg Cr(VI)/m³	3.25×10^{-6}	6.61×10^{-3} µg Cr(VI)/m³	2.92×10^{-5}
Oral	3.66×10^{-5} µg Cr(VI)/kg bw/d	7.31×10^{-9}	2.73×10^{-4} µg Cr(VI)/kg bw/d	5.45×10^{-8}

Based on exposure for 70 years (24 hours/day, 7 days/week), the excess lifetime lung cancer mortality risk according to the RAC reference dose response relationship is 2.9×10^{-2} per µg Cr(VI)/m³ and the excess lifetime intestinal cancer risk is 8×10^{-4} per µg Cr(VI)/kg bw/day.

The assessment of human exposure via the environment at local and regional scale is based on EUSES modelling, version 2.12, using monitoring data as input data. However, RAC acknowledges that exposure to humans via the environment for the regional scale is not considered relevant for the risk characterisation since the estimated inhalation and oral exposure is far below the background values for both exposure routes.

Table 12: Exposure and excess lifetime risk to humans via the environment – local scale (risk values per exposed person)

Parameter	Local			
	Trostre site		IJmuiden site	
	Exposure	Excess risk	Exposure	Excess risk
Human via Environment – Inhalation	8.12×10^{-4} µg Cr(VI)/m^3	2.35×10^{-5}	6.61×10^{-3} µg Cr(VI)/m^3	1.92×10^{-4}
Human via Environment – Oral	3.66×10^{-5} µg Cr(VI)/kg bw/d	2.92×10^{-8}	2.73×10^{-4} µg Cr(VI)/kg bw/d	2.18×10^{-7}
Human via Environment – Combined		2.36×10^{-5}		$1.93^* \times 10^{-4}$

* Differences are due to rounding.

3.3. Shortcomings or uncertainties in the risk characterisation

The applicants have conservatively assumed that all inhaled chromium trioxide particles are in the respirable range and contribute to the lung cancer risk. The applicants also considered a task-independent upper end exposure estimate of 0.220 µg/m^3 for all different types of workers. RAC supports this conservative approach for shift operators and team leaders at the IJmuiden site as well as for team leaders, exit operators, anode operators and inspectors at the Trostre site. However, RAC is of the opinion that for the other types of workers the risk should be based on the respective exposure estimate. It might be a too conservative overestimate to base the risk in general on an exposure value of 0.220 µg/m^3 which results in a risk estimate of 8.8×10^{-4}.

It is not clear which type of operators are performing tasks in the control room (WCS 10) and there is no excess cancer risk estimate for WCS 8 (Dissolution of solid CT/SD). RAC notes that the risk for this task would be 2.25×10^{-3} considering no technical RMMs although a LEV with an effectiveness of 90 %[18] will be implemented according to information by the applicants on RAC's request.

However, the uncertainties affecting the risk characterisation seem to be minor and related mainly due to the shortcomings identified in the exposure assessment for workers and humans via the environment (see section 2.6). The worst-case approach to use 8.8×10^{-4} might be too conservative, particularly for the IJmuiden site since the measurements provided underpin that the workplace concentration is below 0.220 µg/m^3.

3.4. Conclusions on risk characterisation

The current exposure of workers or the exposure of man via environment (including indirectly exposed workers) reported in this application is below the DNELs for reproductive toxicity (RAC/35/2015/09, discussed at RAC-35) for all relevant exposure routes, therefore the risk of reproductive effects is considered to be adequately controlled. Such exposures still may cause a risk of lung or intestinal cancer. Taking that into account, the assessment of carcinogenic risk is central to the risk-benefits analyses for authorisation purposes, given that for the estimated exposure levels the reproductive toxicity would not contribute to the total ill-health risk.

[18] RAC notes that the effectiveness of 90 % has to be demonstrated.

The risk characterisation might be an overestimate since workers not engaged in any specific tasks related to Cr(VI) exposure end up in the highest risk. However, this shortcoming will be addressed with monitoring arrangements for the authorisation since more measurements would clarify the exposure for this type of workers.

Summing up, the tendency to overestimate the risk does not impede the risk characterisation.

RAC considers that the estimates of excess cancer risk for workers and for indirect exposure of humans via the environment (including indirectly exposed workers) calculated by the applicants allow a health impact assessment.

4. Analysis of Alternatives and substitution plan[19]

The applicants are end-users: the suitability of alternative is assessed from the perspective of the applicants.

What is the amount of substance that the applicants use per year for the use applied for?

29.28 tonnes per annum (expressed as Cr(VI) equivalent)

4.1. Summary of the Analysis of Alternatives and substitution plan by the applicants and of the comments received during the consultation and other information available

The Applied for Use scenario assumes that production of ETP will continue with the use of the chromium trioxide and sodium dichromate for the duration of the R&D efforts, and during this time, applicants will gradually convert their ETP lines to the use of the selected alternative.

The passivation of the tinplate coil is done to prevent oxidation. The tin oxide layer is passivated with a very thin layer of chromium oxide. This is an electrochemical treatment performed in a bath of chromium trioxide and/or sodium dichromate. As a result, a stable protective layer is formed, which consists of tin oxides, Cr(III) oxides, hydroxides and metallic chromium, and is free of Cr(VI).

Food contact materials and articles are strictly regulated both at EU level and national level. In this context the ETP chromium passivation is critical to make this material suitable for food packaging. Cr(VI) is used due to its chemical and electrochemical properties at providing corrosion inhibition to ferrous and non-ferrous metals. Any alternative substance or alternative technique must result in a product with the following technical requirements:

1. Tin oxide growth resistance (Critical)

2. Lacquer adhesion (Critical)

3. Suitability and Compatibility with the can making process (Critical)

[19] The judgment of the ECJ Case T-837/16 Sweden vs Commission stated that the applicant has to submit a substitution plan if alternatives are available in general. The Commission is currently preparing the criteria, derived from the judgment for establishing when an alternative is available in general. Once these are prepared this opinion format will be amended accordingly. The European Commission informed the REACH Committee in 9-10 July 2019 of its preliminary views on the criteria. In that note that Commission considered that the criteria defining a 'suitable alternative' would imply that it was i) *safer* and ii) *suitable*. Suitability would not mean it to be *"in abstracto"* or "*in laboratory or exceptional conditions*" but it should be "*technically and economically feasible in the EU*" and "*available, from the point of view of production capacities of the substance or feasibility of the technology, and legal and factual conditions for placing on the market*".

4. Sulphide staining resistance (Critical)

5. Market acceptance (Critical)

6. Compliance with the Food Contact Materials regulations (Critical)

7. Ability of the applicants to implement (Critical)

8. Temperature resistance (Important)

9. Tinplate process speed compatibilities (Important)

The research related to alternatives has taken place on both global level, where the screening of alternatives was initiated by The International Tin Research Institute (ITRI) and the International Tin Association (ITA), and on the European level, where the European tinplate manufacturers (APEAL) have continued the development of the most promising alternative. Applicants are APEAL-members and thus take active part in the R&D work.

As part of the ITRI/ITA Chromium Free Passivation development activities, a systematic review of the research work done in order to replace Cr(VI) based passivation of tinplate was performed. Applicants refer to this review in the application.

Alternative packaging materials such as glass, aluminium, plastic and composite carton, were also compared with the steel packaging.

Table 13: Possible alternative packaging materials

ECCS*	Could be an alternative for some applications, however this technology also uses Cr(VI) and it does not allow welding which is required for certain types of packaging (e.g. three-piece cans[20]).
Alternative not steel packaging materials	Can replace steel packaging only to a certain extent given the specific properties of steel packaging such as low weight, high recyclability, storage strength, vitamin preservation, etc. Additionally, from the applicants' perspective, other types of packaging are not available because these would require a totally different type of technology.

