Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

a use of Sodium dichromate: Use of sodium dichromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 1.05 % w/w (corresponding to 0.42 % w/w as Cr(VI)) in the refrigerant solution

Submitting applicant

Robur S.p.A

ECHA/RAC/SEAC: AFA-O-0000007078-70-01/F

Consolidated version

Date: 25 May 2022

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

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

Applicant	**Robur S.p.A**
Role of the applicant in the supply chain	Upstream ☐ Manufacturer ☐ Importer ☐ Only representative ☐ Formulator Downstream ☒ Downstream user
Use performed by	☒ Applicant ☐ Downstream user(s) of the applicant
Substance ID EC No CAS No	**Sodium dichromate** 234-190-3 10588-01-9
Intrinsic properties referred to in Annex XIV	☒ Carcinogenic (Article 57(a)) ☒ Mutagenic (Article 57(b)) ☒ Toxic to reproduction (Article 57(c)) ☐ Persistent, bioaccumulative and toxic (Article 57(d)) ☐ Very persistent and very bioaccumulative (Article 57(e)) ☐ Other properties in accordance with Article 57(f)
Use title	**Use of sodium dichromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 1.05 % w/w (corresponding to 0.42 % w/w as Cr(VI)) in the refrigerant solution**

	Other connected uses: -
	Similar uses applied for: <u>Sodium dichromate</u> 0042-01: ARLANXEO Netherlands B.V. – use as corrosion inhibitor in ammonia absorption deep cooling systems 0074-01: TOTAL RAFFINERIE MITTELDEUTSCHLAND GMBH – use as a corrosion inhibitor in an ammonia absorption deep cooling system of a methanol synthesis plant 0075-01: Jacobs Douwe Egberts DE GmbH – use as a corrosion inhibitor in ammonia absorption deep cooling systems as applied in the industrial production of freeze dried products such as coffee, herbs, spices and comparable products 0104-01: Borealis Plastomers B.V. – use as in-situ corrosion inhibitor in a closed water/ammonia absorption cooling system 0124-01: H&R Ölwerke Schindler GmbH and H&R Chemisch-Pharmazeutische Spezialitäten GmbH – use as corrosion inhibitor in ammonia absorption deep cooling systems, applied for the dewaxing and deoiling process steps of petroleum raffinate <u>Sodium chromate</u> 0030-01: Dometic GmbH and Dometic Hűtőgépgyártó és Kereskedelmi Zrt. – use as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75 % by weight (Cr6+) in the cooling solution 0136-01: Ariston Thermo SpA – use as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr6+) in the refrigerant solution
Number and location of sites covered	1 industrial site in Italy
Annual tonnage of the Annex XIV substance used	≤ 0.35 tonnes per year
Function(s) of the Annex XIV substance	Added to the water-ammonia solution in the circuit of the appliance, it protects the inner surfaces and behaves well under given operating conditions: • Inhibits corrosion of sealed circuits • Prevention of gas formation

	• Effectiveness at high operating temperatures • High functionality under high pressure • Long-lasting service
Type of products (e.g. articles or mixtures) made with the Annex XIV substance and their market sectors	Gas absorption appliances, such as gas absorption heat pumps (GAHP) and gas absorption chillers (GA chillers).
Annex XIV substance present in concentrations above 0.1% in the products (e.g. articles) made	☒ Yes ☐ No ☐ Unclear ☐ Not relevant
Review period requested by the applicant (length)	12 years
Use ID (ECHA website)	0236-01
Reference number	11-2120888956-27-0001

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	09/04/2021
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	02/08/2021
Was the application submitted by the Latest Application Date for the substance and can the applicant consequently benefit from the transitional arrangements described in Article 58(1)(c)(ii)?	☐ Yes ☒ No
Date of consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	18/08/2021-13/10/2021
Were comments received in the consultation?	☐ Yes ☒ No
Request for additional information in accordance with Article 64(3)	On 07/09/2021 and 04/11/2021 Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/66207/del/200/col/synonymDynamicField_1512/type/asc/pre/2/view
Trialogue meeting	Not held – no new information submitted in consultation and no need for discussion on any technical or scientific issues related to the application from the side of the rapporteurs
Was the time limit set in Article 64(1) for the sending of the draft opinions to the applicant extended?	☐ Yes, by: Not Applicable (NA) Reason: NA ☒ No
Did the application include all the necessary information specified in Article 62 that is relevant to the Committees' remit?	☒ Yes ☐ No
Date of agreement of the draft opinion in accordance with Article 64(4)(a) and (b)	RAC: 18/03/2022, agreed by consensus
	SEAC: 16/03/2022, agreed by consensus
Date of sending of the draft opinions to the	10/05/2022

applicant	
Date of decision of the applicant not to comment on the draft opinions, in accordance with Article 64(5)	25/05/2022
Date of receipt of comments in accordance with Article 64(5)	Not relevant
Date of adoption of the opinion in accordance with Article 64(5)	RAC: 25/05/2022, adopted by consensus
	SEAC: 25/05/2022, adopted by consensus
Minority positions	RAC: No minority positions
	SEAC: No minority positions
RAC Rapporteur	Bogusław BARAŃSKI
SEAC Rapporteur SEAC Co-rapporteur	Derrick JONES Darko DOLENC
ECHA Secretariat	Greta FRANKE Jesus VAZQUEZ-RODRIGUEZ Simone GERVASUTTI

LIST OF ACRONYMS

AfA	Application for authorisation
AoA	Analysis of alternatives
bw	Body weight
CBA	Cost-benefit analysis
C-E	Cost-effectiveness
CSR	Chemical safety report
DNEL	Derived no-effect level
ES	Exposure scenario
ECS	Environmental contributing scenario
GA	Gas absorption
GAHP	Gas absorption heat pumps
LAD	Latest application date
LEV	Local exhaust ventilation
OC	Operational condition
PBT	Persistent, bioaccumulative and toxic
PNEC	Predicted no-effect concentration
PPE	Personal protective equipment
RAC	Committee for Risk Assessment
REACH	European Union regulation on registration, evaluation, authorisation and restriction of chemicals
RMM	Risk management measure
RP	Review period
RR	Review report
SDS	Safety data sheet
SEA	Socio-economic analysis
SEAC	Committee for Socio-economic Analysis
SP	Substitution plan
SSD	Sunset date
vPvB	Very persistent and very bioaccumulative
WCS	Worker contributing scenario

This document provides the opinions of the Committees for Risk Assessment and for Socio-economic Analysis based on their scientific assessment of the application for authorisation. It thus provides scientific input to the European Commission's broader overall balancing of interests.

THE OPINION OF RAC

RAC has formulated its opinion on:

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

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

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

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

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

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

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

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

THE OPINION OF SEAC

SEAC has formulated its opinion on the socio-economic factors and the suitability and availability of alternatives associated with the use of the substance taking into account the information in the application as well as other available information. SEAC's evaluation is based on relevant guidance, which comprises Commission's Better Regulation guidance, the Guidance documents on applications for authorisation and the socio-economic analysis as well as specific guidance related to how SEAC evaluates the applications (e.g. dose response functions, values of health endpoints).

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

SEAC took note of RAC's conclusion that it is possible to determine a DNEL for the reprotoxic properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC has assessed the availability, and technical and economic feasibility of alternatives for the applicant and in the EU. These are described in section 4. The applicant short-listed the following alternatives:

- **Alternative 1:** no inhibitor. This is the simplest of the possible solutions but shortens the lifetime of the appliance.
- **Alternative 2:** different chemical composition of the inhibitor. The applicant has presented a list of 8 promising substitutes for sodium dichromate.
- **Alternative 3:** metallurgical alternatives. This alternative involves the potential use of a construction material other than carbon steel, which would be resistant to corrosion.

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

- The applicant has demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the applicant by the date of application submission (April 2021).
- There is information available in the application for authorisation indicating that there are no alternatives available that are technically and economically feasible in the EU.
- The applicant submitted a substitution plan. The substitution plan is credible for the review period requested and consistent with the analysis of alternatives and the socio-economic analysis.

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

The expected societal costs of not granting an authorisation, which are estimated to be €0.28-2.77 million per year, consisting of lost profits, site closure costs and job losses.

The risks arising from granting an authorisation, which consider:

- the endpoints relevant for listing the substance in Annex XIV of REACH;
- the 1-100 directly exposed workers (actual number is confidential);
- the general population exposed at local scale (approximately 1 100 people);
- that the risk of continued use as assessed by RAC may result in 1.20×10^{-4} expected additional cases of cancer over 12 years;
- the value of these expected additional cases has been monetised based on the willingness-to-pay methodology and corresponds to an estimate of up to €38 per year.

Risks to human health of alternatives have not been assessed.

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

PROPOSED CONDITIONS, MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

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

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

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

REVIEW PERIOD

Taking into account the information provided in the application for authorisation submitted by the applicant and any comments received in the consultation, a **12-year** review period is recommended for this use, i.e. until the end of March 2033.

JUSTIFICATIONS

0. Short description of use

The applicant, Robur S.p.A, applies for the use of sodium dichromate as a corrosion inhibitor in the carbon steel sealed circuits of gas absorption heat pumps (GAHPs) and gas absorption chillers (GA chillers). The gas absorption (GA) appliances utilise natural gas as a source of energy and are used for heating and cooling of public and industrial buildings as well as multifamily homes. They are installed and serviced by professionals. The applicant uses ≤ 0.35 tonnes of sodium dichromate per year at 1 industrial site in Italy.

In response to a question by RAC and SEAC, the applicant informed that their use is currently covered by Authorisation REACH/20/5/5 – Use for surface treatment of metals (such as aluminium, steel, zinc, magnesium, titanium, alloys), composites and sealings of anodic films for the aerospace sector in surface treatment processes in which any of the key functionalities listed in the Annex is required[1].

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

The principal part of gas absorption appliances is a hermetically sealed circuit, constructed of carbon steel and filled with a mixture of water and ammonia. This mixture of liquid and gas is circulating through the circuit in such a way that in one part ammonia evaporates from the water solution and thus absorbs heat, and in the other part the gaseous ammonia is absorbed in water, thus releasing heat. Hence the name heat pump. The driving force of this process is heating of the evaporating liquid with a natural gas or other fuel. The heat released from the pump is greater than absorbed, therefore the efficiency of the fuel consumed is over 100 % (typically up to 170 %). In the reverse mode the technology can be used for cooling.

The mixture of ammonia and water is corrosive to most metals. Carbon steel is one of the most resistant metals, yet not completely inert. Without the addition of a corrosion inhibitor, it undergoes corrosion which produces solid (rust) and gaseous products. Both are harmful for the device, since solid particles can clog the valves and the exceeded pressure of gases can break the circuit. Cr(VI) compounds in the working solution are reduced to Cr(III), which forms a passivation layer on the surface of carbon steel, thus preventing it from further corrosion.

GA appliances are built for a long-lasting service (14-25 years) and should not suffer from sudden breakdowns of the circuit before the end of the service life is reached or at least is close to being reached. To achieve this, the addition of an inhibitor to the working liquid is essential. The only known efficient inhibitors in the time of application are Cr(VI) compounds, e.g. sodium dichromate.

The use covers three exposure scenarios (ES). The applicant describes ES 1 with one Environmental Contribution Scenario (ECS 1) and six Worker Contribution Scenarios (WCS) (see Table 1). ES 2 covering service life at consumers' site does not have any WCS and no release of Cr(VI) is expected due to full containment of refrigerant solution in the closed carbon steel circuit. It is however noted that in ES 3 covering service life (professional) maintenance and repair of GA appliances containing sodium dichromate, the only WCS is almost identical to the WCS 4 of ES 1. The activity (less than 0.01 tonnes of sodium dichromate used) is performed at the applicant's site (for small models sold to consumers and the malfunctioning GA appliance

[1] EUR-Lex - 52020XC0421(03) - EN - EUR-Lex (europa.eu)

is transported from the customers' site) or directly at the customers' sites where malfunctioning GA appliances are located (for big models sold to industrial/professional customer). This operation is only performed indoor and also uses the applicant's recovery solution device. It is performed by trained workers acting in line with the company's protocol when the GA appliance is malfunctioning at the consumer's site. Nevertheless, this maintenance and repair activity involves the emptying of the refrigerant solution that may still contain residual Cr(VI), and the refilling of a 'fresh' refrigerant solution that contains sodium dichromate. Therefore ES 3 should be included in the scope of the eventual authorisation (see Table 1).

WCS 1: Loading and mixing of sodium dichromate solution

Sodium dichromate is supplied to the manufacturing site in IBC tanks as an aqueous solution (17.5 % w/w). Sodium dichromate solution from the original IBC tank, located on a dedicated spill basin, is transferred through a flexible delivery tube to a closed fixed dedicated tank where the solution is further diluted with demineralized water to obtain the desired concentration of 1.75 % sodium dichromate, corresponding to 0.69 % Cr(VI). This operation is semi-automated, as the worker has to operate the system by starting and ending the dilution process from a panel. Twice a year, the worker also manually disconnects and connects again the delivery tube and valve when the original IBC tank need to be switched with a new one.

