Helsinki, 07/03/2022

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

dichromium tris(chromate) use: Use of dichromium tris(chromate) in a post-treatment step of the autodeposition coating process of shock absorbers for automotive vehicles.

Submitting applicant

Monroe Czechia s.r.o.

ECHA/RAC/SEAC: AFA-O-0000007066-75-01/F

Consolidated version

Date: 07/03/2022

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	**Monroe Czechia s.r.o.**
Role of the applicant in the supply chain	Upstream ☐[group of] manufacturer[s] ☐[group of] importer[s] ☐[group of] only representative[s] ☐[group of] formulator[s] Downstream ☒downstream user
Use performed by	☒Applicant ☐Downstream user(s) of the applicant
Substance ID EC No CAS No	**dichromium tris(chromate)** 246-356-2 24613-89-6
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 dichromium tris(chromate) in a post-treatment step of the autodeposition coating process of shock absorbers for automotive vehicles.**

	Other connected uses: N/A.
	Similar uses applied for: N/A.
Indicative number and location of sites covered	1 site in Czech Republic
Annual tonnage of the Annex XIV substance used	0.5-2 tons per year of dichromium tris(chromate) (DCTC)
Functions of the Annex XIV substance	To provide corrosion and chemical resistance to shock absorbers for automotive vehicles
Type of products (e.g. articles or mixtures) made with the Annex XIV substance and their market sectors	Shock absorbers for automotive vehicles
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	3 years (until 21 September 2024)
Use ID (ECHA website)	0232-01
Reference number	11-2120880521-56-0001

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	05/05/2021
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	19/05/2021-14/07/2021
Were comments received in the consultation?	☐Yes ☒No
Request for additional information in accordance with Article 64(3)	On: 12/05/2021 11/06/2021 20/07/2021 27/08/2021
Trialogue meeting	Not held – no new information submitted in consultation, no need for additional information/discussion on any technical or scientific issues related to the application
Was the time limit set in Article 64(1) for the sending of the draft opinions to the applicant extended?	☐Yes ☒No
Did the application include all the necessary information specified in Article 62 that is relevant to the Committees' remit?	☒Yes ☐No
Date of agreement of the draft opinion in accordance with Article 64(4)(a) and (b)	RAC: 26/11/2021, agreed by consensus
	SEAC: 08/12/2021, agreed by consensus
Date of sending of the draft opinions to the applicant	01/02/2022
Date of decision of the applicant not to comment on the draft opinions, in	18/02/2022

accordance with Article 64(5)	
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: 18/02/2022, adopted by consensus
	SEAC: 18/02/2022, adopted by consensus
Minority positions	RAC: No minority positions
	SEAC: No minority positions
RAC Rapporteur RAC Co-rapporteur	Elena R. CHIURTU Pietro PARIS
SEAC Rapporteur	Derrick JONES
ECHA Secretariat	Nina LAZIC Monique PILLET 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
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

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,
- the assessment of the hazards related to the alternatives as documented in the application, as well as
- other available information.

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

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

RAC concluded that the operational conditions and risk management measures described in the application are **not** appropriate and effective[1] in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and 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 as a result of additional conditions and on associated 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 a possible 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 use applied for may result in up to 0.01 kg Cr(VI) per year releases of the substance to the environment.

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

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

functions, values of health endpoints).

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

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

- one spray coating technique and
- a dip coating process (KTL).

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 at the date of the submission of the application.
- There is information available in the application for authorisation indicating that there might be alternatives available that are technically and economically feasible in the EU. However, RAC is unable to conclude on whether these alternatives are safer.
- The applicant submitted a substitution plan. The substitution plan was 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 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 and the environment resulting from the granting of an authorisation.

The expected societal costs of not granting an authorisation, which are estimated to be at least €195 000-1 900 000 over the requested review, corresponding to approximately €65 000-630 000 per year. These economic impacts consist of costs of disposing unused chemicals and social costs of job losses.

The risks arising from granting an authorisation, which consider:

- the endpoints relevant for listing the substance in Annex XIV of REACH;
- the 3-30 directly exposed workers;
- the general population exposed at local scale (up to approximately 2 960 persons) and at regional scale (up to approximately 7 089 623 persons);
- that the risk of continued use as assessed by RAC may result in up to approximately 4.05×10^{-5}-4.05×10^{-4} expected additional cases of cancer cases among workers per year, corresponding to 1.22×10^{-4}-1.22×10^{-3} (over RP) and to 1.19×10^{-5} (cancer cases per year) in the general population, corresponding to 3.5×10^{-5} over the requested review period.
- the value of these expected additional cases has been monetised based on the willingness-to-pay methodology and corresponds to an estimate of €350-3 000 per year (€1 160-10 000 over the requested review period of 3 years).

Risks to human health and the environment 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 **3-year** review period is recommended for this use (until **21 September 2024).**

JUSTIFICATIONS

0. Short description of use

Monroe Czechia s.r.o. (the applicant) uses dichromium tris(chromate) (DCTC) in a treatment step of the auto-deposition coating[2] process of shock absorbers for automotive vehicles. The use is conducted at one site located in Hodkovice nad Mohelkou, Czech Republic. The auto-deposition coating process is also referred to as the "*ACC process*".

The applicant uses Bonderite 1087 RR, a mixture which contains 10-20 % (w/w) DCTC as well as 5-10 % (w/w) chromium trioxide (CrO_3). The annual consumption is 1-6 tonnes of Bonderite, representing 0.5-2 tonnes of DCTC.

