Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

chromium trioxide use:

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

ECHA/RAC/SEAC: AFA-O-0000006678-59-01/D

Consolidated version

Date: 09/01/2019

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

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

Applicant(s)	**Doosan Electro-Materials Luxembourg SARL** (position in supply chain: importer) **Doosan Energy Solution Kft** (position in supply chain: downstream user)
Substance ID EC No CAS No	**Chromium trioxide** 215-607-8 1333-82-0
Intrinsic property(ies) 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: Not applicable
	Same uses applied for: 0058-01 (use ID ECHA website)
Use performed by	☒Applicant(s) (Doosan Energy Solution Kft) ☐Downstream User(s) of the applicant(s)
Use ID (ECHA website)	0128-01
AfA Reference number	11-2120777054-53-0001 11-2120777054-53-0002

RAC Rapporteur	Lina Dunauskienė
SEAC Rapporteur SEAC Co-rapporteur	Luisa Cavalieri Christos Anastasiou
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PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	18/05/2018
Date of payment, in accordance with Fee Regulation (EC) No 340/2008 on	27/07/2018
The application has been submitted by the Latest Application Date for the substance and applicant(s) can benefit from the transitional arrangements described in Article 58(1)(c)(ii).	☐Yes ☒No
Public Consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	08/08/2018 – 03/10/2018
Comments received	☐Yes ☒No Link: Not applicable
Request for additional information in accordance with Article 64(3)	14/09/2018; 18/09/2018; 12/10/2018; 19/10/2018; Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations
The trialogue meeting	16/10/2018
Extension of the time limit set in Article 64(1) for the sending of the draft opinions to the applicant	☐Yes ☒No
The application included all the necessary information specified in Article 62 that is relevant to the Committee's remit.	☒Yes ☐No Comment:
Agreement of draft opinion in accordance with Article 64(4)(a) and (b) on	RAC: 30/11/2018, agreed by consensus.
	SEAC: 29/11/2018, agreed by consensus.
Date of sending of the draft opinion to applicant	08/01/2019

Date of applicant's decision not to comment on the draft opinion, according to Article 64(5)	09/01/2019
Date of receipt of applicant's comments, according to Article 64(5), received	Not relevant
Adoption of opinion, according to Article 64(5), on	RAC: 09/01/2019, adopted by consensus.
	SEAC: 09/01/2019, 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,
- the assessment of the hazards and risks related to the alternatives as documented in the application, as well as
- other available information.

RAC concluded that it is not possible to determine a DNEL for the carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

RAC concluded that there appear to be no alternatives that would further reduce the overall risks.

RAC concluded that the operational conditions and risk management measures described in the application are expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

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 application, as well as
- other available information.

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

SEAC concluded that there appear to be no suitable and available alternatives by the Sunset Date[1].

SEAC concluded that the applicant's assessment of: (a) the potential socio-economic benefits of the continued use, (b) the potential adverse effects to human health of the continued use and (c) the comparison of the two is based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the continued use outweigh the risk to human health, whilst taking account of any uncertainties in the assessment provided that the recommended conditions are adhered to.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Additional monitoring arrangements are proposed. These are listed in sections 8 and 9 of this opinion.

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicant and the comments received on the broad information on use, the duration of the review period for the use is recommended to be **12 years**.

[1] The sunset date for CrO_3 was 21/09/2017. In this opinion, it is considered if there appear to be suitable and available alternatives by January 2020 when the applicants plan to start production in the future plant.

SUMMARY OF THE APPLICATION FOR AUTHORISATION / USE

Type of application (applicant)	☐Upstream (M/I/OR or group of) ☐Upstream (Formulator or group of) ☐Downstream (group of users) ☒Downstream (single user) ☐Other
Indicative number and location of sites covered	This Application for Authorisation (AfA) is for a future use that will take place at one site.The installation is planned to be built in Környe, nearby the city of Tatabanya, Hungary.
Annual tonnage of Annex XIV substance used per site (or total for all sites)	15 tonnes
Function(s) of the Annex XIV substance. Type of products (e.g. articles) made with Annex XIV substance and their market sectors	The applicants apply for the use of chromium trioxide in the 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 for motorised vehicles. Chromium trioxide has no independent function during formulation. During the passivation of the foil, 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 batteries anodes; • Prevent the propagation of cupric ions throughout the battery during its life-time use; • Improve battery performance (capacity, cell's impedance and peel strength of anode film). While the use applied for is 'formulation', the solution prepared contains less than 0.1 % of Cr(VI) **and is therefore not subject to authorisation**. This solution is used on-site by the applicants to produce passivated copper foils further used in the manufacture of lithium ion batteries for motorised vehicles. The new plant will be the first installation in the EEA territory to produce copper foil for this specific application.

Shortlisted alternatives discussed in the application	Alternative substances considered: • Chrome III bath • Tri Mac III/MA Chrome Cl3 • Gardolene D (Zinc) • Silane • Tin • Other metals like Cobalt , tungsten, indium etc. • Benzotriazole • Other organic resins Alternative technologies considered: • Ionic implantation • Vacuum / Nitrogen packaging
Annex XIV substance present in the products (e.g. articles) made by the downstream users	☐Yes ☒No ☐Unclear ☐Not relevant
Number of workers exposed per site (or total for all sites):	Directly: 25
Number of humans exposed via the environment	Local scale: 10 000 Regional scale: Not relevant
Environmental compartments affected:	☒Air ☒Water ☐Soil ☐None
Applicant has used the Dose response relationship recommend-ded by RAC	☒Yes https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf ☐No

All endpoints listed in Annex XIV were addressed in the assessment	☒Yes ☐No
All relevant routes of exposure were considered	☒Yes ☐No
Adequate control concluded by applicant for the relevant endpoint(s)	☐Yes ☐No ☒Not Applicable – non-threshold substance
Level of (combined, daily) exposure/release used by applicant for risk characterisation	Workers: Inhalation: 2.62 × 10^{-5} to 1.30 × 10^{-3} µg Cr(VI)/m^3 no combined exposure foreseen Dermal: not applicable Consumer: not applicable Humans via environment: Inhalation: 3.42 × 10^{-8} mg Cr(VI)/m^3 Dermal: not applicable Oral: 9.24 × 10^{-8} mg Cr(VI)/kg bw/d Environment: not applicable
Applicant is seeking authorisation for the period of time needed to finalise substitution ('*bridging application*')	☐Yes ☒No ☐Unclear

Review period argued for by the applicant (length)	15 years
Most likely Non-Use scenario	No new plant will be established in Hungary for the production of copper foils – passivated foil will be imported from outside of EU.
Applicant concludes that benefits of continued use outweigh the risks of continued use	☒Yes ☐No For the review period requested: - Applicants' benefits of continued use: € 100-200M - Society's benefits of continued use: € 119.2M (applicants' benefits + social impacts) - Monetised health impact on workers: € 1.18 - Monetised health impact on the general population: € 234.33 ☐Not Applicable – threshold substance with adequate control

SUMMARY OF RAC AND SEAC CONCLUSIONS[2]

2. Operational Conditions and Risk Management Measures are appropriate and effective in limiting the risk?

2.1. Conclusions of RAC:

Conclusion for workers:

The applicants plan to implement technical measures for those activities where they have identified an exposure potential (except for WCS 3, Maintenance (repairing) of machinery), supplemented and further supported by an OSH management system including organisational measures and personal measures.

As the plant is not operational yet there is no measured data available to confirm that the planned OCs and RMMs will deliver the claimed protection levels.

OCs / RMMs to be implemented are expected to be:

Appropriate: ☒Yes ☐No

Effective: ☒Yes ☐No

Given the information provided in the application and from knowledge of similar chromate applications, RAC considers that the RMMs as proposed would be appropriate and effective in limiting the risk, if implemented as described.

Therefore the applicants should validate the effectiveness of the OC and RMMs by generating and evaluating relevant on site monitoring data once the plant has been commissioned and is in use.

Conclusion for environment and / or Humans via environment (HvE):

The applicants plan to implement technical measures to minimise the releases to the air and water compartment.

As the plant is not operational yet there is no measured data available to confirm that the planned OCs and RMMs will deliver the claimed protection levels.

OCs / RMMs to be implemented are expected to be:

Appropriate: ☒Yes ☐No

Effective: ☒Yes ☐No

Given the information provided in the application and from knowledge of similar chromate applications, RAC considers that the RMMs as proposed would be appropriate and effective in limiting the risk, if implemented as described. Therefore the applicants should validate the effectiveness of the OC and RMMs by generating and evaluating relevant on site monitoring data once the plant has been commissioned and is in use.

Additional monitoring arrangements related to the operational conditions and risk management measures are recommended for the authorisation:

☒Yes ☐No

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

Recommendations to the applicants related to the content of the potential Review Report are made:

☒Yes ☐No

3. Exposure Assessment

Combined exposure level used by RAC for risk characterisation:

Workers: Direct exposure

- Inhalation: no combined exposure foreseen; highest exposure level 1.30 × 10^{-3} µg Cr(VI)/m^3

Humans via environment

- Inhalation: 3.42 × 10^{-8} mg Cr(VI)/m^3
- Oral: 9.24 × 10^{-8} mg Cr(VI)/kg bw/d

Releases to the environmental compartments:

- Air: 1.46 kg/year of Cr(VI)
- Water: 3.65 kg/year of Cr(VI)
- Soil: -

Conclusions of RAC:

The applicants relied on modelling to estimate worker and environmental exposure and provided detailed information regarding the input parameters and results including the predicted 90th percentile modelled exposure estimates for all WCSs.

RAC considers that the overall description of the use provided in the CSR and in the applicants' answers to RAC's requests is sufficient to conclude on the reliability of the worker exposure assessment.

RAC considers that the exposure assessment for a future use contains some inherent weaknesses due to the obvious lack of workplace air measurement and environmental emissions data.

RAC considers that on the basis of the planned RMM's and the modelled exposure data presented, these weaknesses would not be expected to lead to significantly higher exposure estimates in comparison with those selected for further risk characterisation. RAC advises the applicants to validate the results of the modelling by measurements as soon as the plant starts mass production and base their exposure assessment for workers and the general population to be potentially presented in any review report on a representative monitoring data set.

Additional monitoring arrangements related to exposure assessment are recommended for the authorisation

☒Yes ☐No

Recommendations to the applicants related to the content of the potential Review Report are made

☒Yes ☐No

4. Risk Characterisation

Risk levels used for health impact assessment calculated by RAC:

Workers:

Direct exposure: 5.20×10^{-6} (highest risk level)

Humans via environment: 1.07×10^{-6} (combined inhalation and oral)

Conclusions of RAC:

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

5. Analysis of alternatives. Are suitable alternatives available?

Conclusions of SEAC and RAC:

☐Yes ☒No

The sunset date for CrO_3 was 21/09/2017. For this reason, this section will consider if the short-listed alternatives are technically and economically feasible and available before January 2020 when the applicants plan to start production in the future plant.

SEAC considers that the documentation of potential alternatives, as provided in the Analysis of Alternatives, was poorly presented and some claims were not well substantiated. These deficiencies made it difficult for SEAC to have a detailed scrutiny of the analysis. However, additional information provided during the opinion making process helped to better consolidate the information collected. SEAC is of the opinion that the overall analysis is scientifically plausible and that the alternatives assessed are not technically feasible and are leading to a product that is not acceptable by the main customers of the applicants.

The applicants have demonstrated with reasonable certainty that there will not be suitable alternatives available in 7 years. SEAC considers that the applicants failed to demonstrate without significant uncertainties that no suitable alternatives would become available and be implemented within the 15-year review period proposed in the application for authorisation.

Additional conditions or monitoring arrangements related to the assessment of alternatives are recommended for the authorisation

☐Yes ☒No

Recommendations to the applicants related to the content of the potential Review Report

☐Yes ☒No

6. Have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

Conclusions of SEAC:

☒Yes ☐No

Despite residual uncertainties resulting from some information gaps and methodological deficiencies in the analysis carried out by the applicants, SEAC considers the margin between benefits of continued use and risk of continued use to be sufficiently large to conclude that benefits outweigh the risks arising from the future use of chromium trioxide associated with

the production of copper foil for lithium ion batteries in the EEA.

Recommendations to the applicants related to the content of the potential Review Report

☐Yes ☒No

7. Proposed review period for the use

☐ 4 years

☐ 7 years

☒ 12 years

☐ Other – … years

8. Proposed additional conditions and monitoring arrangements for the authorisation

RAC:

Additional conditions:

For workers	☐Yes	☒No
For the environment / HvE	☐Yes	☒No

Monitoring arrangements:

For workers	☒Yes	☐No
For the environment / HvE	☒Yes	☐No

SEAC:

Additional conditions:	☐Yes	☒No
Monitoring arrangements:	☐Yes	☒No

9. Proposed recommendations for the review report

RAC:

For workers	☒Yes	☐No
For the environment / HvE	☒Yes	☐No

SEAC:

AoA	☐Yes	☒No
SEA	☐Yes	☒No

10. Applicant(s) commented on the draft opinion

☐Yes ☒No

Action(s) taken resulting from the analysis of the applicant's comments?