WCS 2: Filling the solutions into the circuits of the GA appliances

The aqueous solution of sodium dichromate at 1.75 % w/w and ammonia solution (both in closed dedicated tanks) are then loaded into the circuits of the GA appliances. This is performed in dedicated filling cells equipped with local exhaust ventilation and a dedicated dosing system. The dosing system consists of 2 dedicated hoses (one for ammonia and one for sodium dichromate solution), with a final valve to be manually connected/disconnected to the GA unit. All other operations are automated and controlled by the worker from outside the filling cells.

WCS 3: Testing of the gas absorption appliances

This task is performed in dedicated cells (testing cells), where forced ventilation and a dedicated test system to check pressure are present. The test system consists of 3 hoses with a final valve, to be manually connected/disconnected to the GA unit. All other operations are automated and controlled by the worker from outside the filling cells.

WCS 4: Maintenance and repair

GA units not passing quality control are repaired, applying the same protocol used by the professional assistance (see ES 3). The task is performed outdoor or indoor (in a cell with forced ventilation) and refrigerant solution (and gas) is transferred by a closed system into a 20L tank. At the end of this operation, the GA unit is empty and the malfunctioning piece can be removed and further analysed for quality purposes (see WCS 6). The remaining unit, if possible, is repaired and the circuit is tested to check it is hermetically sealed. If so, the hoses are connected again to the GA unit and the solution is transferred back to the sealed circuit by the use of the recovery solution device. If the GA unit cannot be repaired, the solution in the 20L tank is stored as waste and directed to external disposal.

WCS 5: Maintenance and cleaning of the equipment in contact with sodium dichromate

When necessary (few times a year), trained workers will perform maintenance and cleaning of the equipment. Potential exposure is limited not only by the short time of exposure but also by the use of proper PPE. Maintenance and cleaning are usually not performed routinely, but only when necessary.

WCS 6: Cleaning of malfunctioning GA appliances elements before analysis

A limited amount of GA units' parts is collected from malfunctioning units and further analysed for research purposes. These pieces come from units which have already been emptied by a recovery solution device (see WCS 4 or ES 3). Inside a dedicated cell they are (if necessary) manually cut and washed with water. All liquid and solid waste is collected in waste container and disposed by licenced external contractors.

A total of 1 to 100 workers (actual number is confidential) in the company which are involved in the use applied for of sodium dichromate. Each worker is involved in only one of these tasks.

Table 1: Contributing scenarios presented in the use

Contri-buting scenario	ERC/PROC	Name of the contributing scenario	Size of the exposed population
ECS 1	ERC 5	Use at industrial site – Use of sodium dichromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 1.05 % w/w (corresponding to 0.42 % w/w as Cr(VI)) in the refrigerant solution.	Regional: Considered as not relevant due to reduction of Cr(VI) released to the environment to non-hazardous Cr(III) Local: 1 100
WCS 1	PROC 3	Loading and mixing of the aqueous 17.5 % w/w sodium dichromate solution into a closed equipment with demineralised water	1-5 Number of workers considered as confidential by the applicant
WCS 2	PROC 8b	Filling of the solutions (sodium dichromate and ammonia solutions) in the circuits of the gas absorption appliances (PROC 8b)	1-5 Number of workers considered as confidential by the applicant
WCS 3	PROC 3	Testing of the GA appliances	1-5 Number of workers considered as confidential by the applicant
WCS 4	PROC 8b	Maintenance and repair: emptying of the refrigerant solution by recovery solution device from the sealed circuits in the gas absorption appliances not passing quality control	1-5 Number of workers considered as confidential by the applicant
WCS 5	PROC 28	Maintenance and cleaning of the equipment in contact with sodium dichromate	1-5 Number of workers considered as confidential by the applicant
WCS 6	PROC 20	Cleaning of malfunctioning GA appliances elements before analysis	1-5 Number of workers considered as confidential by the applicant
ECS 2	ERC10a - ERC 11a	Service life (consumers) – Use of GA appliances including Cr(VI) (sodium dichromate) up to 0.42 % w/w (as Cr(VI)) in the refrigerant solution, as an anticorrosion agent of the carbon steel circuit – indoor/outdoor	Regional: Considered as not relevant due to reduction of Cr(VI) released to the environment to non-hazardous Cr(III)

			Local: None, since there is no emission of Cr(VI) during service life at consumers' sites
ECS 3	ERC10a - ERC 11a	Service life (professional) – maintenance and repair of GA appliances including Cr(VI) (sodium dichromate) up to 0.42 % by weight (as Cr(VI)) in the refrigerant solution, as an anticorrosion agent of the carbon steel circuit – indoor/outdoor	Regional: Considered as not relevant due to reduction of Cr(VI) released to the environment to non-hazardous Cr(III) Local: None, since there is no emission of Cr(VI) is expected during service life at consumers' sites
WCS 1	PROC 8b AC 2	Maintenance and repair – emptying and refilling of the refrigerant solution from the sealed circuits in the malfunctioning gas absorption appliances by recovery solution device. Service life of the gas absorption appliances.	5-10 Number of workers considered as confidential by the applicant

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

The applicant stresses that sodium dichromate ($Na_2Cr_2O_7$), added to the water-ammonia solution in the circuit of the GA appliance, protects the inner surfaces while being able to also tolerate given operating conditions:

- Inhibition of corrosion of the sealed circuit,
- Prevention of gas formation,
- Effectiveness at high operating temperatures (up to 200 °C),
- Effectiveness at high operating pressures, and
- Long-lasting service (at least 14-25 years).

Sodium dichromate creates a film inside the circuit to prevent ammonia and water from corroding the metal. Uninhibited corrosion, followed by deposition of solids and gas formation, would cause the circuit to break with consequent liquid leakage and loss of the heating or cooling function of the GA appliance. Furthermore, sodium dichromate allows the GA appliance to operate at high temperatures and high pressures. These two technical factors represent the major limitations that, to date, the alternatives substances studied and tested are not able to overcome. The factor of the durability of the GA appliance is ultimately achieved by the protective function that sodium dichromate provides for the internal metal surfaces of the circuits. The applicant considers that a comparable service life of the appliance is strictly needed to ensure competitiveness on the market for GA appliances.

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

Gas absorption heat pumps (GAHP) and gas absorption chillers (GA chillers) are used for high-

efficiency heating, ventilation and air conditioning (HVAC) systems or hot water production in industrial buildings, public buildings, multifamily houses, etc (both in public and private settings).

1. Operational Conditions and Risk Management Measures

1.1. Workers

Table 2 summarises the OCs, technical RMMs and PPE with their effectiveness as described by the applicant. In addition, the following RMMs are implemented:

Technical RMMs:

- Sodium dichromate is provided in aqueous solution in tanks equipped with special valves to avoid any dispersion during use
- Semi-automated operations are implemented. Sodium dichromate solution, water and ammonia are automatically dosed and transferred in closed equipment
- LEV and forced ventilation (at least 3 ACH) in rooms where filling or testing of the equipment is performed
- Use of a closed system between the GA unit and the collecting device during all maintenance operations
- Use of RPE, protective gloves and clothing

Organisational RMMs:

- Access to all production and maintenance operations is restricted to a pool of authorised and trained staff
- Workers involved in the used of sodium dichromate are specially trained in the handling of hazardous substances, with particular reference to sodium dichromate
- Applicant is currently implementing UNE-EN ISO 45001 occupational health and safety managing system (certification planned for Q1 2022)

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

Contributing scenario	**Concentration of the sodium dichromate**	**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)
ES 1. Use at industrial site – Use of sodium dichromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 1.05 % w/w (corresponding to 0.42 % w/w as Cr(VI)) in the refrigerant solution.					
WCS 1. Loading and mixing of the aqueous solution	17.5 % w/w 1.75 % w/w	Connecting the IBC tank to the automated dosing equipment: ≤ 30 min ≤ 2 times per year, Operation of the semi-automated dilution system: ≤ 20 min ≤ 20 times/year	Semi-automated operation. Level of containment: good (very rare manual step needed: potential short exposure is only possible during change of the sodium dichromate container. Sodium dichromate solution and water are automatically dosed and transferred, in a closed equipment (the worker only activated the transfer by operating a panel)	RPE APF 4 (ABEK P1) with face shield, chemically resistant gloves (complying with the requirements of EN 420, EN 388 and EN 374-1/2), Standard safety clothing	Access is restricted to authorised and trained staff Indoor use General good occupational hygiene practices
WCS 2. Filling of the solutions (sodium dichromate and ammonia solutions) in the circuits of the gas absorption appliances	1.75 % w/w	≤ 60 min/day	Dedicated filling cells with integral LEV. Level of containment: high (limited interventions needed. The filling system is highly automated essentially and closed. Potential short exposure is only possible during connection/disconnection of the flexible hoses bringing solutions to the units)	Chemically resistant gloves (complying with the requirements of EN 420, EN 388 and EN 374-1/2) and standard safety clothing.	Access is restricted to authorised and trained staff Indoor use General good occupational hygiene practices
WCS 3. Testing of the gas absorption appliances	1.05 % w/w	Up to 480 min (worst-case)	Dedicated testing cells with forced ventilation (at least 3 ACH). Level of containment: high (limited interventions needed.	Chemically resistant gloves (complying with the requirements of EN 420, EN 388 and EN 374-1/2) and standard safety clothing.	Access is restricted to authorised and trained staff Indoor use

			The testing system is highly automated and essentially closed. Potential short exposure is only possible during connection/disconnection of the flexible hoses, but these do not transfer chromium).		General good occupational Hygiene practices
WCS 4. Maintenance and repair: emptying of the refrigerant solution by recovery solution device from the sealed circuits in the gas absorption appliances not passing quality control	1.05 % w/w	< 60 min/day repeated very limited times a year	Use of a closed system between the GA unit and the collecting device, in order to avoid exposure to Cr(VI). The operator only connects/disconnects the flexible hoses transferring solutions and gas and cuts/removes a damaged piece of the GA appliance.	RPE APF 4 (ABEK P1) with face shield, chemically resistant gloves (complying with the requirements of EN 420, EN 388 and EN 374-1/2), Standard safety clothing	Access is restricted to authorised and trained staff Indoor/outdoor use General good occupational Hygiene practices
WCS 5. Maintenance and cleaning of the equipment in contact with sodium dichromate	1.05 % w/w	240 min/day max. 5 days/year	No containment. LEV or force ventilation are active during cleaning procedures	RPE APF 4 (ABEK P1) with face shield, chemically resistant gloves (complying with the requirements of EN 420, EN 388 and EN 374-1/2), Standard safety clothing	Access is restricted to authorised and trained staff Indoor use General good occupational Hygiene practices
WCS 6. Cleaning of malfunctioning GA appliances elements before analysis	0.11-1.05 % w/w Most of Cr(VI) should be transformed in Cr(III)	≤ 30 min/day ≤ 30 days/year	Dedicated cells with forced ventilation (at least 3 ACH) Level of containment: Open process. intermittent contact. No direct handling	RPE APF 4 (ABEK P1) with face shield, chemically resistant gloves (complying with the requirements of EN 420, EN 388 and EN 374-1/2), Standard safety clothing	Access is restricted to authorised and trained staff Indoor use General good occupational Hygiene practices
ES 2. Service life (consumers) at the sites of the users of GA appliances – Use of GA appliances including Cr(VI) (sodium dichromate) up to 0.42 % w/w (as Cr(VI)) in the refrigerant solution, as an anticorrosion agent of the carbon steel circuit					

There is no exposure of the consumers to the substance, as the closure of a sealed circuit is tested during production and homologation by several tests. The refrigerant solution in the cooling unit is under pressure, therefore all cooling liquid would be suddenly released all at once, producing a loud noise and an unpleasant ammonia smell. Consumers would naturally run away from the source and ventilate the room before re-entering, especially to remove the strong and unpleasant ammonia smell. Nevertheless, a sudden rupture of the circuit would be only of accidental nature.
Also, the system has a safety feature that activates in case the pressure inside the system is too high and thus further lowering the chance of Cr(VI) release by the cooling system.
In addition, most of the Cr(VI) contained in the cooling liquid is transformed to Cr(III) during the first year of operation. Cr(VI) is used in order to oxidise iron to iron(III) oxide (Fe_2O_3), which forms a layer on the surface of the tubing of the system. Chromate is reduced to chromium oxide (Cr_2O_3), which will spontaneously form a passive layer on top of iron(III) oxide. The chromium oxide layer protects the steel underneath from corrosion.
Therefore, although there is not much Cr(VI) remaining, Cr(VI) has been essential at the beginning to form a protective layer in situ.
A consumer would never be exposed to the full Cr(VI) concentration originally included in the cooling unit. Therefore, the applicant considers exposure of consumers by any route as not relevant.
In relation to the end of life fate of GA appliance, in their response to RAC's question, the applicant has clarified that the user manual provided with each GA appliance sold explains that the GA appliance and its related accessories cannot be disposed as household waste but must be disposed of in accordance with the regulation in force for Waste Electrical and Electronic Equipment. The user manual also informs about the possibility to contact the manufacturer (Robur S.p.A) in order to dispose of the appliance, who collects the appliance free of charge by sending it to authorised disposal companies (the appliance is treated as a waste electrical and electronic equipment-WEEE).