*At present the TCCT (Trivalent Chromium Coating Technology) material is being developed for the substitution of ECCS process. The alternative does not allow welding and thus it is not a technically feasible alternative for the applicant

Based on the key requirements for the end-product, the ITRI/ITA-project, initiated in 2006, considered numerous alternatives. The list of potential alternatives assessed include a long list of alternative surface treatments of the same substrate (i.e. tinned steel) as well as different substrates. Table 14 presents a summary of the long list of alternatives. Even though SEAC's opinion is that the table lacks some detail, SEAC acknowledges that applicants identified for each of the discarded possible alternative the main issue that led to not further pursue the alternative.

[20] In general, there are three types of metal package: two-piece cans, they consist of a separate top, bottom and side walls which are formed from one piece of steel; three-piece cans, they are composed of a cylinder (the wall of the can is rolled to form a cylinder and the seam is welded), a top and a bottom; and closures that are used to seal containers.

Table 14: Long list of alternatives

Alternative	Main issues identified by the applicant
Ti-based coatings (e.g.H_2TiF_6, Zr-Ti) (CFPA*)	Process issues, problems with bath stability
Ti^{III}/Ti^{IV} sulphate	Technical performance, problems with bath stability
K/Ti oxalate	Technical performance issues
Zr sulphates	Technical performance issues
Zirconium-based (Zirconium oxides / Zr-Ti / organic Zirconates)	Electrochemical process stability, Tin build-up in the solution
TripleHard Chrome coating (Savroc Ltd concept)	Regulatory issues (Ni used in process)
Silane/Siloxane (organometallics)	Technical performance and regulatory issues
Acidic anodising	Technical performance issues
Confidential (available to SEAC)	Confidential (available to SEAC)
Al-based coatings (e.g. Surtec 650, Alseal 5000, Liburdi LSR)	Technical performance and regulatory issues
Iridite NCP (Al, F, Oxygen)	Technical performance issues
Manganese-based treatments	Technical performance issues
Mineral Tie-Coat (cathodic Mineralisation)	Technical performance issues
Molybdate conversion coatings	Technical performance issues
Plasma electrolytic oxidation	Technical performance issues
Polymers - not specified	Technical performance issues
Polymers - Polyurethane	No main issue identified
Tagnite (inorganic Silica or vanadate	Technical performance issues
Vapor deposition based technologies: PVD (Physical vapor deposition), Sputtering (Materials used: TiN, ZrN)	Process issues, problems with process speed
Zn-Tin based coatings	Regulatory issues
Colophony RA 405	Technical and regulatory issues
Oleic Acid	Technical performance issues
Tungstates	Technical performance issues
Cr(III)-based passivation	Technical performance and regulatory issues

* Chromium-Free Passivation Alternative

From the long-list of alternatives, applicants list the three most likely candidates for substitution of Cr(VI) in ETP: CFPA, Cr(III)- and Zr-based -alternatives. Based on the initial screening, they were evaluated against the key functional parameters, CFPA was the only one to fulfil all parameters expect the applicants' customers' acceptance, as shown in Table 15. After the identification of the CFPA, 2014, as the most promising alternative, the applicants' efforts are focused on the development and implementation of this alternative. In 2017 a workgroup (a consortium) was established with this aim.

Table 15: Shortlisted alternatives

Required characteristic	Cr(VI)	CFPA	Zr Based	CR(III)*
Tin oxide Growth resistance	Acceptable	Acceptable	Partially Acceptable	Unknown
Lacquer Adhesion	Acceptable	Acceptable	Unknown	Unknown
Suitability and compatibility with the can making process	Acceptable	Acceptable	Unknown	Unknown
Sulphide staining resistance	Acceptable	Acceptable	Unknown	Unknown
Market acceptance	Acceptable	Partially Acceptable	Partially Acceptable	Unknown
Compliance with FCM Regulations	Acceptable	Acceptable	Unknown	Unknown
Ability of the Applicants to implement	Acceptable	Acceptable	Partially Acceptable	Unknown
Temperature Resistance	Acceptable	Acceptable	Unknown	Unknown
Tinplate Process Speed Compatibility	Acceptable	Acceptable	Unknown	Unknown

*Cr (III) coatings are too hard for can production.

The can-makers have to observe the full length of shelf-life testing. The can-makers are on their second iteration of the qualification process with CFPA, as the initial trials of CFPA failed due to detinning of the can in the customers' retorting processes. This issue resulted in a delay for the CFPA implementation. This issue was rectified in 2018. There is also some concern from the can-makers for the current process not being successful, which would require in the minimum reformulation of internal can coatings, but might also involve additional changes in CFPA alternative.

Overall, the assessment of alternatives gives a clear picture of the substitution of Cr(VI) at an industrial scale, and shows the commitment of the APEAL and the applicant, in doing so. SEAC concurs with the conclusion reached by the applicants in terms of suitability of alternatives, and the decision is in line with similar AfAs already subjected to SEAC scrutiny (0032-06; 0043-03; 0134-01).

Two comments were received in the consultation, from APEAL (Association of European Producers of Steel) and MPE (Metal Packaging Europe). Both are in support of the application, and the requested review period, stating that at present there are no suitable alternatives to the passivated ETP material and describe the substitution efforts, which are in line with the applicants' statement.

4.2. 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

The substances used in the Chromium-Free Passivation Alternative (CFPA) do not have a harmonised classification. Based on the notified classifications, the applicants compared the classification of the CPFA substances (skin corrosion and acute toxicity properties) with the classification of chromium trioxide. Due to this comparison, the applicants conclude that using the alternative would be a shift to less hazardous substances.

In addition, the applicants did not assess the risks of the alternative. RAC notes that without any proper risk characterisation no conclusion can be drawn with regard to the risk reduction capacity of CFPA.

4.3. Availability and technical and economic feasibility of alternatives for the applicant

Are there alternatives with the same function and similar level of performance that are technically and economically feasible to the applicants before the adoption of this opinion?

☐Yes ☒No

SEAC considers that the approach by the applicants in identifying and assessing alternatives allows for conclusions on the availability and suitability of alternatives. The AoA points out the applicants' past substitution R&D efforts which according to the information provided go back to at least 2006 with the participation on the International Tin Research Institute (ITRI) Global Chromium-free Passivation project. Moreover, AoA reports the R&D efforts to substitute the Cr(VI) passivation and to solve the issues raised during the implementation of the identified alternative technology. These issues are the ground for the applicants' need to extend the timeline for the full implementation of the alternative.

The applicants only provide details on the analysis of the most promising alternative that is the CFPA technology, Chromium-Free Passivation Alternative, that uses a Zirconium/Titanium Fluoride liquid solution to passivate the ETP with a mixture of zirconium and titanium oxides. This alternative currently is in an advanced stage of implementation with a manufacturing readiness level, for the applicants, close to the current industry standard. At present, the applicants have two ETP/CFPA swing lines, one in each site covered by the application, that are able to produce CFPA material for packaging purposes.

CFPA, is not an electrolytic process, the zirconium and titanium-based mixture is applied by spraying. Therefore, its implementation requires a substantial adaptation of the production process of passivated ETP. The applicants are waiting for the results of the customers' qualification tests to continue the gradual conversion of the current Cr(VI) ETP passivation lines. The lines conversion will require considerable engineering work and relevant financial resources that constrain the timeframe for the full implementation of CFPA. Applicants state that it is expected that by the end of 2027 all ETP lines have been converted.

CFPA implementation

The applicants' ETP passivation process using Cr(VI) is covered by CTAC and CCST AfAs submission consortia[21], that requested a review period of four years to implement the CFPA

[21] The applicants have applied for authorisation for the ETP process using chromium trioxide and sodium

alternative.

CTAC application was submitted in 2015 and CCST in 2016, and the respective opinions were issued in 2016 and 2017. In both of the applications it was stated that the substitution should take place by 2021, with the assumption that no major drawbacks are encountered.