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

JUSTIFICATIONS: FULL VERSION:

1. Short description of use

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

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, SpERC Eurometaux 2.2c.v2.1 for air releases	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 for motorised vehicles	Regional: Claimed not relevant Local: 10 000 for oral route, 0 for inhalation
WCS 1	PROC 1	Delivery and storage *Short description:* *- CrO_3 will be delivered as flakes in 25 kg sealed drums and stored in a dedicated area.*	No of workers: 5
WCS 2	PROC 4	Dissolution of CrO_3 flakes into water *Short description:* *See description below the table*	No of workers: 5
WCS 3	PROC 28	Maintenance (repairing) of machinery *Short description:* *- Actual maintenance of the equipment by maintenance operators will take place in case of malfunctions of equipment and only after the device of concern will be abundantly washed with clean water.*	No of workers: 15
WCS 4	PROC 13	Passivation *Short description:* *See description below the table* *-operators will monitor remotely 32 passivation bath in operation*	No of workers: 50

This is an Application for Authorisation (AfA) submitted by a company for their own future use that will take place at one site which, at the time of submission of the AfA, is yet to be built. The installation is planned to be built in Környe, nearby the city of Tatabanya, Hungary. The choice of location was driven by the proximity of the main foreseen customers for the foil.

The applicants are subsidiaries of Doosan Corporation, South Korea, and sister companies of Circuit Foil Luxembourg SARL (for which a similar AfA was received in December 2015). The applicants refer in their application to the Circuit Foil AfA documents[3].

Chromium trioxide is formulated into a solution used for the passivation of copper foil used in

[3] https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/12439/del/200/col/synonymDynamicField_302/type/asc/pre/1/view

the manufacture of lithium ion batteries for motorised vehicles.

The whole process can be divided into the following steps:

CrO_3 is delivered as flakes in 25 kg sealed barrels and stored in a dedicated area of the installation (WCS 1). The sealed barrels are placed on a track by an operator and moved into a dissolution box. Once the door of the dissolution box is closed, the further steps are automated: barrel is opened by a robot, slowly and carefully toggled to transfer the flakes into the filler's funnel which is connected to the dissolution tank filled with water. The empty barrel is inserted into the funnel to be rinsed with water, after which it is closed and moved out of the box. The operator removes the barrel from the track (WCS 2).

The solution is then pumped to a second tank, where it is further diluted to a concentration of CrO_3 below 0.1 % w/w. The diluted CrO_3 solution is then fed into the passivation baths and recycled back. Those transfers are conducted automatically and in closed system. The copper foil moves through the passivation baths automatically at low speed and is dried after treatment. During the process Cr(VI) is converted into Cr(III) (Cu is a strong reductor) so no residual hexavalent chromium is present on the passivated foil (WCS 4).

At the passivation stage (WCS 4), 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 applicants have 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 applicants and the fact that they are producers of passivated copper foil, including the passivation stage in this AfA is essential to substantiate the analysis of the activities planned by the applicants and their business strategy.

1.2. 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 batteries anodes;
- Prevent the propagation of cupric ions throughout the battery during its life-time use;
- Improve battery performance (capacity, cell's impedance and peel strength of anode film).

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

While the use applied for is formulation, the solution prepared is used by the applicants to produce passivated copper foil used in the manufacture of lithium ion batteries for motorised vehicles.

The new plant will be the first installation in the EEA territory to produce copper foil for this specific application.

The volume of copper foil expected to be produced at the applicants' factory is in the order of 11,500 tonnes/year, representing one sixth of the current worldwide production of copper foil that is dedicated to the production of lithium ion batteries.

1.4. For upstream applications: Downstream User survey

This is an AfA submitted by a company for their own use, and therefore this section is not applicable.

2. Operational Conditions and Risk Management Measures are appropriate[4] and effective[5] in limiting the risk?

Workers ☒Yes ☐No

Environment/Humans via Environment ☒Yes ☐No

2.1. Workers

The OCs and technical RMMs and PPE that are taken into consideration in exposure assessment per WCS, with their effectiveness as described by the applicant, are summarised in Table 2. In addition, the following will be implemented:

Technical measures:

- All tasks related to the use of CrO_3 will be automated and it is planned that involvement of workers will be limited to surveillance of industrial processes or handling of sealed containers.
- Automated closed transfer systems for CrO_3 solution.
- Regular checks of the proper functioning of the ventilation systems, including fans and wet scrubber will be performed in parallel with several monitoring systems in place to continuously monitor the process and react in case of malfunctioning (visual/audible alarm) and appropriate actions will be taken in case of malfunction.
- On-line measurement of the air velocity in ventilation system, as well as the pressure differential at the filters, will be continuously conducted. All the installation will be annually checked to ensure a proper effectiveness.
- The aspiration velocity of Local Exhaust Ventilations (capturing hood, fume cupboard) will be continuously monitored (anemometers).
- The pressure differential between the interior (depression) and the exterior (atmospheric pressure) of the dissolution box will be continuously monitored.
- Automatic blocking system on dissolution box to prevent the use of equipment in case of malfunction.

Organisational measures:

- The new plant will be certified ISO 9001, ISO 14001 and ISO 45001 (new version of the BS-OHSAS 18001 standard). The certification will be done within two years after the start-up of the plant.
- Operators will be trained on general working procedures, health and safety issues and use of PPE. Trainings will be repeated regularly, once per year on chemical safety, monthly on general safety procedures and bimonthly on use of PPE.
- Regular field audits will be planned and performed as well as spot checks permitting to ensure PPE performances and use.

[4] 'Appropriateness' – relates to following of the principles of the hierarchy of controls and compliance with the relevant legislation

[5] '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.

- Good standard of personal hygiene will be implemented.
- Specific hygiene and safety instructions for all WCS.
- Specific medical trimestral surveys, with analysis of urinary chromium concentrations with immediate medical check-up in case of abnormal level of urinary level (target at 3 µg Cr/L urine – threshold for the general population), will be performed and all workers who are likely to come into contact with Cr(VI) will be tested.

Some additional details about the PPE used, which were provided by the applicant, are provided below:

- *Protection for inhalation route:* a 3M Versaflo S-855 E (hood) (APF = 1 000, effectiveness – 99.9 %) will be used by workers performing tasks where potential for exposure is expected (WCS 2 and 3). Workers will be regularly trained in the proper use and maintenance of the personal protection equipment and (full-face) respirators will be assigned personally. RPE will be visually checked to detect any damages, scratches or visual distortion of the hood or the tubes. The hood will be cleaned up in a dedicated automatic washing machine, after each operation. The frequency of replacement of the filters will be according to the manufacturer instructions.

- *Protection for dermal route:* Nitrile Rubber Gloves (EN 374, such as Solvex 37-675, NBR 92-600) will be used by all workers (WCS 1, 2, 3 and 4). The gloves will be disposed after each operation.

- *Additional PPE:* Protective clothing (Tychem coveralls) will be used by workers involved in WCS 1, 2, 3, 4, and safety boots (EN ISO 20345:2011) will be worn by all the workers. Safety googles (EN 166) indicated for WCS 1.

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

Contributing scenario	**Concentration of the substance***	**Duration and frequency of exposure**	**Engineering controls** (e.g. containment, segregation, automation, LEV) **+ effectiveness as stated by the applicant**	**PPE** (RPE and Skin protection used) **+ effectiveness as stated by the applicant**	**Organisational controls** (access control, procedures, training)
WCS 1, Delivery and storage (PROC 1)	99.7 %	Frequency: 50 × per year Duration: ≤ 60 min per shift	- Storage in sealed drums. - General ventilation: 5-10 ACH	- Nitrile Rubber Gloves (EN 374),	- dedicated closed and locked storage area with restricted access for authorised personnel
WCS 2, Dissolution of CrO_3 flakes into water (PROC 4)	99.7 %	Frequency: 50 × per year Duration: ≤ 45 min per	- Semi-automated process - General ventilation: 5-	- 3M Versaflo S-855 E (hood) (effectiveness – 99.9 %	- Dedicated room with restricted access for authorised personnel

		shift	10 ACH - Filler funnel fitted with a fixed capturing hood (effectiveness – 90 %) and enclosed in a fume cupboard like device (effectiveness – 99 %)	- Nitrile Rubber Gloves (EN 374)	
WCS 3, Maintenance (repairing) of machinery (PROC 28)	Extremely small	Frequency: 48 × per year** Duration: 120 min per shift	- General ventilation: 5-10 ACH	- 3M Versaflo S-855 E (hood) (effectiveness – 99.9 %) - Nitrile Rubber Gloves (EN 374)	
WCS 4 Passivation	less than 0.1 % w/w	Frequency: daily activity Duration: ≤ 480 min per shift	- automated open process with no aerosol formation - General ventilation: 5-10 ACH - receiving hoods (effectiveness – 80 %)	- Nitrile Rubber Gloves (EN 374)	- Dedicated room

**If changing through the process*

*** As 2 workers perform the task it comes to 2*24 = 48 times per year*

2.2. Environment / Humans via Environment

The applicants considered that "Formulation of preparations (ERC 2)" is the most appropriate Environmental Release Category for the use. No release of Cr(VI) is expected to the environment, except for: (1) exhausts from the air extraction and (2) release to fresh water (via treated process water released from on-site STP).

Technical measures in place for control of emissions to:

Air:

All air extracted from the installations and workshops where chromium trioxide is used will be treated by wet scrubbers (claimed effectiveness 99 %).

Water:

The generated chromium trioxide effluents from all processes will be collected by the wastewater network and sent to the fully automated on-site sewage treatment plant were it will undergo reduction of Cr (VI) to Cr(III) (using bisulfite), pH neutralisation and settlement into a decantation cuve.

Effectiveness of the process will be continuously checked by the continuous measurements of

the pH and redox potential of the treated solution, in order to ensure full reduction of Cr(VI) to Cr(III). After the on-site treatment, the effluent will be released to the municipal sewage network. The concentration of chromium trioxide in an effluent sent to municipal sewage network will be monitored (automated process) and in case Cr(VI) is detected above the limit of 0.1 ppm, redox potential and pH is outside the optimum treatment conditions, or the measurement system is malfunctioning, the effluent will be automatically re-directed to a safety tank with a volume capacity enabling to store 20 h of effluent flowing (maximum effluent daily flow rate: 100 m^3/day). The contaminated effluent will be re-treated in the on-site sewage treatment plant, until the Cr(VI) concentration falls below 0.1 ppm.

The measures of all parameters mentioned above will be recoded, and kept for inspection by the authorities.

Soil:

No direct emissions of chromium trioxide will occur during the formulation process. The basements of the installation will be on retention in order to avoid emissions to soil in case of incidental releases.

Waste:

All the emptied and sealed barrels that previously contained CrO_3 will be stored in a special area for contaminated products. These containers will be treated by a chemical waste processing company according to national/local legislation.

The on-site treatment of effluent containing Cr(VI) will involve the production of sludge, which will contain chromium only as Cr(III). The handling of the sludge will be fully automated. The sludge will be decanted, then hoovered, pressed-filtered, and conditioned in dedicated tanks before being sent to landfill by a subcontracted company.

Table 3: Environmental RMMs

Compartment	RMM	Stated effectiveness
Air	Scrubber	99 %
Water	On-site STP	not specified*
Soil	-	-

** discharges of Cr(VI) will be below threshold limit of Cr(VI) in effluent (< 0.1 ppm).*

2.3. Discussion on OCs and RMMs in place and relevant uncertainties

RAC notes that the applicants plan to implement technical measures for most of those activities where they have identified an exposure potential, supplemented and further supported by an OSH management system including organisational measures (e.g. access restriction, training, supervision) and personal measures (e.g. PPE).

RMMs described in the CSR and in the answers to RAC questions include mainly: general and local exhaust ventilation, closed automated process (WCS 2), full automation of the passivation process (WCS 4), closed system for dissolution of CrO_3, closed transfers of Cr(VI) solution, process monitoring, restricted access to specific areas, and PPEs such as the use of RPE, gloves, protective clothing. Organisational measures (training, exposure testing and certification) are also included.

Regarding the RMMs to reduce worker exposure and environmental emissions, RAC identified some residual uncertainty due to the fact that – as the plant is not operational yet – there is no measured data available to confirm that the planned OCs and RMMs will deliver the claimed protection levels. RAC points out that actual on site measurements should be used to prove the effectiveness of the RMMs to be implemented and used on site. RAC also notes that PPE,

which according to the applicants will be used to minimise the exposure and to reinforce the training related to the toxicity of the chemicals used, should be used as a last resort thus, after the monitoring results will become available, the applicants should re-evaluate the type of RPE initially proposed and based on such evaluation decide what kind of RPE, if any, is needed for minimisation of exposures.

Even though some uncertainties have been identified, RAC considers that they are relatively minor and is of the opinion that overall RMMs described in the application can be considered to be appropriate and effective in limiting the risk to workers and general population via the environment.

2.4. Conclusions on OCs and RMMs

Conclusion for workers:

The applicants plan to implement technical measures for those activities where they have identified an exposure potential (except for WCS 3, Maintenance (repairing) of machinery), supplemented and further supported by an OSH management system including organisational measures and personal measures.

As the plant is not operational yet there is no measured data available to confirm that the planned OCs and RMMs will deliver the claimed protection levels.

Conclusion for Humans via environment:

The applicants plan to implement technical measures to minimise the releases to the air and water compartment.

As the plant is not operational yet there is no measured data available to confirm that the planned OCs and RMMs will deliver the claimed protection levels.

Overall conclusion: RMMs as proposed in the application are expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

Given the information provided in the application and from knowledge of similar chromate applications, RAC considers that the RMMs as proposed would be appropriate and effective in limiting the risk, if implemented as described.

Therefore the applicants should validate the effectiveness of the OC and RMMs by generating and evaluating relevant on site monitoring data once the plant has been commissioned and is in use.

3. Exposure assessment

3.1. Inhalation exposure

Monitoring:

As this application is for the future use, no monitoring data were provided in the application.

The applicants plan to implement worker exposure monitoring programme in the future installation. Measurements to determine CrO_3 concentrations in the work place will be taken at least annually in order to control the performance of the safety measures in place. According to the applicant, the objective of the monitoring programme will be to identify traces of Cr(VI), using the method with LoD of 0.01 µg Cr(VI)/m^3.

