Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on a Review Report for

Chromium trioxide

Industrial formulation of a chromium trioxide solution below 0.1 % w/w concentration for the passivation of copper foil used in the manufacture of Lithium-Ion Batteries (LiB) for motorised vehicles

Submitting authorisation holder

Volta Energy Solutions Hungary Kft

ECHA/RAC/SEAC: AFA-O-0000007018-76-01/F

Consolidated version

Date: 02/12/2021

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

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

Authorisation holder	**Volta Energy Solutions Hungary Kft** (position in supply chain: downstream)
Substance ID EC No CAS No	**Chromium trioxide** 215-607-8 1333-82-0
Intrinsic properties referred to in Annex XIV	☒Carcinogenic (Article 57(a)) ☒Mutagenic (Article 57(b)) ☐Toxic to reproduction (Article 57(c)) ☐Persistent, bioaccumulative and toxic (Article 57(d)) ☐Very persistent and very bioaccumulative (Article 57(e)) ☐Other properties in accordance with Article 57(f)
Use title	**Industrial formulation of a chromium trioxide solution below 0.1 % w/w concentration for the passivation of copper foil used in the manufacture of Lithium-Ion Batteries (LiB) for motorised vehicles**
	Other connected uses: N/A
	Same uses applied for: 0128-01 (initial application for authorisation)
Use performed by	☒Authorisation holder ☐Downstream User(s) of the authorisation holder
Use ID (ECHA website)	0229-01
Reference number	11-2120869648-33-0001
RAC Rapporteur	Rudolf VAN DER HAAR
SEAC Rapporteur SEAC Co-rapporteur	Luisa CAVALIERI Christos ANASTASIOU

ECHA Secretariat	Monique PILLET Simone GERVASUTTI

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the review report	22/12/2020
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	02/02/2021
The review report has been submitted 18 months before the expiry of the review period of the granted authorisation and the authorisation holder can benefit from the transitional arrangements	☒Yes ☐No
Consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	17/02/2021-14/04/2021
Comments received	☐Yes ☒No Link: N/A
Request for additional information in accordance with Article 64(3)	On 23/03/2021, 11/05/2021 and 15/06/2021 Link: Adopted opinions and previous consultations on applications for authorisation - ECHA (europa.eu)
Trialogue meeting	Not held – not needed considering no new information submitted in the consultation and the responses of the authorisation holder to the Committees' requests for additional information.
Extension of the time limit set in Article 64(1) for the sending of the draft opinions to the authorisation holder	☐Yes ☒No
The review report included all the necessary information specified in Article 62 that is relevant to the Committees' remit	☒Yes ☐No
Date of agreement of the draft opinion in accordance with Article 64(4)(a) and (b)	RAC: 16/09/2021, agreed by consensus.
	SEAC: 15/09/2021, agreed by consensus.

Date of sending of the draft opinion to the authorisation holder	27/10/2021
Date of decision of the authorisation holder not to comment on the draft opinion, in accordance with Article 64(5)	02/12/2021
Date of receipt of comments in accordance with Article 64(5)	Not relevant
Date of adoption of the opinion in accordance with Article 64(5)	RAC: 02/12/2021, adopted by consensus.
	SEAC: 02/12/2021, 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 DNEL(s) for the carcinogenic properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC concluded that currently there are no technically and economically feasible alternatives available for the authorisation holder 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 review report are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

The highest inhalation exposure (8h adjusted TWA) to workers was estimated to be 1.0×10^{-3} µg Cr(VI)/m^3. For reference, the Binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025).

The exposure to the general population was estimated to be (inhalation, local) 2.3×10^{-4} µg Cr(VI)/m^3 per 24h and (oral, local) 6.4×10^{-4} µg Cr(VI)/kg bw/day.

The excess lifetime cancer risk for workers is estimated to be 4.0×10^{-6} (inhalation, 8h TWA exposure for 40 years, highest value) and 6.6×10^{-6} (inhalation, local, for 24h exposure for 70 years) for the general population.

THE OPINION OF SEAC

SEAC has formulated its opinion on:

- the socio-economic factors, and
- the suitability and availability of alternatives associated with the use of the substance as documented in the review report, 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 substance in accordance with Annex I of the REACH Regulation.

The following alternatives have been assessed (see section 4 of the Justifications):

- Molybdate plating
- Cr(III) plating
- Silane application on the foil
- Electrophoretic deposition of graphene
- Self-assembled monolayers
- 'Chemical' solutions (e.g., conversion coatings)
- Vacuum techniques (physical vapour deposition, chemical vapour deposition)

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

- By the date of adoption of the 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 authorisation holder.
- 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 at least €10-100 million per year and additional benefits to society have been assessed qualitatively but have not been monetised. These additional benefits comprise the avoided loss of job opportunities and avoided wider economic impacts.
- Considering:
    - the endpoints relevant for listing the substance in Annex XIV of REACH;
    - the 28 directly exposed workers;
    - the general population exposed at local scale (up to 10 000 persons for oral exposure and up to 200 persons for inhalation exposure);
    - the risk of continued use as assessed by RAC may result in up to 4.03×10^{-5} additional cases of cancer per year;
    - the monetised risk of continued use is up to €128 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 authorisation holder's assessment of the benefits and the 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:

- cease altogether
- 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]

- 100-300 jobs would be lost

PROPOSED CONDITIONS AND MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

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

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

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

REVIEW PERIOD

Taking into account the information provided in the review report submitted by the authorisation holder, a review period **until 10 January 2032** is recommended for this use.

SUMMARY OF THE USE APPLIED FOR

Role of the authorisation holder in the supply chain	Upstream ☐[group of] manufacturer[s] ☐[group of] importer[s] ☐[group of] only representative[s] ☐[group of] formulator[s] Downstream ☒downstream user
Number and location of sites covered	One site in Környe (near the city of Tatabanya), Hungary
Annual tonnage of Annex XIV substance used per site (or total for all sites)	100 tonnes CrO_3/year (15 tonnes CrO_3/year in the initial application)
Function(s) of the Annex XIV substance	Chromium trioxide has no independent function at the formulation stage. During the passivation, the substance fulfils three major technical roles in copper foil used for Lithium-Ion Batteries: • Prevent oxidisation of the foil during storage or further processing and during the use of Lithium-Ion Battery anodes; • Prevent the propagation of cupric ions throughout the battery during its lifetime use; • Improve battery performance (capacity, cell's impedance, and peel strength of anode film).
Type of products (e.g., articles or mixtures) made with Annex XIV substance and their market sectors	The use applied for is the formulation of a chromium trioxide solution that is subsequently used by the authorisation holder to produce passivated copper foil for the manufacture of Lithium-Ion Batteries for motorised vehicles.
Shortlisted alternatives discussed in the review report	Molybdate plating Cr(III) plating Silane application on the foil Electrophoretic deposition of graphene Self-assembled monolayers 'Chemical' solutions (e.g. conversion coatings) Vacuum techniques (physical vapour deposition, chemical vapour deposition)

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: 28 Indirectly: -
Number of humans exposed via the environment	Local scale: 200 (inhalation), 10 000 (oral) Regional scale: Not relevant
Releases to the environmental compartments	☒Air ☒Water ☐Soil ☐None
The authorisation holder has used the dose-response relationship recommended by RAC	☒Yes ☐No ☐Not relevant
All endpoints listed in Annex XIV were addressed in the assessment	☒Yes ☐No
All relevant routes of exposure were considered	☒Yes ☐No
Adequate control demonstrated by the authorisation holder for the relevant endpoint(s)	☐Yes ☐No ☒Not applicable – non-threshold substance
Level of (combined, daily/shift-long) exposure/release used by the authorisation holder for risk characterisation	Workers: Inhalation:0.072 µg Cr(VI)/m^3 (highest value) Humans via environment: Inhalation: 2.28 × 10^{-7} mg Cr(VI)/m^3 Oral: 4.42 × 10^{-7} mg Cr(VI)/kg bw/day
Risk characterisation	Workers: 1.5 × 10^{-4} (highest value) Humans via environment: 1.3 × 10^{-5}
Authorisation holder is seeking authorisation for the period needed to finalise substitution (‘*bridging application*’)	☐Yes ☒No ☐Unclear

Review period argued for by the authorisation holder (length)	Until 10 January 2032
Most likely non-use scenario	Permanent shutdown of the current production facility and the planned two new production facilities will not be built
Authorisation holder concludes that benefits of continued use outweigh the risks of continued use	☒Yes ☐No ☐Not applicable – threshold substance with adequate control
Authorisation holder's benefits of continued use	Avoided EBIT losses: €10-100 million (annualised)
Society's benefits of continued use	Avoided job losses: €0.1-1 million (annualised) Avoided loss of job opportunities Avoided wider economic impacts
Monetised health impact	Workers directly exposed: €7 (annualised) General population: €121 (annualised)
Job loss impacts if authorisation is not granted	100-300

SUMMARY OF RAC AND SEAC CONCLUSIONS[2]

1. Operational Conditions and Risk Management Measures

1.1. Conclusions of RAC

Conclusion for workers

The Operational Conditions (OCs) and Risk Management Measures (RMMs) implemented for the workers' protection, including the selection of PPE, are appropriate and follow the hierarchy of control principles.

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

☒Yes ☐No

Conclusion for humans via environment

In terms of the minimisation of environmental releases, the RMMs in place are appropriate and effective in limiting the risk to the general population via the environment for the amount of Cr(VI) used. However, RAC has some minor concerns due to the absence of clear information that supports the air and wastewater abatement efficiencies.

These concerns lead to recommendations for the review report (see section 9).

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 management measures for the review report?

☒Yes ☐No

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

2. Exposure assessment

Exposure level used by RAC for risk characterisation:

Workers: highest level of individual, shift-long exposure[3]

Inhalation: 1.0×10^{-3} µg Cr(VI)/m^3

Humans via environment

Inhalation: 2.28×10^{-4} µg Cr(VI)/m^3

Oral: 6.44×10^{-5} µg Cr(VI)/kg bw/day

Conclusions of RAC

RAC identified minor shortcomings in the exposure estimates for workers due to the still limited number of measurements per WCS and the lack of measurement data that confirm the authorisation holder's conclusion that tasks performed in the on-site WWTP will not lead to Cr(VI) exposure.

The air emission estimates are based on a poorly substantiated release factor.

RAC considers that the exposure assessment for workers and the general population via the environment, due to the future increased use of CrO_3, contains some inherent uncertainties, although these are not likely to affect the exposure assessment significantly.

The above leads to proposed monitoring arrangements for the authorisation and recommendations for the review report (see sections 8 and 9).

Does RAC propose additional conditions[4] related to exposure assessment for the authorisation?

☐Yes ☒No

Does RAC propose monitoring arrangements[5] related to exposure assessment for the authorisation?

☒Yes ☐No

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

☒Yes ☐No

[3] For details on exposure levels see section 2 of the Justifications, exposure levels and numbers of workers exposed are presented in Table 13 in section 5.
[4] 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.
[5] 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.

3. Risk characterisation

Risk level used for health impact assessment calculated by RAC:

Excess lifetime cancer risk:

Workers (inhalation, directly exposed, over 40 years) (highest exposure): 4.0×10^{-6}

Humans via environment (inhalation, local indirect exposed, over 70 years): 6.6×10^{-6}

Conclusions of RAC

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

RAC considers that the estimates of excess cancer risk for workers based on the measured exposure values and indirect exposure of humans (workers and general population) via the environment at local level calculated by the authorisation holder allow a health impact assessment.

4. Analysis of alternatives and substitution plan[6]

What is the amount of substance that the authorisation holder uses per year for the use applied for?

100 tonnes CrO_3/year (15 tonnes CrO_3/year in the initial application)

Are there alternatives with the same function and similar level of performance that are technically and economically feasible to the authorisation holder by the date of adoption of the opinion?

☐Yes ☒No

Has the authorisation holder 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

By the date of adoption of the opinion there are no alternatives available with the same

[6] 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 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*".

function and similar level of performance that are safer and technically and/or economically feasible for the authorisation holder. The substitution plan was credible and consistent with the analysis of alternatives and the socio-economic analysis.

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

☐Yes ☒No

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

☒Yes ☐No

5. Benefits and risks of continued use

Has the authorisation holder adequately assessed the benefits and the risks of continued use?

Conclusions of SEAC

☒Yes ☐No

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

- the review report,
- SEAC's assessment of the benefits of continued use,
- SEAC's assessment of the availability, technical and economic feasibility of alternatives,
- additional information provided by the authorisation holder, and
- RAC's assessment of the risks to human health.