However, in 2017, the customers' testing of the CFPA revealed detinning issues that occurred when the cans were submitted to post-treatments needed for food packaging. Detinning is undesirable from both aesthetic as well as a consumer safety perspective. Detinning means that there is a separation of tin from the can causing rust, which may involve flaking of tin pieces into the can filling, and is likely to lead to lacquer adhesion issues. A project was developed to solve this issue in cooperation with the tinplate manufacturers and can-makers. The project followed a Design of Experiments methodology, where several factors were tested as possible contributing factors to the deficient performance of the material. After six months, in early 2018, working together in the project, the applicants and their customers achieved a solution.

After the detinning project, yet another round of R&D was needed to solve issues related to the homogeneity of the CFPA material. This new project was also developed based in a Design of Experiments methodology and was successfully concluded in 2019.

Finally, in 2019, another R&D round was performed to fine-tune the tin oxide growth of CFPA, according to a specification set in the draft of the EN 10202. EN 10202 is currently being revised to incorporate CFPA as the new European standard passivation[22].

After the finalisation of the R&D rounds, CFPA material now needs to be tested in real-time over the shelf-life of the products, or up to 5 years. At present, can-makers' qualification testing is ongoing. The applicants reported that preliminary results suggest good performance for many product categories. Although these positive initial results, full shelf-life testing cannot be completed until 2024, allowing for 4-5 years for those products requiring the longest timelines. After successful tests, applicants need approximately 2 years to set up the full-scale production.

SEAC's evaluation / view on the availability and technical and economic feasibility of alternatives for the applicant

SEAC notes that the applicants' assessment of alternatives is transparent and includes not only alternative substances and processes but also alternative substrates and packaging materials. The applicants' selection of the alternatives is based on the aim to achieve a set of characteristics which allow to substitute Cr(VI)-based passivation of tinplate while retaining the desirable properties associated with the material.

SEAC also notes that the applicants' consumers are involved on the substitution effort with a relevant contribution to the R&D work.

SEAC agrees with the approach taken by the applicants to develop the CFPA in the various R&D rounds and do not find reasons to challenge the respective reported timelines.

The assessment of alternatives gives a clear picture of the feasibility of the substitution of

dichromate as part of CTAC (0032-06) and CCST (0043-03) submission consortia. The use of sodium dichromate for passivation of ETP has been granted by the commission for AD International BV (No. REACH/20/5/8). The relevant Commission decision is C(2020)2084. The CTAC application is pending.

[22] CanTech International, https://www.cantechonline.com/news/23954/thyssenkrupp-rasselstein-now-offers-chromium-free-passivation-alternative/, 16/09/2020

Cr(VI) at an industrial scale, and shows the commitment of the applicants in doing so.

The applicants state that the CFPA formulation and the production process, including human resources, is equivalent in costs to the current ETP passivation process. Therefore, it can be considered an economically feasible alternative. However, the adaptation of current ETP production lines will require relevant financial resources. Although this impact is taken as affordable by the applicants, it will constraint the alternative implementation pace. Also, based on the socio-economic analysis, the immediate substitution would results in high economic costs for the applicants without offsetting benefits, hindering their possibility for the investment.

The assessment regarding technical feasibility, economic feasibility and availability of the short-listed alternative is sufficiently detailed, and SEAC is thus able to concur with the conclusions reached by the applicants in terms of the suitability of alternatives.

The applicants justify quite well the ground for the extension of the timeframe to the CFPA implementation, and in response to SEAC's questions, clarify the uncertainties related to the AoA and the efforts made to the implementation of the CFPA since the previous application for authorisation. Both the AoA's results and the requested review period for the substitution are supported by the comments received during the consultation. Considering the advanced status of the CFPA substitution process, and some lack of information related to the observed unexpected failures, SEAC considered that seven years of review period can be challenged. Therefore, SEAC asked for more information on this, but the applicants only confirm the information already provided and claim confidentiality about other failures and difficulties observed. However, the information provided by the MPE[23] in the external consultation, which reported their own efforts and difficulties to adopt the CFPA material, specifically mentioned the issues related with organic coatings. These problems and difficulties can complicate the CFPA's implementation and are, per se, valid arguments which contribute to clarify the needs to expand the timeline for the Cr(VI) substitution.

Therefore, taking into account the information provided by the applicant, related to the issues faced during the substitution, and the information provided in the external consultation, in SEAC's view, a feasible alternative will not become available in a short period. This opinion is grounded mainly on time needed for the ongoing qualification testing of the upgraded CFPA material samples, as well as in the gradual conversion of the production lines that will be aligned with the gradual adoption of the CFPA material by the customers. SEAC, therefore, agrees with the applicants' outcome of the AoA and indeed, more time will be needed for the full substitution of Cr(VI).

4.4. Substitution activities / plan

Have the applicants submitted a substitution plan?

☒Yes ☐No

If yes, is the substitution plan credible and consistent with the analysis of alternatives and the socio-economic analysis?

☒Yes ☐No

The applicants performed a profound research and development work to substitute Cr(VI) in the ETP passivation. At present, the CFPA process is in a development stage during which a

[23] Metal Packaging Europe

full qualification testing is performed after the failures observed in the first samples tested by the applicants' costumers. The applicants' experience contributes to a clear substitution plan (where the timelines seem realistic, and which foresees an evaluation of the relevant implementation phases related with the technical feasibility of the CFPA material) with well-defined milestones.

In the current stage, the preliminary tests are ongoing, with promising early results. Qualification tests are also ongoing under the clients' responsibility and are expected to produce some results already, but the applicants, questioned by SEAC, reply that they do not have access to those results since they only will be published in 2021 and APEAL consortium "is not privy to specific results from any one can maker on any of its member's material" for compliance reasons. Since CFPA material will be exposed to a large diversity of environments and will be protected with quite different lacquers, the applicants do not exclude the possibility of some issues appearing during the qualification tests. Therefore, SEAC acknowledges the applicants' careful approach in the conversion of the current lines to achieve a CFPA full implementation.

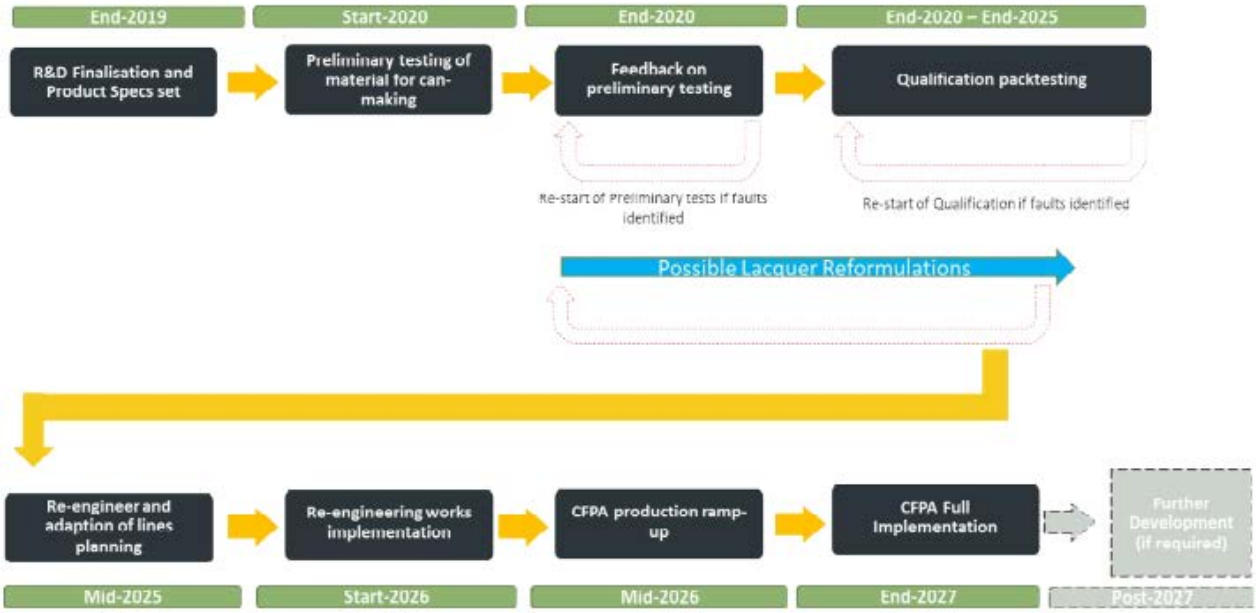

Figure 1: Flow Diagram of the expected timetable for complete implementation of CFPA.