Modelling:

The modelled inhalatory exposure estimations with ART 1.5 were provided for all relevant WCSs described in the application. In all estimations, the applicants have taken a conservative approach, assuming the worst possible scenario with maximum duration of potential exposure for each WCS. It is noted that, on request, the applicants provided detailed information regarding the input parameters and results including the predicted 90th percentile modelled exposure estimates for all WCSs.

Table 4 provides the results of the exposure assessment of the applicant. All values are given as whole shift time-weighted exposures and converted to Cr(VI) from the results found in the corresponding ART printouts. Figures in bold are those taken forward by RAC for risk characterisation.

The modelled exposure values were not corrected for the effects of the RPE to be used.

Table 4: Exposure – inhalation

Contributing scenario	Route of exposure	Method of assessment	Exposure value (8h TWA), (µg Cr(VI) / m³)	Exposure value corrected for frequency, (µg Cr(VI) / m³)*
WCS 1	Inhalation	Modelled (ART)	no exposure	no exposure
WCS 2	Inhalation	Modelled (ART)	3.12×10^{-2}	**1.30×10^{-3}**[a]
WCS 3	Inhalation	Modelled (ART)	3.02×10^{-3}	**4.02×10^{-5}**[b]
WCS 4	Inhalation	Modelled (ART)	3.28×10^{-5}	**2.62×10^{-5}**[c]

** Frequencies were taken from Table 2 and correspond to the data provided by the applicants in the CSR.*

[a] *The correction factor for frequency used by the applicant: 25 = 240/(50/5).*

[b] *The correction factor for frequency used by the applicant: 75 = 240/(24×2/15).*

[c] *The correction factor for frequency used by the applicant: 1.25 = 240/(240×40/50).*

3.2. 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 (RAC27/2013/06 Rev 1).

3.3. Biomonitoring

RAC noted that biomonitoring is one of the measures proposed by the applicants to assess the exposure. The applicants stated in the CSR that specific medical trimestral surveys, with analysis of urinary chromium concentrations with immediate medical check-up in case of abnormal level of urinary level (target at 3 µg Cr/L urine – threshold for the general population), will be performed and all workers who are likely to come into contact with Cr(VI) will be tested.

Even though the applicants propose to perform biomonitoring in order to ensure that OCs and RMMs will function as intended, RAC is of the opinion that, taking into consideration high technical level of OCs and RMMs proposed, the set target value of 3 µg Cr/L urine might be too high and will not enable detection of possible exposures. Thus, in order to obtain meaningfull results, RAC suggests to the applicant to set lower “target” value.

Combined exposure:

According to the applicants all activities described under the different WCSs will be performed by different workers, thus no combined exposure is expected.

3.4. Environmental emissions

Water:

No measurements of chromium trioxide in effluents are available as the installation in question has not been built yet. The applicant explains that a limit for chromium trioxide releases in effluent will be fixed by the company at 0.1 ppm, after onsite treatement. The concentration of chromium trioxide in effluents will be automated and monitored continuously. The release factor used in the CSR is based on this limit and considering a flow rate of 100 m^3/h.

Air:

No measurements of air emissions of chromium trioxide are available as the installation in question has not been built yet. The local release factor of 0.01 % to air for the future installation is based on spERC factsheet eurometaux 2.2c.v2.1. This air release factor is applicable for formulation of metal compounds in other than plastics and paint sectors when specific RMMs are applied (wet scrubbers will be in place to prevent potential release to the air, effectiveness 99 %). It can be noted that the applicants calrified during the trialogue that measurements of emmisions to the air will be performed at least annually.

Soil:

There are no direct emissions to soil resulting from the use applied for.

Table 5 presents the applicant's release estimations.

Table 5: Summary of environmental emissions

Release route	Release factor	Release per year*	Release estimation method and details
Water	0.0243 % 0.01 kg/day of Cr(VI)	3.65 kg/year of Cr(VI)	Based on limit of chromium trioxide in effluents releases "at the end of the pipe", i.e. after on-site treatment and before releases to sewage network (threshold limit 0.1 ppm)**
Air	0.01 % 0.004 kg/day of Cr(VI)	1.46 kg/year of Cr(VI)	Based on spERC eurometaux 2.2c.v2.1
Soil	0	0	Expert judgement; no soil releases
Waste	0	0	Waste is sent for incineration/landfill via a certified hazardous waste treatment company

** Assuming 365 working days per year.*

*** It should be noted that formulation of the chromium trioxide solution is the only use subject to authorisation, however the approach applied to assess emissions to water also takes into account potential releases of CrO_3 from the passivation step of copper foil.*

The applicants used EUSES 2.1.2 to calculate the local air concentration as well as possible local intake by drinking water and food based on the releases given in the Table 5. The results are summarised in Table 6.

For the assessment of indirect exposure of the general population the applicants considered two exposure routes – inhalation and oral intake (ingestion of drinking water and food).

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

Parameter	Local
PEC in air (mg/m^3)	3.42×10^{-8}
PEC in surface water (mg/L)	3.06×10^{-6}
Daily dose via oral route (mg/kg bw/d)	9.24×10^{-8}

3.5 Discussion of the information provided and uncertainties related to exposure assessment

RAC notes that in the CSR and in the answers to RAC questions the applicants provided sufficient information on the tasks and work organisation under each WCS and on the exposure estimation approach.

Workers exposure

RAC notes that the inhalation exposure assessment is based on on modelling with ART 1.5 for WCS 2, 3 and 4 and qualitative analysis for WCS 1 - delivery and storage. The applicants considered that the potential inhalation exposure for WCS 1 is virtually non-existent as during the delivery and storage chromium trioxide is in sealed drums (solid flakes). With regard to modelling, it could be noted that after the request from RAC, the applicants provided additional detailed information regarding the input parameters for all modelled activities. In all estimations the applicants have taken the most conservative approach assuming the worst possible scenario with maximum potential exposure duration for each WCS. It should be noted that the exposure estimates obtained have not been corrected for the effectiveness of the foreseen PPE. As no personal or static measurement were available for all WCSs, modelled data using the ART 1.5, 90th percentile values, were used by applicants for the risk characterisation. RAC found no deficiencies in the information provided by the applicant regarding the modelling parameters, the 8 h TWA exposure estimates obtained using ART 1.5 and the exposure estimates adjusted for the frequency of use. Thus the adjusted exposure values obtained by the applicants were taken forward for risk characterisation (see Table 4).

Humans via the environment

RAC points out that evaluation of environmental emissions accounts for all processes at the applicants site, including the passivation step (not subject to authorisation). For this reason, the emissions are likely to be an overestimation of the emissions to air and surface water from the formulation step.

RAC notes that the release factors relevant for the future installation are estimates based on plant-specific information and risk management measures to be implemented. The limit of release of chromium trioxide in effluent will be fixed by the company at 0.1 ppm for chromium trioxide. The company is planning to measure continuously the concentration of chromium trioxide in the effluents from on-site STP. The local release factor of 0.01 % to air for the future installation is based on spERC eurometaux 2.2c.v2.1. The applicants used the EUSES 2.1.2 tool to calculate local air concentrations and local intake of Cr(VI) via drinking water and food (via the consumption of fish) using these assumptions:

- Only local impact of emission from the use is taken into account as 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 (section 3.1.1 of the EU-RAR(2005)).
- The removal of Cr(VI) during the waste water treatment in municipal STP used for the risk

assessment was as follows: 50 % adsorbed onto sewage sludge, 50 % in effluent.
- For all relevant compartments of the environment, it was assumed that 3 % of the estimated Cr(VI) concentration will remain as Cr(VI), and 97 % converted to Cr(III) (section 3.1.1.2.1 of the EU-RAR(2005).
- For calculation of the local water concentration, only dilution and adsorption are taken into account, considering both acidic (i.e. pH < 6) and neutral-alkaline (i.e. pH > 6) environments. The adsorption coefficient fo Cr(VI) described in section 3.1.1.2.2 of the EU-RAR (2005) has been taken into account.
- As Cr(VI) released to soil or sediment is rapidly converted into Cr(III), the exposure of man via the environment form these sources has been considered as limited. As a consequence, only drinking water and fish consumption has been taken into account for the oral route of man via the environment.

RAC considers that the indirect exposure calculated by the applicants is acceptable for risk characterisation and impact assessment.

Uncertainties related to the exposure assessment:

RAC points out that workplace exposure measurement data and environmental emission data are not available for the (future) installation and worker exposure values and enviromental releases are estimations only.

Taking into account the exposure assessment performed by the applicants as well as all the information provided on RMMs and OCs, RAC considers the uncertainties detailed above to be of relatively minor significance for the purpose of exposure and further risk assessment[6].

3.6 Conclusions on exposure assessment

The applicants relied on modelling to estimate worker and environmental exposure and provided detailed information regarding the input parameters and results including the predicted 90th percentile modelled exposure estimates for all WCSs.

RAC considers that the overall description of the use provided in the CSR and in the applicants' answers to RAC's requests is sufficient to conclude on the reliability of the worker exposure assessment.

RAC considers that the exposure assessment for a future use contains some inherent weaknesses due to the obvious lack of workplace air measurement and environmental emissions data.

RAC considers that on the basis of the planned RMM's and the modelled exposure data presented, these weaknesses would not be expected to lead to significantly higher exposure estimates in comparison with those selected for further risk characterisation. RAC advises the applicants to validate the results of the modelling by measurements as soon as the plant starts mass production and base their exposure assessment for wrkers and the general population to be potentially presented in any review report on a representative monitoring data set.

[6] RAC has considered future uses previously [e.g. 0023-01, 0084-01]. Where the evidence in the form of planned OC and RMM as well as modelled exposure estimates is sufficiently convincing, RAC has considered the OC and RMM to be appropriate and effective in limiting the risk to workers and the environment. This is the case here, provided the exposure scenario can be validated with actual measured data shortly after commissioning and start-up of the plant.

4. Risk characterisation

4.1. Workers

Risk characterisation for workers is based on ECHA's reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1, agreed at RAC 27). The applicants conservatively assumed that all inhaled chromium trioxide particles are in the respirable range and contribute to lung cancer risk. Thus, an excess life-time lung cancer risk of 4×10^{-3} per µg Cr(VI)/m^3 for 40 years of exposure (8 h/day, 5 d/week) was considered for the risk assessment.

It could be noted that applicants took a conservative approach in estimating excess cancer risk and did not use the frequency adjustment factor of 0.923 to account for actual 240 working days in applicants site vs 260 days used while developing ECHA's reference dose-response relationship for carcinogenicity of hexavalent chromium. RAC made its own estimations and values estimated by the applicants and RAC are shown in Table 7. It should be noted that after additional adjustment the excess cancer risk values become even lower, however, taking into account that this application is for the future site and effectiveness of RMMs and OCs are not yet proven by actual measurements, RAC considers that excess cancer risk values estimated by the applicants (shown in bold in Table 7) should be further used for health impact assessment.

Table 7 summarises the excess cancer risk for workers estimated based on the exposures displayed in Table 4.

Table 7: Combined exposure and risk characterisation

Contributing scenario	Route	Exposure value corrected for PPE and frequency	Excess risk
WCS 1	Inhalation	No exposure	-
WCS 2	Inhalation	1.30×10^{-3}	**5.20×10^{-6}** $4.80 \times 10^{-6*}$
WCS 3	Inhalation	4.02×10^{-5}	**1.61×10^{-7}** $1.48 \times 10^{-7*}$
WCS 4	Inhalation	2.62×10^{-5f}	**1.05×10^{-7}** $9.68 \times 10^{-8*}$

** Excess cancer risk values estimated by RAC using the frequency adjustment factor of 0.923 to account for actuall 240 working days in applicants site vs 260 days used while developing ECHA's reference dose-response relationship for carcinogenicity of hexavalent chromium.*

4.2. Environment and/or Humans via Environment

Risk characterisation for humans via the environment is based on ECHA's reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1): an excess life-time lung cancer risk is 2.9×10^{-2} per 1 µg of Cr(VI)/m^3 for 70 years of exposure (24 h/day, 7 d/week) and an excess life-time lung cancer risk is 8×10^{-4} per 1 µg Cr(VI)/kg bw/day over an exposure duration of 70 years (24 h/day, 7 d/week).

General population may potentially be exposed to chromium trioxide via the environment through oral and inhalation routes. Based on the release estimations and subsequent EUSES modelling, the airborne concentration (PEC local) 100 m from the emission source was estimated (see section 3.4 above). With this local PEC of 3.42×10^{-8} mg/m^3 and the corresponding excess life-time lung cancer risk of 2.9×10^{-2} per 1 µg of Cr(VI)/m^3, the excess life-time lung cancer for the general population (humans via the environment) at the local scale via the inhalation route is calculated to be 1.0×10^{-6}.

Similarly, with the total oral dose of 9.24×10^{-8} mg/kg bw/d and the corresponding excess life-time lung cancer risk of 8×10^{-4} per 1 µg Cr(VI)/kg bw/day, the excess life-time lung cancer for the general population (humans via the environment) at the local scale via the oral route is calculated to be 7.4×10^{-8}.

The excess life-time lung cancer for the general population (humans via the environment) at the local scale via the combined oral and inhalation routes is calculated to be 1.074×10^{-6}.

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

Parameter	Local	
	Exposure	Excess risk
Human via Environment – Inhalation	3.42×10^{-8}, mg/m^3	1.0×10^{-6}
Human via Environment – Oral	9.24×10^{-8}, mg/kg bw/d	7.4×10^{-8}
Human via Environment - Combined		1.074×10^{-6}

RAC acknowledges that the assessment of indirect exposure to humans via the environment using default assumptions in the EUSES model are likely to overestimate exposure, particularly at the local scale, leading to an overestimation of risk (and number of statistical cancer cases).