ES 3. Service life (professional) at the sites of the users of GA appliances – maintenance and repair of GA appliances including Cr(VI) (sodium dichromate) up to 0.42 % by weight (as Cr(VI)) in the refrigerant solution, as an anticorrosion agent of the carbon steel circuit – indoor/outdoor					
WCS 1. Maintenance and repair: emptying and refilling of the refrigerant solution from the sealed circuits in the malfunctioning gas absorption appliances by recovery solution device. Service life of the gas absorption appliances PROC: 8b	0.11-1.05 % w/w Most of Cr(VI) should be transformed in Cr(III) during the first year of operation.	≤ 60 min/day ≤ 40 days/year	Use of a dedicated semi-automated equipment which creates a closed system between the GA appliance and the collecting device, in order to avoid exposure to Cr(VI). The operator only connects/disconnects the flexible hoses transferring solutions and gas and cuts/removes a damaged piece of the GA appliance.	RPE APF 4 (ABEK P1) with face shield, chemically resistant gloves (complying with the requirements of EN 420, EN 388 and EN 374-1/2), Standard safety clothing	Access is restricted to authorised and trained staff Indoor use General good occupational Hygiene practices

1.2. Consumers

Sodium dichromate is part of the cooling solution in the closed circuits of gas absorption heat pumps and gas absorption chillers.

The cooling unit is factory-sealed, tested during production and homologation and cannot be opened anymore under normal usage conditions.

The only potential exposure would be if the cooling unit starts leaking. As the refrigerant solution in the cooling unit is under pressure, all the cooling liquid would be suddenly release at once, producing a loud noise and an unpleasant ammonia smell. Consumers would naturally run away from the source and ventilate the room before re-entering, especially to remove the strong and unpleasant ammonia smell. Nevertheless, a sudden rupture of the circuit would be only of accidental nature.

In addition, most of the Cr(VI) contained in the cooling liquid is transformed to Cr(III) during the first year of operation. Cr(VI) is used in order to oxidise iron to iron(III) oxide (Fe_2O_3), which forms a layer on the surface of the tubing of the system. Chromate is reduced to chromium oxide (Cr_2O_3), which will spontaneously form a passive layer on top of iron(III) oxide. The chromium oxide layer protects the steel underneath from corrosion.
Therefore, although there is not much Cr(VI) remaining after several years, Cr(VI) has been essential at the beginning to form a protective layer in situ.

A consumer would never be exposed to the full Cr(VI) concentration originally included in the cooling unit.

Therefore, the applicant considers exposure of consumers by any route as not relevant.

1.3. Environment/Humans via the environment

The following risk management measures are implemented to avoid release of Cr(IV) into the environment:

- Sodium dichromate is supplied and used only as aqueous solution in the closed systems and transferred from tanks to tanks by electric pumps controlled from distant panels automatically or to closed circuits through detachable hoses. Only connections of the hoses to valves of tanks or circuits are done manually. The contaminated sodium dichromate tanks are returned to the supplier.
- The loading area is equipped with a dedicated spill basin to prevent any possible spill going into the drainage system of the facility and entering wastewater/STP system.
- All contaminated material (containers, paper, contaminated parts et cetera) is either re-used for the same process or collected and stored in a dedicated area for external disposal by licensed waste management companies.
- All liquid and solid waste is collected, stored in dedicated container/facilities and disposed by licensed waste management companies. Cr(VI) is neither directly nor indirectly released to soil.

Air

No release of Cr(VI) to air is expected since sodium dichromate is supplied as aqueous solution

(low vapour pressure) and the dosing takes place in a semi-automated system. The results of environmental monitoring presented in this AfA supports that no release of Cr(VI) to air occurs (lower than LOQ).

Water

No release of Cr(VI) to wastewater is expected as sodium dichromate is used in the closed systems and any liquid wastes are collected and disposed by licenced waste management companies.

Soil

No release of Cr(VI) to soil is expected as sodium dichromate is used in the closed systems and any liquid and solid wastes are collected and disposed by licenced waste management companies.

Table 3: Environmental RMMs – summary

Compartment	RMM	Stated effectiveness
Air	Supply of sodium dichromate in aqueous solution. Automated closed dosing system.	The effectiveness is considered to be close to 100 %.
Water	Sodium dichromate in aqueous solution is used in the closed systems and any liquid wastes are collected and disposed by the licenced waste management companies	The effectiveness is considered to be close to 100 %.
Soil	All liquid and solid waste is collected, stored in dedicated container/facilities and disposed by licensed waste management companies.	The effectiveness is considered to be close to 100 %.

1.4. RAC's evaluation on the OCs and RMMs

The applicant claims that the OCs and RMMs described in the CSR are implemented in the context of the hierarchy of control principles with regard to the use of sodium dichromate. During all exposure scenarios the aqueous solutions of sodium dichromate (1.05-17.5 %) are used in the closed systems with semi-automated transfer operations between IBC tank to the automated dosing equipment, and further to the circuits of the gas absorption appliances.

During maintenance and repair of gas absorption appliances the specially designed recovery solution device ensures a closed system between the GA unit and the collecting device in order to avoid exposure to Cr(VI). All solid and liquid waste are collected for later disposal of special waste by specialized company. The effectiveness of OCs and RMMs in relation to minimisation of releases to air, water and soil is considered to be close to 100 %. The contaminated sodium dichromate tanks are returned to the supplier.

RAC does not identify any relevant shortcomings with regard to the OCs and RMMs in place, neither for workers nor for the indirect exposure to humans via the environment.

1.5. RAC's conclusions on the OCs and RMMs

RAC is of the opinion that the OCs and RMMs implemented in relation to the exposure of workers and humans via the environment to Cr(VI) are appropriate and effective in limiting the risk.

Overall conclusion

Are the operational conditions and risk management measures appropriate[2] and effective[3] in limiting the risks?

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

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

2. Exposure assessment

The exposure assessment is relevant for workers and humans via the environment.

2.1. Inhalation exposure

The assessment on inhalation exposure of workers in ES 1 and ES 3 is based on results of the static and personal air measurements and/or modelling of exposure with the Advanced Reach Tool (ART) version 1.5, which were underpinned by biomonitoring data (see section 2.3.).

During ES 2, a service life (consumers) at the sites of the users of GA appliances sodium dichromate is used as inhibitor of corrosion in the aqueous ammonia mixture acting as refrigerant and its release to the working or local environment is not possible, therefore no exposure is expected during ES 2.

Monitoring

The exposure of workers was measured in ES 1 by personal sampling of air in the breathing

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

zone and by monitoring of Cr(VI) concentration in the working environment and performed by an external company. Eight static measurements and five personal measurements were done for all worker contributing scenarios, except for WCS 5: i.e. maintenance and cleaning of the equipment in contact with sodium dichromate. The assessment of worker exposure in WCS 5 was done using ART 1.5 modelling. Samplings were performed in December 2020 during the normal activities; thus, they are representative of the current situation. Description of the tasks or activity during which a sampling was performed has been provided. The sampling duration in all cases was 16 hours, that is during two consecutive 8-hour shifts in order to comply with European Standard UNI EN 689 requiring to estimate the exposure at least at 10 % of the limit value (the same activities were carried out to make the sampling representative). The analytical method used to perform sampling and analysis was NIOSH 7600:2015. The LoQ of the analytical method was established at 0.02 µg/m^3. All the measurements (see Table 4) resulted in concentration values < 0.02 µg/m^3.
No measurement of exposure were done in ES 2 where Cr(VI) is used only in the closed system and in ES 3/WCS 1 which is done only at the sites of users of GA appliances.

Modelling

The Advanced Reach Tool (ART) Version 1.5 was used to perform the inhalation exposure assessment for Cr(VI). According to the applicant PPE is worn for all tasks included in the Exposure Scenarios. The input data (e.g. duration of activity during a day, frequency of activity during a year, concentration of substance in the aqueous solution, Assigned Protection Factor for RPE, air exchange rate) seem reliable. In the exposure scenarios, as recommended in the ECHA guidance R.14 (ECHA 2016), full-shift exposure and the 90th percentile (that provides the exposure level, which has a 10 % probability of being exceeded by the exposure from a randomly selected worker on a randomly selected day) was used. Exposure was calculated with input related to sodium dichromate solution (physico-chemical parameters, physical state and viscosity and concentration) and then re-calculated to Cr(VI) using the Cr content of sodium dichromate (39.7 %). The results of inhalation exposure estimation of worker with ART 1.5 in each WCS is provided in Table 4.

2.2. Dermal exposure

Modelling

Dermal exposure assessment for sodium dichromate was done by using MEASE (version 2.0), which was then recalculated to Cr(VI). The applicant considers that modelling results are based on conservative approaches and calculations and they should be seen as representative worst case. The results of dermal exposure estimation of worker with MEASE v.2.0 in each WCS is provided in Table 4.

Monitoring

Measured data on dermal exposure were not presented in the CSR. Wipe samples or any other monitoring data based on a similar approach are not available.

2.3. Biomonitoring

The results of measurement of total chromium in urine were provided for one professional

worker working in each of the following contributing scenarios: WCS 1, WCS 2, WCS 3, WCS 4 and WCS 6, in total for 5 workers exposed to sodium dichromate. In addition, concentration of chromium was also measured in 6 non-exposed workers. The samples of urine from each exposed and non-exposed worker were taken at the beginning of shift and at the end of shift. The sampling of urine was repeated 3 times for each worker. The exact data on total chromium level in urine of exposed and non-exposed workers are considered confidential by the applicant but known to RAC. There was not significant increase in level of chromium in urine in exposed workers at the end of shift. The level of chromium in exposed workers and not exposed workers was very similar, all being below 1 µg/L. There results of these measurements indicate that occupational exposure of workers to sodium dichromate is very low, what is confirmed by monitoring of inhalation exposure and estimation of inhalation exposure by ART 1.5 and estimation of dermal exposure by MEASE 2.0. RAC notes that measurements of total chromium in the urine may not be sensitive enough at very low exposure levels because of the background urine chromium levels in the general population. Urine chromium 90th to 95th percentile levels in the general population are usually at the level of 0.5 to 1 µg/L. The German reference background value of total chromium in urine for the general public is 0.6 µg /L[4].

Table 4: Summary of exposure information – dermal and inhalation

Contributing scenario	Route of exposure	Method of assessment	Exposure value (8h TWA)	Exposure value corrected for PPE	Exposure value corrected for PPE and frequency
WCS 1 / PROC 3 Loading into a closed equipment and mixing	Inhalation	Measurement	< 0.02	< 0.005	$< 3.8 \times 10^{-4}$
	Inhalation	ART 1.5	4.4 × 10-2	1.1×10^{-2}	8.5×10^{-4}
	Dermal	MEASE	0.71	0.71	5.5×10^{-2}
	Biomonitoring	Measurements End of the shift	-	-	0.65-0.78
WCS 2 / PROC 8b Filling the circuits of the GA unit	Inhalation	Measurements	< 0.02	< 0.005	$< 3.8 \times 10^{-4}$
	Inhalation	ART 1.5	5.96×10^{-7}	5.96×10^{-7}	5.73×10^{-7}
	Dermal	MEASE	0.48	0.48	0.46
	Biomonitoring	Measurements End of the shift	-	-	0.47-0.79
WCS 3 / PROC 3 Testing of the gas absorption	Inhalation	Measurements	< 0.02	< 0.005	$< 3.8 \times 10^{-4}$
	Inhalation	ART 1.5	2.82×10^{-5}	2.82×10^{-5}	2.71×10^{-5}
	Dermal	MEASE	1.37	1.37	1.32
	Biomonitoring	Measurements	-	-	0.32-0.53
WCS 4 / PROC 8b Maintenance and repair of sealed circuits in GA unit	Inhalation	Measurements	< 0.02	< 0.005	$< 3.8 \times 10^{-4}$
	Inhalation	ART 1.5	3.97×10^{-3}	9.93×10^{-4}	9.53×10^{-5}
	Dermal	MEASE	4.76	4.76	0.46
	Biomonitoring	Measurement End of the shift	-	-	0.29-0.7
WCS 5 / PROC 28 Maintenance and cleaning of equipment in	Inhalation	Measurements	-	-	-
	Inhalation	ART 1.5	7.54	1.89	0.068
	Dermal	MEASE	32.44	32.44	0.62
	Biomonitoring	Measurement	-	-	-

[4] Reference value established by the German MAK commission as "Biologischer Arbeitsstoff-Referenzwert" (BAR).

contact with sodium dichromate		End of the shift			
WCS 6 / PROC 20 Cleaning of malfunctioning GA unit elements	Inhalation	Measurements	< 0.02	< 0.005	$< 3.8 \times 10^{-4}$
	Inhalation	ART 1.5	1.67×10^{-2}	4.17×10^{-3}	4.8×10^{-4}
	Dermal	MEASE	2.7×10^{-3}	2.7×10^{-3}	3.1×10^{-4}
	Biomonitoring	Measurement End of the shift	-	-	0.35-0.58
Combined exposure in ES 1 assuming in the worst case that worker is working in all WCSs	Inhalation	Measurements	< 0.02	< 0.005	$< 3.8 \times 10^{-4}$
	Inhalation	ART 1.5			6.9×10^{-2}
	Dermal	MEASE			2.91
ES 3 WCS 1 / PROC 8b Maintenance and repair of sealed circuits in GA appliances	Inhalation	Measurements	as in WCS 4		
	Inhalation	ART 1.5	3.18×10^{-6}	7.94×10^{-7}	1.22×10^{-7}
	Dermal	MEASE	5	5	0.77
	Biomonitoring	Measurements	as in WCS 4		

Inhalation: µg Cr(VI)/m^3
Dermal: µg/kg bw/d
HBM: µg Cr/L in urine

2.4. Environmental releases

The applicant noted that Cr(VI) released to the environment is expected to be reduced to non-hazardous Cr(III) in most situations in the environment as highlighted in the European Union Risk Assessment Report (2005), so the impact of Cr(VI) as such is likely to be limited to the area around the source. For this reason, the assessment of the impact of chromium release to the environment on human health is conducted by the applicant only for the local scale in ES 1 (i.e. the area around the production site) and no regional background is considered in this CSR, as also proposed in the RAR. No environmental release in ES 2 for Service life (consumers) is expected in virtue of the sealed closed system, and the fact that Cr(VI) reacts by forming a passive chromium (III) oxide layer in the circuit. Therefore, no exposure of the environment or of men via environment following consumer use is foreseen. No environmental releases are also expected during ES 3, in virtue of the sealed closed system, the closed transfer system and the fact that Cr(VI) reacts by forming a passive chromium (III) oxide layer in the circuit. RAC agrees with this approach.