SEAC's evaluation / view on the substitution plan

The applicants' substitution plan clearly outlines the actions needed to complete substitution, the timetable for implementing the changes and the current status of the substitution schedule. Upon request, the applicants clarified the current implementation stage and provided additional information on the ongoing testing of the improved CFPA material.

The substitution plan also includes a clearly defined organisational structure that considers the customers' involvement and includes a monitoring system to keep track of the success of the substitution project. In SEAC's view the substitution plan convincingly demonstrates that the substitution is likely to be completed by the end of 2027, but the issues that can occur in the qualification tests are identified and may lead to an eventual re-start of the qualification process.

4.5. Conclusions on the analysis of alternatives and the substitution plan

By the time of adoption of this opinion there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicants. The substitution plan was credible and consistent with the analysis of alternatives and socio-economic analysis.

5. Benefits and risks of continued use

Have the applicants adequately assessed the benefits and the risks of continued use?

☒ Yes

☐ No

5.1. Human health and environmental impacts of continued use

The main focus of the quantitative exposure estimation and risk characterisation for the workers is on the carcinogenic effects of inhalation exposure, i.e. lung cancer. Risks to the general population have been defined by the applicants in terms of lung cancer from inhalation and intestinal cancer from oral exposure (by ingestion of drinking water and consumption of fish) at local scale. The applicants stressed, however, that the reagents subject of the application are used in closed processes with a high degree of closure from an environmental point of view.

In the application, detailed information relative to the IJmuiden and Trostre production sites are provided confidentially, included in an spreadsheet requested by SEAC. Non-confidential values of excess cancer risks for the two plants for workers and general population were provided upon further request. Excess risks for the general population on the regional scale were omitted as negligible. Applicants provided both a base-case and a worst-case estimates for the health impact assessment, with the worst-case applying a conservative task-independent exposure level for all the workers. As explained by RAC in Section 3.3., and in Tables 9 and 10, RAC considers this risk value relevant for some WCSs, but not for all. SEAC has recalculated the health impacts based on the values provided by RAC.

In their calculations, the applicants applied a value of statistical life of €3.8 million, while for morbidity cost per statistical cancer case was used a WTP cost equal to €440 000 and medical costs estimate as €29 948 for lung cancer and €82 287 for intestinal cancer.

Workers

Since the excess cancer risk estimates apply to each exposed worker for a total working life of 40 years, to reflect exposures over the length of the review period, the applicants adjusted exposures over 7 years.

According to the applicants, a total of less than **400 workers** (public data provided on SEAC's request, more precise estimate is available for SEAC) are **directly exposed** at both sites. Combining these figures with excess risk values provided by RAC (Table 9), under the applied for use scenario there would be 2.1×10^{-3} statistical lung cancer cases among workers in Trostre and 1.77×10^{-2} in IJmuiden.

These translate into residual monetised risks for directly exposed workers of **€54 554** in total for the **directly exposed workers** over the requested review period of 7 years, as well as

the overall 12-year assessment period, since the use of the substances is expected to halt at the end of the review period.

General population

Indirectly exposed workers at local level

At local level, a total of less than 4 000 (< 2 000 at each site) (public range provided at SEAC's request, more precise estimate is available for SEAC) workers in an area within a radius of 1km the plants are indirectly exposed.

According to the excess risk values provided by RAC in Table 11, under the applied for use scenario there would be less than 1.15×10^{-3} statistical lung cancer cases among indirectly exposed workers in Trostre and less than 1.02×10^{-2} in IJmuiden. The exact values are confidential (but known to RAC and SEAC) so that the exact amount of workers cannot be calculated based on the excess cancer cases.

The monetised excess risk for the indirectly exposed workers would amount to €22 248 in total over the requested review period of 7 years.

Local population

For the local population, since excess cancer risks estimates apply for a lifetime of 70 years, the applicants adapted these figures over the 7 years review period.

At local level, according to the applicants' estimate, none is exposed in the area surrounding IJmuiden, while **1 000** (public range provided at SEAC's request) people living in an area with a radius of 1 km around Trostre are indirectly exposed.

According to the excess risk values provided by RAC in Table 12, under the applied for use scenario there are less than 2.35×10^{-3} statistical lung cancer cases for the local population living around Trostre while there are no statistical cancer cases in IJmuiden.

The monetised excess risk for the local population amounts at less than €5 556 in total over the requested review period of 7 years.

Total workers and general population (workers + local + regional)

Therefore, overall, a total monetised excess risk from the continued use of chromates can be estimated at **€87 330** (directly and indirectly exposed workers plus local general population) over the 7-year review period.

The table below summarises the additional statistical cancer cases and the related monetised risks.

Table 16: Summary of additional statistical cancer cases:

	Excess cancer risk[1]	**Number of exposed people**	**Estimated statistical cancer cases over the RP**	**Monetised excess risk over the RP**
Directly exposed workers[2]	Trostre: - Lung cancer: maximum value 8.8 × 10^{-4} IJmuiden: - Lung cancer: maximum value 8.8 × 10^{-4}	Trostre: < 100 IJmuiden: < 300 **Total: < 400**	Trostre: 2.1× 10^{-3} IJmuiden: 1.77 × 10^{-2} Total: 1.98 × 10^{-2}	Trostre: €4 965 IJmuiden: €49 589 Both sites: **€54 554**
Indirectly exposed workers[3]	Trostre: - Lung cancer 3.25× 10^{-6} - Intestinal cancer 7.31 × 10^{-9} IJmuiden: - Lung cancer 2.92 × 10^{-5} - Intestinal cancer 5.45 × 10^{-8}	Trostre: < 2 000 IJmuiden: < 2 000 **Total: < 4 000**	Trostre: < 1.15 × 10^{-3} IJmuiden: < 1.02 × 10^{-2} Total: < 1.14 × 10^{-2}	Trostre: €2 402 IJmuiden: €19 846 Both sites: **€22 248**
Subtotal		Trostre: < 2 100 IJmuiden: 2 300 **Total: < 4 400**	Trostre: < 3.25 × 10^{-3} IJmuiden: < 2.79 × 10^{-2} Total: < 3.12 × 10^{-2}	Trostre: €7 367 IJmuiden: €74 400 Both sites: **€81 767**
General population				
Local	Trostre: - Lung cancer 2.35 × 10^{-5} - Intestinal cancer 2.92 × 10^{-8}	Trostre: 1 000 IJmuiden: 0	Trostre: 2.35 × 10^{-3} IJmuiden: 0	Trostre: €5 563 IJmuiden: €0 Total: **€5 563**
Total			< 3.35 × 10^{-2}	 Both sites: **€87 330**

Notes:
1. Excess risk is estimated over a lifetime working exposure (typically 40 years) and via the environment over a typical lifetime exposure (typically 70 years);
2. Directly exposed workers perform tasks described in the worker contributing scenarios, typically based on 8-hour Time Weighted Average (TWA) of a representative worker;
3. Indirectly exposed workers (bystanders) do not use the substance;

Environment

The applicants did not carry out an environmental risks assessment since chromium trioxide and sodium dichromate have not been identified as SVHC for the environment; environmental releases are extremely low and Cr(VI) from chromium trioxide is expected to reduce to Cr(III) under most environmental conditions.

5.2. Benefits of continued use

Non-use scenarios

Consultations were carried out by APEAL at sectoral level with key members of the can-makers association (Metal Packing Europe (MPE) association), representing 40-50 % in 2018 of the total ETP consumption, as well as with national associations of can-makers.