4.3. Uncertainties

Risk characterisation is affected by the uncertainties related to the RMMs and OCs considered and the methodology used. These uncertainties were discussed and addressed in the relevant sections above. RAC concluded that the uncertainties identified are relatively minor and not likely to affect the risk characterisation significantly.

4.4. Conclusions on risk characterisation

RAC concludes that:

- The highest calculated excess cancer risk for workers is 4.80×10^{-6} (WCS 2).
- The excess cancer risk calculated for humans via the environment (local scale for combined routes (inhalation and oral)), is 1.074×10^{-6}.

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

5. Evaluation of the suitability and availability of alternatives

This AfA covers the industrial formulation of a chromium trioxide solution that will be used for the passivation of copper foil, which will, in turn, be used to manufacture lithium ion batteries for motorised vehicles. Chromium trioxide is applied to prevent corrosion/oxidization to shiny and matt side surfaces of copper foil that may occur during storage or further processing into Lithium-ion batteries anodes. Inside the battery itself the passivation prevents the copper from releasing its ions and therefore corrupting the battery. The concentration of hexavalent chrome in the chromium trioxide solution produced is below 0.1 % w/w and, therefore the use of this solution is not subject to authorisation.

The product that the applicants will produce and place on the market is not the formulated passivation solution but the passivated copper foil. Therefore, the production is integrated into a continuous system (i.e. formulation and passivation). As hexavalent chrome has no function in the passivation solution an AoA for that formulation use would not be relevant. Therefore, the AoA is examining alternatives for the subsequent use of the formulated solution (i.e. the passivation of copper foil for the use in the batteries of motorised vehicles).

The applicants for this AfA are part of the same group as Circuit Foil SARL – Luxembourg (CFL). CFL was the applicants in a similar application for authorisation submitted on 7 December 2015. The applicants make reference to all the elements of the CFL application with permission of the latter.

Due to the close relation of this AoA with the one submitted by CFL, alternatives presented often refer to two passivation steps. However, the Doosan case only involves a single passivation step (unlike the CFL case, in which a first and a second passivation step were used). It is also important to note that the copper foils produced by CFL are used in a broad range of electric/electronic equipment within several industry sectors whereas the foils produced by the applicants are used only for lithium ion batteries for motorised vehicles. For these reasons, the conclusions reached in the CFL case[7] are not necessarily directly applicable to this case.

5.1. Summary of the Analysis of Alternatives by the applicant/s and of the comments received during the public consultation

The approach taken by the applicants relied heavily on the fact that their main customers have required them to use chrome to passivate the copper foil. This fact may have prevented the applicants from putting the necessary effort into actually evaluating alternatives that do not require CrO_3 passivation of copper foil. Instead, the applicants focused their efforts on reducing the concentration of chrome needed in the passivation bath that would make their product acceptable to the specifications of their main customers (section 4.2 of AoA).

5.1.1 - Summary of the Literature Review Methodology:

The applicants conducted a literature review that included the following sources of information: 1) commercial websites of manufacturers, 2) patents accessible through online databases, 3) bibliographical review produced through a collaborative effort between CFL and Luxembourg Institute of Sciences and Technology (LIST), and 4) the results obtained from in-house experimentation / substitution efforts by CFL.

Although initially limited, the bibliographical review results presented in the AoA were reinforced by data provided after the trialogue for this case. These data were produced by the CFL/LIST partnership, and the reports were indicated as confidential.

The current AoA did not describe any direct contact of the applicants with alternative suppliers. However, such direct consultation with alternative suppliers was documented in the CFL application for authorsation.

5.1.2 - Summary of Alternatives Identified / Examined:

Combining the information from the aforementioned sources, which was presented in two separate AoAs (i.e. the one by CFL and the one by Doosan), the applicants state that they attempted to examine the availability of alternatives through the following pathways:

[7] For reference, the CFL opinion is available at https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/12439/term

- Availability of alternative manufacturers of copper foils
  Investigation of whether there are any manufacturers, globally, who may supply copper foil for lithium ion batteries that has not been passivated by CrO_3.
- Alternative techniques to satisfy customers specifications
  Investigation of 1) alternative packaging processes for copper foil to mitigate the effects of oxidation during storing, shipment and packaging and therefore reduce or eliminate the need for passivation (i.e. nitrogen packaging), 2) alternate supply routes of copper foil so as to alleviate concerns of customers concerning security of supply, 3) possibility of applicants supplying copper foil to customers from a non-EU location, and 4) possibility of supplying copper foil from more distant non-EU sources.
- Reviewing and revisiting alternatives examined in the CFL application
  The applicants claim to have reviewed the alternatives examined, tested and presented in the CFL application, in addition to investigating potential new alternatives.

5.1.3 - Summary of the Comments received during the Public Consultation:

No comments were received during the public consultation for this application.

5.2. Short-listed alternatives and past substitution R&D efforts

5.2.1. Past Substitution R&D Efforts

5.2.1.1. Literature Review

The applicants conducted a literature review that included the following sources of information:

- Commercial websites of manufacturers (from around the globe) who supply copper foil for lithium ion batteries (e.g. OAK Mitsui, Furukawa, Nippon-Denkai, Iljin, LSMtron),
- Several patents that could be accessed through online databases (i.e. www.patentgenious.com and https://patents.google.com),
- Further, the applicants (through their sister company CFL) have been collaborating with the Luxembourg Institute of Sciences and Technology (LIST) to conduct a research project that started in 2016 and will run until 2024. Extension of the project is expected if evidence of progress exists. The primary focus of this research has been to find a replacement for the second step passivation (that occurs at much higher chromate concentrations than the first step passivation) for copper foil used in Printed Circuit Boards (PCB) produced at CFL. The applicants state that the vision is that this research will eventually lead to the development of the technology needed to eliminate the first step as well.

  The first step of this project was to perform a “wide screening of the existing literature, either scientific (scientific publications) or technologic (patents), in order to identify the potential solutions to the problem”. In parallel, the applicants claim that “a scientific watch procedure is being established, in the form of automatic and periodic alerts informing CFL of the last scientific papers and patents matching the researched criteria”. The research project contract, according to the applicants, has been renewed in 2018, and it now includes a work section that seeks to develop chromate-free passivation for copper foil used in lithium ion batteries. During this effort, three selected alternatives to Cr(VI) will be evaluated. These selected alternatives are 1) molybdate plating (currently under testing by CFL), 2) Cr(III) plating, and 3) silane application on the foil. The applicants claim that currently a thorough bibliographic review is well under way.

The applicants claim that the obtained literature was “quite exhaustive and overwhelming”. Further, the applicants refer to the literature review conducted by LIST in concluding that “no alternatives have been developed that substitute chrome passivation”. A summary of the literature review reports that resulted from the collaboration effort between CFL and LIST was provided to SEAC following the trialogue for this case.

5.2.1.2. In-house experiments conducted

The applicants have presented the results from several experiments that have been conducted by their sister company, CFL, as these experiments were conducted in the framework of CFL’s AfA. It should be noted that the applicants have not conducted any experiments on their own, because in the Doosan group, R&D related to the passivation of copper foil is performed in CFL. For this reason, CFL has gained significant experience in its attempt to identify alternatives to chrome passivation of copper foil, for its current operations. CFL initially conducted laboratory tests in 2004 for a set of nine commercial chromium trioxide-free products. These nine alternative products were selected from a list of 24 different alternatives presented in the CFL AoA (these 24 alternatives, according to the applicant, were provided by the consortium CCST – Chromium (VI) Compounds for Surface Treatment REACH Authorisation Consortium). All of the products tested by CFL failed the required criteria of product corrosion resistance tests (i.e. a heat test: 200 °C for 2 hours; a saline test; and a humidity test: 60 °C in 90 % humidity for 3 weeks). The results of these tests and the pertinent analysis of alternatives were presented in the CFL application.

In the current AoA, the applicants have presented experiments concerning the “manner of storing, shipment and packaging” of copper foil. These experiments were carried out between October 2016 and August 2017 by CFL. The results of these experiments show that while chromium (VI) cannot be eliminated from the production line leading to lithium ion batteries, its volume can be reduced.

5.2.2. Short-listed Alternatives

5.2.2.1. Availability of manufacturers of copper foils made with Cr(VI) free alternatives

The applicants have searched for manufacturers around the globe who could possibly supply copper foil that does not make use of CrO_3 passivation and that can be used in lithium ion batteries.

According to the applicants, only companies from Japan and Korea produce copper foil for lithium ion batteries. In their investigation, the analogous products of six separate companies (four from Japan and two from Korea) were examined by the applicant. The investigation of alternative manufacturers of copper foil for lithium ion batteries was conducted via an examination of information publicly available on their websites. Specifically, the Japanese companies investigated were OAK-Mitsui, Furukawa electric, Nippon Foil, and Nippon Denkai. The Korean companies were Iljin and LSMtron.

As a summary of the findings presented by the applicant, the following main points can be indicated:

- There are about 4 500 patents related to copper foil production and/or passivation. Furukawa and OAK Mitsui hold a large part of this intellectual property.
- When examining the patents from OAK Mitsui and Furukawa, the applicants say that they include the use of a chrome layer to passivate the copper.
- Much of the information included in the public websites of these companies offer little specific information on the passivation chemicals used.

For instance, OAK Mitsui, according to the applicant, makes use of a “unique anti-tarnish coating specifically designed for lithium ion batteries”, but they never divulge the nature of this coating. The applicants assume it is CrO_3. This Assumption has not been substantiated in the AoA.

- Nippon Foil maintains a smaller website with no information regarding the technical characteristics of passivation foil. This manufacturer has a deeper knowledge of aluminium foil as a cathode, as opposed to copper foil as an anode.
- Nippon-Denkai has little technical information with regards to its products. However, they explicitly say that first step chromate passivation is a requirement for copper foil.
- Iljin patents show the use of chrome, tungsten, nickel, cobalt, indium or molybdenum as potential passivation agents. The applicants assume, though, that since this patent also makes mention of chromate passivation, the whole passivation process should include at least one step chrome passivation.
- No patents are held by LSMtron with truly chrome-free passivation.
- According to the applicants, some of their global competitors claim to produce chromate-free copper foil. However, the applicants dismiss this claim, since they say that chrome is always used in the first passivation step. Substantiation of their dismissal of this claim is scant.
- The applicants, in their section conclusions, reiterate that their primary customer stipulates a minimum amount of chrome on the surface of copper foil.

5.2.2.2. Alternative techniques to satisfy customers' specifications

The applicants have claimed to have investigated 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 applicants supplying copper foil to customer from a non-EU location, and 4) possibility of supplying copper foil from more distant non-EU sources.

With regards to item (1) above, the applicants' sister company, CFL, undertook specific research that has been presented. However, this testing, which is described in the AoA, has been focusing on eliminating the second step passivation required for PCB copper foil. Also, CFL has achieved lower chromium concentrations for passivation of copper foil to be used in lithium ion batteries.

Items (2), (3), and (4) above are more related to non-use-scenarios, and no technical discussions have been provided by the applicants in their AoA.

5.2.2.3. Reviewing and revisiting alternatives examined in the CFL application

Although not explicitly claimed in the current AoA, with regards to the CFL application, the applicant consulted passivation chemical suppliers in their search for potential alternatives. Consultation with other suppliers of other products portfolios, other chemicals and technical solutions was carried out to some extent. However further consultation could have been justified in order to identify additional potential alternatives.

In the CFL application, there was an initial list of 24 potential alternatives that were considered. This list was produced by CCST, and it was presented in Annex 1 of the CFL application. CFL had initially excluded 13 alternatives from this list as being technically infeasible (presence of SVHCs, chemical incompatibility).

CFL had evaluated the remaining eleven alternatives, while testing nine of the 24 in their laboratory. The eleven alternatives evaluated were categorized in four groups; 1) Chromium (III)-based solutions, 2) Organic resins, 3) Silane-based coatings, and 4) Ionic implantation.

The nine alternatives were subjected to three corrosion resistance tests; 1) a heat test: 200 °C for 2 hours; 2) a saline test; and 3) a humidity test: 60 °C in 90 % humidity for 3 weeks.

All of the products coated with alternative substances failed the corrosion resistance tests (either a high heat test or a humidity test) performed by an external laboratory. The laboratory tests were conducted in 2004 and have not been repeated since. CFL claimed in their application that since the same criteria and test methods were still in use (at the time of their application), their findings remain valid.

The Opinion on the CFL AfA (dated March 16, 2017) provides more details on those tests and can be referenced accordingly, instead of being copied here. Specifically, Sections 7.1 and 7.2 of the Opinion provide a detailed discussion of tests presented in the CFL AfA and its AoA.

For the current case (i.e. Doosan), the applicants have reviewed the requirements presented in CFL's AfA, and believe that whilst the saline and humidity-resistance tests are still relevant, the heat test is not relevant for the use of copper foil in lithium ion batteries. According to the applicants, "PCB uses (i.e. related to the CFL AfA) are more demanding on the copper foil and consequently require higher degrees of quality in the passivation".

The applicants claim that specific client requirements have dictated the following criteria for the approval of copper foil for use in lithium ion batteries production:

- 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 10 minutes at 150 °C.
- 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 – produced with potential alternatives - to humid environment (60 % and 90 % of humidity) for three weeks.

The applicants state that the primary client's specifications for a trivlaent chromium concentration of 2.5-3 µg/mm^2 of copper foil is meant to address the issue of propagation of cupric ions throughout the lithium ion batteries' lifetime. The applicants claim that in the AoA, "it will be examined whether the alternatives could meet this requirement with another metal or an organic barrier rather than a chromium deposit". The results of such tests were presented in the CFL application, as well as in the responses to questions asked of applicants.