6. Proposed review period for the use

☐4 years

☐7 years

☐12 years

☒Other – Until 10 January 2032

7. Proposed additional conditions for the authorisation

RAC

Additional conditions:

For workers	☐Yes	☒No
For humans via 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. Authorisation holder's comments on the draft opinion

Has the authorisation holder commented the draft opinion?

☐Yes ☒No

Has action been taken resulting from the analysis of the authorisation holder's comments?

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

JUSTIFICATIONS

0. Short description of use

The review report submitted by Volta Energy Solutions Hungary Kft (hereafter referred to as authorisation holder)[7] covers the continued use of chromium trioxide for the industrial formulation of a chromium trioxide solution below 0.1 % w/w concentration. Chromium trioxide flakes are dissolved and diluted in water and used for the passivation of copper foil used in the manufacture of Lithium-Ion Batteries for motorised vehicles.

At the passivation stage, the substance is present in a mixture below the concentration limit set in Article 56.6 of REACH and is therefore not subject to authorisation. However, the authorisation holder has included the passivation stage in their CSR and this information is considered in this opinion. In addition, considering the integrated nature of the process described by the authorisation holder and the fact that it is a producer of passivated copper foil, including the passivation stage in this review report is relevant to substantiate the analysis of the activities planned by the authorisation holder and its business strategy.

The authorisation holder is part of the same group as Circuit Foil Luxembourg SARL who submitted a similar application for authorisation on 7 December 2015 for the industrial use of chromium trioxide for the treatment of copper foil used in the manufacture of Printed Circuit Board[8]. The authorisation holder refers to the documentation of the Circuit Foil application with permission of the latter.

The initial application for authorisation[9] (submitted on 18 May 2018) was for the future use of 15 tonnes CrO_3/year in a production facility that was planned to be built on a greenfield site in Környe (near the city of Tatabanya), Hungary. In its decision dated 10 January 2020, the European Commission granted authorisation for 12 years (date of expiry of the review period: 10 January 2032)[10]. In the meantime, the production facility has been built and is operational since March 2020.

The present review report was submitted less than one year into the review period of the granted authorisation because the authorisation holder faces the need to increase the tonnage used from 15 tonnes CrO_3/year to 100 tonnes CrO_3/year. This is due to the expected demand for copper foil for Lithium-Ion Batteries exceeding even the most optimistic projections made initially by the authorisation holder, caused by rapid growth in the market for electric vehicles. The authorisation holder expects the currently authorised tonnage to be insufficient to meet the increased copper foil demand by the end of 2023. The authorisation holder plans to build two new production facilities at the Környe site next to the original facility, as soon as an authorisation on this review report is granted[11].

The Committees inquired into the reasons why such a tonnage increase was not foreseen when

[7] The initial application for authorisation was submitted by two applicants, Doosan Electro-Materials Luxembourg SARL and Doosan Energy Solution Kft. Doosan Energy Solution Kft has in the meantime changed its name to Volta Energy Solutions Hungary Kft which is the sole submitter of the present review report.

[8] Circuit Foil application for authorisation: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/20709/del/50/col/synonymDynamicField_1512/type/asc/pre/3/view

[9] Initial application for authorisation: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/33302/del/50/col/synonymDynamicField_1512/type/asc/pre/5/view

[10] Adopted Commission decision (OJ summary): https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.C_.2020.016.01.0003.01.ENG; Authorisation decision: https://ec.europa.eu/docsroom/documents/39529/attachments/1/translations/en/renditions/native

[11] The construction of the second facility has already started and will be completed in December 2021 with expected ramp-up in June 2022. The construction of the third facility will start in May 2022 and will be completed in August 2023 with expected ramp-up in the middle of 2024.

the initial application for authorisation was submitted less than three years before the current review report. The authorisation holder replied with the following three reasons:

- The initial application for authorisation was submitted under time pressure to avoid compromising the site's opening in the absence of a decision by the European Commission. Moreover, the authorisation holder added that, during the drafting of the initial application, the projections of production capacity and volumes of chromium trioxide to be used were already increased twice and it did not want to exaggerate its market perspectives. Also, at the time of submitting the initial application, investment was confirmed to the first facility to be built but did not consider any expansion of facilities.
- The initial application was based on the best understanding of the market perspectives at the time and that the growth of the electric vehicle market, and hence the rise in demand for Lithium-Ion Batteries and copper foil for the anodes, has accelerated to an extent that was not expected initially.
- Since the initial application was drafted based on modelling results before building the first facility, it seemed risky to request authorisation for 100 tonnes CrO_3/year without being able to provide critical designs and real monitoring data.

The Committees also requested further clarifications on whether the authorisation holder considers the described tonnage increase sufficient to cover possible future increases in the demand for copper foil until the end of the requested review period. According to the authorisation holder, no guarantee can be given at this point and it is difficult to make projections beyond 2025 with a high degree of confidence due to the market dynamics. Nevertheless, the authorisation holder gave three reasons why a further similar change is considered unlikely:

- The tonnage requested is sufficient to accommodate the tripling in size of the site.
- The tonnage requested covers the full amount required at the maximum estimated output capacity.
- No further site enlargement is possible at this time due to physical limitations and land ownership.

In response to the Committees' questions, the authorisation holder also stated that no enforcement action has yet taken place at the site. However, the Department for Chemical Safety in the Hungarian Ministry of Human Resources and relevant competent authorities have been in contact via phone since the launch of the site and are aware of the ongoing activities, including the planned capacity increase.

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

The authorisation holder presented one Exposure Scenario (ES 1) with one Environmental Contributing Scenario (ECS 1) and four Workers Contributing Scenarios (WCS), although WCS 4 (Passivation) is out of the scope of the authorisation (see Table 1).

Compared to the initial application, more details about the OCs and RMMs are provided in the review report. Also, some operational conditions have been adapted based on the experience gained during the first months of operation of the plant (see also Table 2).

Table 1: Contributing Scenarios presented in the Use

Contributing scenario	ERC/PROC	Name of the contributing scenario	Size of the exposed population
ECS 1	ERC 2	Formulation into a mixture	Local: 200 (inhalation) (1) 10 000 (oral) (2)
WCS 1	PROC 1	Storage and handling	12 workers (1 worker per task)
WCS 2	PROC 4	Dissolution of CrO_3 flakes into water	12 workers (2 workers per task)
WCS 3	PROC 28	Maintenance (repairing) of machinery	16 workers (2 workers per task
WCS 4	PROC 13	Passivation *(out of scope of the authorisation)*	

(1): 100 m radius from the plant site
(2): 1 km radius from the plant site

The plant (original facility and the two expansion facilities) will operate continuously (365 days a year and 24h a day), in two shifts of 12 hours per day. The number of working days per operator is 180 days (excluding holidays) per year, 42 hours per week, alternating a long working week (4 working days/3 days off) with a short week (3 working days/4 days off).

CrO_3 is delivered as flakes in 25 kg sealed drums and stored in a locked cabinet with restricted access to authorised workers only (WCS 1). The physical integrity of each barrel (e.g. absence of deformation, leakage) is visually checked after each shipping, before storage and before delivery for the dissolution.

For preparing the CrO_3 solution (WCS 2), the operator in charge takes out full barrels from the warehouse storage area and brings them to the dissolution cabinet. Before opening the dissolution cabinet, the operator turns the exhaust system on to create a negative pressure inside the cabinet. After having checked the conformity of the installation (cleaning status, traces of contamination, functioning of the LEV, etc.), the operator puts the barrel on the trail, using a leverage device. Then the barrel transfer sequence is launched. The door of the barrel reverser is opened, the barrel is automatically transferred inside the barrel reverser and the door is tightly closed. The barrel is then automatically opened and slowly and carefully toggled to transfer the flakes into the filler funnel, which is connected to the dissolution tank (drop height of 40 cm). This tank is filled with water and continuously stirred to create a homogenous solution at 250 g CrO_3/L. Once empty, the barrel is inserted into the funnel to be rinsed with water, automatically closed, and passed out of the barrel reverser. Then a new cycle can be launched by the operator. All the emptied and sealed barrels are stored in a special container for contaminated products. These containers are treated by a chemical waste processing company.

The operator never enters the barrel reverser. A cleaning cycle is performed once a day, at the end of the dissolution sequence. Water is flushed into the entire barrel reverser to remove chromium residues from the air space and surfaces. The wastewater is then neutralised with sodium bisulfite and transferred to the wastewater treatment plant (WWTP).

During and after each dissolution operation, the operator checks the presence of red dust deposited on any surface of the barrel reverser (CrO_3 flakes have a deep red colour). The material used to build the barrel reverser is white to allow detection of such a deposit. In case of detection of red dust, the operator stops any ongoing process and ask the maintenance team to intervene. Before any direct intervention, a new cleaning cycle is launched.

Currently, the plant has one dissolution box in operation. In future, the plant will have three dissolution boxes in operation located in different buildings.

Two operators of the morning shift will operate the three dissolution boxes in sequence. In the afternoon shift, no dissolution operations take place. Three to four barrels are dissolved per dissolution box (11 in total), taking not more than 3 hours in total (1 hour per box). While performing this task the operators wear RPE. The total amount of CrO_3 dissolved per day will be around 275 kg/day and not more than 100 tonnes/year in total. This amount will be equally split amongst the three dissolution boxes.

The third operator of the morning shift and the three operators of the afternoon shift will monitor the onsite WWTP. The internal organisational procedures allow for an equal share of the roles between the 12 operators involved in the dissolution operations.

The tasks related to the monitoring of the WWTP includes sample collection (treated effluent, sludges) for lab analyses, lab measurements, process control system monitoring, intervention (e.g., liquid transfer from storage vessels to wastewater treating lines Cu and Cr with valves and vacuums, cleaning, minor maintenance, press filter cleaning, physical observation in every 2 hours on-site, etc. According to the authorisation holder, none of these tasks may lead to exposure to Cr(VI) as they will take place after the reduction of Cr(VI) to Cr(III) by sodium bisulfite.

The CrO_3 solution is automatically diluted and transferred into storage tanks. Then this diluted solution feeds the passivation baths (WCS 4) and is recycled back. The quality of the passivation baths is continuously monitored with online measurement of conductivity, pH and colourimetry. Spent solutions are sent to the wastewater treatment installation. As limpid passivation solution is a quality criterion, no sludge, due to dust deposition or precipitation, is anticipated in the passivation bath.

The passivation bath is an open system, fitted with air extraction, with a very slowly rotating drum (less than one revolution per minute) where the copper foil is dipped into the Cr(VI) diluted solution.

The passivation process does not require the intervention of operators. Only monitoring activities are necessary. A team of 45 to 50 people per shift will operate in the passivation workshop, with not more than 40 people at a time. Once under full capacity, around 80 copper foil production lines, with the corresponding passivation baths will be set in the workshops. At the passivation stage the CrO_3 concentration in the solution is below the concentration limit set in Article 56.6 of REACH (< 0.1 % w/w), therefore this step of the process is not subject to authorisation.

The maintenance activities (WCS 3) are limited to the repair of malfunctioning devices (e.g. tanks, pumps, pipes, passivation installations) detected by workers' observation and monitoring of integrated measures. No preventive maintenance is performed.

Based on the feedback from the first months of plant operation and the historical data from the reference site of Wiltz (Luxembourg; application from Circuit Foil Luxembourg SARL), not more than two interventions per month on devices likely to be in contact with Cr(VI) are expected. These operations require two workers for around two hours.

Before any intervention, the device of concern is abundantly washed with clean hot water, to optimise dissolution of any trace of CrO_3, and every surface is visually checked before intervention (CrO_3 stains in red contaminated surfaces). The wastewater is then directed to the water treatment system. Operators wear full PPEs, including RPE. Operators are instructed to not use abrasive technics to avoid the formation of contaminated particles. After the intervention, the water tightness of the installation is checked before starting again the

production.

In order to have always at least four maintenance operators per 12h shifts fully authorised to intervene on the chromium devices, the maintenance team dedicated to the Cr(VI) devices will be increased from the initial three to 16 operators at full operation.

As can be observed in Table 2, besides the increase in the amount of CrO_3 used, there are some differences in the number of workers involved, the duration and frequency of the tasks between the initial application and the review report.

Also, it was mentioned in the initial application that all activities described under the different WCS would be performed by different workers, thus no combined exposure was expected. However, as a consequence of the gained experience in the past months, it is now planned that WCS 1 and WCS 2 will be performed by the same workers.