Air

Sodium dichromate is a substance of negligible volatility and the process does not generate any mists or aerosol. Substance is handled mainly in closed cells, where forced ventilation or LEV is present. In other dedicated points where the substance is handled (mixing and loading of initial solution, storage site, waste storage) all containers are tightly closed and, where necessary, connected by a closed system to other tanks. Negligible release to the air is foreseen.

Based on the process descriptions and the handling in the closed cell, the release factor to air was defined according to the TGD Part II, Appendix I (Table A3.16). For Corrosion inhibitors the TGD, by default, allocates a release factor to air of 1×10^{-5} (EUSES Industry Category (IC)

= 15/0, others EUSES Use Category (UC) = 14, corrosion inhibitors EUSES Main Category (MC) industrial use = III, non-dispersive use).

Cr(VI) emitted in the air coming out from the stack of the production facility was measured in December 2020 taking three samples during filling the GA appliances circuit with the Cr(VI) solution in the dedicated cab (WCS 2) and three samples during Cleaning of malfunctioning parts in the dedicated cab (WCS 6) . The sampling was done in triplicate as required by current legislation. In all samples the concentration of Cr(VI) measured with method NIOSH 7600:2015 was below a detection limit of 2-3 µg/m^3. Relatively high detection limit of Cr(VI) in air released through stacks is due to low volume and short time of samples taking. In case of workplace air concentration the LoQ was < 0.02 µg Cr(VI)/m^3.

Water

Substance is handled in closed cells (filling and testing cells) or in dedicated points (mixing and loading of initial solution, storage site, waste storage) where a collection system for spills is present. Waste from spillage or abatement system (such as bubblers,) will be conveyed by a closed system to an appropriate storage tank for later disposal of special waste by specialized company (licenced contractor).

Soil

There is no direct emission of Cr(VI) to soil.

Table 5: Summary of releases to the environment

Release route	**Release factor**	**Release per year** kilograms	**Release estimation method and details**
Air	Initial release factor (ERC based): 50 % Final release factor (TGD Part II, Appendix I): 1×10^{-5} (0.001 %) Local release rate: < 0.001 kg/day	< 0.01	Default release factor for corrosion inhibitors according (TGD Part II, Appendix I): 1×10^{-5} Assessment of occupational conditions and risk management method.
Water	Initial release factor (ERC based): 50 % Initial refined release factor (TGD Part II, Appendix I): 5 % Final release factor: 0 % Local release rate: 0 kg/day	0	No release to the wastewater system or STP is possible or foreseen. Therefore, the total wastewater emission of Cr(VI) was estimated as 0 kg/year
Soil	Initial release factor (ERC based): 1 % Final release factor: 0 % Local release rate: 0 kg/day	0	No direct emission to soil

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

Parameter	Local	Regional
PEC in air (µg Cr(VI)/m^3)	1.06×10^{-6}	-
Daily dose via oral route (µg Cr(VI)/kg bw/d) via drinking water and fish consumption	1.77×10^{-7}	-

2.5. RAC's evaluation of the exposure assessment

Workers' exposure

The applicant has provided the results of 8 static and 5 personal measurements of inhalation exposure of workers for all, but one, working contribution scenarios in ES 1 and ES 3 using a relevant method (NIOSH 7600:2015). There is no worker exposure in ES 2. The inhalation exposure was not measured only during WCS 5 i.e. Maintenance and cleaning of the equipment in contact with sodium dichromate, but it is noted that this task is done only for 4 hour/day in 5 days a year. In all WCSs the inhalation exposure was below 0.02 µg/m^3, which was a LoQ of the method applied. The estimation of exposure using the Advanced Reach Tool (ART) Version 1.5 using appropriate input parameters for modelling has confirmed a low level of exposure in all WCSs. The evaluation of workers exposure is considered as representative in relation to tasks performed, since the contextual data on tasks performed during measurements were provided. However, it is noted that all the inhalation exposure measurements were done only once in December 2020, what introduce a shortcoming since they are not confirmed by earlier annual monitoring programme. RAC notes that results of the biomonitoring confirm a low level of inhalation and dermal exposure of workers since no increase of Cr(VI) in urine at the end of shift was noted in comparison with that before the shift and with that in urine of unexposed workers or that in general population.

Dermal exposure in all WCSs was not measured but estimated using MEASE (version 2.0).

RAC notes that inhalation and dermal exposure of workers is highly controlled by using engineering controls such a closed tanks and circuits, automated transfer of solutions requiring only manual connection of a hose with valves of tank or circuit. Lack of measurements during WCS 5 is considered by RAC as minor shortcoming, noting short duration and PPE applied during this task.

Humans via the environment

The applicant has provided the results of 6 measurements of Cr(VI) stack emission to environmental air for ES 1. As explained in point 2.4 above no environmental exposure is estimated to occur in ES 2 and ES 3. Sampling of the emissions was performed only for WCS 2 and WCS 6 located in rooms where the air is released to the outside of the building by the stacks/chimneys equipped with a sampling line as required by the environmental authorisation issued to the Company. During the other WCSs the tasks are performed in closed cabin with air extraction (WCS 3), in areas with natural ventilation (WCS 1), outdoor (WCS 4) while WCS 5 can be performed in all areas where other WCSs are performed. The emissions from these other WCSs to the outside of the building may be estimated as very low based on the results of measurements of Cr(VI) in the air of their working environment in the near-field from the source of emissions. All these measurements demonstrated that the concentration of Cr(VI) in

air was below LOQ being 0.02 µg/m^3.

RAC notes that use of sodium dichromate in closed tanks or circuits as aqueous solution at concentration of 17.5 % in WCS 1 and at concentration 1.05 % in all other WCSs, is not expected to generate any mists or aerosol containing Cr(VI), therefore low emissions of Cr(VI) to environmental air is predictable and acceptable.

Taking into account a high level of containment of all production processes and a collection of all liquid and solid wastes for later disposal by specialized company (licenced contractor) RAC is of the opinion that absence of emission of Cr(VI) to water and soil is acceptable.

2.6. RAC's conclusions on the exposure assessment

RAC considers that for both worker exposure and human exposure via the environment:

- description of use allows to draw conclusions related to exposure situations.
- methodology used and the information provided, related to exposure resulting from the use applied for, is considered to be sufficient for risk characterisation.
- concerning workers´ exposure via inhalation, there are minor shortcomings related to lack of measurements for one worker contribution scenario and performing all measurements only once.
- releases of Cr(VI) with stack air to the environment were measured only at one point of time by method with relatively high level of quantification most probably due to short duration of sampling

Overall, the shortcomings identified are considered to be minor and do not invalidate the applicant´s exposure assessment.

3. Risk characterisation

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

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

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

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

3.1. Workers

The excess lifetime lung cancer mortality risk is 4×10^{-3} per µg Cr(VI)/m^3 according to the RAC reference dose response relationship, based on a 40 year working life (8 hours/day,

5 days/week). Since workers do not eat or drink while performing tasks during all working contribution scenarios, it is reasonably assumed that there is no any oral exposure of workers to Cr(VI) during working hours.

The exposure assessment for the inhalation route is based on measured data (all measurements were below LoQ of 0.02 µg Cr(VI)/m^3) and on modelling using the Advanced Reach Tool (ART) Version 1.5 Cr(VI)/m^3), whereas the assessment for the dermal route is based on modelling, using MEASE v.2.0.

The applicant pointed out that modelling results are based on conservative approaches and calculations and they should be seen as representative worst case.

The applicant calculated the excess cancer risk (inhalation route) and the risk characterisation ratio for reproductive toxicity (dermal route) for individual exposure for workers directly exposed to Cr(VI) based on the tasks performed by the operators throughout a working day.

As informed by the applicant each worker performs tasks only within one Worker Contributing Scenario, therefore the exposure to Cr(VI) is not increased by work at other WCSs. However, assuming that in the very worst case that worker could be working in all WCSs RAC has calculated the combined exposure and combined risk in ES 1 in the table below. It is not relevant for ES 2 for which exposure is estimated to be 0 and for ES 3 in which there is only one WCS.

Table 7: Individual exposure and risk characterisation

Contributing scenario	**Route**	**Exposure value corrected for PPE and frequency**	**Excess risk or RCR ***		
			Excess lung cancer risk	**RCR for reproductive toxicity**	**Combined RCR for reproductive toxicity**
WCS 1	Inhalation Measurement	< 3.8×10^{-4} µg Cr(VI)/m^3	< 1.5×10^{-6}	< 0.001	0.001
	Inhalation ART 1.5	8.5×10^{-4} µg Cr(VI)/m^3	3.4×10^{-6}	< 0.001	
	Dermal	5.5×10^{-2} µg/kg bw/d	-	0.001	
WCS 2	Inhalation Measurement	< 3.8×10^{-4} µg Cr(VI)/m^3	< 1.5×10^{-6}	< 0.001	0.01
	Inhalation ART 1.5	5.73×10^{-7} µg Cr(VI)/m^3	2.3×10^{-9}	< 0.001	
	Dermal	0.46 µg/kg bw/d	-	0.01	
WCS 3	Inhalation Measurement	< 3.8×10^{-4} µg Cr(VI)/m^3	< 1.5×10^{-6}	< 0.001	0.03
	Inhalation ART 1.5	2.71×10^{-5} µg Cr(VI)/m^3	1.08×10^{-7}	< 0.001	
	Dermal	1.32 µg/kg bw/d	-	0.03	
WCS 4	Inhalation Measurement	< 3.8×10^{-4} µg Cr(VI)/m^3	< 1.5×10^{-6}	< 0.001	0.01
	Inhalation ART 1.5	9.53×10^{-5} µg Cr(VI)/m^3	3.81×10^{-7}	< 0.001	
	Dermal	0.46 µg/kg bw/d	-	0.01	
WCS 5	Inhalation Measurement	-	-	-	0.014
	Inhalation	0.068 µg Cr(VI)/m^3	1.44×10^{-4}	< 0.001	

	ART 1.5				
	Dermal	0.62 µg/kg bw/d	-	0.014	
WCS 6	Inhalation Measurement	< 3.8×10^{-4} µg Cr(VI)/m^3	< 1.5×10^{-6}	< 0.001	< 0.001
	Inhalation ART 1.5	4.8×10^{-4} µg Cr(VI)/m^3	1.92×10^{-6}	< 0.001	
	Dermal	3.1×10^{-4} µg/kg bw/d	-	< 0.001	
Combined exposure in ES 1 assuming in the worst case that worker is working in all WCSs	Inhalation Measurement	< 3.8×10^{-4} µg Cr(VI)/m^3	< 1.5×10^{-6}	< 0.001	0.067
	Inhalation ART 1.5	6.9×10^{-2} µg Cr(VI) /m^3	2.76×10^{-4}	< 0.001	
	Dermal	2.91 µg/kg bw/d	-	0.067	
ES 3 WCS 1	Inhalation Measurement	-	-	-	< 0.018
	Inhalation ART 1.5	1.22×10^{-7} µg Cr(VI)/m^3	4.88×10^{-10}	< 0.001	
	Dermal	0.77 µg/kg bw/d	-	< 0.018	

* Estimated individual risk resulting from exposure

It is noted that based on the measured inhalation exposure, the excess lung cancer risk is below 1.5×10^{-6} in all WCSs except WCS 5 for which no measured exposure data are available. The tasks performed within WCS 5 are maintenance and cleaning of the equipment in contact with sodium dichromate and they are not performed routinely, but only when necessary (a few times a year), for maximum 240 minutes per shift by workers protected by use of proper PPE. It is also noted that the excess lung cancer risk calculated based on the inhalation exposure derived with ART 1.5 model was for WCS 2, WCS 3 and WCS 4 considerably lower, and for WCS 1 and WCS 6 at approximately the same level as the excess lung cancer risk calculated based on measured exposure data for these worker contributing scenarios, which strengthens the reliability of the inhalation exposure and the excess lung cancer risk assessment. RAC has calculated the combined exposure and the combined excess lung cancer risk in ES1 assuming in the worst case that the same worker is working in all WCSs. However, these values are mostly driven by relatively higher inhalation exposure in WCS 5 calculated with ART 1.5 model and measured exposure data for WCS 5 are not available, while the inhalation exposure in all other worker contributing scenarios is much lower than that in WCS 5. Taking these considerations into account in the opinion of RAC for the assessment of health impact and socio-economic analysis the excess lung cancer risk calculated for individual worker contributing scenarios should be used, particularly considering that the applicant has declared in the application for authorisation (CSR) that although several workers are involved in the use applied for of sodium dichromate each worker is involved in only one of the described tasks.