A summary of ten of the alternatives examined has been provided by the applicants during the questions/answers stage of the application. This summary is presented below in the form of a table.

Table 9: Summary of the alternatives examined

Alt	Description / Name of Alternative	Technical Feasibility			Economic Feasibility		Risk Reduction
		Criterion 1: Prevent cupric ion propagation	Criterion 2: Improve battery impedance	Criterion 3: Passivation test/reactivity with battery content	Criterion 1: Cost of alternative	Criterion 2: Practical implementation	
NO CHROME PASSIVATION AT ALL							
1	Ionic implantation	Not tested	Not tested – likely negative	OK	N/A	Impossible to achieve vacuum operation for scale of operation	Pass

2	Vacuum / Nitrogen packaging	Not tested	Not tested likely negative	Too sensitive to small variations, noticeable oxidation still occurs			Pass
CHROME III – BASED SOLUTIONS							
3	Chrome III bath	Not tested – likely positive	Not tested – likely positive	Fails the humidity and salinity tests	N/A	N/A	Fail. KS Cn- (cyanide) bath required
4	Tri Mac III/MA Chrome Cl3	Fail	Unknown	Fail			
OTHER METALS							
5	Gardolene D (Zinc)	Not tested	Not tested – likely negative	Uses zinc which is reactive with lithium hydroxide	N/A	Pass	
6	Silane	Not tested	Not tested	Fails for now – is subject of research with LIST. Manufacture r does not recommend for use with copper.		No improvement at this time as silane use presumes first step passivation with chrome.	
7	Tin	Unknown- likely positive	Positive according to Nippon Foil/Furuka wa	Fail as stronger passivation required according to Nippon Foil/Furuka wa		Pass	
8	Other metals like Cobalt, tungsten, indium etc.	Never tested	Never tested	Unknown – patents imply that such methods are possible but they always list several metals including Chrome. The applicants believe the other metals are red herrings.		Unknown	

ORGANIC RESINS							
9	Benzotriazole	Not tested	Not tested – likely negative	Failed in house testing by CFL together with Evonik (Supplier)	N/A	N/A	Fail. Unacceptable effluent pollution
10	Other organic resins	Not tested	Not tested – likely negative	Believed to be incompatible with the organic solvents in the battery or not resistant to the acidic environment			

5.3. Would the implementation of short-listed alternative/s lead to an overall reduction of overall risks?

☐Yes

☐No

☒Not applicable

A detailed risk assessment of the alternatives to facilitate a comparison with CrO_3 has not been conducted.

At the formulation stage, chromium trioxide has no (separate) function. Therefore, no specific Analysis of Alternatives was performed by the applicants for that step and no alternatives have therefore been identified.

An Analysis of Alternatives was performed for the subsequent passivation step (WCS 4). In the AoA the applicants noted that it is allowed to refer to the application for authorisation dossier of Circuit Foil Luxembourg (CFL) and thus referred to it in the analysis of the risks of possible alternatives. It should be noted that the alternative assessments do not provide an overview of general information on the substances used within the alternatives and alternative processes as well as the risk to human health and environment.

In the original CFL application 24 potential alternatives to Cr (VI) were identified for passivation (WCS 4). 13 out of those were rejected without testing, for various reasons (presence of SVHCs, clear technical infeasibility even without testing). Among these alternatives were: Tin depositions that cannot be etched, Nickel depositions for which also boric acid would have been required and plasma vapour depositions which requires specific setup and high vacuum. Other alternatives like titanium or aluminium passivate copper by anodisation which lead to copper oxidation. The remaining eleven alternatives were further evaluated or tested (by CFL or by an external laboratory), and grouped in the following four groups:

- Chromium (III) based solutions: two of the alternative treatments use SVHCs. Others contain hazardous acids, but it is possible to use them with precautions.
- Organic resins: incompatible with the organic solvents in the battery or not resistant to the acidic environment. Benzotriazole failed in-house testing and is itself the target of

regulatory action.

- Ionic implantation: No risks identified. However the operation would need to be carried out in vacuum and applicants noted that creation of a vacuum based environment for the size and number of machines required in copper foil production is impractical.

In conclusion, no alternatives have been identified for the formulation step. As to passivation step, in terms of risks, the transition from use of Cr(VI) to the alternative substances or by substances used in alternative treatments might constitute a shift to substances or treatments presenting a lower hazard with the exemption of some SVHC substances needed for alternative treatments based on chromium (III) solutions.

5.4. Are the short-listed alternatives technically and economically feasible and available before the Sunset Date?

☐Yes

☒No

The sunset date for CrO3 was 21/09/2017. For this reason, this section will consider if the short-listed alternatives are technically and economically feasible and available before January 2020 when the applicants plan to start production in the future plant.

Alternative Approach 1: Suitability and availability of copper foils passivated without the use of Cr(VI)

Alternative approach 1 is introduced in Section 4.2.1.2 in the AoA.

First, it should be noted that the applicants are the only producer of passivated copper foil for lithium ion batteries in the EEA.

The applicants explained that some competitors outside the EEA claim they produce CrO_3-free copper foil. The applicants consider this is to be understood as “no Cr(VI) in the passivated foil” rather than “no Cr(VI) used in the passivation process”.

The absence of specific information in either the patented processes or technical specifications of the competitors’ products make difficult the comparison with copper foils produced by the applicants. It is doubtful that there are other manufacturers outside the EEA that can produce copper foil for lithium ion batteries without using CrO_3 in the first passivation step. However, evidence of direct consultation of the applicants with other suppliers outside the EEA have not been provided in the AoA. At the same time, it may be reiterated that no comments in this regard were received during the public consultation for this case.

Technical Feasibility

As there is no evidence that copper foils passivated without the use of Cr(VI) exist the technical feasibility is not relevant.

Economic Feasibility

This parameter has not been discussed by the applicant.

Alternative Approach 2: Alternatives techniques to satisfy customers’ specifications

Alternative approach 2 is introduced in Section 4.2.1.3 in the AoA.

Technical Feasibility

The item investigated was the alternate packaging arrangement. The applicants claim that CFL has made substantial advances in the reduction of the quantity of CrO_3 in the passivation of

copper foil. The applicants deduce that CFL may subsequently identify ways in which chromate can be substituted altogether, despite the fact that their current research has not led to such new insights.

Economic Feasibility

This parameter has not been discussed by the applicants.

Alternative Approach 3: Reviewing and revisiting alternatives examined in the CFL application

Alternative approach 3 is introduced in Section 4.2.1.4 in the AoA.

Based on the results presented in the CFL application, the alternatives assessed are not technically feasible, a conclusion reached by SEAC during their examination of the CFL AfA. The applicants (Doosan) also reevaluated the four groups of alternatives presented in the CFL application against the criteria for the approval of copper foil for use in lithium ion batteries production and concluded that they are also not feasible to produce copper foils for lithium ion batteries for technical (Chromium (III) based solutions and organic resins) or economical reasons (ionic implantation) (see Table 9).

Timeframe of identification and implementation of suitable alternatives

With regards to the timeframe of identifying suitable alternatives, the applicants are claiming that it takes on average 2 years (along a range in the order of 1-5 years) before a newly-found technology can be implemented in a lithium ion battery. As stated by the applicants, such technology does not exist yet, while current research and development is not showing promising findings to date (and is likely to require more than 12 years to identify such). The applicants expect a total time to discover and to implement an appropriate technology within an expected time range of 13 (= 12 + 1) years to 17 (= 12 + 5) years. However, SEAC notes that research is progressing at a fast pace (as evidenced by recent advances in the field – some of which having been achieved by the applicants' group) in a direction that could produce future suitable alternatives. In the absence of additional information, it is difficult for SEAC to fully evaluate the time needed to identify and implement suitable alternatives.

SEAC's evaluation / view on the suitability and availability of alternatives:

Despite the fact that both literature review and in-house experimentation did not identify any suitable alternatives, the applicants had, at the same time, placed large emphasis on the reduction of chrome content in their second passivation step, as opposed to complete elimination of use.

Despite not being included in the initial AoA, the applicants provided on SEAC's request copies of a more thorough literature review, which came in the form of briefs produced through the CFL/LIST research collaboration effort. Concerning patents claiming chrome-free passivation, primarily from China, the applicants stated that such alternatives would already be heavily marketed in the EU had these claims been valid. Furthermore, the applicants referred to possible quality deficiencies of Chinese patents as they are issued more easily and often contain misleading information. This, coupled with the applicants' analysis of claims made by some patent holders, helps SEAC to concur with the applicants' conclusions concerning the current hesitance of the market to accept a chrome-free passivation of copper foil for the lithium ion battery industry.

Alternatives examined are therefore not suitable and not available at this point in time. With the information presented by the applicants, it is not possible for SEAC to confirm that 15 years would indeed be needed to identify and implement suitable alternatives.

5.5. Is the applicant already engaged in a substitution programme and / or R&D and is it seeking a defined transitional period to phase out the use the Annex XIV substance?

The applicants have not identified a suitable alternative yet.

The applicants' group Doosan/CFL has been conducting research in collaboration with LIST. More details have been provided in sections 5.2 and 5.4. CFL's research contract with LIST will be ending in 2024. A renewal is expected, if evidence of progress exists.

5.6 Conclusions on the analysis of alternatives

The documentation of possible alternatives, as provided in the AfA, was neither thorough nor sound as it relied heavily on the CFL application. However, the information provided during the opinion making process helped to better consolidate and present the information collected. For this reason SEAC accepts that, in principle, the methodology for collecting information has been adequate.

The analysis of alternatives carried out by the applicants is poorly presented and some claims are not well substantiated. This made it difficult for SEAC to conduct a detailed scrutiny. However, the overall analysis is scientifically plausible and according to the information provided in the application (including the CFL application), the alternatives assessed are either not technically feasible or leading to a product that is not acceptable by the main customers of the applicants.

Despite these shortcomings, SEAC considers that the applicants have demonstrated reasonably well that there won't be suitable alternatives at the time the new plant will start the production of the copper foils.

6. Have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ Yes

☐ No

☐ Not relevant (adequate control demonstrated for threshold substance)

6.1. Additional statistical cancer cases and costs (monetised Human Health risks) of continued use

The applicants take into consideration the excess risk linked to the future use of chromium trioxide at the new plant.

Lung cancer and small intestine cancer are the main health endpoints associated with direct exposure to chromium trioxide. Therefore, the applicants carried out a quantitative human health impact assessment based on the estimated excess risk of lung cancer for future workers and of small intestine cancer for the local general population.

The estimated number of additional statistical cancer cases has been calculated using the excess risk value presented in section 4 and the estimation of the number of exposed people provided by the applicant. It reflects the expected statistical number of lung and small intestine cancer cases for an exposure over the working life of workers (40 years) and the entire life for the general population (70 years).

As a matter of fact, the applicants considered only the inhalation route relevant for workers, while the oral route was not considered as explained in the CSR (section 9.0.2.2), because it was assumed that all particulate fractions are in the inhalation size range. On the contrary, for the general population only the oral intake has been considered relevant (by water drinking and fish consumption), while the inhalation route was disregarded as exposure source, since according to the applicants nobody would live or work within a 100 m radius from the future plant.

RAC notes that these calculations are based on the estimation of exposed populations as provided by the applicants. RAC also notes that during the opinion making process some changes were made by the applicants in the exposure assessment leading to changes in the excess cancer risk levels. Table 10 and Table 11 show the changes in excess cancer risk and how they translate into monetised health impacts.

SEAC considers that the change in total monetised health impacts over 15 years is negligible in comparison to the cost of the NUS. For this reason SEAC's assessment is based on the original values provided by the applicants.

Table 10: Summary of additional statistical cancer cases[1]

		Excess cancer risk	Number of exposed people	Estimated statistical cancer cases		Value per statistical cancer case (€)	Monetised excess risk (€)[2]
Lung cancer (inhalation)							
Directly exposed workers[3]	WCS 2	**5.20×10^{-6}** (3.16×10^{-8})	5	**2.91×10^{-5}** (1.77×10^{-7})	**3.19×10^{-5}** (1.48×10^{-6})	2 681 759	**2.28** (0.11)
	WCS 3	**1.61×10^{-7}** (7.73×10^{-8})	15	**2.71×10^{-6}** (1.3×10^{-6})			
General local population[4]		1.0×10^{-6}	0	0			0
Small intestine cancer (oral uptake)							
General local population		7.4×10^{-8}	10 000	1.48×10^{-3}		**857 466** (893 789)[5]	**20.29** (21.08)
Total							**22.57** (21.19)

1. Values in () are the original values presented by the applicants. Values in bold are the values recalculated by RAC/SEAC.
2. Annualised to a typical year based on the time horizon used in the SEA;
3. Worker exposure is estimated over a lifetime working exposure (typically 40 years) and then converted to a typical exposure year; directly exposed workers perform tasks described in the worker contributing scenarios, typically based on 8 hour Time Weighted Average (TWA) of a representative worker;
4. General population exposure via the environment is estimated over a typical lifetime exposure (typically 70 years) and then converted to a typical exposure year;
5. The applicants mixed up the survival rate with the fatality probability for this value and SEAC recalculated this value;

Table 11: Comparison of applicants' and SEAC's calculations for monetised health impacts over 15 years

	Applicants' values (€)	SEAC's values (€)
Workers, lung cancer via inhalation	1.18	25.30

General population (MvE), small intestine cancer via oral intake	234.33	225.63
Total over 15 years	**235.51**	**250.93**

When analysing all the impacts in the non-use scenario, the applicants provided confidential data but also non-confidential ranges of the monetisation of the residual risks of lung cancer for workers and small intestine cancer for the general population.