Table 2: Comparison of the operational conditions between the initial application and review report

WCS	**Operational conditions**	
	Initial application 15 tonnes CrO_3/year	Review report 100 tonnes CrO_3/year
WCS 1 Delivery/ Storage	duration: < 1h/day frequency: 1 day/month number of workers/task: 1 number of workers/team: 5	duration: < 1h/day frequency: 1 day/month number of workers/task: 1 number of workers/team: 12
WCS 2 Dissolution	duration: <45 min/day frequency: 1day/week number of workers/task: 1 number of workers/team: 5	duration: 3h/day frequency: 365 day/year number of workers/task: 2 number of workers/team: 12
WCS 3 Maintenance	duration: 2h/day frequency: 2 days/month number of workers/task: 2 number of workers/team: 3(1)	duration: 2h/day frequency: 2 days/month number of workers/task: 2 number of workers/team: 16
WCS 4 Passivation	duration: 8h/day frequency: 260 days/year number of workers/task: 40 number of workers/team: 50	duration: 12h/day frequency: 365 days/year number of workers/task: 40 number of workers/team: 50

(1): In the initial application, the number of maintenance operators dedicated to the Cr(VI) devices was reported to be 15. The authorisation holder clarified that this was a mistake and that only three operators were involved in CrO_3 related maintenance tasks. The total number of maintenance operators acting on the plant was 15.

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

Chromium trioxide has no independent function at the formulation stage. During the passivation, the substance fulfils three major technical roles in copper foil used for Lithium-Ion Batteries:

- Prevent oxidisation of the foil during storage or further processing and during the use of Lithium-Ion Battery anodes;
- Prevent the propagation of cupric ions throughout the battery during its lifetime use;
- Improve battery performance (capacity, cell's impedance and peel strength of anode film).

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

The use applied for is the formulation of a chromium trioxide solution that is subsequently used by the authorisation holder to produce passivated copper foil for the manufacture of Lithium Ion Batteries for motorised vehicles.

1. Operational Conditions and Risk Management Measures

1.1. Workers

According to the authorisation holder, the following Operational Conditions (OCs) and Risk Management Measures (RMMs) are in place at the current facility and will also be implemented in the two expansion facilities.

Technical Risk Management Measures

- The formulation process is fully automated and takes place in an isolated closed room (the dissolution cabinet).
- All the workshops are equipped with mechanical ventilation (5-10 ACH reflecting a worst-case situation).
- The dissolution cabinet is fitted with air extraction allowing 35 ACH. Inside the barrel reverser, the air exhaust rate is around 50 ACH.
- The barrel reverser is airtight and under negative pressure.
- The upper part of the filler funnel is a dust aspiration system, aiming to capture all the CrO_3 dust potentially emitted during the emptying.
- The dust is instantly flushed with water into the dissolution tank. The mixing tank is equipped with an air extractor (10 ACH) to remove the particles still in suspension in the tank.
- LEV functioning is continuously monitored by online measurement of the air velocity, as well as of the differential pressure at the filters. In case of malfunction, the maintenance team is automatically alerted, and a visual alarm is activated at the entrance of the cabinet and the installation is locked. No further intervention by workers is allowed before action from the maintenance team.
- LEVs are regularly (monthly) rinsed with water suction pipes to remove any potential dust. Rinsing water is directed to the on-site WWTP.
- The extracted air is continuously passed through a water curtain which binds the dust. The contaminated water goes directly into the WWTP system, where it is treated.
- LEV systems are annually checked by external contractors to ensure proper efficiency.

Organisational Risk Management Measures

- The authorisation holder started the procedure to obtain the ISO 9001, ISO 14001 and ISO 45001 certifications, with a target date of the end of 2021.
- Workers are specifically trained for performing adequately their tasks (two full-day training for newcomers, a monthly safety sensitisation and an annual sensitisation dedicated to chemical safety).

- Workers receive instructions related to hygiene and safety rules, maintenance and wearing of PPEs (sealing tests, facial hairstyle restrictions).
- RPE is visually checked to detect any damages, scratches or visual distortion of the masks or the cartridges. The frequency of replacement of the filters is according to the manufacturer instructions.
- Regular field audits are planned as well as spot checks, permitting to ensure PPE performances.

Medical examination

Workers receive a specific medical trimestral survey that includes a biological monitoring (Cr in urine) control. According to the Hungarian laws, this should be performed once a year.

Due to the potential tissue effects related to high exposure to Cr(VI), during the medical examination special attention is given to skin and mucosal tissues. This is intended to detect the first signs of skin or mucosal ulcer, characteristic of Cr(VI) exposure. The authorisation holder will not use biological monitoring for the exposure assessment (see section 2.3 for their justification).

Table 3: Operational Conditions and Risk Management Measures

Contributing scenario	Concentration CrO_3	Duration and frequency of exposure	Engineering controls	PPE(1)	Organisational controls
WCS 1 Storage and handling	99.7 %	< 1h/day, 1day/month	Ventilation (ACH = 5-10), closed system	Protective gloves, chemical resistant boots, safety goggles, working clothes	Trained personnel, restricted access, specific hygiene and safety instructions
WCS 2 Dissolution of CrO3 flakes into water	99.5 %	3 h/day, 60 days/year per worker(3)	Ventilation ACH = 35(2), fume cupboard (99 % eff.), fixed capturing hood (90 % eff.)	Protective gloves, chemical resistant boots coverall, full face mask (P3)	Trained personnel, specific hygiene and safety instructions
WCS 3 Maintenance (repairing) of machinery		2 h/day, 2 days per month (3 days/year/ worker) (4)	Ventilation ACH = 5-10	Protective gloves, chemical resistant boots coverall, full face mask (P3)	Trained personnel, specific hygiene and safety instructions
WCS 4 Passivation (out of scope of the authorisation)	< 0.1 % CrO_3 w/w	8 h/day, 260 days/year (208 days/year/worker)	Ventilation ACH = 5-10, LEV (receiving hood) (80 % eff.)	Protective gloves, chemical resistant boots, disposable all-in-one suite	Trained personnel, specific hygiene and safety instructions

(1): details of the PPE have been provided by the authorisation holder.
(2): for the modelling exposure estimate, an ACH of 30 is used since that is the maximum air exhaust rate available in ART 1.5.
(3): 365 days per year divided by 12 workers in a team and multiplied by 2 workers at a time.
(4): 24 days per year divided by 16 workers in a team and multiplied by 2 workers at a time.

1.2. Environment/Humans via environment

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

According to the authorisation holder, the following Operational Conditions (OCs) and Risk Management Measures (RMMs) are in place at the current facility and will also be implemented in the two expansion facilities.

Air

Extracted air from the whole process (formulation of the CrO_3 solution and passivation) is treated through wet scrubbers. Every facility will have its own separate wet scrubber system. According to the authorisation holder, the abatement efficiency of the wet scrubber is nearly 100 %. The parameters of the scrubber system are set so that the washing water is changed frequently enough to maintain a constant high scrubbing efficiency. The wastewater generated is collected by the wastewater network and sent to the on-site sewage treatment plant.

Water

The CrO_3 containing effluents from all processes are sent to the fully automated on-site sewage treatment plant where Cr(VI) is reduced to Cr(III) using bisulfite. The efficiency of the process is continuously checked based on the pH and redox potential of the treated solution, in order to ensure the reduction of Cr(VI) to Cr(III).

After the on-site treatment, the effluent is sent to the municipal sewage network. The concentration of Cr(VI) in the effluent is continuously measured (automatized process). If the Cr(VI) concentration is above the limit of 0.1 ppm, the redox potential and pH are outside the optimum treatment conditions, or malfunctioning of the measurements system occurs, the effluent is automatically sent to a safety tank with a current volume capacity of 54 m^3, enabling to store 1.12 days of effluent flowing (current effluent daily flow rate: 48 m^3/day). The contaminated effluent is retreated in the on-site sewage treatment plant until the Cr(VI) concentration falls below 0.1 ppm.

In the next years, when the facility is expanded for the annual use of 100 tonnes of CrO_3, a safety tank of 60 m^3 will be added. The total volume of the safety tanks will increase from 54 to 114 m^3. Considering the maximum effluent flow rate of 145 m^3/day, the safety tanks will enable to store 0.78 days of effluent.

The current WWTP that is connected to the existing facility will be scaled up to receive wastewaters from the second facility. The third facility will have its own separate WWTP.

Soil

Direct release to soil is strictly excluded as the basements are on retention. Therefore, direct releases to soil are considered negligible.

Waste

Waste (e.g., emptied barrels) is collected and stored in a special container and disposed of and treated by a chemical waste processing company according to the national legislation. The on-site treatment of effluent containing Cr(VI) involves the production of sludge that contains chromium only as Cr(III). The sludge is pumped from the decantation tank and sent to be treated by a dedicated company to recover the heavy metals.

Table 4: Environmental RMMs – summary

Compartment	RMM	Stated effectiveness
Air	Wet scrubber	Near 100 %
Water	On-site WWTP (reduction Cr(VI) to Cr(III))	Not specified (1)
Soil	Basement on retention	100 %

(1): discharges of Cr(VI) are below the threshold limit of Cr(VI) in the effluent (< 0.1 ppm).

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

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

RAC notes that the RMMs are similar to those described in the initial application for authorisation, except for the ventilation rate for WCS 2[12], and some differences exist concerning OCs, such as frequency and duration of the tasks.

RAC notes that the authorisation holder has further considered the use of RPE and adjusted their work organisation to ensure the use of RPE is limited to a maximum of 3 hours per day.

RAC considers that the OCs and RMMs in place to limit the workers' exposure during the formulation of CrO_3 are adequate (LEV systems, closed automated process, trained operators, adequate working procedures for repair activities).

The authorisation holder did not provide data that support the stated air abatement efficiency and no information about the effectiveness of the on-site WWTP was presented.

However, RAC acknowledges that wet scrubbers, and WWTP based on reduction of Cr(VI) to Cr(III), are generally used to control the releases of Cr(VI) to the environment with relatively high efficiencies.

1.4. Conclusions on OCs and RMMs

The OCs and RMMs implemented for the workers' protection, including the selection of PPE, are appropriate and following the hierarchy of control principles.

In terms of the minimisation of environmental releases, the RMMs in place are appropriate and effective in limiting the risk to the general population via the environment for the amount of Cr(VI) used. However, RAC has some minor concerns due to the absence of clear information that supports the air and wastewater abatement efficiencies.

These concerns lead to recommendations for the review report (see section 9).

[12] For WCS 2, the initial application for the authorisation had an ACH = 10, while for the review report an ACH = 35 was given.

Overall conclusion

Are the operational conditions and risk management measures appropriate[13] and effective[14] 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

2. Exposure assessment

2.1. Inhalation exposure

In line with the monitoring arrangement stipulated in the authorisation decision, the authorisation holder provided measurement data including personal and static sampling for the inhalable fraction of airborne particles, covering the tasks performed by the different types of workers potentially exposed to Cr(VI) (WCS 2 and WCS 3), including those involving maintenance workers. These measurements correspond to their first monitoring programme launched in August 2020, 6 months after the plant started operating.

During storage and handling (WCS 1), the drums are sealed and therefore no potential for exposure to CrO_3 is considered by the authorisation holder, as also concluded in the initial application for authorisation.

The authorisation holder also presented modelled exposure estimates using ART version 1.5.

The authorisation holder did not adjust the exposure for the use of RPE as a worst-case approach. According to the authorisation holder, the APF factor for the used RPE should be at least 20 regarding supplier specification.

More relevant data about the inhalation exposure assessment are detailed below and the results are summarized in Table 5.

Air monitoring

For the workers' air monitoring, the sampling method EN13284-1-2018 and the analytical method ISO 16740 with an LoQ of 0.02 µg per sample were used. The authorisation holder presented a detailed description of the applied measurement strategy and the sampling procedure[15]. The measurement results relevant to the formulation process are presented in the Annex.

For the exposure assessment for WCS 2, personal sampling was performed on one worker equipped with 2 personal samplers. The first one was collected at the end of the dissolution task and the second one also included the disposal of the emptied barrels in the dedicated storage area. Also, static sampling was performed, one located close to the barrel reverser

[13] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls in application of RMMs and compliance with the relevant legislation.
[14] '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.
[15] Considered confidential information by the authorisation holder but known to RAC.

door and one to the control panel. The sampling period was about 2 hours.

For the maintenance operations (WCS 3), a real maintenance task was monitored on the first day and on the next day a task of similar nature was simulated, with one operator performing the maintenance task, and another worker being present as a helper to control and facilitate the work. In addition, static samplers were deployed, one close to the workplace and one in the walkway, close to the workplace. The sampling period was about 1 hour.

For the passivation operations (WCS 4), samplings were made during 3 consecutive days, for not less than 293 minutes, with 8 personal samplings (6 different operators), and 6 static samplings located either close to the passivation bath (n = 3) or in the pathway close to the copper foil production lines with the sampling head directed towards the passivation units. Operators did their daily job, controlling and monitoring the copper foil production. Like in the initial application for authorisation, RAC did not assess further the measurement data of the passivation process, since it is out of the scope of this review report.