The survey aimed at gathering a better understanding on how the supply chain would be impacted and what would be their reactions (non-use scenarios) in case the authorisation was not granted. Consultation with can-makers also intended to gain further information at sectoral level on tonnages, R&D efforts and the time required to complete current testing of CFPA (including testing required by their downstream can-fillers).

Based on this survey, the applicants drafted three potential non-use scenarios:

1. A **worst-case scenario** under which the ETP passivated with CFPA will not be accepted by can-makers within the next 4-5 years
2. A **main non-use scenario** under which can-makers would accept **35-55 %** of current use of ETP passivated with the selected chromium-free alternative from 2021, but they would not accept the remaining uses until the end of 2023 at the earliest and the end of 2026 for the more problematic applications or where new internal coatings are needed.
3. An ***overly-optimistic case*** under which ETP passivated with CFPA will be accepted by can-makers for 55-80 % of current use of passivated ETP from 2021 as pack tests prove positive for most applications, but will not be accepted for the remaining uses until 2023 at the earliest and 2026 for the more problematic applications or where new internal coatings are needed.

Table 17: Comparison of the non-use scenarios

	Acceptance of products passivated with CFPA	**Non acceptance of products passivated with CFPA**
Overly-optimistic case	ETP passivated with CFPA will be accepted by can-makers for 55-80 % of current use of passivated ETP from 2021 as pack tests prove positive for most applications.	ETP passivated with CFPA not be accepted for the remaining uses until 2023 at the earliest and 2026 for the more problematic applications or where new internal coatings are needed.
Main (most likely)	ETP passivated with CFPA will be accepted by 35-55 % of the existing EU passivated ETP market (e.g. general line/non-food products, such as paint cans).	ETP passivated with CFPA not be accepted by 45-65 % of the market, not feasible for technical and can performance reasons.
Worst-case scenario		ETP passivated with CFPA will not be accepted by can-makers within the next 4-5 years.

The applicants consider the main scenario (NUS2) as the most likely one.

In response to a question from SEAC, the applicants explained that current use of passivated ETP refers to the share of passivated ETP out of total ETP that is currently used on the steel packaging market (65-90 %).

The applicants estimated these and future percentages based on the results of the survey and on the assumption that the substitution would not face significant delays. In response to SEAC's question, the applicants clarified that the results of the survey concerning the can-makers' acceptance of the ETP passivated using CFPA were validated further by discussing

with the larger EU can-makers and other members of APEAL. Therefore, it was confirmed to SEAC that, complemented by these additional discussions, the survey is considered to be representative.

Under the most likely non-use scenario, the applicants expect that the ETP passivated with CFPA may be able to serve between 35-55 % of the existing EU passivated ETP market, e.g. general line/non-food products, such as paint cans. The applicants underlined that, to demonstrate equivalent performance of CFPA to Cr(VI) passivation, the remaining use of 45-65 % of applications would require further testing for the qualification of CFPA material before being accepted by the can-makers. According to the applicants, the most important user of passivated ETP, the food packing industry, will not be able to make the switch until all quality issues are solved to guarantee the safety of canned food and until pack-tests are finished.

According to the applicants, in 2021, there would be a loss of the remaining 45-65 % of EU demand, since can-makers will import from Asia given that the use of ETP produced using CFPA may not yet be technically feasible for the reasons explained earlier. In response to a specific question by SEAC on what could accelerate the can-makers willingness to accept ETP passivated with CFPA, the applicants indicated that it would depend on several factors. The applicants explained further that, first and foremost, the new CFPA-passivated material will have to pass the pack-tests to be able to fulfil legal food safety obligations. Moreover, the applicants underlined that changes of equipment or manufacturing processes will have to be made throughout the whole food can supply chain to ensure the compatibility with the lacquers inside the food cans. Processing the new material and ensuring its performance would need time.

During the consultation on this application for authorisation, MPE provided its support to the authorisation underlying that the substitution with CFPA involves complex changes within the can-making sector. Time is considered necessary to ensure that the continued safety of products is maintained to the highest standard.

According to the applicants, as a result of lower demand and loss in sales of 45-65 % of passivated ETP, there will be a significant negative impact on the applicants in terms of revenues. In the event of a substantial loss of the current demand (more than 50-70 %), corresponding to worst-case scenario, and for a continued period of time of several years, the applicants would have to completely **shut down** IJmuiden and Trostre plants, since the profits would no longer cover their fixed costs.

What is likely to happen to the use of the substance if an authorisation was not granted?

- the use would be taken up by market actors operating outside and inside the EU

What is likely to happen to jobs in the European Union if an authorisation was refused?

- Less than **750** jobs in the European Union would be lost

Economic impacts of continued use

The application presents a common impact assessment on a sectoral basis developed by all five members of **APEAL** who carried out together the survey with can-makers. The application is complemented by an annex (Annex 7) containing information specific for the applicants

(non-confidential ranges provided on SEAC's request, more precise estimate available to SEAC). It has to be noted that the sectoral analysis is based on the assumption that there would be significant impacts in terms of a shortage of passivated ETP in Europe, significant increase of import of ETP from Asia, and potentially significant impacts on retailers and consumers, should the authorisation not be granted. However, once only the impacts specific to the applicants and to their supply chain are considered, the picture changes since other members of APEAL, possible holders of their own authorisations in the future, could take part of the market which would reduce the overall impacts at the EU-level.

Moreover, it has to be underlined that, even if the applicants requested for a 7 year review period until the end of 2027, their impact assessment was carried out over a period of 12 years considering that the non-use scenario would entail negative impacts for **5 additional years** after the 2027. In the assessment done by SEAC, only 1-year profit losses for the applicants and their supply chain are taken into account to account for the loss of producer surplus during the entire assessment period. The reasons for this are explained in paragraph 5.5.

According to the applicants, there would be negative socio-economic impacts all along the vertically integrated supply chain associated with the manufacture of ETP. At sectoral level, under the non-use scenario, the whole European packaging steel industry would be impacted from steel mills, suppliers of raw materials and services to the manufacture of hot rolled coil (HRC) and of passivated ETP, can-makers, can-fillers, retailers and final consumers.

In Annex 7 and in response to further questions by SEAC, the applicants identified the avoided socio-economic impacts of continued use for themselves and for their supply chain:

- Monetised impacts for the suppliers of raw material in terms of avoided loss of profit due to lower demand of raw materials
- Monetised impacts on the applicants in terms of avoided foregone EBITDA (proxy for profit loss) due to lower sales in the most likely non-use scenario and avoided social costs of unemployment
- Monetised impacts for the can-makers in terms of avoided import costs
- Qualitative description of the impacts on can-fillers for moving to alternative packaging materials
- Qualitative description of the impacts on retailers, consumers, suppliers of alternatives, and importers

The following paragraphs report the sectoral picture as well as the specific impacts related to the applicants and their supply chain.

Impacts on suppliers of raw materials

In the application it is explained that EU suppliers of raw materials might be impacted at sectoral level. On SEAC's request the applicants provided figures on the impacts to their own suppliers.

Avoided profit losses

The sectoral part of the application explains that the reduced demand for HRC and ETP would entail profit losses to European **suppliers** of raw materials to the sector. The analysis by the applicants is based on the assumption that raw materials and services account for roughly 10-30 % of the tin mill costs for the production of ETP, the manufacturing costs of ETP is between €700-1 320 per tonne, and suppliers will face a profit margin of 12 %.

At SEAC's demand, for the avoided losses related only to their suppliers, the applicants provided a public range of less than €150 million over 12 years, i.e. a single year of avoided profit loss in the range of less than €13 million (estimated by SEAC).

Impacts on the applicants

In case an authorisation was not granted, the applicants would no longer be able to produce chromate-passivated ETP to meet the demand by can-makers. The applicants would lose a large part of their European sales and associated turnover. Moreover, most likely the whole **export** of the applicants' passivated ETP would be lost, since Cr(VI) passivated ETP would be available to non-EU can-makers from non-EU competitors who are not subject to the REACH requirements for authorisation.