The applicants estimated the human health impact as the sum of medical treatment costs, productivity loss and welfare loss, with the latter being represented by the willingness to pay to avoid increases in cancer mortality and morbidity.

To monetise the economic burden of lung cancer, the applicants assumed that, due to the rapid progression of lung cancer, medical treatment costs would mostly be occurring within the year of diagnosis.

Using Hungarian data for the year 2012 on the total number of lung cancer cases (9 288), the total population (9.9M people), the economic burden of lung cancer per Hungarian citizen (€ 4.23)[8] and GDP deflator for Hungary, the applicants estimate the annual economic burden for one lung cancer case in Hungary at € 4 939 (2017 price level). Assuming an expected annual growth rate for the period 2017-2020 based on the average growth of the previous 5 years, the applicants obtained a value of € 5 078 as estimated annual economic burden of one case of lung cancer in Hungary for the reference year 2020. The applicants discounted future values of medical treatment costs at an annual rate of 4 %.

SEAC acknowledges that the use of the GDP deflator for Hungary as well as the methodology used by the applicants for assessing the medical treatment costs is sound and provides a reliable estimate. However, SEAC notes that to monetise costs per cancer cost, the applicants implicitly assumed that all workers will be cured in Hungary which is probably an overestimation that tends to underestimate benefits of the continued use.

The applicants used the EUROCARE-5 data on the five-year relative survival rate for lung cancer in Eastern European countries, showing that in 10.8 % of cases the patients would survive their disease for five or more years or, in other words, that in 89.2 % of cases the patients would live maximum five years after the diagnosis.

The applicants used the Cancer Research UK data for England and Wales which indicates that only 5 % of patients survives for ten years or more after their lung cancer diagnosis.

SEAC notes that there are uncertainties regarding data quality due to the mix of different data sources used by the applicants. For instance, the lung cancer survival rate after five years from diagnosis is based on EUROCARE-5 data but this value refers to the average of Eastern European countries rather than a figure specific for Hungary. The ten-year survival rate, on the other hand, was taken from Cancer Research UK and refers to England and Wales.

Medical treatment costs of small intestine cancer have been conservatively estimated by the applicants to be equal to that of lung cancer, though treatment costs of the lung cancer are much higher.

As far as productivity loss is concerned, SEAC notes that, for estimating medical treatment costs, the applicants used the study Luego-Fernandez et al. 2013. This study also provides

[8] Value refers to lung cancer-related health care costs taken from Luego-Fernandez et al. 2013.

productivity loss estimates but the applicants made their own estimation instead. For monetising the net productivity loss due to lung cancer, the applicants followed the human capital approach. Among other factors, the estimation considers the age incidence of lung cancer, the number of years to the retirement and the average earnings in the manufacturing sector in Hungary.

The applicants considered that 62.2 years is the average age of retirement for men and women in Hungary during the period 2011-2016, and that € 10 328 is the annual mean earnings in the sectors of industry, construction and services in Hungary in 2014. Furthermore, the applicants assumed that employees contracting lung cancer would cease working within one year after the diagnosis, and they would not work during the treatment period, even though people affected by cancer can usually work at least part-time. The productivity loss due to lung cancer was estimated by the applicants at € 40.2K. Productivity loss due to small intestine cancer has been conservatively estimated by the applicants to be equal to that of lung cancer, which is assumed to be much higher.

The formula used by the applicants to estimate the welfare loss due to increased mortality and morbidity is "Value of cancer case = discount factor × (fatality probability × VSL + VCM)", with:

- discount factor = $(1 + 4\ \%)^{-L}$; L being the latency period, assumed to be 10 years for lung cancer and 26 years for small intestine cancer,
- fatality probability derived from EUROCARE-5 as the average of the values for Eastern European countries (and applied to Hungary),
- the value of a statistical life (VSL) and the value of cancer morbidity (VCM) have been calculated from the value for 2012 (€ 3.5M and € 0.41M respectively) and updated to 2020 using the GDP deflator and a price adjuster (1.028).

Based on these calculations, the welfare loss would be approximately € 2.68M for lung cancer. For small intestine cancer the applicants calculated a value of € 0.89M. However, the applicants mixed up the survival rate with the fatality probability for this value and SEAC recalculated this value as € 0.86M.

Table 12: Summary of the estimated costs for a cancer case, used in the following to monetise human health impacts

	Lung cancer Costs (€)	**Small intestine cancer Costs (€)**
Medical treatment	25 175	25 175
Productivity loss	40 258	40 258
Welfare loss	2 681 759	**857 466** (893 789)

Note: Value in () is the original value presented by the applicants. Value in bold is the value recalculated by SEAC.

The applicants were able to provide the expected number of future workers directly exposed to chromium trioxide. According to the applicants, at their future production site in Hungary, the potentially exposed workers would be 5 upon CrO_3 dissolution and 15 during plant maintenance operations, no exposure would occur during the production phases.

In line with RAC/27/2013/06 Rev.1, only the excess carcinogenic risk associated with the exposure to Cr(VI) has been considered by the applicants. The individual excess risk for developing lung cancer from the use applied for would be in the order of 10^{-6} for both workers involved in WCS2 and WCS3 exposed for the whole duration of their working life (40 years).

In terms of costs of continued use, the applicants' monetised residual risk of lung cancer

related to workers who would be operating in the new plant was quantified at € 0.63 over 7 years, € 0.99 over 12 years and € 1.18 over 15 years.

The applicants also provided a quantification of the estimated statistical small intestine cancer cases due to the exposure of man via the environment. As mentioned above, for the general population only oral intake via water drinking and fish consumption has been considered by the applicants. The inhalation route as potential exposure source was discarded, since neither inhabitants nor workers from other nearby plants would live or work within a 100 m radius from the plant. Therefore, the MvE risks for lung cancer via inhalation for the general population have been monetised by the applicants at € 0 over 7, 12, and 15 years. The number of people considered by the applicants for the oral route via drinking water and fish consumption has been assumed by the applicants to be 10 000 within a 1 km radius. The applicants consider this as a conservative estimate because the village of Környe, where the new plant would be located, has only about 5 000 inhabitants.

At the local scale, some Cr release to the environment is expected. Of this, 3 % will remain as Cr (VI) while 97 % will be converted to Cr (III). The MvE oral intake would occur by drinking water (8.74×10^{-8} mg/kg bw/day) and fish consumption (5.03×10^{-9} mg/kg bw/day). To calculate the number of additional statistical small intestine cancer cases for MvE (1.48×10^{-3}), the applicants used as size of the exposed population by oral intake that of a standard town of 10 000 inhabitants. This number represents the expected statistical cancer cases for an exposure over the entire life for the general population. The small intestine cancer risk via drinking water and fish consumption was estimated at € 126.50, € 197.80 and € 234.33, over 7, 12 and 15 years respectively.

Table 13: Summary of monetised health impacts

	HH costs over 7 years (€)	HH costs over 12 years (€)	HH costs over 15 years (€)
Workers, lung cancer via inhalation	0.63	0.99	1.18
General population (MvE), small intestine cancer via oral intake	126.5	197.8	234.33
General population (MvE), lung cancer, inhalation (100 m radius)	0	0	0

Initially, it was not fully clear to SEAC if the impacts on workers and general population were derived under the assumption that the entire tonnage of chromium trioxide applied for (15 t/y) would be used every year or by assuming a lower initial annual tonnage that would be growing from one year to another over the 15 years' timeframe taken into consideration in the application. Therefore, SEAC requested further information from the applicants to understand to what extent this the annual tonnage of 15 t/y applied for in the original application (SEA p. 9-10) would cover the expected business increase. In their answer, the applicants clarified that for each year all socio-economic impacts are calculated based on an annual tonnage of 15 t. Based on the contracts with the future customers, according to the applicants, the volume of chromium trioxide will not increase over the 15 t/y. Furthermore, the applicants are confident that the annual tonnage applied for is sufficient as a future reduction in the concentration of chromium is likely. The applicants also added that the plant will operate always at its full capacity because the lithium ion batteries demand in EU will be much larger than the potential production capacity of the new plant.

SEAC's view on the additional statistical cancer cases and costs of continued use

In conclusion, SEAC acknowledges that overall the analysis carried out by the applicants is sound but still there are some small shortcomings, in particular:

- Uncertainties in terms of data quality due to the use of a mix of different data sources for the derivation of survival rates;
- Inaccuracies in the interpretation of survival rates and mixing up survival rate and fatality probability for small intestine cancer;
- Potential double counting of health impacts due to the adding up of medical treatment costs (direct costs), productivity loss (indirect costs) and welfare loss (willingness to pay). The welfare loss could include the direct and indirect costs.

In response to the last point, the applicants explained in their answers to SEAC questions that willingness to pay only accounts for the private costs of the disease in terms of pain and suffering and welfare loss from the increased mortality. On the contrary the costs of treatment represent the public economic burden for national health-care systems.

SEAC agrees with the applicants that in case in the SEA a double counting would exist, it can be considered to be negligible. Therefore, such overlapping would probably only slightly overestimate the benefits of non-use of chromium trioxide hence increasing the margin by which the costs outweigh the human health benefits of the non-use scenario.

More generally, SEAC notes that overall the mentioned shortcomings do not make a big difference due to the very small magnitude of human health impacts in the analysis.

6.2. Benefits of continued use (cost of non-use scenario)

Non-use scenario

Applied for (future) use scenario

The application for authorisation covers the 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 for motorised vehicles.

SEAC acknowledges that the scope of the application is quite narrow and well defined including only one future use, in one future plant for an amount of chromium trioxide (15 tonnes per year) over 15 years.

According to the applicants, the applied for use scenario is the future construction of the new plant in Hungary to passivate coppers foils needed by lithium ion batteries battery companies in the EEA.

Even if at present, in the EEA, copper foils and lithium ion batteries for Hybrid and Electric Vehicle (xEV) batteries are not yet produced, the applicants claim that, based on forecasts for the sector, the European market of lithium ion batteries for xEV is expected to grow at annual rate of 42.1 % between 2019 and 2030.

The copper foils to be produced in the future are required by the expected customers of the applicants. According to the applicants, the main potential future customers are three Korean lithium ion batteries battery producers (names provided but claimed confidential) who have invested to start lithium ion batteries manufacturing in the EEA. Moreover, other foreign companies and existing European players are expected by the applicants to become their future customers in the EEA (companies' names quoted but claimed confidential by the applicants). The applicants claim that the three Korean lithium ion batteries producers would use the whole production of copper foils from the new plant only for the manufacture of lithium

ion batteries used in motorised vehicles, namely hybrid and electric vehicles.

The applicants argue that CFL, subsidiary company of Doosan South Korea, does not have the production capacity to passivate copper foils for lithium ion batteries in a sufficient quantity, beyond its standard production of copper foils for printed circuit board (PCB). Moreover, the processes of CFL and the future passivation of copper foils for lithium ion batteries seem different as according to the applicants two passivation steps are needed by CFL for PCB while only one step would be needed in the new plant for lithium ion batteries. The applicants highlighted that to date in the EEA CFL in Luxemburg is the only producer of electrodeposited copper foils accounting for a 75 % market share in the EEA although these copper foils are not for lithium ion batteries but for different applications. Therefore, since CFL does not have the production capacity to satisfy the future demand of copper foils of the expected customers; in case the authorisation would be granted, the applicants' new plant would fill the gap of the remaining 25 % of copper foils which otherwise will have to be covered by imports from Asia, mainly from Japan, South Korea and China. According to the applicants, this way the new plant will become the second producer of copper foils in the EEA after CFL. Moreover, the applicants note that CFL already applied for and was granted an authorisation for using chromium trioxide for a similar production process of copper foils.

SEAC notes that in the original application, the applicants did not explain if contracts or at least some sort of initial agreements were signed with these customers that could make the applicants confident that such customers would actually buy the future production of copper foils for lithium ion batteries. After specific questions by SEAC in this regard, the applicants made clear that preliminary agreements, contracts or memoranda of understanding have already been signed or are under negotiation with their customers to guarantee sales and purchases in the long-term in order to secure such big investment in the new plant. The applicants explained that, for instance, by February 2019, their biggest future customer will pay a substantial advance for the first lot of production to be delivered in 2021. The applicants also quoted the possibility that one or more of the customers will take a financial stake in their company.

Moreover, in their application for authorisation, the applicants state that pilot production would start in January 2020 and regular production in July 2020. SEAC notes that this timeframe seems hardly consistent with the time needed for granting the authorisation, for building a brand-new plant and then for starting commercial production. Therefore, SEAC could conclude that either some construction activities are already ongoing, or the timeframe suggested by the applicants for the applied for use scenario is indeed too optimistic. In case construction has already started regardless of a granted authorisation, it could be assumed that other production activities than the manufacturing of copper foils for lithium ion batteries would take place in the new plant. After being questioned by SEAC, the applicants clarified that no other productions than the passivated copper foils will be manufactured in the Hungarian plant. The plan design has started and some machinery ordered betting on the good outcome of the authorization request.

Non-use scenario

In line with the conclusions of their analysis of alternatives and with the review period requested, the applicants' non-use scenario assumes that by 2020 there would be no technically nor economically feasible alternatives available for the passivation of copper foils for lithium ion batteries. Concerning the scenario of switching to a Cr(VI)-free passivation of copper foils, the applicants explain that, for their expected customers, it would not be technically possible to use copper foils passivated using a worse performing alternative. However, SEAC notes that in the AoA, the applicants refer to four potential alternatives to the

use of Cu in the passivation of copper foils for lithium ion batteries, but two of them are not described at all (2iii, 2iv p. 18-19). SEAC expected these alternatives to be identified and eventually discarded by the applicants as potential NUS in the SEA but this was not the case.