With regard to the potential intestinal cancer risk, following the approach in RAC/27/2013/06 Rev.1, "in cases where the applicant only provides data for the exposure to the inhalable particulate fraction, as a default, it will be assumed that all particles were in the respirable size range". Therefore, real measured exposure data and modelled exposure are used as exposure value for the inhalation route considering 100 % of the particles in the respirable fraction. This is a worst-case approach, since the potential lung cancer risk is an order of magnitude higher compared to the potential intestinal cancer risk, based on the dose-response relationship agreed by the Committee of Risk Assessment. The oral exposure of workers to Cr(VI) was not measured or estimated based on assumption that all inhalable particles were ingested but it is considered that oral exposure of workers is negligible due to risk management measures

implemented in all workplaces, including training of workers.

3.2. Humans via the environment

Based on the dose-response relationship derived by the RAC, considering a 70-year exposure time (24h/day, 7d/week), the following excess lifetime risk for the general population is derived based on the estimated exposure – 3.1×10^{-8} for lung cancer and 1.42×10^{-10} for intestinal cancer.

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

Parameter	**Local**		
	Exposed population: 1 100		
	Exposure	**Excess lifetime lung or small intestine cancer risk***	**RCR for reproductive toxicity**
Humans via the environment – Inhalation	1.06×10^{-6} µg Cr(VI)/m³	3.1×10^{-8}	< 0.001
Humans via the environment – Oral	1.77×10^{-7} µg Cr(VI) /kg/d	1.42×10^{-10}	< 0.001

* Estimated individual risk resulting from exposure.

As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range (i.e. below an exposure concentration of 1 µg Cr(VI)/m³) might be an overestimate.

Based on the available DNEL, RCR for inhalation and oral exposure are < 0.001.

As already explained in section 2.4, the exposure for man via the environment at the regional level were not estimated by the applicant and therefore the corresponding excess cancer risks at the regional level are no available.

Excess life time risk of cancer for combined routes (inhalation and oral) is not applicable since both lung cancer and intestinal cancer caused by Cr(VI) are local, (site-of-contact) tumours; therefore, this cancer risk actually represents an aggregated risk for different types of tumours instead of a risk arising from a systemic dose due to combined exposure.

It should be considered that, based on the properties of chromium described in the EU RAR (2005), it is very likely that these values are overestimations of the actual risk deriving from the exposure, as Cr(VI) is expected to rapidly reduce to Cr(III) at environmentally relevant conditions. Monitoring data support the evidence that releases to air, and therefore related exposure, are negligible (below LOQ).

3.3. RAC's evaluation of the risk characterisation

The exposure levels of workers and humans via the environment reported in the application for authorisation are below the DNELs for reproductive toxicity for the relevant exposure route, therefore the risk of reproductive effects is considered to be adequately controlled. Such

exposures still may cause an excess risk of lung cancer.

The risk characterisation as presented in the CSR might overestimate the lung cancer risk due inhalation exposure of workers and humans via the environment since a dose-response relationships were derived by linear extrapolation while the mechanistic evidence is suggestive of non-linearity RAC/27/2013/06 Rev.1.). The inhalation exposure measurements and estimation of exposure using an ART 1.5 model both indicate that exposure of workers to Cr(VI) is well below 1 µg Cr(VI)/m^3, therefore it is acknowledged that the excess risks in the low exposure range might be an overestimate.

It is also considered, taking into account OCs and RMMs implemented in all WCSs, that the risk of intestinal cancer due to ingestion of inhalable particles containing Cr(VI) is much lower than the risk of lung cancer due to this inhalation exposure. In addition, the calculation of intestinal cancer risk assuming ingestion of all inhalable particles would be double counting. Lung cancer in workers due to inhalation exposure of hexavalent chromium is considered to be the critical effect for risk assessment.

3.4. RAC's conclusions on the risk characterisation

RAC considers that the estimates of excess cancer risk for workers and for indirect exposure of humans via the environment as calculated by the applicant and complemented by RAC allow a health impact assessment.

4. Analysis of alternatives and substitution plan

The applicant, Robur S.p.A, is a downstream user of sodium dichromate using the substance as a corrosion inhibitor in the carbon steel circuit of gas absorption appliances. Potential alternatives and required steps in the substitution of sodium dichromate are assessed from the perspective of the applicant, but also by taking into consideration the functionality of the end product for the applicant's customers.

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

The applicant has conducted periodical studies of alternatives to sodium dichromate in the use as an inhibitor and aims to continue and intensify these activities in the future.

In the past, the approach to the analysis of alternatives included the following activities:

- Research in databases of the Development Ministry,
- Meetings with trade associations,
- The study of applications for authorisation submitted by companies that use chromate substances with the same function (e.g. Ariston, 2019; Dometic, 2015), and
- Own research and testing conducted by the company-internal R&D division in cooperation with the production division (hereafter referred to as operational campaigns).

During the last 15 years, 3 operational campaigns took place, each lasting approximately one year. In total, these campaigns studied 9 mixtures as anti-corrosion agents, the compositions

of which are known to SEAC but are kept confidential by the applicant. Some details of the test results are likewise claimed confidential, but available to SEAC. The applicant notes that not all the documentation of results from the first two of 3 operational campaigns was found in the applicant's archives. It assumed that missing technical reports were destroyed after 15 years of storage. However, the applicant states that general test results were retained and are able to indicate the overall outcomes of the performed tests.

In the context of the last campaign, the applicant also started to experiment with systems that do not contain any inhibitors, to study more closely the production of non-condensable gases in connection with the process of corrosion.

In addition, between 2016 and 2020, the applicant conducted more intensive tests on the appliances that are still using sodium dichromate as an inhibitor in order to better describe the performance characteristics which an alternative would likewise have to match.

As discussed in further detail in the next section, the results of these previous studies were found to be discouraging by the applicant, as no feasible alternative was found.

Following the rejection of alternative substances studied as corrosion inhibitors during past testing campaigns, the applicant conducted further literature research and updated the list of potential alternative substances. But also, alternative technologies (not involving the use of an anti-corrosion agent) were included in the focus of continued research (see Alternative 1 and 3 below).

The resulting updated list of short-listed alternatives features 3 categories of alternatives:

- **Alternative 1: no inhibitor.** This is the simplest of the possible solutions but shortens the lifetime of the appliance.
- **Alternative 2: different chemical composition of the inhibitor.** The applicant has presented a list of 8 promising substitutes for sodium dichromate.
- **Alternative 3: metallurgical alternatives.** This alternative involves the potential use of a construction material other than carbon steel, which would be resistant to corrosion.

In the analysis of alternatives, the applicant presents an assessment of these short-listed alternatives, elaborating on the findings of the conducted literature review. These findings form the basis of the applicant's evaluation of technical feasibility, economic feasibility and availability of alternatives.

The substitution plan submitted by the applicant presents the efforts that the applicant is planning to make in order to find and implement one or more alternatives in the production of GA appliances. It describes the R&D activities and the allocated timeline expected to be necessary in order to put in place a suitable alternative inhibitor or technology in the applicant's production. This assessment is complemented by an overview of estimated costs of substitution in the AoA. In addition, the plan is meant to cover factors that might affect the success of the process, possible mitigating actions and activities in progress monitoring.

During the consultation, no comments were received on the analysis of alternatives and/or substitution plan.

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

The applicant presents in the application their previous efforts to find an alternative to the use of sodium dichromate as a corrosion inhibitor. Despite the partial loss of records about the first two testing campaigns, the applicant manages to describe sufficiently which substances have been studied before. This allows SEAC to take note of the number and type of alternatives that have already been subject to operational testing (confidential information is available to SEAC). However, SEAC notes that the pauses between the different campaigns implemented in the last 15 years are considerably long.

The applicant clearly describes the functional requirements that alternatives must comply with and provides a comprehensive list of alternative substances and technologies identified for further research. Especially the description of alternative substances included in the category of Alternative 2 seems to be well supported by a recently conducted literature review and some own tests conducted by the applicant.

The reasons for selecting the short-listed alternatives for continued assessment are mostly clear, although the applicant seems to have short-listed some alternatives (Alternative 2.6 and 2.7) which are later stated not to be subject to further testing. In response to a question by SEAC aiming to clarify the potential of such alternatives, the applicant responded that development resources are assigned to other alternatives, yet the applicant may reassess this prioritisation at a later stage. SEAC acknowledges the need to prioritise limited economic resources and agrees with the inclusion of comparatively lower-priority alternatives on the short list for the sake of completeness of the analysis.

SEAC notes that the substitution plan presents clear information on the efforts needed to find and implement an alternative and the timeline of the described steps. However, less extensive information is provided on the factors affecting the success of the process and possible mitigating actions.

4.2. Availability and technical and economic feasibility of alternatives for the applicant and in the EU in general

Has the applicant demonstrated that there are no alternatives with the same function and similar level of performance that are technically and/or economically feasible for the applicant by the date of submission of the application (April 2021)?

☒ Yes ☐ No

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

☐ Yes ☒ No

According to the applicant, an adequate inhibitor that would be feasible (both technically and economically) as well as available, could not yet be identified. Hence, the need for research

and development continues.

As outlined by the applicant's analysis, it is expected to take a long review period of 12 years to find an alternative which will fulfil all the basic functional requirements, described as:

- **Resistance to corrosion for sealed circuits and the prevention of gas formation.** The core of the gas absorption appliance is a sealed circuit, made of carbon steel and containing a mixture of water and ammonia with possible additives, such as corrosion inhibitors. During the operation, corrosion of the inner parts of the circuit and the formation of gases leads to worse performance and, in worst cases, even to a breaking of the sealed circuit.
- **Effectiveness at high operating temperatures and at high pressure.** GA appliances operate at high temperatures (up to 200 °C) and substantial pressures. The alternative must be as effective as the current technology under these operating conditions.
- **Long-lasting service.** The GA appliances are produced to operate for a long period of time (on average 14–25 years). An alternative must allow for comparable service time.
- **Economic feasibility.** The alternative (substance or technology) must not be substantially more costly than the use of sodium dichromate in the current products. Sodium dichromate currently has an economic feasibility not matched by other processes, allowing the sale of GA appliances both at an industrial and domestic scale, with uniform prices worldwide. This makes GA appliances accessible even for a family with an income included in the national average.

In different ways, all of these requirements contribute to the price-performance relationship of the final product and are thus a requirement for ensuring continued customer-acceptance of the appliances.

The applicant's analysis of alternatives presents an assessment of the technical feasibility, economic feasibility and availability of the identified potential alternatives against the background of the above-mentioned requirements.

4.2.1. Summary of Alternative 1: no inhibitor

Currently, the operation of the appliances without any inhibitor considerably shortens the lifetime of GA appliances, as they become susceptible to various technical problems. The lack of reliability of the technology without the inhibitor is explained to result in a rejection of the products on the market for heating and cooling appliances.

The goal of further research and development activity on Alternative 1 is to find operating conditions which produce only a low quantity of incondensable gases (0.01-1.5 cc/h). The applicant plans to continue studying this alternative by modifying the composition of the cooling liquid and/or making adjustments to the technology in a combination with work on Alternative 3.

Technical feasibility for the applicant

Tests conducted by the applicant show that, without the inhibitor, the GA appliance can operate for a certain period of time, but the appliance would have a service life reduced by a quarter compared to the one with inhibitor. Not using the inhibitor would lead to rapid corrosion of steel tanks and pipes with a formation of solid (rust or calamine) and gaseous products (i.e. incondensable gases). This in turn results in clogging or sudden breaking of the circuit.