The authorisation holder considered the measurement data only as supporting information for the modelled exposure estimates that were used for the risk assessment. However, RAC is of the opinion that the measurement data are sufficiently robust to be taken forward for the risk characterisation. This is also in line with the ECHA guidance on occupational exposure estimation, where it is explained that preference should be given to measured exposure data over modelled exposure estimates that have inherent uncertainties. For WCS 2, RAC used the maximum measured value due to the limited number of measurements (n = 4) while for WCS 3, RAC used the 90th percentile (n = 8).

Modelling

The modelled exposure estimations were provided for WCS 2, WCS 3 and WCS 4 using ART 1.5. The authorisation holder applied a conversion factor of 0.52 to convert the modelled exposure estimates of CrO_3 into Cr(VI), as in the initial application for authorisation.

For WCS 3 and WCS 4, the same input parameters were used for the modelling and therefore the same exposure estimates were obtained as for the initial application for authorisation. However, after reanalysis of a full emptying cycle (from handling of a new/full barrel to its automatic sealing and removal from the dissolution box), for WCS 2, some different input parameters were used for the modelling[16], leading to different exposure estimates between the initial application for authorisation and the current review report.

The current modelled exposure estimate represents the potential exposure during the automatic transfer of the CrO_3 flakes from the barrel into the filler funnel. The time needed for this process is around 10 seconds per barrel. Emptying 11 barrels a day amount to a total exposure time of 2 minutes per day.

The authorisation holder pointed out that, although the transfer of the flakes into to the dissolution tank takes place in the barrel reverser and is therefore segregated from the place where the operator is, no segregation is considered in the exposure modelling since there is a breach of the containment when the emptied barrel is replaced by a full one. Therefore, even if the emission phase (dropping off the flakes) is performed in full containment (dissolution box tightly closed), a worst-case situation has been taken forward by the authorisation holder.

[16] Duration of the task leading to exposure was reduced from 15 min to 2 min; transferring velocity was increased from 10-100 kg/min to 100-1 000 kg/min; the ACH was increased from 10 ACH to 30 ACH.

2.2. Dermal exposure

Dermal exposure has not been assessed as dermal exposure to Cr(VI) compounds is not expected to present a cancer risk to humans (RAC/27/2013/06 Rev. 1).

2.3. Biomonitoring

Contrary to what was proposed by the authorisation holder in the initial application for authorisation, i.e. to perform biomonitoring (analysis of urinary chromium) as one of the measures to assess the exposure, the authorisation holder concluded now that the modelled and measured exposure levels are such that exposure level in urine cannot be adequately measured given the background chromium exposure from other sources (diet, drinking water, smoking). Therefore, the authorisation holder considered that it is not relevant to implement a generalised biomonitoring programme as a tool to monitor the level of exposure of operators to Cr(VI) compounds. However, the authorisation holder performs chromium analysis in the urine as part of the medical examination, as this is also required by the Hungarian legislation.

Table 5: Exposure – inhalation

Contributing scenario	Method of assessment	Exposure value (8h TWA) Cr(VI) µg/m³	Duration and frequency	Exposure value corrected for frequency µg Cr(VI)/m³ (1) (4)
WCS 1 Delivery and storage	Qualitative	0	< 1h/day, 1 day/month	**0**
WCS 2 Dilution of the substance into a large container	Modelled	1.56×10^{-3}	2 min/60 days per year per worker (5)	2.60×10^{-4}
	Measured	6.0×10^{-3} (2) (max. value)	180 min/60 days per year per worker	**1.00×10^{-3}**
WCS 3 Manual maintenance (repair) of machinery	Modelled	3.02×10^{-3}	2 h/day, 3 days per year per worker	2.48×10^{-5}
	Measured	1.93×10^{-2} (3) (90th percentile)		**1.59×10^{-4}**
WCS 4 (6) Passivation *(out of scope of the authorisation)*	Modelled	3.28×10^{-5}	8 h/day	2.62×10^{-5}

(1) Exposure values are not adjusted for the use of RPE (worst-case approach).
(2) Calculated by RAC based on the measurement results and assuming a 3h exposure during the working day.
(3) Calculated by RAC based on the measurement results and assuming a 2h exposure during the working day.
(4) The exposure values in bold are taken forward by RAC for the risk assessment.
(5) Modelled exposure estimate based on the transfer of CrO_3 flakes into the filler funnel that takes in total 2 min, although all tasks related to WCS 2 takes 3h.
(6) As WCS 4 is not in the scope of authorisation, RAC has not assessed the values for WCS 4.

The exposure estimates used by RAC in the opinion on the initial application are all based on modelling (ART 1.5). A comparison with the exposure data used by RAC in the opinion on the initial application for authorisation is presented in Table 6. The different exposure values between the initial application and the current review report can be explained by the different approaches taken for the exposure assessment (modelling estimates versus measurement data) and the differences in the number of days per year of exposure per worker. Related to WCS 2, the input parameters for the modelling in the initial application were rather conservative, leading to a relatively high exposure estimate (see also section 2.1).

Table 6: Comparison of workers' inhalation exposure data between the initial application and the current review report per WCS related to the formulation activities

WCS	Initial application		Current review report	
	Days per year	Exposure value (8h TWA) corrected for frequency (µg Cr(VI)/m^3)	Days per year	Exposure value (8h TWA) corrected for frequency (µg Cr(VI)/m^3)
WCS 1 Delivery and storage	50 days per year	0	12 days per year	0
WCS 2 Dilution of the substance into a large container	10 days per year per worker	1.30×10^{-3}	60 days per year per worker	1.00×10^{-3}
WCS 3 Manual maintenance (repair) of machinery	3.2 days per year per worker(1)	4.02×10^{-5}	3 days per year per worker	1.59×10^{-4}

(1): This should be 16 days per year per worker since, as the authorisation holder explained, the number of maintenance workers dedicated to the Cr(VI) devices was 3 instead of 15.

2.4. Environmental emissions and exposure

In agreement with the monitoring arrangement of the authorisation decision, the authorisation holder measured the Cr(VI) concentrations in wastewater and exhaust air.

Water

The company measures continually the concentration of Cr(VI) in their effluents and the concentration limit of the release to the sewage network is fixed by the company at 0.1 mg Cr(VI)/L. The authorisation holder provided measurement data at the WWTP discharge point (n = 3) and the final drain to the sewage (n = 3), with Cr(VI) concentrations all below de LoQ of 5 µg/L. However, the authorisation holder did not use these data to determine the releases, but the reference limit of 0.1 mg Cr(VI)/L, as a worst-case approach.

The current wastewater flow rate is 48 m^3/day. In the next years, and to take into account the increase of the facility (using 100 tonnes CrO_3/year), the maximum effluent flow rate will be 145 m^3/day, leading to a local release rate of 0.0145 kg Cr(VI)/day, and with a consumption of 142 kg Cr(VI) per day, to a release factor of 1.0×10^{-2} %.

Air

To calculate the air emissions the authorisation holder applied the release factor of 0.01 % based on SPERC Eurometaux 2.2c.v.2.1. that is applicable for the formulation of metal compounds in other than plastics and paint sectors when specific RMMs are applied. According to the authorisation holder, the release factor of 0.01 % should be considered as the worst-case since wet scrubber efficiency is nearly 100 %.

The authorisation holder presented one measurement of the air emissions release with a total chromium concentration below the LoQ < 0.001 mg/m^3.

The authorisation holder stated that the monitoring of air emissions will continue to be performed on every discharge chimney. This will be done once a year and an accredited sub-

contractor has already been committed.

Soil

Soil contamination is considered non-relevant by the authorisation holder since there is no direct or indirect release to the soil from the use applied for.

Table 7: Summary of environmental emissions

Release route	Release factor	Release per year Cr(VI) (tonnes or kilograms)	Release estimation method and details
Water	1.0×10^{-2} %	5.3 kg/year	Based on the limit of the release of Cr(VI) (0.1 mg/L) fixed by the company
Air	0.01 %	5.2 kg/year	Release factor based on SPERC Eurometaux 2.2c.v.2.1
Soil	0 %	0	There is no release to the soil according to the authorisation holder
Waste	0 %	0	Waste is collected and disposed of by a certified company

The risk assessment has been focused only on the local impact of emission from the use of Cr(VI), in line with EU-RAR (2005) that stated that releases of Cr(VI) from any sources are expected to be reduced to Cr(III) in the environment, the impact of Cr(VI) as such is therefore likely to be limited to the area around the source.

For all relevant compartments of the environment, the authorisation holder assumed that 3 % of the estimated Cr(VI) concentration will remain as Cr(VI), and 97 % is converted to Cr(III).

As Cr(VI) released to soil or sediment is rapidly converted into Cr(III), the exposure of human via the environment from these sources has been considered as limited. As a consequence, the authorisation holder took into account only drinking water and fish consumption for the oral route of man via the environment.

Only the exposure concentrations for neutral/alkaline environment are presented and considered as worst-case compared to an acidic environment (i.e. higher exposure concentrations for the compartments relevant for the man via environment risk assessment).

Table 8: Summary of indirect exposure to the environment and human via the environment

Parameter	Local
PEC in air (mg/m^3)	2.28×10^{-7}
PEC in surface water (mg/L)	2.13×10^{-5}
Daily dose via oral route (mg/kg bw/day)	6.44×10^{-8}

The increase in the releases of Cr(VI) to the air that can be observed in the current review report is solely caused by the increase in the yearly amount used since the applied release factor remains identical (see Table 9).

For the water releases, the initial application and the current review report used the same reference limit of 0.1 mg Cr(VI)/L of the release to the sewage network to calculate the release

factor. However, the proportion of the daily flow rate of the effluent to the daily consumption has changed in the current review report[17] and this explains the difference between the calculated release factors.

Table 9: Comparison of the environmental releases between the initial application and the current review report

Release route	Initial application		Current review report	
	Release factor	Release Cr(VI) kg/year	Release factor	Release Cr(VI) kg/year
Air	0.01 %	0.78 (1)	0.01 %	5.2
Water	4.7×10^{-2} % (2)	3.65	1.0×10^{-2} %	5.3
Soil	0	0	0	0

(1) In the opinion document of the initial application, a release of 1.46 Cr(VI) kg/year was wrongly reported (the release factor of 0.01 % was multiplied by the yearly CrO_3 tonnage instead of the yearly Cr(VI) tonnage).

(2) In the opinion document of the initial application, a release factor of 2.4 $x10^{-2}$ % was wrongly reported. For the calculation, the daily release of Cr(VI) was divided by the daily use of CrO_3 instead of the daily use of Cr(VI)

As a consequence of the abovementioned differences in the releases, the environmental exposures of the initial application and the current review report also differ, as presented in Table 10.

Table 10: Comparison of exposure to the environment and humans via the environment data

Parameter	Initial application (*)	Current review report
	Local	Local
PEC in air (mg/m^3)	3.42×10^{-8}	2.28×10^{-7}
Daily dose via oral route (mg/kg bw/day)	9.24×10^{-8}	6.44×10^{-8}

(*) These values correspond to the exposure values as presented in the opinion document of the initial application using the wrong values mentioned in the footnotes of Table 9.

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

Workers exposure

The tasks of the workers, their duration and frequency are sufficiently well described.

RAC agrees with the authorisation holder's conclusion that for WCS 1 (Storage and handling) no exposure is expected due to the nature of the activity.

In line with the monitoring arrangements for the authorisation, the authorisation holder launched their worker monitoring programme in August 2020, 6 months after the plant started its production, and included static and personal sampling, covering all relevant WCS. The results were presented in the review report together with extensive contextual information of measurements, e.g., duration of sampling, applied method with its LoQ, and tasks performed during sampling.

[17] The initial application had a daily consumption of 41 kg CrO_3 with a relatively high estimated flow rate of 100 m^3/day while the current review report has a foreseen daily flow rate of 145 m^3/day with a daily consumption of 274 kg CrO_3.

RAC takes note that the exposure assessment reflects the current Cr(VI) amount used in the original facility and although the OCs and RMMs in the two expansion facilities will be the same, some uncertainties remain about the impact of the expansion on the exposure of workers.

As indicated in section 2.1, the measurement data are used by RAC for the worker's exposure and risk assessment.

RAC concludes that the measurement data demonstrate that the implemented OCs and RMMs are effective.

However, RAC points out that the number of measurements is still limited and that a yearly monitoring programme should be continued to obtain a more representative exposure assessment, considering also the future expansion of the production process. The authorisation holder pointed out that annual monitoring is required as set by the current Hungarian legislation.

Although the authorisation holder mentioned that exposure to Cr(VI) when performing tasks in the on-site WWTP will not occur, RAC is of the opinion that this should be confirmed by measurement data, especially considering that the authorisation holder explains that the treated wastewater may still contain < 0.1 ppm Cr(VI) before it is released to the sewer system. This would also be in line with other applications with automated on-site WWTP systems.