The applicants consider in detail only one (most likely) non-use scenario, that their new industrial plant would not be built in the EEA in Hungary and that their expected customers will need to import copper foils from Asia.

SEAC's view on the credibility of the non-use scenario

Whilst SEAC finds imports from outside the EEA a plausible NUS, in the original application only limited information was provided by the applicants concerning other possible non-use scenarios. More detailed arguments were provided by the applicants only concerning the selected most likely NUS. In fact, in the application a systematic justification of the reasons why other NUS were discarded was missing or not clear enough. For instance, as outlined in the AoA of this application, the hypothesis of an extension of the CFL industrial site in Luxembourg, where the passivation of copper foils already takes place, was considered impractical and it was therefore discarded by the applicants because of lack of space to install any additional machine for the required increase of production due to geographical reasons. However, it was not fully clear to SEAC if additional work shifts, e.g. at night-time and during weekends, are already in place at CFL or if they could be introduced by the applicants. In response to further written questions from SEAC, the applicants made clear that, to avoid crystallisation of the copper sulphate bath, the Wiltz facility in Luxembourg is already operating at its maximum capacity 24 hours per day and 365 days per year. Therefore, the new investment would be needed.

Moreover, SEAC notes that the outsourcing of the formulation step for the passivation of copper foils as possible NUS was quoted but not clearly explained by the applicants. In response to further written questions from SEAC, the applicants clarified that extra-EEA outsourcing of the formulation is not plausible for three different reasons. Firstly, exporting the negative impacts on human health and the environment to non-EEA countries is not in line with the applicants' ethical and sustainability principles. Secondly, in the market there are no companies able to supply in a reliable way large quantities of such a low concentration formulation. Thirdly, 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.

Furthermore, in the original application, the proximity of the new plant to the three main future customers (hence reducing transport costs) was claimed by the applicants as main reason for locating the future industrial site in Hungary. This claim was not very well substantiated in the original application as only the geographical location of the industrial site of one customer was disclosed (Tatabanya, Hungary), but those of the two other main expected customers were not quoted, not even in a confidential manner.

In response to further questions in this regard, the applicants confirmed that the plant of the second future customer would be located in the Göd area, north of Budapest. The plant of the third future customer is located in Wrocław (Poland). The applicants better explained that the choice of the location in Hungary depends on proximity to lithium ion batteries factories of two out of three main future customers explicitly requiring a close location for minimizing the risk of the supply of copper foils. Moreover, the applicants clarified that, without building the new plant close to the customers, they would lose their competitive advantage and their customers would lose commercial interest and they would start purchasing copper foil elsewhere. The applicants also added, as a positive impact of such proximity, the minimization of pollution.

In the original application, it was not entirely clear to SEAC to what extent the new plant would only manufacture copper foils or if other industrial activities would also take place in the future plant. In such a case, only a smaller share of the missed future benefits described in the application could be attributed to a potential refusal of authorisation. After specific SEAC questions in this regard, the applicants confirmed that the new plant will produce only copper foils for lithium ion batteries. However, even if the applicants claim that the authorisation is a *conditio sine qua non* of the investment, they seem to be sufficiently confident that it will be granted to have already started investing. The applicants pointed out that the application for authorisation was done before the critical investment to start the production.

In addition, the applicants explained that starting the investment before getting the authorisation means only that they are betting on the fact that the authorisation will be granted. Moreover, the applicants pointed out that the investment will be gradual and that it could be stopped in the future if needed. For instance, some of the investments, even the heaviest such as the machines, which had to be ordered years in advance, if not installed in the new plant, they could be used elsewhere or sold, hence reducing the losses for the applicants.

In view of the application and of the complementary information provided by the applicants. SEAC concludes that the combined non-use scenario proposed by the applicants is indeed credible.

Costs of non-use scenario

Economic costs

The applicants' analysis of the costs of a refused authorisation is based on the most plausible non-use scenario in which the applicants would not build a new plant in the EEA and their customers would have to import copper foils.

In their assessment, the applicants estimated quantitatively the main socio-economic impacts for the European society in terms of the loss of the expected production of copper foils in the EEA (calculated by using either EBIT or net profits) and the loss of future job creation (direct potential social losses) in the future plant (number of workers provided but claimed confidential by the applicants), as a consequence of the non-use scenario.

SEAC notes that even if some data on the amount of the investment in the new plant is provided by the applicants in the original application, further information concerning the investment cycle would have been useful for SEAC to formulate its opinion on the length of the review period to be proposed. After a specific question, the applicants confirmed that the main machines (referring only to the drums, which are the main components of the machines) need to be changed every ten years. The other parts of the main machines (e.g. the baths) can continue to operate and they are expected to be changed after 20 years. Other machines (e.g. pumps, filters, belts) have an amortisation period of eight years and are expected to be changed after 15 years. The new building will have an amortisation period of 20 years. The applicants claim that their investment in the new plant would have a positive impact on the local economy as well as indirectly on the whole Hungarian economy (the investment representing 0.1 % to 0.5 % of the 2017 Hungarian GDP). SEAC acknowledges also that the applicants' assessment does not include investment costs.

Relying on sales forecasts based on signed initial agreements with future customers, the future direct loss was expressed by the applicants both in terms of loss of EBIT and loss of net profit (10 % of sales on average). To be conservative, the applicants finally used the ranges of the net profit loss. On SEAC request, the applicants provided a more detailed overview of their business plan including the forecast of the actual expected net profits. Although this additional

information did not explain how the EBIT was calculated, it seems to confirm that the assumption of a 10 % profit rate is indeed conservative which means that the costs of non-use would be underestimated.

For assessing welfare impacts, being a net indicator, SEAC considers that the loss of net profit provides a better estimate of future producer surplus loss, because EBIT tends to overestimate the economic impacts.

The net profit losses were estimated by the applicants using the average value of missed expected profits related to the review period (2020-2035) requested in the application.

According to the applicants, their direct loss, claimed to be conservative, would range from € 100M to € 200M. The claim of conservatism made by the applicants would suggest that the actual economic impacts would be even larger.

Social costs

The applicants assessed the social impacts in terms of missed job creation, i.e. future losses of potential employment opportunities associated with the NUS. According to the applicants' analysis, in terms of social costs, the non-construction of the Hungarian plant, as a consequence of a non-granted authorisation, would imply the loss of employment opportunities (missed job creation) in the new plant.

Initially in the application, the applicants considered that, in case of a refusal of the authorisation, the workers, who would have been employed in the new plant, would not get immediately a job, but they would further remain unemployed.

SEAC notes that this case is somewhat peculiar because the factory does not exist yet and therefore there would be no increase in unemployment under the NUS. However, SEAC recognizes that there is an important social value associated with the applicants' job creation in case of a granted authorisation.

To quantify the social costs, the applicants used the methodology described in the SEAC note on the social cost of unemployment[9] which was prepared for and is generally applied to cases in which the NUS would cause new unemployment. SEAC notes that conceptually the use of this approach doesn't seem fully appropriate to such a reverse situation in which no one is made unemployed but people would rather remain unemployed in case the plant would not be built. However, in the absence of a specific approach to estimate the costs of lost employment opportunities, SEAC acknowledges that the use of the existing methodology, even if it does not fit 100 % to this specific situation, can be accepted.

SEAC notes that the approach taken provides an upper bound of social costs, while the lower bound corresponds to zero as no new unemployment would be created under the NUS. SEAC recognises that the social costs of unemployment, i.e. in this case the missed social benefits of the job creation, should be somewhere in between these two bounds. Therefore, SEAC considers that the applicants could have overestimated the social costs.

However, even if the social impacts would be lower, SEAC notes that the economic impacts alone would already outweigh the health impacts by a lower but still considerable margin. In this respect, SEAC considers that the uncertainties associated with the applicants' analysis are small in relation to the ratio between the assessed socio-economic benefits and health costs of future use.

SEAC notes that the social costs of unemployment were estimated by the applicants in the range from € 0 to € 5M by using the delay in finding a job based on unemployment statistics

[9] https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/

for Hungary. However, SEAC considers not fully acceptable the assumption that all future workers would come from the unemployment market, in particular given the low long-term Hungarian unemployment rate.

In answering to further written questions by SEAC, the applicants considered that not all workers would have been unemployed before starting to work at the new plant. The applicants assumed that 50 % of the workers with a university degree will be hired immediately after the University.

Furthermore, after the Trialogue, as suggested by SEAC, the applicants modified their assessment introducing the assumption that the workers in the future plant could also come from other companies. In this case, the applicants assume that the annual gross salary they would pay to the hired workers would be higher than the average salary paid by other companies and that such difference in salaries will remain over the 15 years period.

If the authorisation would not be granted, SEAC notes that, even if some workers would come from other companies, it can be assumed that somewhere in this chain of reemployed workers the same expected number of workers indicated (but claimed confidential) by the applicants would remain unemployed.

In line with the applicants' calculations, even with the introduction of these two new assumptions, SEAC agrees with the applicants that the ratio between the aggregated socio-economic benefits and the aggregated monetised excess risk would not change much.

Table 14: Socio-economic benefits of continued use

Description of major impacts	Quantification of impacts [annualised to € million per year]
1. Benefits to the applicant(s) and/or their supply chain	
1.1 Avoided profit loss due to investment and/or production costs related to the adoption of an alternative	Not relevant
1.2 Avoided profit loss due to ceasing the use applied for[10]	€ 10-15M
1.3 Avoided relocation or closure cost	Not relevant
1.4 Residual value of capital	Not quantified
1.5 Avoided additional cost for transportation, quality testing, etc.	Not relevant
Sum of benefits to the applicant(s) and / or their supply chain	€ 10-15M
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[11]	€ 0.3-0.4M
2.2 Spill-over impact on surplus of alternative producers	Not quantified

[10] Profit losses to be counted in only for the first [x] years, see SEAC note on economic surplus changes (not yet available).

[11] Job losses to be accounted for only for the arithmetic mean period of unemployment in the concerned region/country as outlined in the SEAC paper on the valuation of job losses (See The social cost of unemployment and Valuing the social costs of job losses in applications for authorisation).

2.3 Avoided consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity, etc.)	Not quantified
2.4 Other societal impacts (e.g. avoided CO_2 emissions or securing the production of drugs)	Not quantified
Sum of impacts of continuation of the use applied for	€ 0.3-0.4M
3. Aggregated socio-economic benefits (1+2)	€ 10-15M

Note: The values in 1.2 and 2.1 refer to avoided profit losses due to not being able to start the operations and avoided loss of job creation opportunity, respectively.

Wider economic impacts

Furthermore, in the SEA, the applicants include a qualitative assessment of wider economic impacts in terms of losses related to worsening of EEA trade balance due to higher imports from Asia, loss of competitiveness of the EEA producers of lithium ion batteries due to the additional costs for import duties (8 %), costs linked to the risk of fluctuation of the exchange rate for import, lower flexibility for their customers' businesses, additional costs related to higher stock level due to delays in delivering as well as loss of new business and employment opportunities for satellite activities generated by the green field investment. As other wider economic impact, the applicants also refer to macroeconomic effects, such as the loss of positive knock-on effects from the investment in case of non-authorisation.

Overall, SEAC can agree with the importance of these qualitatively described negative impacts.

The applicants' benefit-cost comparison conservatively didn't take into account quantitatively these wider economic impacts, which would increase the margin by which benefits outweigh costs associated with the non-use scenario.

SEAC's view on the costs of the non-use scenario

Even if most probably the social impacts are lower than those estimated by the applicants, SEAC notes that the economic impacts alone would still outweigh health impacts by a considerable margin. SEAC acknowledges that, if quantified, the other economic impacts only qualitatively described by the applicants would partially compensate the overestimation of the social costs.

In this respect, SEAC considers that the uncertainties associated with the approach adopted by the applicants' analysis are small in relation to the ratio between the assessed socio-economic benefits and health costs of future use.

6.3. Combined assessment of impacts

The applicants are applying for an authorisation for an extra-long review period of 15 years, stretching from 2020 to 2035. In fact, the applicants claim that an excellent passivation of copper foils is essential for their customers to manufacture lithium ion batteries and that the chromate-free copper foils are not yet satisfactory in terms of technical performance. Therefore, for the socio-economic analysis, the applicants use as a reference base the year 2020 because it is the year during which the production at the new plant is expected to start (pilot production in January 2020 and mass production in July 2020). All present values of costs and benefits refer to the base year 2020. In this respect, the applicants' primary motivation is to have at least the timeframe estimated to be needed to get a return on the investment of the new plant and for completing research and development activities aiming at identifying, testing, validating and placing on the market a suitable chromate-free alternative.

The applicants' assessment adjusts the most recent available data (often for the year 2017) to the price level of the reference year 2020. SEAC acknowledges that the applicants made good use of available statistics from EUROSTAT to take inflation into account whenever past price levels are adjusted to the base year (using Hungarian GDP). With the caveat introduced above concerning the data for Eastern European countries, SEAC acknowledges the use of data from EUROCARE-5 to estimate the survival at least 5 years after diagnosis for lung cancer patients in Europe.

SEAC notes that the geographical scope of the SEA is the territory of the European Economic Area (EEA), though the applicants make reference also to extra-EEA impacts.

According to the SEA carried out in the application, the total benefits for the European society in case of a refused authorisation would be € 127, € 199 and € 236, over 7, 12 and 15 years respectively, while the total costs for the European society would be *at least* € 55.1M over 7 years, € 96.3M over 12 years, and € 119.2M over 15 years.