Avoided loss of EBITDA

The steel industry's average EBITDA ranged from 10.5 % to 14 % with an average value around 12 % in 2017. For the estimation of loss of profit, this average was used by the applicants. The loss in profits was estimated over the period of 2019-2031 (over 12 years), based on the expected loss of export and expected loss of turnover with a 12 % profit margin. The loss of profit was estimated by the applicants to be less than €600 million over the assessment period of 12 years for an annual range of less than €50 million (estimated by SEAC). To simplify their monetised assessment, the applicants assume that the **steel makers** would incur all costs without entailing downstream impacts.

Avoided social costs of unemployment

Under the main scenario, **less than 750 direct** jobs are expected to be lost at the applicants' sites. The number of job losses is estimated to be equal to the proportion of loss of sales of the passivated ETP defined in the main non-use scenario. Thus, most of the job losses are expected to take place before 2026.

Based on the ECHA's methodology (2016) for the assessment of social costs of unemployment, the applicants estimated the costs of this **direct unemployment** at less than **€200 million**.

Other avoided costs not included in the applicants' assessment

According to the applicants, for unpassivated ETP-producing lines to remain economically viable sufficient amount of unpassivated ETP should continue to be sold to EU and non-EU clients. The applicants argue that there might be knock-on effects for the manufacture and sales of **HRC**, although these are not included in the applicants' assessment to avoid double-counting of losses.

According to the applicants, under the non-use scenario, they would incur additional costs of less than €30 million for the conversion of their current lines for producing ETP by using CFPA. However, since this amount would be spent under both the applied for use scenario and non-use scenario, this cost does not constitute an actual economic impact.

Moreover, according to the applicants, the applied for use scenario would avoid lack of competitiveness of the steel sectors and EU can-makers.

Impacts on can-makers

Based on the survey, in the case of non-use, at sectoral level, to continue to supply can-fillers, can-makers would start importing passivated ETP. According to the applicants, to get a comparable high-quality steel from Asian countries can-makers might experience higher prices to purchase chromium passivated ETP.

At sectoral level, it is expected that, by the end of 2027, EU can-makers would stop importing passivated ETP and start using ETP passivated with CFPA hence ETP suppliers would gradually recover 75 % of their current market shares. The remaining 15-20 % of their current market shares are expected to be regained over the next five years up to the end of 2032, while between 5-10 % of market share is assumed to be lost forever due to import or to the supply of alternative materials. In the consultations on the sectoral impacts, some can-makers indicated that they could decide to discontinue production or relocate all or a significant proportion of production to a country outside the EU.

Under the use applied for, at sectoral level the can-makers would continue operating as usual, using ETP in their production, until an alternative will cover all their uses. Among the impacts on can-makers of granting the authorisation, the applicants reported also costs savings on R&D into new can lacquers for certain food products.

Avoided import costs

Under the continued use the can-makers would not incur logistic costs to ship the ETP from South East Asia. The avoided import costs for the applicants' can-makers, including the increase in the price of ETP due to its shortage on the market, were monetised by the applicants, and a public range of less than €100 million over 12 years, i.e. less than €9 million for a single year (estimate done by SEAC).

Other European sectors

Avoided social costs

According to the applicants, if the authorisation was not granted, there would also be indirect and induced job losses within the EU for other relevant economic sectors). In the application, the sectors as well as the mechanism of induced job losses was not described clearly enough and clarifications were provided in response to SEAC's questions.

The applicants assessed the number of these job losses within the EU by using a multiplier approach, based on a study by Oxford Economics which estimates the indirect job losses resulting from reduced output in the steel sector. Through such multiplier effect, the applicants estimated that less than 4 000 jobs would be lost and the related social cost of unemployment would amount at less than €600 million.

Environmental impacts

In the application, the negative environmental externality associated with the shipping related to the need to import from Asia was monetised. Avoided environmental impacts are estimated based on an average of 8.4 g of CO_2 emitted per tonne and km. Using the UK guidelines, the monetization of environmental costs of CO_2 emissions is based on a value of €48 per tonne. The avoided environmental impact to replace the applicants' sales by import, is estimated by the applicants at less than €20 million over the assessment period, i.e. less than €2 million

over a single year (estimate done by SEAC).

Moreover, according to the applicants, the applied for use scenario would potentially avoid a negative impact in terms of recyclability of the alternative packaging types.

Wider economic impacts

In the application, wider economic impacts are qualitatively described at sectoral level in the application. Can-fillers would potentially need to change to alternative packaging materials, retailers might face costs due to a decreased shelf-life of the products, consumers might experience minor increases of final prices of canned food, importers of passivated ETP and suppliers of alternative packaging materials might gain market share. These sectoral impacts are shortly described below.

Impacts on can-fillers

In the sectoral analysis, as well as on that specific for the applicants, it is assumed that can-makers would absorb most of the costs increase without passing them to can-fillers. Therefore, there would be no or only minor impacts on can-fillers. However, according to the sectoral analysis, in the case of absence of an EU production, if there would not be sufficient chromate passivated ETP at global level, to meet EU demand, can-fillers might start using new packaging materials. Can-fillers might need to shift to alternative sources of packaging, with this resulting in the need to invest in new filling technologies potentially impacting their product ranges.

Impacts on retailers

In the sectoral analysis it is also indicated that the potential shift to alternative packaging materials might lead to increased costs for retailers, due to a reduction in the shelf-life of food packed in alternative packaging. If costs to retailers rise, for the end consumers there might be minor increases of prices.

Impacts on importers of passivated ETP

According to the sectoral part of the application, importers of passivated ETP would benefit from increases in demand and obtain a market advantage over EU producers who will be unable to supply EU can-makers in the short term.

Impacts on consumers

As a consequence, in the sectoral analysis, it is explained that **consumers** might experience minor increases of final prices of food cans. Moreover, in case an alternative packaging would have to be used, the applicants claim that there might be an increase of food waste due to reduced shelf-lives or to the failure of packaging.

Impacts on suppliers of alternatives

In the sectoral analysis, the EU producers of alternative packaging might gain market share if there are shortages of passivated ETP at global level. However, the applicants claim that alternative packaging may not be suitable for all food products.

Table 18: Socio-economic benefits of continued use for the assessment period

Description of major impacts	Quantification of impacts
1. Benefits to the applicants and/or their supply chain	
1.1 Avoided profit loss due to investment and/or production costs related to the adoption of an alternative	
1.2 Avoided profit loss due to ceasing the use applied for[24]	< €50 million for the applicants (annual estimate done by SEAC to account for the entire assessment period) < €13 million for suppliers of materials (annual estimate done by SEAC to account for the entire assessment period)
1.3 Avoided relocation or closure cost	
1.4 Avoided residual value of capital	
1.5 Avoided additional cost for transportation, quality testing, etc.	< €9 million import costs for the can-makers (annual estimate done by SEAC to account for the entire assessment period)
Sum of benefits to the applicants and / or their supply chain	< €72 million
2. Quantified impacts of the continuation of the SVHC use applied for on other actors	
2.1 Avoided net job loss in the affected industry[25]	< €200 million for direct job loss
2.2 Foregone spill-over impact on surplus of alternative producers	
2.3 Avoided consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity, etc.)	
2.4 Avoided other societal impacts (avoided CO_2 emissions)	< €2 million (annual estimate done by SEAC to account for the entire assessment period)
Sum of impacts of continuation of the use applied for	< €202 million
3. Aggregated socio-economic benefits (1+2)	< €274 million

5.3. Combined assessment of impacts

The total benefits of continued use of Cr(VI) for the passivation of ETP are estimated at less than €274 million for the assessment period, while the health risks are estimated at €87 330.

[24] Profit losses to be counted in only for a single year, see SEAC note on economic surplus changes (not yet available).
[25] Job losses to be accounted for only for the arithmetic mean period of unemployment in the concerned region/country as outlined in the SEAC paper on the valuation of job losses (See The social cost of unemployment and Valuing the social costs of job losses in applications for authorisation).