RAC considers that the authorisation holder's future monitoring strategy as included in the Annex of the CSR, defining the number and kind of samples per WCS and in alignment with the sampling procedure for workplace measurements and analysis seems adequate.

For WCS 2 and WCS 3 (which consist of different subtasks with probably different exposure profiles), the modelled exposure has been defined using only one activity class. This leads to uncertainty about the representativeness of the modelled exposure estimates used by the authorisation holder for the risk assessment. These modelled exposure estimates do not necessarily provide an appropriate level of detail and specificity to accurately represent the activities that can lead to exposure. This is the case for WCS 2 where the transfer of CrO_3 flakes into the filling funnel was used to model the exposure, while WCS 2 includes also other tasks such as the transfer of full barrels to the dissolution cabinet, starting up the automatic dissolution process and the transfer of emptied barrels to the dedicated containers of contaminated products.

RAC acknowledges the conservative approach taken by the authorisation holder for the modelled exposure estimate of WCS 2 by not considering that the operator is segregated from the place where the transfer of the flakes occurs.

RAC takes note that the exposure estimates presented by the authorisation holder are not adjusted for the use of RPE and therefore represent a conservative approach.

RAC acknowledges that the inhalation exposure to Cr(VI) with the levels as provided by the authorisation holder will not be reflected by an increase of the chromium concentration in urine, given the background chromium exposure from other sources. However, the authorisation holder should regularly review the quarterly biomonitoring data and take action if the levels show chromium urine concentrations higher than levels expected from the background concentrations.

Humans via environment

The authorisation holder measured Cr(VI) concentrations in wastewater and exhaust air, as stipulated as a condition for the authorisation.

RAC acknowledges that the wastewater releases of Cr(VI) are probably an overestimation since they also include the releases from the passivation process. In addition the measurement data of the Cr(VI) in wastewater fall below the detection limit of 5 µg/L, which is 20 times lower than the reference value of 0.1 mg Cr(VI)/L taken forward to calculate the releases.

RAC informed the authorisation holder that the SPERC Eurometaux 2.2c.v2.1 used to justify the release factor to air was obsoleted in 2019. The authorisation holder responded that the release factor to air of 0.01 % remains applicable and should be considered as a worst-case taking into account that the abatement efficiencies of the wet scrubber are nearly 100 % and that OCs and RMMs in place are such that potential emission of chromium to the air is very low.

RAC points out that the conservative approach claimed by the authorisation holder for the releases to air emission has not been substantiated. No specific information about the abatement efficiency of the wet scrubber has been provided and the SPERC used is no longer valid. The authorisation holder presented a single measurement of total chromium in the air emissions. This information could have been taken forward to estimate the releases to air and to substantiate the conservative character of the release factor used by the authorisation holder. However, RAC acknowledges that wet scrubbers are generally used to control the releases of Cr(VI) to the environment with relatively high efficiencies.

The same abatement systems will be implemented for the two expansion facilities. Some uncertainties remain on the impact the expansion will have on the environmental releases. However, RAC is of the opinion that these uncertainties are not likely to affect the release estimates significantly.

RAC takes note that the authorisation holder applied a reduction factor of 97 % for the environmental exposures at the local level, to account for the conversion of Cr(VI) into Cr(III) in the environment. RAC is of the opinion that EUSES outcomes should generally not be modified without robust justifications; although reduction of Cr(VI) to Cr(III) is likely to further reduce the exposure of the general population, this may not occur so rapidly in the air to reach 97 % at the local scale. However, this is not likely to have a significant impact on the actual exposure of the general population, considering the RMMs in place, the conservative approach taken forward to calculate the releases to the water environment and the fact that there is no residential area or other plant in the direct vicinity (i.e., within a 100 m radius) of the authorisation holder's plant[18].

2.6. Conclusions on exposure assessment

RAC identified minor shortcomings in the exposure estimates for workers due to the still limited number of measurements per WCS and the lack of measurement data that confirm the authorisation holder's conclusion that tasks performed in the on-site WWTP will not lead to Cr(VI) exposure.

The air emission estimates are based on a poorly substantiated release factor.

[18] The nearest houses of the nearest residential area are about 300 m from the plant and there is no other residential area within a 1-km radius of the plant.

RAC considers that the exposure assessment for workers and the general population via the environment, due to the future increased use of CrO_3, contains some inherent uncertainties, although these are not likely to affect the exposure assessment significantly.

The above leads to proposed monitoring arrangements for the authorisation and recommendations for the review report (see sections 8 and 9).

3. Risk characterisation

The cancer risk is estimated according to the RAC reference dose-response relationship for the carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1, agreed at RAC 27)[19].

Considering the RAC report RAC/27/2013/Rev. 1, the authorisation holder has conservatively assumed that all inhaled CrO_3 particles are in the respirable range and contribute to the lung cancer risk and therefore no exposure via the oral route needs to be taken into account.

The authorisation holder pointed out that the mechanistic evidence is suggestive of non-linearity, and it is acknowledged by RAC that the excess risks in the low exposure range might be overestimated.

3.1. Workers

Although the same workers are involved in both WCS 1 and WCS 2, this is not relevant for the combined exposure assessment and risk characterisation since there is no exposure for WCS 1.

Table 11: Combined exposure and risk characterisation

Contributing scenario	Exposure value corrected for frequency 8h TWA Cr(VI) µg/m³	Excess risk[20]
WCS 1 Delivery and storage	0	0
WCS 2 Dilution of the substance into a large container	1.00×10^{-3}	4.00×10^{-6}
WCS 3 Manual maintenance (repair) of machinery	1.59×10^{-4}	6.35×10^{-7}

[19] For workers for 40 years of exposure (8h/day, 5 days/week):
Inhalation: excess lifetime lung cancer risk of 4×10^{-3} per µg Cr(VI)/m³
Oral intake: excess lifetime intestinal cancer risk of 2.0×10^{-4} per µg Cr(VI)/kg bw/day

For general population for 70 years of exposure (24h/day, 7 days/week):
Inhalation: excess lifetime lung cancer mortality risk of 2.9×10^{-2} per µg Cr(VI)/m³
Oral intake: excess lifetime intestinal cancer risk of 8.0×10^{-4} per µg Cr(VI)/kg bw/day

[20] Estimated individual risk resulting from exposure.

3.2. Humans via environment

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

Parameter	Local	
	Exposure	**Excess risk**
Humans via environment – Inhalation	2.28×10^{-7} mg/m^3	6.6×10^{-6}
Humans via Environment – Oral	6.44×10^{-8} mg/kg bw/day	5.15×10^{-8}

3.3. Shortcomings or uncertainties in the risk characterisation

RAC notes that the risk characterisation is affected by some shortcomings in the workers' exposure assessment and the estimation of emissions to the environment.

These shortcomings are addressed and discussed in section 2.5 and summarised in section 2.6. RAC concludes that these shortcomings are not likely to affect the risk characterisation significantly.

3.4. Conclusions on risk characterisation

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

RAC considers that the estimates of excess cancer risk for workers based on the measured exposure values and indirect exposure of humans (workers and general population) via the environment at local level calculated by the authorisation holder allow a health impact assessment.

4. Analysis of alternatives and substitution plan[21]

What is the amount of substance that the authorisation holder uses per year for the use applied for?

100 tonnes CrO_3/year (15 tonnes CrO_3/year in the initial application)

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

Background to the review report

According to the authorisation holder, the technical function and requirements of the passivation of copper foil have not changed from the initial application of 2018. In the initial application it was stated that passivated copper foil must pass the following criteria:

- A thickness of 6-14 µm for differing types of copper foil.
- A chromium concentration of 2.5-3 µg/mm^2 of copper foil as per client specifications.
- An oxidation test at 130 °C for 30 minutes and at 150 °C for 10 minutes.
- A 24-hour saline test, during which the foils are packed in a plastic bag containing a filter paper, soaked with a 3.5 % NaCl solution between each sample.
- A humidity test aimed at evaluating the resistance of copper foils to humid environment (60 % and 90 % of humidity) for three weeks.

Regarding the customer requirement for a minimum amount of chromium on the surface of the copper foil, it was explained in the initial application that this is meant to address the issue of propagation of cupric ions throughout the Lithium-Ion Batteries during their lifetime. In the review report it is also stated that the presence of chromium on the anode has a beneficial effect on battery performance and that any alternative should at the very least match this effect. In response to a question by SEAC, the authorisation holder further explained that this beneficial effect is the reason why the customer requirement on the amount of chromium is unlikely to change in the short to medium term. To mitigate the problem of lack of acceptance of alternatives by customers, the authorisation holder states to have involved anode/battery manufacturers and automotive Original Equipment Manufacturers (OEMs) in the development of alternatives through a collaborative research proposal that was to be submitted to the EU's Horizon 2020 funding scheme. It is therefore SEAC's understanding that the authorisation holder's work towards identifying and implementing alternatives that fulfil the above criteria is carried out with a view to achieve the key functions and properties currently provided by chromium trioxide outlined in section 0.2 above.

Research into alternatives is undertaken by the authorisation holder's sister company, Circuit Foil. In the initial application the following list of possible alternatives was presented:

- Availability of alternative manufacturers of copper foils.

[21] 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 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*".

- Alternative techniques to satisfy customers' specifications, such as the following: 1) alternative packaging processes for copper foil (i.e., nitrogen packaging), 2) alternate supply routes of copper foil so as to alleviate concerns of customer concerning security of supply, 3) possibility of supplying copper foil to customers from a non-EU location in proximity to the EU, and 4) possibility of supplying copper foil to customers from more distant non-EU sources.
- A review of the 24 alternatives examined in the Circuit Foil application, from which 13 alternatives were rejected without testing. The remaining 11 alternatives were further evaluated or tested and grouped in the following four groups: 1) Cr(III)-based solutions, 2) organic resins, 3) silane-based coatings, and 4) ionic implantation.

Advances made since initial application

In the current review report, the authorisation holder provides an update on the advances that have been made towards identifying an alternative technology since the initial application. These advances are summarized as follows:

- *Data searches*:

  The focus has been on basic academic research. The authorisation holder presents the following information sources that have been utilized:

  - In-house and customer expertise on copper foil passivation requirements;
  - Existing offered alternatives to chromium trioxide that were found to be unsatisfactory but whose faults might be attenuated or resolved through some combination of techniques, combination of substances or additional treatments;
  - Analysis of new patents and scientific publications pertinent to passivation of copper foil (or other metals).

  The authorisation holder has retained the Luxembourg Institute of Science and Technology (LIST) to survey patents and publications. Furthermore, the authorisation holder reports on a collaboration with Findest, a technology scouting service, through which artificial intelligence was employed to identify other potential alternatives or areas for further inquiry. A brief summary of the results of this collaboration was shared with SEAC upon request.

  The conclusion reached by the authorisation holder, and which is based on academic research and patents, is that there are a number of possible passivation methods using known substances in a novel manner which might provide a solution.

- *Characterisation of electro-chemical properties of copper foil:*

  A difficulty that was identified by the authorisation holder was the lack of a specific characterisation method for the performance of alternatives. Through a continued collaboration with LIST, a protocol of optimised characterisation methods for corrosion properties of copper foil samples was developed. This characterisation method relies on the use of electron microscopes that can show the different surface structures of different foils corresponding to different electro-chemical characteristics. The developed methodology is based on the following parameters:

  - Quantitative measurements analytics:
    - Open circuit potential: This is the potential taken by any sample brought into contact with an electrolyte and describes the equilibrium of the

system. Its variations provide information on the degradation, passivation or immunity of a metal surface.

- Tafel curves: These are graphical plots showing the relationship between the current generated in an electrochemical cell and the electrode potential of a specific metal.

- Qualitative analytics:
  - Cyclic voltammetry behaviour: Cyclic voltammetry is generally used to study the electrochemical properties of an analyte in solution.
  - Bode diagrams behaviour: Electrochemical Impedance Spectroscopy (EIS) is a method to obtain information on water permeation and diffusivity of moisture for barrier layers. EIS makes it possible to study the reaction mechanisms taking place at the electrode/electrolyte interface. Bode diagrams are used to graphically represent the EIS results.

The qualitative analytics allow insight into the behaviour of the species and the role of corrosion protection. The quantitative analytics provide a benchmark of the protection that is required to copper foil, currently granted by chromium, and these then serve as control values for the performance of alternatives.