Table 15: Overview of impacts

Type of impacts in the NUS	People / region impacted	Impacts over 7 years (€)	Impacts over 12 years (€)	Impacts over 15 years (€)
Benefits for the avoided lung and small intestine cancer cases	Workers at the new plant and the local population close to Környe	127	199	236
Social costs due to unemployment	Unemployed people who would not be hired in Hungary (most likely living close to Környe)	0-5M	0-5M	0-5M
Loss of net profits in the EEA	EEA society, village of Környe and its local economy	50-100M	50-100M	100-200M
Net costs of a refused authorisation		**55.1M**	**96.3M**	**119.2M**

According to the applicants, the costs of a refused authorisation would be equal to *at least* 433 626 times, 484 323 times and 506 064 times the benefits over 7, 12 and 15 years, respectively. Even under very conservative assumptions, the applicants claim that the costs of a refused authorisation would be equal to *at least* 40 943 times, 45 731 times and 47 749 times the benefits over 7, 12 and 15 years respectively.

The applicants' claim that, compared to the authorisation for the use of chromium trioxide granted to CFL, this application would concern a lower tonnage, a limited volume of wastewater released into the aquatic environment and a less risky new plant where, thanks to better workers' protection practices, workers would face lower risks while carrying out their tasks. Hence, the applicants suggest that granting this authorisation for the future use of chromium trioxide for the formulation of a solution used in the passivation process of copper foils would imply a reduced level of risk for both workers and the general population compared to the CFL case.

SEAC agrees with the applicants that there are no technically suitable alternatives for passivating copper foils for the manufacture of lithium ion batteries for motorised vehicles. Moreover, SEAC considers that the information provided in the application is sufficient to assess both the benefits and health impacts and to conclude on a positive benefit-cost ratio. SEAC notes that monetised risks of future use should be in the order of up to hundreds of €

over the review period, while socio-economic impacts of a non-granted authorisation (profit losses and job losses together) should be in the order of hundreds of millions of € over the requested review period (15 years). Both for risks and benefits data concerning a period of 7 and 12 years were also provided by the applicants. Such orders of magnitude largely account for any residual uncertainty related to this assessment, providing a good margin to support SEAC's conclusions on benefits and risks of future use.

Table 16: Comparison of socio-economic benefits and risks of continued use

Socio-economic benefits of continued use [annualised to € million per year]		**Monetised excess risks associated with continued use [annualised to € per year]**	
Benefits to the applicant(s) and/or their supply chain	€ 10-15M	Monetised excess risks to workers directly exposed in the use applied for	€ 0.11
Quantified impacts of the continuation of the SVHC use applied for on other actors	Unemployment: € 0.3-0.4M	Monetised excess risks to the general population and indirectly exposed workers	€ 21.08
Additional qualitatively assessed impacts	Worsening of the EEA trade balance due to rise in imports from Asia; Additional costs for import duties and worsening of the competitiveness of the EEA producers of lithium ion batteries; Risk of exchange rate; Less flexibility for business due to delays in delivering; Loss of new business opportunities for satellite activities.	Additional qualitatively assessed risks	None
Aggregated socio-economic benefits	€ 10-15M	Aggregated monetised excess risk	€ 21.19

Table 17: Benefit/cost summary

Net benefits (€)[annualised to € million per year]	€ 10-15M
Benefit/monetised risk ratio	500 000-1 000 000 times

The applicants also calculated the annualised values of socio-economic benefits and risks applying the conservative assumptions included in the uncertainty analysis.

Table 18: Comparison of socio-economic benefits and risks of continued use applying the conservative assumptions included in the uncertainty analysis

Socio-economic benefits of continued use annualised to € million per year		**Monetised excess risks associated with continued use annualised to € per year**	
Benefits to the applicant(s) and/or their supply chain	€ 5-10M	Monetised excess risks to workers directly exposed in the use applied for	€ 51.79
Quantified impacts of the continuation of the SVHC use applied for on other actors	Unemployment: € 0.1-0.3M	Monetised excess risks to the general population and indirectly exposed workers	€ 60.38
Additional qualitatively assessed impacts	Worsening of the EEA trade balance due to rise in imports from Asia; Additional costs for import duties and worsening of the competitiveness of the EEA producers of lithium ion batteries; Risk of exchange rate; Less flexibility for business due to delays in delivering; Loss of new business opportunities for satellite activities.	Additional qualitatively assessed risks	None
Aggregated socio-economic benefits	€ 5-10M	Aggregated monetised excess risk	€ 112.17

Table 19: Benefit/cost summary applying the conservative assumptions included in the uncertainty analysis

Net benefits (€)annualised to € million per year	€ 5-10M
Benefit/monetised risk ratio	40 000-50 000 times

6.4. Conclusion on the socio-economic analysis

The assessment conducted by the applicants includes a comparative quantitative analysis of the impacts of the future use applied for and non-use scenario related to the passivation step. SEAC notes that all benefits and costs included in the applicants' assessment are only theoretical as they do not refer to a current situation but to a future use of chromium trioxide for the formulation of a solution for the passivation of copper foils for lithium ion batteries in an industrial site yet to be built.

The applicants' impact assessment encompasses all the main positive and negative impacts of a refused authorisation occurring within the EEA and which are incremental to the baseline

under the future use applied for and non-use scenarios. Overall, the applicants adopted a conservative approach by making assumptions which tend to overestimate the monetised health risks of the future use, in case of a granted authorisation.

Uncertainty and sensitivity analysis

The SEA carried out by the applicants also included an analysis of uncertainties associated with several specific values such as, among others, the direct cost of treating lung and small intestine cancer as well as the production loss under the NUS.

With the aim of minimising the level of uncertainty and for assessing the impact of each remaining uncertainty, the applicants carried out a sensitivity analysis ("stress test scenario"). In the original SEA and then in response to SEAC questions, costs and benefits under the NUS were recalculated using more conservative assumptions compared to the main socio-economic analysis.

The uncertainties related to the **benefits of the NUS** are:

- **Exposure** are magnified assuming that:
  - **Workers** in WCS2 and WCS3 are assumed to be in contact with chromium trioxide more time (8 h/day, 5 days/week);
  - **More people** of the general population (from nobody within a 100 m radius to 200 people within a 1 km radius) are considered exposed via the environment (inhalation route);
- **Welfare losses** from mortality and morbidity are monetised by using the upper bound for the VSL (€ 5M).

The uncertainties related to the **costs of the NUS** are:

- **Net profits** are assumed to be equal to a lower share of annual sales (5 % instead of the 10 % of sales which was already a very conservative figure);
- **Social impacts** of unemployment have been reassessed by assuming that:
  - workers would be paid half of the actual salary
  - future workers could be hired from:
    - the unemployment market (in response to SEAC questions, the proportion of workers hired from the unemployment market was reduced from 100 % to 50 %);
    - the university immediately after the end of their studies (in response to SEAC questions, the proportion of workers hired directly from university was increased from 0 to 50 %);
    - another company assuming that gross salary expected to be paid by the applicants will be higher than in other companies.

Based on these assumptions, the applicants recalculated the monetisation of the positive and negative impacts that can be attributed to the use applied for. However, in the original application, in the absence of the related spreadsheet, SEAC could not verify the calculations included in the sensitivity analysis carried out by the applicants and thus SEAC requested the spreadsheet.

Even under the more conservative assumptions of the "stress test scenario", the applicants conclude that the costs of a refused authorisation are considerably higher than the associated health benefits.

SEAC notes that in the uncertainty analysis in the original application two key assumptions were not addressed. However, in response to SEAC questions, some clarifications were provided by the applicants.

While in the uncertainty analysis net profits were more conservatively assumed to be 5 % of annual sales, the underlying sales projections were not changed in the sensitivity analysis. However, the applicants clarified that these values are based on the negotiated sales with the three future customers which are embedded in the initial signed agreements.

In the initial calculation of social impacts the applicants assumed that all future workers would come from the unemployment market. However, as mentioned above, in response to SEAC questions, the applicants tested their assumptions (and their calculations accordingly) considering that future workers would come from the unemployment market, directly from universities or from other companies. Through this sort of sensitivity analysis the applicants demonstrated the robustness of their conclusions which are not really affected by such changes.

Moreover, SEAC notes that, if the social impacts were lowered even further, the economic impacts alone would already outweigh the health impacts.

In summary, SEAC acknowledges that the applicants' approach tested the robustness of their findings by introducing very restrictive (and in some cases almost unrealistic) assumptions, which tend to overestimate the human health costs and underestimate the benefits of the future use.

Conclusion

SEAC considers that the analysis carried out by the applicants sufficiently captures the changes in impacts that allow to conclude that benefits outweigh risks, resulting from the future use of chromium trioxide associated with copper foil production for lithium ion batteries in the EEA.

Although in the AoA and in the socio-economic assessment there are some missing information, methodological deficiencies and residual uncertainties, taking into consideration the limited human health impacts associated with this application, SEAC considers that the applicants' analysis allows to conclude that the benefits of the future use of chromium trioxide for the formulation of the solution for the passivation of copper foils for the production of lithium ion batteries substantially outweigh the related risks arising from the associated exposure to Cr(VI).

7. Proposed review period

☐ Normal (7 years)

☒ Long (12 years)

☐ Short (…. years)

☐ Other:

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

7.1. RAC's advice:

RAC has no advice concerning the length of the review period.

7.2. Substitution and socio-economic considerations

The applicants have requested a 15-year review period.

When recommending the duration of the review period, SEAC took note of the following

considerations:

- The applicants demonstrate that the investment cycle of the new plant is very long. The main machines will need to be changed every 10 years. Other machines will have an amortization period of 8 years, and some other parts of the main machines (e.g. the baths) can continue to operate and they are expected to be changed after 20 years. The buildings have an amortization period of 20 years and the applicants plan a phased expansion as customer demand will grow. Moreover, to finance the investment of the new plant investors need strong guarantees and a very high level of confidence concerning the granting of the authorisation.
- The applicants demonstrate that proactive R&D efforts, carried out during several years by the applicants' sister company CFL, did not lead to the development of an alternative with equal performances than chromium trioxide. The development of such an alternative would not be possible within the normal review period.
- The applicants demonstrate that in case of a granted authorisation the health costs of the use will be low and the socio-economic benefits will be high, and this situation is not likely to change in the next decade.

Taking into account these points, SEAC considers that the criteria for a 12-year review period are fulfilled.

Taking into account the CARACAL document: policy guidance for recommending the review period for "exceptional cases"[12], SEAC considers that the levels of excess lifetime cancer risk derived from the exposure assessment are in line with the first requirement set by CARACAL. However, RAC recommends additional monitoring arrangements to address the uncertainties related to the lack of measurements, and therefore the second requirement set by CARACAL is not fulfilled.

In addition, SEAC considers that the applicants failed to demonstrate without significant uncertainties that no suitable alternatives would become available for the use concerned within the 15-year review period proposed in the application for authorisation.

Taking into account these points, SEAC recommends a 12-year review period.

8. Additional conditions and/or monitoring arrangements for the authorisation proposed

☒ Yes

☐ No

8.1. Description:

RAC

Additional conditions

None

Monitoring arrangements

(a) the applicants shall implement an exposure monitoring programmes for chromium (VI)

12 https://echa.europa.eu/documents/10162/13580/ca_101_2017_criteria_longer_review_period_afa_en.pdf/

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

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

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

(iii) the number of workers potentially exposed;

(b) the applicants shall implement monitoring programmes for chromium (VI) emissions to wastewater and air from local exhaust ventilation at least annually. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the OCs and RMMs used at the applicants site.

(c) the information gathered via the measurements referred to in points (a) and (b) and related contextual information shall be used by the applicants to confirm the effectiveness of proposed RMM and OCs as well as to review annually the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to chromium trioxide and emissions to the environment to as low a level as technically and practically feasible;

(d) the applicants shall ensure that the application of risk management measures at his site is in accordance with the hierarchy of control principles;

(e) the information from the monitoring programmes referred to in points (a) and (b), including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the applicants, upon request, to the competent national authorihy of the Member State where the authorised use will take place;

(f) following implementation of the RMMs and OCs proposed for the new installation, the applicants may reduce the frequency of measurements, once the applicants 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;

SEAC

Additional conditions

None

Monitoring arrangements

None

8.2. Justification:

Although RAC considers the OCs and RMMs described in the application and planned to be implemented in relation to both workers and general population to be appropriate and effective in limiting the risk resulting from exposure through inhalation and oral route, this is a future use and it is clear that there are some uncertainties related to the lack of actual exposure measurements. For this reason RAC felt it necessary to apply additional monitoring arrangements to address this; this is further explained below.

Static and personal monitoring data are important sources of information about occupational

exposure and, as this application is for the future site, there is no monitoring dataset available for this use. RAC is of the opinion that the level of certainty of the exposure assessment for the future installation would be strengthened by obtaining a representative measurement data set (as the applicants have already committed to do in the CSR), corresponding to all relevant WCSs. RAC also notes that PPE should be used as a last resort thus applicants should reevaluate the use of suggested PPE use after the monitoring results will become available.

The applicants also should obtain a representative monitoring data set for the emissions to the environment (water and air compartments, as the applicants have already committed to do in the CSR) as that will allow to evaluate/ confirm the appropriateness and effectiveness of implemented RMMs.

9. Recommendations for the review report proposed

☒ Yes

☐ No

9.1. Description:

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

9.2. Justification:

Provision of the representative monitoring results for both worker exposure and environment would allow for better evaluation of the actual situation in the applicants site and would confirm the appropriateness and effectiveness of OCs and RMMs actually used.

10. Did the applicant provide comments on the draft final opinion?

☐ Yes

☒ No

10.1. Action/s taken resulting from the analysis of the applicant's comments:

☐ Yes

☐ No

☒ Not applicable – the applicant did not comment