As a result of the additional explanations provided by the applicants on SEAC's request, SEAC considers that any remaining uncertainties would not change SEAC conclusion.

Table 19: Socio-economic benefits and risks of continued use

Socio-economic benefits of continued use		**Excess risks associated with continued use**	
Benefits	**For the applicants:** **total annual EBITDA loss for** < €50 million (annual estimate done by SEAC to account for the entire assessment period) Avoided **social cost** of direct unemployment < €200 million **For suppliers of materials**: Avoided losses of < **€13 million due to** reduced demand for HRC and ETP (annual estimate done by SEAC to account for the entire assessment period) **For can-makers** Avoided economic losses of < **€9 million** to replace passivated ETP with imported material or alternative packaging. (annual estimate done by SEAC to account for the entire assessment period) **Environmental avoided impacts:** < €2 million benefits from avoided increased CO_2 emissions due to shipping of of ETP from Asia and to the less efficient steel production process outside Europe. (annual estimate done by SEAC to account for the entire assessment period)	Monetised excess risks to workers directly exposed in the use applied for	€54 554 over the review period
Quantified impacts of the continuation of the SVHC use applied for	Avoided **direct job loss** to Tata Steel for less than **750** (public data on job loss provided at SEAC's request)	Monetised excess risks to the general population and indirectly exposed workers	€32 776 over the review period
Additional qualitatively assessed impacts	**For the applicants** Avoided knock-on effects for the manufacture and sales of HRC. Avoided lack of competitiveness **For EU can-makers** Avoided potential loss of competitiveness **Additional impacts in the assessment at sectoral level** **For the EU society** Avoided **circular economy** impacts if the whole sector will be impacted less recyclable packaging materials and increased food wastage. **For retailers**	Additional qualitatively assessed risks	

	Avoided increased costs due to a reduction in the shelf-life of food packed in alternative packaging. **For consumers** Potentially avoided increase in prices **For other EU sectors** Indirect and induced job losses and related social costs		
Summary of socio-economic benefits	< €274 million over the assessment period	**Summary of excess risk**	€87 330 over the review and assessment periods

5.4. SEAC's view on Socio-economic analysis

SEAC notes that the application is mostly based on a sectoral assessment. Even if indeed Annex 7 of the application contains the specific (but confidential) data for the two applicants, from the application it could be misunderstood that the applicants for authorisation are all five members of **APEAL**. In response to SEAC's question, the applicants clarified that this application only covers the Tata Steel legal entities, i.e. Tata Steel UK and Tata Steel IJmuiden B.V. It was clarified that the application is based on a joint effort of the APEAL members, covering 100 % of the European market of passivated ETP, who collaborated for developing the CFPA as a common alternative, as well as for drafting a sectoral impact assessment based on a common survey. On SEAC's request, the applicants explained that, while, in the main part of the application for the sectoral analysis, all members of APEAL use the same common bundle of core documents, the application was complemented by an annex containing company specific information. Though in the application, all company specific figures were claimed confidential (but available to SEAC), on SEAC's request, the two applicants provided non-confidential socio-economic figures.

The applicants explained that other APEAL members will submit their own applications complemented by annexes including their company specific information.

SEAC notes that three **non-use scenarios** have been considered by the applicants: a worst-case scenario, a main (and most likely) scenario and an overly optimistic scenario. These scenarios were drafted by taking into consideration the potential percentage of current uses of ETP passivated by using CFPA accepted by the can-makers, and the timeframe within which this would happen (2021, 2023 or 2026). SEAC notes that the applicants established the main and most likely non-use scenario based on the results of the survey carried out by the applicants prior to this application.

Taking into consideration the additional information provided by the applicants on SEAC's request, SEAC considers credible the applicants' main non-use scenario under which can-makers would accept 35-55 % of current use of ETP passivated with the selected alternative from 2021, but they would not accept the remaining uses until the end of 2023 at the earliest and by the end of 2026 for the more problematic applications or where new internal coatings are needed.

SEAC notes that the applicants consider that the non-use scenario would entail negative impacts for **5 additional years** after the requested review period until the end of 2027. As a consequence, the applicants have carried out their assessment over a 12-year assessment

period. SEAC notes that in principle, the assessment period should correspond to the review period applied for. Anyway, SEAC considers that, since only 1-year profit losses along the supply chain are to be considered, a longer assessment period does not contribute to any potential overestimation in the final comparison of impacts.

With regard to **economic impacts**, SEAC notes that, according to the application, the non-use scenario would entail socio-economic impacts on the whole large and vertically **integrated EU supply chain** associated with the manufacture of passivated ETP: steel mills, suppliers of raw materials and services, can-makers, can-fillers, retailers and final consumers.

Considering this application from the point of view of the two Tata Steel applicants and not of the steel sector, in SEAC's view, in case the authorisation was not granted, there would be negative socio-economic impacts only along the applicants' supply chain. SEAC considers that, at least until substitution with CFPA is completed, European competitors could take over most of the applicants' market share of passivated ETP, while competitors from outside the EEA would gain only the remaining share since European can-makers would prefer not to import. In fact, SEAC notes that at least one member of APEAL has already applied for an authorisation for the use of Chromium Trioxide for the passivation of ETP with a positive opinion and a recommendation for a seven year review period by SEAC. Because of this, SEAC assumes that applicants' competitors can respond to the demand from the market with passivated ETP with some temporal friction.

SEAC notes that the applicants estimated their economic impacts during the assessment period in terms of foregone EBITDA.

SEAC considers, that the annual value of **EBITDA loss**, both for the applicants and the suppliers, is a more relevant measure of changes in producer surplus than the total EBITDA loss over the assessment period, and the appropriate measure to monetise the welfare implications of continued use. Considering the economic losses over a long time period does not take into account the possibility of mitigating actions that could reduce the socio-economic impacts (e.g. resources being redeployed by the applicants or by other companies) and it may overestimate the long-term impacts, to account for the net changes in producer surplus over the assessment period, SEAC considers more appropriate to use a single year loss in EBITDA (< €50 million – estimated by SEAC) instead the EBITDA loss incurred by the applicants over 12 years. The same applies for loss of profit for suppliers (< €13 million calculated by SEAC), to additional import costs for the can-makers' (< €9 million calculated by SEAC).

In addition, based on the explanation provided by the applicants in response to further questions, SEAC considers plausible the applicants' claim that some of their existing production configuration and production lines might have to be restructured as a consequence of a reduction of 50-70 % sales.

SEAC notes that in the main NUS, the applicants estimated a total loss of less than 750 direct jobs entailing a social cost of unemployment monetised at less than €200 million. SEAC recognises that in their assessment, the applicants have followed the methodology in the ECHA's note to estimate the **social costs** of unemployment.

Concerning the loss of less than 4 000 indirect and induced jobs (for a social cost of unemployment of €600 million) for other EU economic sectors, on SEAC's request, the applicants explained that the indirect employment multiplier of 7.5 was applied. This was based on a study referred to in the application. However, SEAC does not include this benefit item in the final assessment of impacts since it is not clear what the concerned European sectors are and since the multiplier is not based on a methodology agreed by ECHA. However, SEAC notes that not considering the maintained employment in other European sectors would likely

underestimate the total benefits of continued use. In the assessment of impacts done by SEAC, these social costs are qualitatively considered as wider economic impacts.

SEAC also takes note of the applicants' assessment of **wider economic impacts** and considers plausible that the non-use scenario might lead to a loss of competitiveness for the applicants and potentially for EU can-makers, as well as negative impacts on the circular economy due to the use of less recyclable packaging and to the potential increase of food wastage. SEAC also recognises that due to at least partial increase of import, the continued use might avoid some environmental impacts in terms of CO_2 related to the need for the can-makers to import at least some passivated ETP from Asia. However, SEAC notes that can-makers might need to import only if other European producers would not be granted an authorisation and would not have spare production capacity to satisfy the demand left unserved by the applicants. Thus, annual value (< €2 million calculated by SEAC) is applied for the environmental impact to account for the entire assessment period.