- *Consultations with alternative providers:*

  In response to a SEAC question, the authorisation holder states that all alternative suppliers were consulted in the Circuit Foil application, which is an integral part of the current review report. None of those suppliers could provide a solution that worked which is why fundamental research was started. In its response, the authorisation holder also informs about new exchanges with alternative suppliers but notes that from these it became apparent that the problem of copper foil passivation was too complex and the market commercially not interesting enough for the alternative suppliers to focus upon. They were ready to supply a standard in-house solution for chrome plating/passivation, but this was not suitable for the thinness of the product of the authorisation holder.

Current status and next steps

The characterisation method for the corrosion properties mentioned above is described in a report prepared by LIST. The report is being transformed into a process that will be used to perform a full characterisation of all the existing qualities of copper foil produced by the authorisation holder.

In response to a request for clarification by SEAC, the authorisation holder explained that the work conducted by LIST should be understood as a screening study together with a sample study in extreme conditions as it was performed in a (very corrosive) liquid phase (i.e., saltwater). The behaviour of the copper foil is expected to be different when it comes to air oxidation. The characterisation method developed by LIST is therefore used as a basis to do further real studies and in particular to make it applicable to air oxidation.

Once the existing qualities of copper foil have been characterised, the collected data will serve as reference against which all identified substances (alone or in combination with other substances/techniques of corrosion protection) that might be developed to substitute chromium trioxide will be benchmarked. Solutions with similar or better characteristics compared to the current Cr(VI)-based passivation will be subject of the next stage of trialling. If no solution proves to be sufficient, a return to the basic research phase will be required.

The review report includes information on the substitution activities planned to be carried out until the end of the requested review period. These are further discussed in section 4.4 below.

Consultation comments

No comments from interested third parties were received on this review report during the consultation period.

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

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

4.3. Availability and technical and economic feasibility of alternatives for the authorisation holder

Are there alternatives with the same function and similar level of performance that are technically and economically feasible to the authorisation holder by the date of adoption of the opinion?

☐Yes ☒No

In the initial application the authorisation holder reported that a renewed research contract with LIST would focus on the evaluation of three selected alternatives to Cr(VI): molybdate plating, Cr(III) plating, and silane application on the foil. At the request of SEAC, the authorisation holder explained that these alternatives will be assessed within the characterisation benchmarking described in section 4.1 above. In addition, further technology variants identified as part of the Findest study will be examined, these include electrophoretic deposition of graphene, self-assembled monolayers, 'chemical' solutions (e.g. conversion coatings), and vacuum techniques (physical vapour deposition, chemical vapour deposition).

Furthermore, the authorisation holder shared with SEAC in a confidential manner the results of a study of the technology, processes and substance(s) currently being considered to be the most promising. The authorisation holder declined to name this potential alternative as a fully-fledged practical alternative at this time and reiterated that all promising alternatives will be ranked according to their electro-chemical performance in 2021-2023 within the above-mentioned characterisation benchmarking.

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

As described in section 4.1, the authorisation holder is currently in the process of characterising and benchmarking possible alternatives. Any substitution candidates identified will then have to undergo further trials (trial phase) and customer qualification (customer phase) before the

actual substitution phase can start. As such, the possible alternatives, presented in the initial application and complemented in the review report, are not technically feasible as of today. The economic feasibility and availability of alternatives was not discussed by the authorisation holder.

4.4. Substitution activities/plan

Has the authorisation holder 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 authorisation holder introduced its substitution process, including timelines, in the analysis of alternatives of the review report. The initial submission of the review report did not contain a standalone substitution plan. A short document entitled substitution plan containing some complementing information to the information presented in the analysis of alternatives was submitted after ECHA invited the authorisation holder to consider the submission of a substitution plan. Further complementing information on the authorisation holder's planned substitution activities and timelines was provided in response to questions by SEAC. Moreover, initially, the review report did not contain information on how the implementation of the substitution plan will be monitored, but in a response to SEAC questions, the authorisation holder detailed elements that support their commitment to substitution. SEAC therefore considers that all the information required as part of a substitution plan has been provided by the authorisation holder.

The authorisation holder emphasizes that, in the absence of a known substitute, it is impossible for them to predict with any precision the steps that would be required to successfully introduce an alternative to the manufacturing process of copper foil and to their customers. Therefore, the submitted substitution plan is outlined only in the context of the discovery of a workable alternative and, as such, it outlines the steps required to implement this as yet unknown alternative substance, process, method or combination thereof.

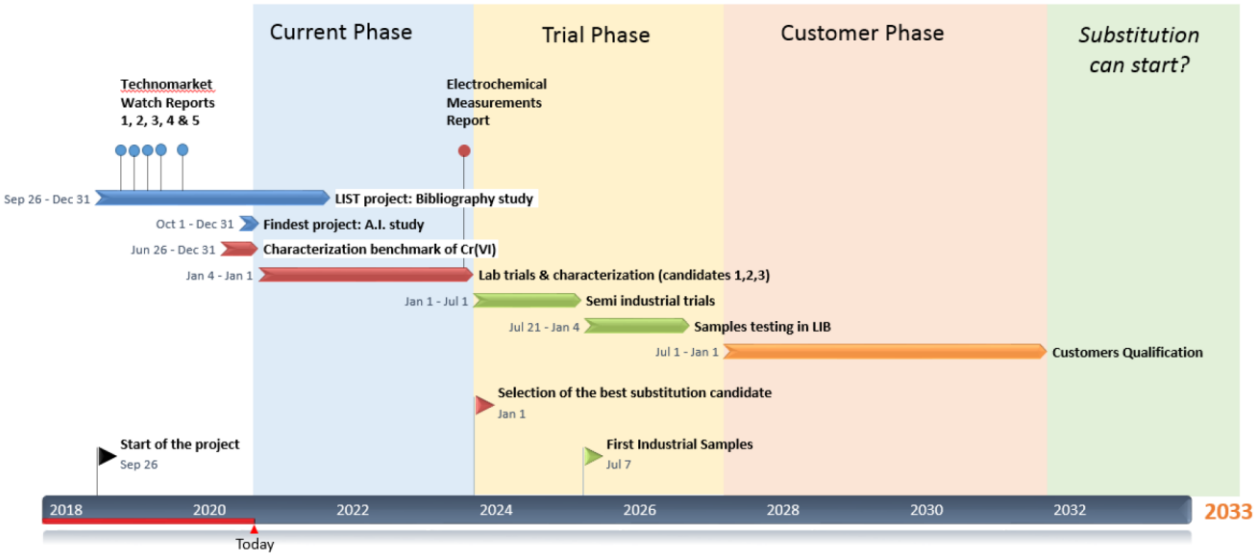
The steps to be taken towards substitution by the authorisation holder comprise the current phase, as well as subsequent substitution steps including trial, customer and substitution phases (see Figure 1). The different phases and the actions to be completed, as described in the analysis of alternatives and in the responses to SEAC questions, are summarised as follows:

- Current phase (2021-2023): All potential alternatives will be characterised on their electro-chemical properties based on the research conducted by LIST. The deliverable will be an electrochemical measurements report ranking the potential solutions. The following steps are foreseen in this phase (some overlap will occur between the steps, hence summing up the durations of the individual steps exceeds the total duration foreseen for the phase):
    - Electro-chemical measurements of existing foil varieties (ca. 4) – Duration: 6 months

    - Electro-chemical measurements of Lithium-Ion Battery foil manufactured with variant alternatives (3-5 different technologies) including first the study of one alternative from Findest research (1 year) and then subsequent study of 1-2 alternatives per year – Duration: 36 months
    - Analysis and conclusions – Duration: 6 months
- Trial phase (2024-2027): Based on the electrochemical measurements report produced in the previous phase, three solutions will be identified for trialling and testing in-house for performance in Lithium-Ion Batteries. The deliverable will be an alternative solution ready to offer to customers. The following steps are foreseen in this phase:
    - Analysis of electrochemical measurements including ranking, combination strategies of technologies, process adaptations (pre/postproduction), elimination of options that have predictable unsurmountable incompatibility with secondary requirements – Duration 6 months
    - Trial manufacture of three solutions – Duration: 16 months
    - Lithium-Ion Battery compatibility study including anodic slurries adherence trials, new passivation electrochemical cycling behaviour trials (cyclic voltammetry in Lithium-Ion Battery conditions), ultrasonic welding trials – Duration: 8 months
    - External performance testing in Lithium-Ion Battery foil with strategic partner – Duration: 6 months
- Customer phase (2028-2030/31): Lifetime testing by battery manufacturers and automotive OEMs (to run concurrently with other development steps) – Duration: 3-4 years
- Substitution phase (beyond 2032): If all previous phases are concluded successfully, the alternative can be rolled out. Contractual and post-production service requirements will not permit instant complete substitution.

The authorisation holder states in the explanatory note accompanying the review report and in response to a SEAC request for clarification that the review period should remain unchanged from the granted authorisation. In other words, the authorisation holder requests a review period that coincides with the date of expiry of the granted authorisation, i.e., until 10 January 2032. This means that the requested review period would allow the authorisation holder to complete the current, trial and customer phases, but the substitution phase would have to be covered by a further review report. The authorisation holder explicitly states that by the time a further review report is submitted (i.e., 18 months before the end of the requested review period) a more detailed substitution plan that includes the final substitution steps can be drafted.

Figure 1: Substitution steps described by the authorisation holder



In their substitution plan, the authorisation holder points out some factors that should be taken into consideration once a solution is found to substitute chromium trioxide. What stands out in those factors are the following statements:

- The market for Lithium-Ion Batteries and electric vehicles is in full development with ever higher demands being set on the performance of the battery. Incorporating major changes at the moment requires a testing period by the customer of about 5 years. However, as batteries become capable of longer usage it is foreseeable that by the time an alternative is found that period will have been extended;
- There will be a considerable period during which post-production service for spare parts or existing models of batteries will have to be assured.

SEAC's evaluation/view on the substitution activities/plan

SEAC initially identified some areas that lacked clarity or detail regarding the substitution activities/plan described in the review report, towards which questions were asked of the authorisation holder. Specifically:

- There was a lack of detail related to the actions to be completed (including their duration) under the various substitution phases to justify the estimated timelines. The authorisation holder responded by providing some more specific steps/actions that are planned for each phase in the substitution activities.
- The reference to a "special internal trial step" was specified to mean a collaborative research proposal together with anode/battery manufacturers and automotive OEMs that was to be submitted to EU's Horizon 2020 proposal funding scheme to facilitate substitution once a working alternative is identified.
- There was confusion as to whether the substitution phase can only start once the customer phase is fully concluded and whether the testing of battery lifetime by customers is fully incorporated in the customer phase. The authorisation holder confirmed that lifetime testing is fully incorporated into the customer phase for which 3-4 years is budgeted. The authorisation holder explained that the 3-4 years were derived based on the expectation of time-limited trials running concurrently between battery manufacturers and automotive OEMs and increased acceptance of alternatives

by customers due to the above-mentioned Horizon 2020 project. However, an absolute worst case would necessitate two 5-year periods, whereby both the battery manufacturers and the automotive OEMs sequentially demand 5 years each. The authorisation holder also confirmed that the substitution phase can only start once the customer phase has been completed.

- It was not quite clear why an additional substitution phase is expected to start beyond 2032 (hence the need for a further review report). SEAC requested explanations of the steps/actions required to achieve substitution and why substitution can only take place over a longer time horizon. The authorisation holder responded by stating that the substitution will not be drop-in but be accompanied by manufacturing, packaging and downstream user process changes. At the same time, they provided information about their experiences with substituting As_2O_3 in their process at Circuit Foil as a means to explaining their anticipated course of action and timeline expectations. With regard to the present review report, the authorisation holder stated that it is realistic to foresee that chrome-containing production will be required 10-12 years after the alternative is found to be fully functional, working and accepted by customers.
- SEAC inquired about the most important uncertainties in the timeline presented and whether/how these have been considered in the estimated duration of the different phases. The authorisation holder stated that the timeline detailed includes periods for contingencies and follows the logic of a realistic worst-case scenario. They listed their most important uncertainties as being the following:
    - uncertainty regarding the multiplicity of changes required;
    - unexpected reactions of the alternative within the Lithium-Ion Batteries (e.g. reactions that are hard to predict given the high reactivity of lithium hydroxide), and the accompanied sensitivity of battery manufacturers to related risks entailed;
    - OEM buy-in and the fact that battery manufacturers often see Volta as only a supplier rather than a partner;
    - the maintenance of multiple production lines, which could bring about difficulties and delays and added expenses.

Despite the authorisation holder's expressed optimism towards finding an alternative solution within the timelines of the requested review period, they intend to submit a further review report by the end of the requested review period since, according to the information provided by the authorisation holder, substitution can only take place over a longer time horizon and is expected to extend beyond 2032 (see Figure 1).