Furthermore, it was confirmed that more frequent maintenance activity would not abate the described negative effects of not using the inhibitor (or using a lower-performing inhibitor).

Economic feasibility for the applicant

The applicant explains that the production price is not the issue in the context of Alternative 1. However, the production of appliances with the significantly shortened service lifetime would make the product uncompetitive on the market because short-lived GA appliances, subject to significantly more frequent internal breakages, would be rejected by the customers.
SEAC asked the applicant about the minimum acceptable service life of GA appliances and, in response, the applicant refers to a document[5] by the European Commission which seems to establish that the average service life is 15.9 years for gas machines. Another external source[6] cited by the applicant reports an even higher average service life of GA appliances of 20 years. Given a range of 14-25 years for the average service life of the applicant's GA appliances, the durability of the applicant's current product portfolio seems to be comparable to the range indicated by external sources. As a premature adoption of Alternative 1 is estimated to reduce the service life by a quarter, the applicant argues that this would cause a notable disadvantage for their customers. This is because products with longer service lifetimes will continue to be supplied by competitors.

Availability for the applicant

In their application, the applicant indicated that this alternative is available in the sense that manufacturers are in principle capable of not adding the corrosion inhibitor. In a question by SEAC, the applicant was asked about availability from the perspective of feasibility of the alternative technology and the applicant confirmed that in that sense it is not recommended to eliminate the corrosion inhibitor. The applicant makes clear that Alternative 1 is not sufficiently developed to meet the existing performance requirements and thus cannot replace the use of sodium dichromate in the circuit.

4.2.2. Summary of Alternative 2: different chemical composition of inhibitor (no Cr(VI))

In the category of Alternative 2, the applicant lists 8 potential substitutes for sodium dichromate to further investigate as part of continued research and development efforts. The selection was made on the basis of previous tests and the study of recently published scientific literature. The applicant's assessment finds that all promising candidates are still in the process of development and thus none of them could be confirmed to be both feasible and available for the applicant's use in GA appliances.

In addition, the applicant is simultaneously investigating alternative solvents (other than water) as the solution of ammonia in water is very corrosive to the carbon steel. However, no promising substitutes for water could be identified so far.

[5] IMPACT ASSESSMENT Accompanying the document Commission Regulation implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for air heating products, cooling products and high temperature process chillers (https://ec.europa.eu/energy/sites/ener/files/documents/swd_2016_422_f1_impact_assesment_en_v3_p1_819871.pdf)

[6] Mapping and analyses of the current and future (2020-2030) - heating/cooling fuel deployment (fossil/renewables) - Work package 2: Assessment of the technologies for the year 2012

Table 9: Summary table of promising substitutes for sodium dichromate

Alter-native	Chem. composition	Status of R&D	Technical feasibility	Economic feasibility	Availability
2.1	Isoxazolidine derivatives	Evaluated in acidic solution.	Literature indicates promising results under laboratory conditions. Not yet verified if performance can be sustained under use conditions in GA appliances.	Unknown	Research chemical
2.2	Glycerin-grafted starch	Evaluated in acidic solution.	Literature indicates promising results under laboratory conditions. Not yet verified if performance can be sustained under use conditions in GA appliances.	Unknown	Research chemical
2.3	Molybdates	Already used as corrosion inhibitor in other appliances and studied by the applicant.	Have been shown to not meet performance criteria in GA appliances.	Yes	Yes
2.4	Semicarbazones	Studied in research labs under the conditions different from those in GA appliances.	Literature indicates promising results under laboratory conditions. Not yet verified if performance can be sustained under use conditions in GA appliances.	Unknown	Research chemical
2.5	Cerium nitrate	Evaluated with aluminium alloys, but not	Literature indicates promising	Yes	Yes

		evaluated with carbon-steel in water-ammonia system (as in GA appliances).	results under laboratory conditions. Not yet verified if performance can be sustained under use conditions in GA appliances.		
2.6	Sodium nitrite	Studied and used in cooling towers with complex and very different technology compared to GA appliances.	Literature indicates promising results under laboratory conditions. Not yet verified if performance can be sustained under use conditions in GA appliances.	Yes	Yes
2.7	Strong alkaline solutions	Already used as corrosion inhibitor in other appliances and studied by the applicant.	Have been shown to not meet performance criteria in GA appliances.	Yes	Yes
2.8	Inhibitor 7, composition unknown	Evaluated by Dometic in their application for authorisation.	No public information available.		

Technical feasibility for the applicant

The applicant uses scientific literature and, where already available, own test results to compare each of the candidates to the defined functional requirements. In terms of technical feasibility, all of the listed alternative substances or mixtures are promising, however, their performance in the use as an inhibitor in the circuit of GA appliances (i.e. under the same conditions) is not confirmed yet.

In two cases (2.3 and 2.7), the applicant's own studies have shown insufficient performance levels when the alternatives were used in GA appliances. In the experimental phase it was not possible to obtain the same technical performance levels as provided by sodium dichromate as corrosion inhibitor in the sealed circuit of GA appliances. For example, the testing of strong alkaline solutions under high temperatures of use resulted in high levels of gas formation that put at risk the integrity of the circuit. Similarly, molybdates exhibited some anticorrosion activity, however not at the same level as sodium dichromate.

In five cases, the applicant has been able to make a first assessment of performance through

the evaluation of scientific publications but requires additional time to conduct performance verification in the specific use in GA appliances. These substances or mixtures were studied or used in different applications; however, none of them under comparable conditions (ammonia and water, temperatures up to 200 °C) to those they will be subjected to in GA appliances. For example, three of the alternatives (2.1, 2.2 and 2.4) were studied only in acidic solutions, a condition which doesn't apply to the use of the applicant. Alternative 2.5 was studied with different material (i.e. aluminium instead of steel). In the case of Alternative 2.6, the applicant considers the existing use of the substance as an inhibitor in cooling towers to be so complex and that much different from the technology of GA appliances that it was decided to prioritise other, more promising alternatives on the list in terms of investments in further research and development.

One possible substitute (Inhibitor 7) is a compound or mixture tested by Dometic, whose composition is not known to the applicant.

Economic feasibility for the applicant
Four promising substitutes (2.3, 2.5, 2.6, and 2.7) are considered economically feasible, as these are industrial chemicals and are found to be commercially available, low-cost chemicals.

For the rest, economic feasibility cannot be determined. Three alternatives (2.1, 2.2, and 2.4) are research chemicals whose price is not known nor easily determinable. Economic feasibility of the Inhibitor 7 cannot be evaluated by the applicant due to the unknown identity of the alternative.

Availability for the applicant
The same as for economic feasibility holds for availability. The same four alternatives that were found to be economically feasible are also available on the EU market.

Availability of the three research chemicals is of low probability because these are not produced industrially but were synthesized by researchers in university laboratories. Again, the applicant could not reach a conclusion for the unknown Inhibitor 7 that was assessed confidentially in a competitor’s application for authorisation. It is worth noting that no comments were received from this competitor during the third-party consultation.

4.2.3. Summary of Alternative 3: metallurgical alternatives

The sealed circuit of the GA appliance is made predominantly of carbon steel. It is more resistant to corrosion with water-ammonia solution than many other metals. A potential alternative to carbon steel is stainless steel which is already used for a few parts of the circuit.

Technical feasibility for the applicant
Stainless steel (AISI316) is more difficult to process mechanically than carbon steel (Fe360) because it does not allow moulding, drawing, bending or calendaring to the same extent. The use of this material would thus require certain adaptations of the geometry of the sealed circuit. Another disadvantage is that thermal conductivity of stainless steel is about 3-times lower than that of a carbon steel. This means the appliance has worse thermal efficiency. The applicant's assessment finds that further research will be necessary to make this alternative feasible in the context of GA appliances.

Economic feasibility for the applicant
Stainless steel as a construction material is more expensive than carbon steel, more difficult to process and reduces the efficiency of the appliance. The applicant argues that it is difficult to assess economic feasibility without knowing to which degree adjustments of the circuit could mitigate the technical problems of using stainless steel.

Availability for the applicant
Similar to the case of Alternative 1, the applicant indicates that Alternative 3 is available in the sense that stainless steel is available, but in the context of the use in GA appliances, the use of stainless steel is not ready as a plug-in alternative. As explained by the applicant, it requires extensive further research and development effort to make the use of this alternative technology feasible and thus implementable in the production of GA appliances.

4.2.4. Feasibility and availability of Alternatives 1, 2 and 3 in the EU in general

In response to SEAC's question, the applicant responded that according to their knowledge, none of the short-listed alternatives (substances or technologies) are already used by the other actors in the EU for the use applied for.

As indicated before, no comments were received during the consultation.

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

Performance requirements of alternatives
The performance requirements defined by the applicant establish equal requirements for any potential alternative as currently fulfilled by the use of sodium dichromate. This is justified with the explanation that without these properties the service life of the appliance is significantly reduced and that this leads to the rejection of the technology on the market. The latter is based on the assumption that other manufacturers would continue to offer heating and cooling solution fulfilling higher average service life expectations and thus make less reliable technologies clearly less attractive.

SEAC find this argumentation reasonable – compared to a different technology of heat pumps, the electric heat pump, GA appliances allow for more alternatives with regard to the energy source consumed and higher overall yield of heat. This makes GA appliances also a valuable alternative to the consumer in terms of costs and availability on a volatile market of energy sources.

Technical feasibility
The applicant argues in their analysis of alternatives that none of the identified alternatives are implementable in the specific context of the production of GA appliances in the next 12 years. This is because extensive further research and development efforts are expected to be needed in order to study the alternatives under the relevant use conditions and find ways to make them operational in the system of GA appliances.

SEAC shares the opinion of the applicant that at current stage the use of an underdeveloped (working) solution, such as the operation of appliances without inhibitor (see Alternative 1), is not a viable alternative, since it would yield a short-lived and non-competitive product.

In the context of Alternative 2, SEAC considers that there is no corrosion inhibitor other than sodium dichromate (or in general, chromium(VI) compounds) on the market to date. All potential substitutes for sodium dichromate need further thorough testing and optimisation to assess if they are feasible for use in GA appliances.

With regard to the analysis of Alternative 3, SEAC also agrees with the applicant's opinion that a replacement of a construction material of a sealed circuit, carbon steel with stainless steel would lead to problems in mechanical processing, higher production costs and worse performance of the product.

Economic feasibility

Alternatives 1 and 2 are in theory seen to be economically feasible, as in these cases just the addition of an inhibitor is either omitted or replaced with another one. However, since these alternatives are not yet implementable by the applicant for technical reasons, economic feasibility may be deemed irrelevant.

Regarding the applicant's conclusion about Alternative 3, SEAC agrees that at this moment it is not possible to evaluate the economic feasibility, but in any respect the production costs would be higher and the performance of the appliance lower due to poor thermal conductivity.

Availability

In line with the problems brought about by not using an inhibitor (as described in section 4.2.1), SEAC accepts that Alternative 1 will likely not be available from the perspective of feasibility of the alternative technology before the end of the requested review period. Availability in the sense of being capable to not add any inhibitor is deemed irrelevant in this case.

Based on the assessment of Alternatives 2.1, 2.2 and 2.4, SEAC has no indication that these alternatives might become commercially available before the end of the requested review period.

The case of Alternative 3 is similar to Alternative 1 in the sense that stainless steel as a material is principally available, but this is of limited help for the substitution of sodium dichromate in the applicant's use. This is because the implementation of this material as an alternative is not possible from the perspective of technical feasibility of the alternative technology. There is also no indication that Alternative 3 would become implementable before the end of the requested review period as extensive research and adaptation of a production process would be required.

4.3. Risk reduction capacity of the alternatives

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

☐ Yes ☐ No ☒ Not applicable

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

4.4. Substitution plan/activities

Did the applicant submit a substitution plan?

☒ Yes ☐ No

Is the substitution plan credible for the review period requested and consistent with the analysis of alternatives and the socio-economic analysis?

☒ Yes ☐ No

Phases and costs of substitution
The substitution plan is divided into 4 phases:

- **Phase 1: Research, testing, monitoring (2021–24)**
  Identification of alternative substances or technologies; Preliminary lab testing, including a realization of a prototype for accelerated testing.
- **Phase 2: Identification-testing (2025–28)**
  Choice of the best alternatives and accelerated testing of them; Internal and external field tests on selected best alternatives.
- **Phase 3: Product development (2029–30)**
  Choice of the single best alternative (substance/technology); Production and tests on final products. Tests of products on customers sites.
- **Phase 4: Distribution and market deployment (2031–32)**
  Planning of realization of alternative production process and training of workers involved; Implementation of the new production and sale of new products; Disposal of the current production line/equipment.

In phase 1, more resources will be channelled into the search for a suitable alternative, i.e. inhibitor or technology. In phases 2 and 3, testing of the chosen alternative and comparisons with the current technology will take place. Phase 4 consists of the implementation of the new inhibitor or technology in the production and distribution.

The applicant intends to test the alternatives in the following sequence: Alternative 3, Alternative 2.1-2.5, Alternative 1. In this process Alternatives 2.1-2.5 will be assessed as a package.