SEAC acknowledges that the applicants have estimated the **human health impacts** following ECHA guidelines. SEAC notes that mortality and morbidity costs constitute the monetised excess **risk** in the applied for use scenario. SEAC acknowledges that the applicants used a methodology based on ECHA's SEA guidance and ECHA's note on **willingness to pay (WTP)** values for various health endpoints associated with chemical exposure. These values were adjusted by the applicants for inflation. SEAC also notes that the applicants used the higher value of statistical life.

SEAC acknowledges that for workers and for general population exposed to Cr(VI) substance, costs related to lung and intestinal cancer have been quantified by the applicants using ECHA's note (2013, RAC-27) that establishes a dose-response relationship for the carcinogenicity of Cr(VI). These dose-response relationships are used in the applicants' calculations to derive the excess lifetime cancer risks for directly and indirectly exposed workers, as well as for the general population on both the local and regional scale. SEAC has recalculated the health impacts based on the excess risk values proposed by RAC in Tables 9, 10 and 11.

SEAC notes that, taking into account the conservative nature of the dose-relationship on small doses, the use of the higher value of statistical life and the fact that the applicants have assumed constant level of exposure to Cr(VI) for workers and the general population despite the on-going substitution, it can be considered that the applicants adopted a conservative approach to estimate the health impacts (i.e. health impacts are likely to be overestimated by the applicants).

SEAC considers that the review period until the end of 2027 requested by the applicants is well justified by the time needed for the line conversion and full market acceptance of the CFPA, with the most time-consuming element being the pack-testing by can-makers. SEAC notes that no major uncertainties are related to the socio-economic analysis nor the justification for the requested review period.

SEAC notes that, during the consultation, APEAL and the MPE expressed their support for this application.

5.5. Conclusion on the socio-economic analysis

SEAC has no reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the risks to the environment associated with the continued use of the substance. This conclusion is made on the basis of:

- the application for authorisation,

- SEAC's assessment of the benefits of continued use,
- SEAC's assessment of the availability, technical feasibility and economic viability of alternatives,
- any additional information provided by the applicants or their downstream users,
- RAC's assessment of the risks.

6. Proposed review period

☐ Normal (7 years)

☐ Long (12 years)

☐ Short (…. years)

☒ Other: until the end of 2027

When recommending the review period SEAC took note of the following considerations:

6.1. RAC's advice

RAC did not offer any advice to SEAC regarding the length of the review period.

6.2. Substitution and socio-economic considerations

- The analysis of alternatives and the public consultation demonstrated without significant uncertainties that currently there are no suitable alternatives for chromium trioxide utilisation under the scope of the use applied for.
- SEAC considers that the applicants have been proactive in undertaking research to develop an alternative and is committed to continuing the R&D efforts to implement the CFPA process.
- SEAC considers that the involvement of the clients in the substitution process is very well integrated in the substitution efforts and add value to the substitution process.
- The applicants have started the process to substitute to the CFPA alternative and show clearly its commitment to implement the CFPA process.
- Taking into account that the applicants authorisation to use sodium dichromate extends until 2024, the review period until the end of 2027, in practice, is an extension of three years to the previously granted period, to complete the substitution. This extension is well justified by the issues faced during the substitution and in the testing related to the demanding requirements for the new material. SEAC has taken into consideration that the new material has to be able to be in contact with food, and so, has to be able to fulfil legal food safety obligations.
- The development of CFPA material is not yet totally satisfactory in terms of performance. However, it is likely that this alternative will become available and be implemented for the use applied for within a normal review period, but that it cannot be assured by the applicants at the present stage of implementation since that also depends on the material client adoption.

- SEAC has no substantial reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the monetised risks to human health associated with the continued use of the substance.

Taking into account these points, SEAC recommends a review period until the end of 2027.

7. Proposed additional conditions for the authorisation

Were additional conditions[26] proposed for the authorisation?

☐ Yes

☒ No

7.1. Description

RAC

Proposed additional conditions

-

SEAC

Proposed additional conditions

-

7.2. Justification

According to RAC, the RMMs and OCs presented by the applicants are appropriate and effective in limiting the risks for workers and humans via the environment, provided that they are adhered to. Therefore, no conditions for the authorisation are proposed.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements[27] proposed for the authorisation?

☒ Yes

☐ No

8.1. Description

(a) The applicants shall continue to implement and conduct an annual occupational/workers exposure monitoring programmes for Cr(VI) for both sites. Those programmes shall be based

[26] Conditions are to be proposed where RCR is > 1, OCs and RMMs are not appropriate and effective, risk is not adequately controlled, minimisation of emissions is not demonstrated.
[27] Monitoring arrangements for the authorisation are to be proposed where RCR is < 1, OCs and RMMs are appropriate and effective, risk is adequately controlled, minimisation of emissions is demonstrated – but there are some moderate concerns.

on relevant standard methodologies or protocols, comprise both static and personal inhalation exposure sampling and be representative of:

(i) the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance workers;

(ii) the OCs and RMMs typical for each of these tasks;

(iii) the number of workers potentially exposed.

In case WCS 8 is implemented, the applicants shall conduct static control measurements immediately after the establishment of this scenario and include this scenario in their regular occupational exposure monitoring programmes.

(b) The applicants shall continue conducting monitoring programmes for Cr(VI) emissions to air at least annually for both sites. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the OCs and RMMs used at the applicants´ site.

(c) The information gathered via the measurements referred to in points (a) and (b) and related contextual information shall be used by the applicants to evaluate the effectiveness of the RMM and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to a level as low as technically and practically feasible.

(d) The applicants shall ensure that the application of RMMs[28] at their site is in accordance with the hierarchy of control principles.

(e) The information from the monitoring programmes referred to in points (a) and (b), 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 point (c), shall be documented, maintained and be made available by the applicants, upon request, to the national competent authority of the Member State where the authorised use will take place.

8.2. Justification

RAC considers that the exposure assessment for workers and humans via the environment (including indirectly exposed workers) contains some residual shortcomings due to the lack of workplace air measurements at the Troste site and measurements on emission to air, specific for the two sites in Trostre and IJmuiden. RAC also considers that exposure estimates should be based on a comprehensive measurement dataset to ensure their representativeness. Therefore, monitoring arrangements were proposed for the authorisation.

RAC points out that since at the IJmuiden site, a higher amount of Cr(VI) will be used, they should continue to measure regularly the exposure to Cr(VI).

Since WCS 8 will be performed in case of shortage of liquid CT/SD, the effectiveness and appropriateness of the RMMs implemented should be confirmed by measured data.

Although RAC considers that these shortcomings would not be expected to lead to significantly higher exposure estimates compared to those considered for the risk characterisation, RAC is of the opinion that the applicants should address these shortcomings by obtaining

[28] PPE is the final level in the hierarchy of control after engineering and organisational RMMs and only acceptable when RMMs higher in the hierarchy do not minimise exposure or are in development.

representative measurements for workers exposure and environmental releases.

9. Recommendations for the review report

Were recommendations for the review report made?

☒ Yes

☐ No

9.1. Description

The information gathered via the measurements referred to in section 8 points (a) and (b) as well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report.

9.2. Justifications

Provision of the representative monitoring results for both worker exposure and releases to the environment would allow for better evaluation of the actual situation at the applicants' sites and would confirm the appropriateness and effectiveness of OCs and RMMs in place.

10. Comments on the draft final opinion

Did the applicants provide comments on the draft final opinion?

☐ Yes

☒ No

10.1. Comments of the applicants

Was action taken resulting from the analysis of the comments of the applicants?

☐ Yes

☐ No

☒ Not applicable – the applicants did not comment

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

Not applicable.

10.3. Reasons for not amending the opinion

Not applicable.