While, based on the information in the review report and the additional clarifications provided by the authorisation holder, SEAC finds it credible that substitution can only be fully achieved over a longer time horizon, SEAC also sees the need for a subsequent review report to provide a more detailed substitution plan covering all phases required to achieve the full phase-out of chromium trioxide (i.e., including the substitution phase). SEAC's recommendation for the review report is described in section 9 of this opinion.

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

By the date of adoption of the 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 authorisation holder. The substitution plan was credible and consistent with the analysis

of alternatives and the socio-economic analysis.

5. Benefits and risks of continued use

Has the authorisation holder adequately assessed the benefits and the risks of continued use?

☒Yes

☐No

5.1. Human health and environmental impacts of continued use

In the assessment of health impacts in this review report, the main end points considered by the authorisation holder are lung cancer via the inhalation route for workers and for the local population as well as small intestinal cancer via oral exposure (ingestion of drinking water and consumption of fish) for the local population.

In the calculations of health impacts, the authorisation holder applied a value of statistical life of €5 million to quantify the welfare loss from increased mortality, while for the quantification of increased morbidity a value of €410 000 was applied. Using these values and following the approach outlined for the upper bound in Box 2 the ECHA (2016)[22] report on valuing selected health impacts of chemicals, the authorisation holder then derived a value of avoiding a lung cancer case (€4 million, rounded) and a value of avoiding a small intestinal cancer case (€1.8 million, rounded).

RAC's scrutiny resulted in some changes in the assessment of worker exposure as well as exposure of humans via the environment and therefore in the excess cancer risks. SEAC has taken the updated values following from RAC's evaluation as the basis for the human health impact assessment.

Workers

According to the authorisation holder, a total of **28 workers** (12 in WCS 2, 16 in WCS 3) are **directly exposed** via the inhalation route. For each WCS, the authorisation holder considered lifetime excess lung cancer risk for a total working life of 40 years. Considering RAC's evaluation of worker exposure, under the applied for use scenario, there would be 7.16×10^{-5} additional statistical **lung cancer cases** among workers. Considering the above-mentioned value of an avoided lung cancer case (€4 million), the monetised excess risk to workers directly exposed would amount to €7 per year over the review period.

Local population

The authorisation holder's site is located outside of the centre of Környe, a village of about 5 000 inhabitants. The nearest houses of the nearest residential area are about 300 m from the site and there is no other residential area within a 1-km radius of the site. The number of people considered by the authorisation holder for the **oral intake** route has been conservatively assumed to be 10 000. The authorisation holder considered lifetime excess intestinal cancer risk for a lifetime exposure of 70 years. Considering RAC's evaluation of exposure of humans via the environment, under the applied for use scenario, there would be 1.07×10^{-3} additional statistical **intestinal cancer cases** for the assumed local population.

[22] ECHA (2016), Valuing selected health impacts of chemicals – Summary of the Results and a Critical Review of the ECHA study: https://echa.europa.eu/documents/10162/13630/echa_review_wtp_en.pdf/dfc3f035-7aa8-4c7b-90ad-4f7d01b6e0bc

Taking into account the above-mentioned value of an avoided intestinal cancer case (€1.8 million), this means a monetised excess risk to the local population of about €28 per year over the review period.

According to the authorisation holder, at local level, there is no exposure (neither residents nor workers from nearby plants) via the **inhalation route** in the area within a 100 m radius from the current and the new facilities as the nearest houses are about 300 m from the site. However, to be conservative, the authorisation holder has assumed a worst-case scenario with 200 people exposed. Considering excess lung cancer risk for a lifetime exposure of 70 years, according to the authorisation holder, under the applied for use scenario, there would be 1.63×10^{-3} additional statistical **lung cancer cases** in the assumed local population. Considering the above-mentioned value of an avoided lung cancer case (€4 million), the monetised excess risk for the local population amounts to about €93 per year over the review period.

Overall, the estimated monetised excess risk for the **local population (via oral intake and inhalation route)** amount to €121 per year over the review period.

Regional population

The authorisation holder stressed that, considering EU RAR (2005)[23] and in line with previous RAC opinions, the focus of the assessment is on local exposure and impacts as Cr(VI) will transform in the environment to Cr(III).

Total monetised excess risk

The total monetised excess risk of continued use, including lung cancer risk to workers and intestinal and lung cancer risk to the local population, is estimated at €128 per year over the review period.

Environment

The authorisation holder did not carry out an assessment of environmental impacts since chromium trioxide is listed on Annex XIV of REACH for its carcinogenic and mutagenic properties.

[23] European Chemicals Bureau (2005), European Union Risk Assessment Report – Chromium Trioxide, Sodium Chromate, Sodium Dichromate, Ammonium Dichromate, Potassium Dichromate: https://echa.europa.eu/documents/10162/3be377f2-cb05-455f-b620-af3cbe2d570b

Table 13: Summary of additional statistical lung and intestinal cancer cases

	Excess lung or intestinal cancer risk[1]	Number of exposed people	Estimated statistical lung or intestinal cancer cases	Value per statistical lung or intestinal cancer case	Monetised excess risk per year[2]
Directly exposed workers (lung cancer)[3]	WCS 2: 4.00×10^{-6} WCS 3: 6.35×10^{-7}	WCS 2: 12 WCS 3: 16	7.16×10^{-5}	€4m	€7
Indirectly exposed workers[4]	n/a	n/a	n/a	n/a	n/a
Local general population (oral – intestinal cancer)	5.15×10^{-8}	10 000	1.07×10^{-3}	€1.8m	€28
Local general population (inhalation – lung cancer)	6.61×10^{-6}	200	1.63×10^{-3}	€4m	€93
Regional general population	n/a	n/a	n/a	n/a	n/a
Total			**2.77×10^{-3}**		**€128**
Latency (years)	10 years for lung cancer, 26 years for intestinal cancer				

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. Annualised to a typical year based on the time horizon used in the SEA.
3. Directly exposed workers perform tasks described in the worker contributing scenarios, typically based on 8-hour Time Weighted Average (TWA) of a representative worker. Risk to workers arising from passivation (WCS 4) is described in the CSR but has not been considered by the authorisation holder in the assessment of human health impacts as the passivation stage is not subject to authorisation. This is consistent with the approach taken in the initial application for authorisation.
4. Indirectly exposed workers (bystanders) do not use the substance.

5.2. Benefits of continued use

Non-use scenario

The authorisation holder claims that a refused authorisation on this review report would be equivalent to a **permanent shutdown** of its current production facility while the planned two new production facilities will not be built, because no technically viable alternative to chromium trioxide exists yet. Under the most likely non-use scenario, the authorisation holder considers that its customers will import a large volume of passivated copper foil from Asia (China or South Korea).

The authorisation holder also analysed the non-use scenario of outsourcing the formulation step for the passivation of copper foil to outside the EEA. However, the authorisation holder considers that this is not a likely non-use scenario for the following reasons:

1. Exporting the negative impacts on human health and the environment to non-EEA countries is not in line with the authorisation holder's ethical and sustainability principles.
2. In the market there are no companies able to supply, in a reliable way, large quantities of such a low concentration formulation.
3. Compared to the risk of an on-site formulation, outsourcing the formulation would increase the risk of industrial accidents related to the transport of large containers with diluted chromium and to the manipulation of such a diluted chromium formulation.

In answer to a SEAC question, the authorisation holder clarified that the closure of the current production facility under the most likely non-use scenario is due to the fact that, if unable to supply the entire (increased) quantity of passivated copper foil required by its customers, the customers would look elsewhere to meet their demand. The authorisation holder explained that Lithium-Ion Battery manufacturers strongly prefer to have a single supplier that could provide the requested volumes instead of splitting demand among several different suppliers. In this specific case, this would mean splitting demand between the authorisation holder and Asian suppliers.

In view of the clarifications provided by the authorisation holder, SEAC considers that the most likely non-use scenario can be considered credible. SEAC notes, however, that a shutdown of the existing production facility may not be immediate since, in the initial application for authorisation, it was explained by the authorisation holder that the investment in the currently existing facility was secured on the basis of long-term contracts that were signed with its customers.

It has to be noted, though, that this reservation regarding the credibility of the non-use scenario would only be relevant in case the authorisation already granted for the initial application (which covers the use of 15 tonnes chromium trioxide per year) would remain valid despite a non-granted authorisation of this review report. However, even if this was the case and production in the non-use scenario using a chromium trioxide volume of 15 tonnes/year could continue, this would only account for a small proportion of the profits expected for the production using the larger volume of chromium trioxide requested in this review report[24]. As such, this possibility would not alter SEAC's conclusion on the socio-economic analysis.

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

- the use would cease altogether
- the use would be taken up by market actors operating outside the EU

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

- 100-300 jobs would be lost in the European Union

[24] In the initial application EBIT figures were reported as €200-300 million over 12 years (NPV, discounted at 4 %) while in the review report the corresponding EBIT figures are reported to be in the range of €1-10 billion (both are non-confidential ranges, but the actual EBIT figures are known to SEAC).

Economic impacts

SEAC acknowledges that the authorisation holder followed the conservative approach adopted by SEAC in previous opinions of using a one-year profit loss (derived from EBIT figures from the authorisation holder's business plan over the period 2020-2031) to account for the economic impacts of the non-use scenario over the requested review period[25]. In annualised terms, the one-year EBIT loss was estimated by authorisation holder in the order of €10-100 million[26]. SEAC notes that, in the initial application, the authorisation holder did not use the same approach and estimated economic impacts as profit lost over the entire review period requested at that time (15 years).

Social impacts

The authorisation holder assessed the social impacts in terms of job losses for **100-300** employees[27] (range narrowed by the authorisation holder as requested by SEAC) if the current production facility would have to close in case a re-authorisation was not granted.

To quantify the social costs, the authorisation holder used the methodology outlined in Dubourg (2016)[28] and endorsed by SEAC (2016)[29]. It was assumed that the total social costs of unemployment in Hungary is equal to 2.14 times the annual gross salary and only 75 % of the average duration of the employment (Eurostat data for Hungary) were considered to take into account the fact that some workers are highly skilled and would need less time to find a job.

According to the authorisation holder, the avoided net job loss in the affected industry would amount to an annualised €0.1-1 million[30].

In addition, the authorisation holder also underlines that, because in the non-use scenario the expansion of the Környe site would not take place, there would be missed job opportunities for **400-800** workers[31] (range narrowed by the authorisation holder following a question from SEAC) who would otherwise be employed in the planned two new production facilities. However, this potential impact was only qualitatively described, but not monetised, by the authorisation holder. SEAC notes that, in this review report, the approach used by the authorisation holder (i.e., not quantifying the missed job opportunities) is different from that adopted in the initial application where also the social cost of the missed job opportunities was monetised.

Wider economic impacts

According to the authorisation holder, under the non-use scenario, the European Lithium-Ion Battery market would become totally dependent on imports of copper foil from Asia. Since it would take four to six weeks to deliver copper foil products from Asia to Europe, according to the authorisation holder, during this period, its customers would have to finance inventory.

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[25] SEAC notes that the authorisation holder based the producer surplus loss on one year of profit losses. Since the review report was submitted, SEAC agreed an updated approach to the assessment of producer surplus loss (SEAC, 2021: https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138). SEAC notes that, given that the authorisation holder has considered profit losses for a shorter time period than suggested in the new approach, the authorisation holder's estimates of economic impacts can be considered an underestimate.

[26] Actual EBIT loss is claimed confidential by the authorisation holder but it is known to SEAC.

[27] Actual number of job losses is claimed confidential by the authorisation holder but it is known to SEAC.

[28] Dubourg (2016): https://echa.europa.eu/documents/10162/13555/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554

[29] SEAC (2016): https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

[30] Actual social costs are claimed confidential by the authorisation holder but they are known to SEAC.

[31] Actual number of workers is claimed confidential by the authorisation holder but it is known to SEAC.

In addition, due to import tariffs and potential exchange rate risk, there would be an increase of costs for the authorisation holder's European customers. As a consequence, a worsening of the competitiveness of the EEA producers of Lithium-Ion Batteries, as well as a worsening of the EEA trade balance as a whole is anticipated by the authorisation holder.

The authorisation holder is planning to invest a total of €100-1 000 million[32] for the expansion of the Környe site. The authorisation holder explains that, since the 2019 GDP of Hungary was about €146 billion, the planned investment would be equivalent to 0.1-1 % of the Hungarian GDP[33], hence entailing a significant positive impact on the local economy and on the Hungarian economy in general.

In addition, the authorisation holder discusses, but does not quantify, the potential loss of gains and employment for satellite businesses.