It can be noted that the substitution plan presents the same schedule of activities for all 3 alternatives, despite the fact that they are very different. Substitution of one inhibitor with another does not alter the production process much. On the contrary, the replacement of the construction material (Alternative 3) would bring about major changes in the production line. SEAC asked the applicant to clarify this approach and received a reply explaining that the method for verifying the alternative (inhibitor change or metallurgical change or absence of inhibitor) must always remain the same to be sure that the production of non-condensable gases is low enough.

The substitution activities will be conducted by the applicant's own R&D department and other personnel in cooperation with external collaborators. Testing of the newly developed products will be achieved with the help of selected customers and installers. Possible development of a technology involving new construction material (Alternative 3) will be carried out in collaboration with university laboratories.

The expected costs of the substitution are assessed by applicant as shown in the following table.

Table 10: Costs of substitution

Phase	Cost
Preparation and Phase 1	€400 000-5 000 000
Phase 2	€300 000-5 000 000
Phase 3	€200 000-3 000 000
Phase 4	€1 000 000-10 000 000
Total	**€1 900 000-23 000 000**

Limiting factors

In addition to the functional requirements and availability of alternatives, the substitution plan lists a number of factors potentially affecting the success of the R&D plan. Depending on the alternative (1, 2 or 3) chosen, the applicant explains that there may be small or major changes in the production process in terms of equipment used, the number of workers needed, additional training requirements, or the floor size and time needed for the production of GA appliances. All of these factors can impact the timeline of substitution in a negative way because they lead to additional costs that must be integrated in the applicant's investment schedule. The economic resources needed for substitution are reported to be an important limiting factor in the implementation of the R&D plan.

Progress monitoring and mitigating of problems

According to the applicant, progress monitoring will be implemented through annual reports that each division involved in substitution must submit to the company's HSE manager. This report will cover results of the activities in each phase and check whether these are on track in terms of timing. The applicant indicates that the choice of corrective actions will be assessed specifically for each identified issue and that a cross-divisional working group will be put in place to analyse the problem and find solutions as quickly as possible.

In terms of the overall timeline for substitution, the applicant states that it is not possible to establish precisely how soon an alternative can be implemented. The applicant has estimated a timeframe of 7 years to conclude the identification of the best alternative. The rest of the process is focused on the implementation of such an alternative. The applicant indicates that, overall, a minimum of 12 years will be required to substitute sodium dichromate as an inhibitor used in GA appliances.

SEAC's evaluation of the substitution plan/activities

SEAC asked the applicant, whether more of the activities described in the substitution plan can be run in parallel. The applicant explained that this is not possible, because the result of a previous phase is crucial to initiate and design of the subsequent one. Another reason is that they do not have enough resources in personnel and space. SEAC's opinion is that, to some minor extent, it would be possible to run some activities in parallel (e.g. performance

comparison of alternatives), but this would not substantially shorten the time of development and implementation of alternatives.

SEAC notes the applicant's argument for maintaining the same schedule of substitution activities for all 3 alternatives, despite the fact that they are very different. SEAC acknowledges that the substitution plan requires some flexibility as it is not known which alternative will prove the most appropriate. SEAC further notes that the applicant does not give extensive consideration to the factors that could go wrong. As a result, some uncertainty pertains to the timeline of activities.

Despite these uncertainties, SEAC considers that a long review period is overall justified. The substitution plan seems consistent with the analysis of alternatives, and it seems credible that (at least) the requested review period of 12 years will be needed to perform the activities related to the implementation of an alternative.

4.5. SEAC's conclusions on the analysis of alternatives and the substitution plan

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

- The applicant has demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the applicant by the date of application submission (April 2021) and that such will likely not become available to the applicant during the requested review period of 12 years.
- There is information available in the application for authorisation indicating that there are no alternatives available that are technically and economically feasible in the EU.
- The applicant submitted a substitution plan. The substitution plan is credible for the review period requested and consistent with the analysis of alternatives and the socio-economic analysis.

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

5. Socio-economic analysis

Did the applicant demonstrate that the societal costs of not granting an authorisation are higher than the risks to human health?

☒ Yes ☐ No ☐ Not relevant (the risk cannot be compared with the costs of non-use)

5.1. Human health impacts of continued use

The applicant states that direct exposure to Cr(VI) compounds in exposure scenario 1 (ES 1) would affect a total of between 1-100 workers (exact number claimed confidential but known to SEAC) at the plant in Zingonia, located in the Bergamo province in northern Italy. The health endpoint that is considered to be most relevant for exposed workers is lung cancer under the assumption that the uptake predominantly occurs via the inhalation route.

In addition to impacts on exposed workers, 1 100 people in the general population located in

an area of 1 km^2 around the site are estimated to be exposed via the environment, leading to increased risk of lung and colon-rectal cancers.

The applicant has estimated incremental cancer risk using RAC's carcinogenicity dose-response analysis for Cr(VI)-containing substances[7] combined with data supplied in the CSR to assess the additional cancer risks. The health impacts have been monetised by the applicant applying the values used in a publication by ECHA (2016)[8], that is, the value of statistical life (VSL) of €3.5 million to 5 million and the value of cancer morbidity (VCM) of €0.41 million expressed as 2012-prices. The applicant converts these values to 2020-prices using an Italian GDP deflator.

In line with ECHA's study (2016), the applicant has assumed a 10-year latency period for lung cancer and 26 years for intestinal cancer in their human health impact assessment and applied a discount rate of 4 % to the values of statistical life and cancer morbidity.

Using the upper bound for the VSL, the applicant has calculated the upper bound of monetised excess cancer risk associated with continued use over 12 years as €338 for workers and €22 for the general population, giving an aggregate total for monetised human health risks of €360 (present value) for the whole requested review period, or approximately €30 per year (€360/12 years). By comparison, using the lower bound VSL gives monetised excess risks of €262 (present value) and approximately €22 per year respectively. The applicant has used the upper bound figures in their overall analysis.

The impact of potential exposure of workers in exposure scenario 3 (ES 3) as well as the impact of exposure of consumers in exposure scenario 2 (ES 2) has not been included by the applicant in the monetisation of health risk.

SEAC's evaluation of the impacts on human health

SEAC notes the applicant's methodological approach and assumptions, which uses ECHA's (2016) report on valuing selected health impacts of chemicals and inflates the values to 2020 using an Italian GDP deflator.

SEAC considers that the estimated impacts on human health reflect the welfare loss in the continued use scenario due to the increased mortality and morbidity. Yet, SEAC notes that the monetised values do not incorporate any increased costs on the healthcare system and other types of indirect costs (such as decrease in labour productivity) associated with cancer. SEAC concurs with the applicant's methodology, while noting that above-mentioned additional costs (in terms of health care costs and productivity loss) could be expected in the continued use scenario and have not been covered in the applicant's socio-economic analysis.

SEAC notes that RAC acknowledges the unlikely exposure of consumers in ES 2, but that RAC derives a certain level of risk for workers in ES 3. Based on RAC's evaluation, SEAC includes the (missing) monetisation of the risk related to exposure scenario 3.

SEAC further notes RAC's conclusion stating that the exposure levels of workers and humans via the environment reported in the application for authorisation are below the DNELs for

[7] RAC/27/2013/06 Rev.1
[8] https://echa.europa.eu/documents/10162/13630/echa_review_wtp_en.pdf/dfc3f035-7aa8-4c7b-90ad-4f7d01b6e0bc

reproductive toxicity for the relevant exposure route, therefore the risk of reproductive effects is considered to be adequately controlled.

Overall, SEAC concludes that the applicant's figures provide a reasonable estimate of the monetised human health costs. However, SEAC derives the cost per average year during the review period (annuity) by dividing the present value by the appropriate annualization factor over 12 years at 4 % (9.385). This leads to slightly higher annuitized values.

Table 11: Summary of additional statistical cancer cases

	Excess lifetime cancer risk[1]	**Number of exposed people**	**Estimated statistical cancer cases over 12 years[5]**	**Value per statistical cancer case**	**Monetised excess risk[4]**
Workers					
Directly exposed workers[2] in ES 1[6] (Endpoint: Lung cancer)	1.51×10^{-4}	1-100 (public range)	1.1×10^{-4}	€5 035 000 VSL €412 870 VCM (upper bounds)	€338 present value of impacts incurred over 12 years €36 per year
Directly exposed workers[2] in ES 3 (Endpoint: Lung cancer)	4.88×10^{-10}	5-10 (public range)	9.14×10^{-10} to 1.83×10^{-9}		€0.003-0.005 present value €0.0003-0.0006 per year
Indirectly exposed workers[3]	Not assessed	Not assessed	Not assessed		Not assessed
Sub-total	1.51×10^{-4}	1-100 (public range)	1.1×10^{-4}		€338 present value €36 per year
General population					
Local (Endpoint: Lung cancer)	3.10×10^{-8}	1 100	7.30×10^{-6}	€5 035 000 VSL €412 870 VCM (upper bounds)	€22 present value €2 per year
Local (Endpoint: Intestinal cancer)	1.42×10^{-10}	1 100	2.68×10^{-8}		€0.03 present value €0.003 per year
Regional	Not assessed	Not assessed	Not assessed		Not assessed
Sub-total	3.11×10^{-8}	1 100	7.32×10^{-6}		€22 present value €2 per year
Total	**1.51×10^{-4}**	**1 101-1 200 (public range)**	**1.20×10^{-4}**		**€360 present value €38 per year**
Latency (years)	10 years for lung cancer and 26 years for intestinal cancer				

Notes:

1. Excess risk is estimated over a typical lifetime working exposure (40 years) and via the environment over a typical lifetime exposure (70 years).
2. Directly exposed workers perform tasks described in the worker contributing scenarios.
3. Indirectly exposed workers (bystanders) do not use the substance.
4. Cost per average year during the review period (annuity) was derived dividing the present value by the appropriate annualization factor over 12 years at 4 % (9.385).
5. Estimated statistical cancer cases over 12 years (here showing the sum of fatal and non-fatal cases) are derived from the number of exposed people and the excess lifetime risk incurred during 40 years of worker exposure and 70 years of general population exposure.
6. Using an ELR of 2.76×10^{-4} resulting from the combined worker exposure estimate derived by RAC, the upper bound of the worker health impacts would be in the range of €310-31 047 (present value) giving €33-3 308 per year. Using this worst-case assumption would not change the conclusion of the impact assessment.

5.2. Societal costs of not granting an authorisation

5.2.1. Non-use scenario (NUS)

The applicant states that currently they have no viable alternative to using sodium dichromate in the production of GA appliances. In the absence of an authorisation, the applicant has described four possible non-use scenarios:

- **NUS 1: Downsizing** of the production site
  NUS 1 would result from a complete stop of production and sale of GA appliances which use sodium dichromate as an anticorrosion agent. In this NUS, the applicant would only continue with the production of other unaffected products. This would lead to the loss of substance-dependent profits and the loss of production line investment according to the applicant's assessment.
- **NUS 2: Outsourcing** of production activities
  Outsourcing production activities associated to GA appliances that are dependent on the use of sodium dichromate would mean that the applicant needs to reach an agreement with competitors that have obtained authorisation to use a chromate substance in the EEA, or with companies located outside EEA. Similar to NUS 1, this would result in the closure of all areas associated with the production of GA appliances. The applicant finds that the potential impacts on the quality of the final product, speed of delivery and higher costs of outsourced production make this option unsustainable.
- **NUS 3: Relocation** of the production to non-EEA countries
  The applicant considered relocating the production of GA appliances to an existing production facility in a non-EEA country (USA) and provided confidential information on the costs and time associated with the relocation process. Achieving current quality standards in the new plant was estimated to take not less than 4-5 years. The products would however lose their "made in Italy" branding and the NUS involves discontinuation of the affected production during the relocation process. Therefore, this NUS was considered highly improbable by the applicant.
- **NUS 4: Production** and sale of GA appliances **without a corrosion agent**
  The applicant considered continued production but without the corrosion agent as part of its search for alternatives. Without sodium dichromate as an inhibitor agent, production would be subject to a number of quality issues and lower longevity, harming the sales and the company's position in the market. The applicant did not consider this option to be economically sustainable.

The applicant concluded that NUS 1, i.e. downsizing the plant with a complete stop of production and sales of GA appliances which use sodium dichromate as an anticorrosion agent, to be the most likely non-use scenario.

SEAC queried why discontinuing production was considered more likely than relocation. The applicant considered the loss of the "made in Italy" branding as important for its worldwide market, and also excluded NUS 3 because relocation was not seen as a solution to reduce the impacts associated with the use of sodium dichromate.

Based on the information provided by the applicant, SEAC agrees that downsizing appears to be the applicant's most likely NUS.