Table 14: Socio-economic benefits of continued use

Description of major impacts	Quantification of impacts (annualised to € million per year)
1. Benefits to the authorisation holder and/or their supply chain	
1.1 Avoided profit loss due to investment and/or production costs related to the adoption of an alternative	n/a
1.2 Avoided profit loss due to ceasing the use applied for	€10-100 million
1.3 Avoided relocation or closure cost	n/a
1.4 Avoided residual value of capital	n/a
1.5 Avoided additional cost for transportation, quality testing, etc.	n/a
Sum of benefits to the authorisation holder and/or their supply chain	*€10-100 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	€0.1-1 million
2.2 Foregone spill-over impact on surplus of alternative producers	n/a
2.3 Avoided consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity, etc.)	n/a
2.4 Avoided other societal impacts (e.g. avoided CO_2 emissions or securing the production of drugs)	n/a
Sum of impacts of continuation of the use applied for	*€0.1-1 million*
3. Aggregated socio-economic benefits (1+2)	**€10-100 million[1]**

Notes:

1. This range includes both the €10-100 million related to avoided profit loss and the €0.1-1 million related to avoided net job loss.

5.3. Combined assessment of impacts

The total monetised benefits of continued use are estimated by the authorisation holder to be in the order of €10-100 million in annualised terms, while the monetised excess risks of continued use, considering changes made following RAC's scrutiny, are estimated at €128 per year. In addition, some benefits of continued use were assessed qualitatively but were not

[32] Actual investment is claimed confidential by the authorisation holder, but it is known to SEAC.
[33] Actual percentage is claimed confidential by the authorisation holder, but it is known to SEAC.

monetised.

Table 15: Socio-economic benefits and risks of continued use

Socio-economic benefits of continued use		**Excess risks associated with continued use**	
Benefits (annualised to € million per year)	€10-100 million	Monetised excess risks to workers directly exposed in the use applied for (annualised to € per year)	€7
Quantified impacts of the continuation of the SVHC use applied for	n/a	Monetised excess risks to the general population and indirectly exposed workers (annualised to € per year)	€121
Additional qualitatively assessed impacts	Avoided loss of job opportunities Avoided wider economic impacts, including: - a rise in the dependency on imports of copper foil from Asia, with a consequent worsening of the EEA trade balance - a worsening of the competitiveness of the EEA producers of Lithium-Ion Batteries due to the additional costs for import duties - risk of exchange rate for EEA customers importing copper foils from Asia - less flexibility for business due to longer delivery times - loss of new business opportunities and employment for satellite activities - loss of a positive knock-on effect from the investment on the Hungarian economy	Additional qualitatively assessed risks	n/a
Summary of socio-economic benefits	**€10-100 million** **Avoided loss of job opportunities** **Avoided wider economic impacts**	**Summary of excess risk**	**€128**

5.4. SEAC's view on socio-economic analysis

SEAC acknowledges that the authorisation holder has estimated the **human health impacts** of continued use following ECHA's SEA guidance. Moreover, SEAC acknowledges that human health impacts for directly exposed workers and for the local population have been quantified by the authorisation holder by using ECHA's note (RAC/27/2013) that establishes a reference dose-response relationship for the carcinogenicity of Cr(VI), and willingness to pay values

presented in ECHA's report on valuing selected health impacts associated with chemical exposure. SEAC also notes that, in its assessment of human health impacts, the authorisation holder conservatively took into account a size of the local population exposed that is likely to be higher than the population actually living in the vicinity of the Környe site. The authorisation holder has also rectified the potential double counting of health impacts identified by SEAC in its opinion on the initial application. Finally, SEAC took into account changes in the assessment of worker exposure as well as exposure of human via the environment following from RAC's evaluation. The total monetised excess risk of continued use incorporating these changes is lower than the value reported in the SEA originally submitted with this review report.

SEAC finds credible that the market would react by importing passivated copper foil from outside the EEA in case of a refused authorisation. In addition, SEAC finds it plausible that, under the non-use scenario, the authorisation holder would not build two additional production facilities as planned. However, SEAC notes that only limited or unclear information was initially provided by the authorisation holder to explain its rationale for closing the current production facility in the **non-use scenario**. In fact, in the review report, it was not entirely clear to SEAC to what extent a refused re-authorisation would imply a permanent shutdown of a recently completed production facility that, only a few years ago, was considered to be profitable. In its answer to SEAC's questions, the authorisation holder made clear that, in case of a refused authorisation on this review report, the whole business would be lost since the authorisation holder would not be able to satisfy the increased demand for copper foil. As a consequence, according to the authorisation holder, manufacturers of Lithium-Ion Batteries would choose to buy copper foil from a single supplier rather than splitting supply among several companies. SEAC considers that this non-use scenario is credible but notes that, if the authorisation already granted for the initial application would remain valid despite a non-granted authorisation of this review report, a shutdown of the existing production facility may not be immediate given that long-term contracts were signed with customers before the investment in the facility. However, this possibility would not alter SEAC's conclusion on the socio-economic analysis.

In SEAC's view, in case the authorisation was not granted, there would be negative socio-economic impacts for the authorisation holder, for manufacturers of Lithium-Ion Batteries as well as for the local and the Hungarian economies.

SEAC acknowledges that the authorisation holder used a one-year EBIT loss to quantify **economic impacts** over the requested review period. In fact, SEAC considers that changes in EBIT are a relevant measure of changes in producer surplus and appropriate to monetise the welfare implications of continued use. SEAC also considers that using a one-year EBIT loss, while being conservative and giving only a lower bound of economic impacts, better reflects net changes in economic surplus across the EU economy than considering losses over a long time period. The approach taken by the authorisation holder takes into account the possibility of mitigating actions that could reduce the economic impacts (e.g., resources being redeployed by the authorisation holder or by other companies). The authorisation holder estimated the **social cost** of unemployment based on the ECHA methodology.

SEAC considers that the authorisation holder did not include any monetised value for the socio-economic impacts on the manufacturers of Lithium-Ion Batteries and of other satellite activities and that this represents a conservative approach that likely underestimates the total benefits of continued use.

In conclusion, SEAC considers that the authorisation holder has adequately assessed the benefits and the risks of continued use. SEAC notes that no major remaining uncertainties in relation to the socio-economic analysis have been identified.

5.5. Conclusion on the socio-economic analysis

SEAC has no substantial reservations on the quantitative and qualitative elements of the authorisation holder's assessment of the benefits and the risks to human health associated with the continued use of the substance. This conclusion is made based on:

- the review report,
- SEAC's assessment of the benefits of continued use,
- SEAC's assessment of the availability, technical and economic feasibility of alternatives,
- additional information provided by the authorisation holder, and
- RAC's assessment of the risks to human health.

6. Proposed review period

☐Normal (7 years)

☐Long (12 years)

☐Short (…. years)

☒Other: Until 10 January 2032

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

6.1. RAC's advice

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

6.2. Substitution and socio-economic considerations

The authorisation holder states in the explanatory note accompanying the review report and in response to a SEAC request for clarification that the review period should remain unchanged from the granted authorisation. In other words, the review period requested coincides with the date of expiry of the granted authorisation, i.e., until 10 January 2032.

SEAC considers that:

- the analysis of alternatives demonstrated without significant uncertainties that by the date of the adoption of this opinion there are no suitable alternatives for the use applied for;
- the authorisation holder has been and continues to be proactive in undertaking research to develop an alternative and is committed to continuing the R&D efforts to substitute chromium trioxide;
- the authorisation holder did not identify up to now any alternative to begin the trial or customer phase, but ongoing efforts to identify a promising alternative as soon as possible are outlined.
- the substitution plan is credible and consistent with review period requested.

- it has no substantial reservations on the quantitative and qualitative elements of the authorisation holder's assessment of the benefits and the risks to human health associated with the continued use of the substance.

Taking into account these points, SEAC recommends a review period until **10 January 2032**.

7. Proposed additional conditions for the authorisation

Were additional conditions[34] proposed for the authorisation?

☐Yes

☒No

7.1. Description

RAC

Proposed additional conditions

None.

SEAC

Proposed additional conditions

None.

7.2. Justification

RAC is of the opinion that the OCs and RMMs are appropriate and effective in limiting the risk for the workers and the general population via the environment. Therefore, no conditions for the authorisation are proposed.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements[35] proposed for the authorisation?

☒Yes

☐No

8.1. Description

1. The authorisation holder shall implement the following monitoring programmes:

a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall:

(i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased

[34] 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.
[35] 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.

to capture any potential change in exposure;

(ii) be based on relevant standard methodologies or protocols;

(iii) comprise personal and/or static inhalation exposure sampling;

(iv) be representative of:

a. the range of tasks undertaken where exposure to Cr(IV) is possible;

b. the OCs and RMMs typical for each of these tasks;

c. the number of workers potentially exposed;

(v) include contextual information about the tasks performed during sampling;

(vi) include exposure measurements for the workers involved in the on-site WWTP activities until it can be demonstrated that the workers' exposure to Cr(VI) has been appropriately minimised.

b) Environmental releases:

(i) the authorisation holder shall continue conducting measurements of Cr(VI) in their wastewater and air emission at least annually or more frequently in the periods following any possible changes in the process

(ii) the monitoring programmes for wastewater and air emissions shall:

a. be based on relevant standard methodologies or protocols; and

b. be representative of the OCs and RMMs used at the authorisation holder's site.

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the authorisation holder to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.

3. The authorisation holder shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.

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

5. The authorisation holder shall conduct the monitoring programmes mentioned in 1.a (i) and 1.b (i) at least until the plant functions at full capacity to ensure the impacts of the expansion are closely monitored. Afterwards, the authorisation holder may reduce the frequency of measurements, once they can clearly demonstrate to the national Competent Authority of the Member State where the use takes place, that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible and that the risk management measures, and operational conditions function appropriately.

8.2. Justification

Although RAC considers the operational conditions and risk management measures described in the review report in relation to both workers and humans via the environment to be appropriate and effective in limiting the risk from exposure through inhalation and the oral route, RAC considers that at least yearly monitoring programmes should be continued to obtain a more representative exposure assessment. This would help address the shortcomings identified due to the poorly substantiated release factor for the air emission estimates as well as the inherent uncertainties caused by the future increased use of CrO_3.

Although RAC considers that these shortcomings and inherent uncertainties would not be expected to lead to significantly higher exposure estimates compared to those considered for the risk characterisation, the authorisation holder shall address them by obtaining representative measurements for workers' exposure and air emissions.

9. Recommendations for the review report

Were recommendations for the review report made?

☒Yes

☐No

9.1. Description

RAC

The results of the measurements referred to in section 8.1 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report. In addition, any subsequent authorisation review report should contain clear information that supports the air and wastewater abatement efficiencies.

SEAC

SEAC recommends the authorisation holder to provide a detailed substitution plan outlining the concrete actions and timelines required to achieve the full phase-out of chromium trioxide.

9.2. Justifications

RAC

Provision of the results of the investigation and representative monitoring results would allow for a better evaluation of the actual and future situation at the authorisation holder’s site and would further confirm the appropriateness and effectiveness of the implemented OCs and RMMs.

SEAC

SEAC notes that the authorisation holder states that the substitution plan is outlined only in the context of the discovery of a workable alternative. The substitution plan presented covers the current, trial and customer phases, but does not detail the final steps, concrete actions and timelines to achieve full substitution. SEAC also notes that the authorisation holder states that by the time a further review report is submitted (i.e., 18 months before the end of the requested review period) a more detailed substitution plan that includes the final substitution

steps can be drafted.

10. Comments on the draft final opinion

Did the authorisation holder provide comments on the draft final opinion?

☐Yes

☒No

10.1. Comments of the authorisation holder

Was action taken resulting from the analysis of the comments of the authorisation holder?

☐Yes

☐No

☒Not applicable – the authorisation holder did not comment

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

Not relevant.

10.3. Reasons for not amending the opinion

Not relevant.

Annex: Workers' exposure measurements

Table 16: Measurement results

WCS	Type	Operator	Sampling period (min)	Cr(VI) concentration µg/m³	
WCS 2	Personal	A	124	0.016	Dissolution of 4 barrels.
WCS 2	Personal	A	138	0.016	Dissolution of 4 barrels, including disposal of the repacked empty barrels in the dedicated waste storage areas.
WCS 2	Static	-	124	0.015	Dissolution of 4 barrels. Control panel.
WCS 2	Static	-	124	0.008 (< LoQ)	Dissolution of 4 barrels. Lid heater.
WCS 3	Personal	B D	55 65	0.0185 (< LoQ) 0.032	Helper- more than 2 m distance to the place of work.
WCS 3	Personal	C C	60 67	0.033 0.061	Maintenance technician doing the repair.
WCS 3	Static	-	61 66	0.034 0.088	Workplace during the repair.
WCS 3	Static	-	61 63	0.0165 (< LoQ) 0.016 (< LoQ)	Walkway, close to the workplace.