5.2.2. Economic, social and environmental impacts of non-use

Continued use would avoid the impacts of the non-use scenario (i.e. downsizing the plant with a complete stop of production and sales of GA appliances which use sodium dichromate as an anticorrosion agent). The applicant's analysis considers total benefits to be worth between €8 million and €90 million (present value of impacts that would be incurred over 12 years). The applicant's analysis considered the following impacts:

- Avoided profit loss related to the discontinued sale of GA appliances over 12 years (€2-20 million)
- Avoided profit loss associated with investment in alternatives (€1-10 million)
- Avoided relocation and closure costs (€0.5-5 million)
- Avoided residual value of capital (€2-30 million)
- Avoided social costs related to loss of jobs (€2-20 million)
- Environmental benefits (CO_2 savings) (€0.5-5 million)

The applicant's public range values for the impacts are given in brackets. The impacts are assessed in more detail below.

Avoided profit loss

The applicant provided confidential information on profits and turnover. The applicant states that around 45 % of total turnover is associated with products produced with sodium dichromate and that the profits from these products would be lost on the NUS. The annual and present value figures are claimed confidential, but the applicant provided a public range of €2-20 million over the 12-year requested review period.

SEAC considers that changes in profits are a relevant measure of changes in producer surplus and appropriate to monetise the welfare implications of continued use. However, changes in profits made by the applicant do not necessarily reflect net changes in economic surplus across the EU economy. Considering the profit losses of the applicant over a long period does not consider the possibility of mitigating actions that could reduce the economic impacts (e.g., resources being redeployed by the applicant or by other companies) and may overstate the long-term impacts. Therefore, SEAC does not consider it appropriate to use the profit loss incurred by the applicant over the whole requested review period. Following the publication of the new guidance on assessing changes in producer surplus[9] agreed at SEAC 52 in September 2021, SEAC has adopted a default period of either 2 years of profit losses, for cases where

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

technically and economically feasible alternatives are generally available, or 4 years of lost profit, where such alternatives are not available. In this application, SEAC considers that there is information available in the application for authorisation indicating that there are no alternatives available that are technically and economically feasible in the EU. SEAC has therefore assumed that using 4 years of lost profits is applicable. SEAC has adjusted the applicant's non-confidential profit loss range of €2-20 million (present value over 12-years) and calculated an approximate four-year present value, which was then annualised dividing by the appropriate annualization factor over 12 years at 4 % (9.385). This results in an annualised value of lost profits of €0.07-0.7 million per year (based on four years of lost profit, annualised over 12 years).

SEAC considers this recalculated annualised range (€0.07-0.7 million), based on four years of lost profit, to be a reasonable estimate of the welfare losses from not being granted authorisation. This figure has been taken forward by SEAC for the subsequent socio-economic analysis.

Avoided profit loss associated with investment in alternatives

The applicant states that a granted authorisation would enable them to continue searching for a viable alternative to sodium dichromate, including investments costs related to developing an alternative, at an estimated cost of €1-10 million (public range). While this cost is reported as avoided profit loss in the SEA (Table 43 in the AoA and SEA document), it is described as "not applicable" elsewhere (Table 41 in the AoA and SEA document).

SEAC queried the inclusion of this figure. SEAC considers that since the applicant intends to carry out this investment (as set out in the substitution plan) the costs should not be included. SEAC has therefore noted the planned expenditure but excluded it from its own analysis.

Avoided relocation costs (read as closure costs related to downsizing)

The applicant included a figure of €0.5-5 million (present value) for avoided relocation costs. SEAC queried why relocation costs had been included, since the stated most likely NUS (downsizing) did not appear to involve relocation. In response, the applicant stated that the estimated relocation costs (associated with NUS 3 described above) are higher than the costs associated with closure, but as a precaution the applicant had chosen to consider avoided relocation costs instead of closure costs. SEAC sought additional clarification from the applicant and requested a public range for the closure costs associated with downsizing.

SEAC understands the applicant's initial response was to compare the costs of downsizing related closure and costs of relocation under this heading, and, while the costs are claimed to be similar, had used the higher of the two figures to represent the costs of (partial) site closure that would result from downsizing. SEAC has used a revised range of €0.1-0.7 million (public range provided by the applicant) that reflects the downsizing-related closure costs in its analysis. SEAC has adjusted these figures from present values to annualised values over 12 years, giving a range of €0.01-0.07 million per year.

Avoided residual value of capital

The applicant's analysis included a present value of €2-30 million (public range) for avoided residual value of capital. In response to questions form SEAC, the applicant stated that the residual value is calculated based on other investments not strictly connected with the old productive line (buildings, equipment, infrastructure) that could be lost in the non-use scenario.

In response to further questions, the applicant provided confidential information on assets that were assumed to be lost. SEAC was unable to determine the extent to which these assets would be lost, directly or indirectly, as a result of the NUS, or the extent to which the assets are in either case essentially sunk costs from an economic perspective. SEAC has therefore taken a conservative approach and noted the residual asset information but excluded the estimated costs from its assessment.

Avoided social costs related to loss of jobs

The applicant claims downsizing their production activities would risk 10-200 jobs (public range) covering all workers directly involved in the production of GA appliances and progressively all workers involved in closed or downsized areas at the plant (which currently employs a total of 177).

The applicant has used the ECHA unemployment valuation methodology described in the paper endorsed by SEAC[10] to calculate the social costs of unemployment, using the relevant industry category wages set by Italian national collective bargaining agreements to calculate the annual wages for affected employees. This resulted in a public range for the social cost for job losses of €2-20 million (present value).

SEAC considers the applicant's calculated overall monetised estimate of €2-20 million (present value) for the cost of unemployment impacts in the NUS to be reasonable and has included them in its analysis. SEAC has taken the €2-20 million (present value) range and converted it to an annualised value of €0.2-2 million per year dividing by a 12-year annualization factor at 4 % (9.385).

Environmental benefits (CO_2 savings)

The applicant also estimated savings in CO_2 emissions related to the use of GA appliances in the EEA because, according to the applicant's analysis, GA appliances replace other less efficient heating technologies. The monetary value for these savings is reported as €0.5-5 million, based on the market value of CO_2 certificates. The applicant also provided additional information on the approach used to value saved CO_2 emissions, using the price of the European Emission Allowance (EUA) certificate for EU ETS.

SEAC considers CO_2 savings to be a legitimate element of socio-economic analysis. However, SEAC noted that in the absence of information about the efficiency of products sold by the applicant's competitors, it was not possible to determine the extent of any potential avoided CO_2 emissions, since it may be that the same amount of CO_2 would be saved if competitors take over the applicant's market share in the NUS. SEAC has therefore noted the applicant's approach, but not included the monetised value in its analysis.

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

Table 12 summarises SEAC's evaluation of the societal costs of non-use.

[10] https://echa.europa.eu/documents/10162/17086/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554

Table 12: Societal costs of non-use

Description of major impacts	Monetised/quantitatively assessed/qualitatively assessed impacts
1. Monetised impacts	
Producer surplus loss due to ceasing the use applied for	€0.07-0.7 million per year based on 4 years of lost profit
Relocation or closure costs	€0.01-0.07 million per year considering closure costs only (relocation costs are excluded to be consistent with most likely NUS)
Loss of residual value of capital	Assessed as zero by SEAC
Social cost of unemployment	€0.2-2 million per year
Spill-over impact on surplus of alternative producers	Not available
Sum of monetised impacts	**€0.28-2.77 million per year**
2. Additional quantitatively assessed impacts	
Not available	
3. Additional qualitatively assessed impacts	
Potential CO_2 emissions noted but not included by SEAC	

For the purpose of its evaluation, SEAC has included the profit losses, closure costs and direct job losses at the applicant's plant in the overall SEA.

Other elements, comprising avoided profit loss associated with investment in alternatives, avoided relocation costs, avoided residual value of capital and environmental benefits from CO_2 savings were noted but not included in the overall monetised SEA, for reasons outlined above.

5.3. Combined assessment of impacts

Based on SEAC's analysis in sections 5.1 and 5.2 above, the comparison of SEAC's views on the human health impacts, as well as continued use and non-use scenario, economic impacts and social impacts can be found in Table 13 below. As mentioned, SEAC agrees with the non-use scenario and SEAC has reworked the applicant's lost profit figures and taken a conservative approach to including elements monetised by the applicant in SEAC's overall analysis. SEAC considers it is appropriate (and conservative) to acknowledge other potential impacts but leave them unquantified given the uncertainty that surrounds them. SEAC also notes that some impacts will be distributional in nature, rather than true societal impacts.

SEAC's assessment, based on the applicant's information in Table 13 is given in annualised terms. Societal costs of non-use sum to €0.28-2.77 million per year which is compared to risks of continued use valued as €38 per year.

Table 13: Societal costs of non-use and risks of continued use[1]

Societal costs of non-use		Risks of continued use	
Monetised impacts (€ per year)	Lost profits €0.07-0.7 million per year Closure costs €0.01-0.07 million per year Direct job losses €0.2-2 million per year	Monetised excess risks to directly and indirectly exposed workers (€ per year)	€36 per year
Additional quantitatively assessed impacts	Not available	Monetised excess risks to the general population	€2 per year
Additional qualitatively assessed impacts	Not available	Additional qualitatively assessed risks	Not available
Summary of societal costs of non-use	**€0.28-2.77 million per year**	**Summary of risks of continued use**	**€38 per year**

Notes:

1. Cost per average year during the review period (annuity) was derived dividing the present value by the appropriate annualization factor over 12 years at 4 % (9.385).

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

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

This conclusion of SEAC is made on the basis of:

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

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

6. Proposed review period

☐ Normal (7 years)

☒ Long (12 years)

☐ Short (4 years)

☐ Other: -

☐ No review period recommended

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

- The applicant has demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the applicant by the date of application submission (April 2021) and that such will likely not become available to the applicant during the requested review period of 12 years.
- There is information available in the application for authorisation indicating that there are no alternatives available that are technically and economically feasible in the EU.
- The applicant submitted a substitution plan. The substitution plan is credible for the review period requested and consistent with the analysis of alternatives and the socio-economic analysis.

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

Taking into account all of the above points, a **12-year** review period is recommended for this use, i.e. until the end of March 2033.

7. Proposed additional conditions for the authorisation

Were additional conditions proposed for the authorisation?

☒ Yes ☐ No

7.1. Description

RAC

Maintenance and repair tasks performed under WCS 1 of ES 3 shall also be subject to the authorisation.

SEAC

None.

7.2. Justification

RAC

Since the maintenance and repair activity involves the emptying of the refrigerant solution that may still contain residual Cr(VI), and the refilling of a 'fresh' refrigerant solution that contains sodium dichromate above 0.1 %, RAC is of the opinion that ES 3 shall also be included in the scope of the authorisation. Tasks described in WCS 1 of ES 3 apply the same protocol

used in WCS 4 of ES 1 in which the GA units are repaired using the applicant's recovery solution device in a closed system.

RAC is of the opinion that the RMMs and OCs are appropriate and effective in limiting the risk. Therefore, no additional conditions for the authorisation related to OCs/RMMs are proposed.

SEAC

Not applicable.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements proposed for the authorisation?

☒ Yes ☐ No

8.1. Description

RAC

1. The applicant shall conduct annual monitoring programme of occupational exposure for Cr(VI) of workers directly or indirectly involved in ES 1 and ES 3, using an sufficiently sensitive analytical method. Those programmes shall be based on relevant standard methodologies or protocols, comprise both static and personal inhalation exposure sampling, include detailed contextual information on the tasks performed, the duration of monitoring, the OCs and RMMs in place and be representative of:
    a. the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance/cleaning tasks;
    b. the OCs and RMMs typical for each of these tasks;
    c. the number of workers potentially exposed, including workers not directly using the substance.
2. The applicant shall continue to conduct at least annual Cr(VI) measurements in exhaust air using a sufficiently sensitive analytical method.
3. The information gathered via the measurements referred to in paragraph 1 and 2 related contextual information shall be used by the applicant to confirm the effectiveness of OCs and RMMs as well as to review regularly the effectiveness of OCs and RMMs in place and to introduce measures to further reduce workplace exposure respectively air emissions to Cr(VI) to as low a level as technically and practically feasible.
4. The information from the monitoring programmes referred to in paragraph 1 and 2, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 3 shall be documented, maintained and be made available by the applicant, upon request, to the competent authority, and included in any subsequent authorisation review report.

8.2. Justification

RAC

Provision of the representative monitoring results for both worker exposure and release of Cr(VI) to environmental air would allow for better evaluation of the actual situation at the applicant site and would confirm the appropriateness and effectiveness of OCs and RMMs in place.

9. Recommendations for the review report

Were recommendations for the review report made?

☒ Yes ☐ No

9.1. Description

RAC

The results of the measurements referred to in section 8 as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 should be documented and included in any subsequent review report.

SEAC

None.

9.2. Justification

RAC

Provision of the representative monitoring results would allow for better evaluation of the actual and future situation at the applicant´s sites and would confirm the appropriateness and effectiveness of OCs and RMMs.

SEAC

Not applicable.

10. Applicant's comments on the draft opinion

Did the applicant comment the draft opinion?

☐ Yes ☒ No

10.1. Comments of the applicant

Was the opinion or the justifications to the opinion amended as a result of the analysis of the applicant's comments?

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

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

Not applicable.

10.3. Reasons for not introducing changes

Not applicable.