The applicant is a downstream user of the mixture. For the use of CrO_3 in the mixture, the applicant is currently covered by the upstream Authorisation REACH/20/18. So, even if DCTC is used together with CrO_3 in the reactive rinse bath, CrO_3 is not relevant to this application for authorisation and is therefore not considered in this assessment.

For the current use of DCTC in the mixture, the applicant is not covered by any authorisation[3].

There are no consumer, further downstream uses, or article service life relevant to the use applied for.

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

DCTC is used, together with a surfactant, in the reactive rinsing step (one of the treatment steps of the autodeposition coating) in the manufacturing process of the shock absorber. After the coating process, the dampers are packaged and sent to the clients.

The main steps of the coating process consist of:

- Manual loading of the assembled shock absorbers onto the conveyor line, after delivery from the production line (no DCTC used).
- Pre-treatment of the uncoated shock absorber in a dedicated "tunnel" area (including degreasing, pickling and neutralising, with rinsing steps in between each of them). No DCTC handling in this step.
- Dipping of the pre-treated parts in the coating tank, followed by rinsing of the coated parts with de-ionised water (no DCTC used). This step is referred to as "Painting" in Figure 1.
- Transporting of the coated dampers on the conveyor belt into the reactive rinse tank for post-treatment. DCTC is used in this step. Cr(VI) from CrO_3 and DCTC within the Bonderite diffuses into the porous coated layer and reacts with oxidisable substances (steel or even certain groups of the polymer), forming Cr(III).
- Passing of the post-treated parts through the curing oven. Any remaining Cr(VI) is reduced to Cr(III) during this step.
- Manual unloading of the cured coated shock absorbers from the conveyor line to special trolleys and sending to post-production (labelling, packaging, etc.).

[2] Generally speaking, autodeposition coatings are thin, corrosion resistant coatings deposited in a chemical reaction with a metal surface. In this AfA, DCTC used in the reactive rinse step of the process provides the source of Cr that will impart the functionalities required for the shock absorber.
[3] The applicant's supplier has submitted an AfA for the use of DCTC but the applicant's use is not covered by that AfA.

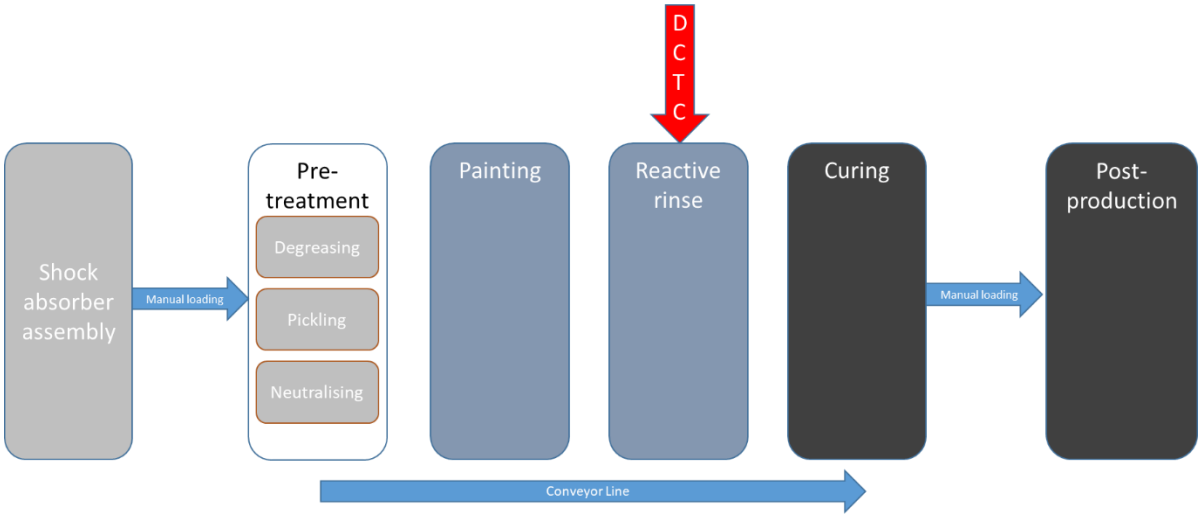

Figure 1: Schematic flow of the process of shock absorber autodeposition coating (ACC) line

In the reactive rinse bath, Cr(VI) from CrO_3 and DCTC within the Bonderite diffuses into the porous coated layer and reacts with oxidisable substances (steel or even certain groups of the polymer), forming Cr(III). In the oven, the residual amounts of Cr(VI) will react with the polymer forming Cr(III), so no Cr(VI) can be found on the surface of the treated parts, according to the applicant.

Table 1: Contributing scenarios presented in the use

Contributing scenario	**ERC/PROC**	**Name of the contributing scenario**	**Size of the exposed population**
ECS 1	ERC 6b	Use of DCTC in the post treatment (reactive rinse) stage of the ACC Line	Regional: 7 089 623 Local: 2 960
WCS 2	PROC 1	Delivery, storage and transfer of raw material	No. of workers: 1
WCS 3	PROC 2	Transfer of DCTC in continuous almost closed process	No. of workers: 1-10
WCS 4	PROC 13	Operation of ACC Line (Reactive Rinse Tank)	No. of workers: 1-10
WCS 5	PROC 28	Cleaning and Maintenance of equipment – Preventative Maintenance	No. of workers: 1-10
WCS 6	PROC 28	Cleaning and Maintenance of equipment – Corrective Maintenance	No. of workers: 1-10
WCS 7	PROC 15	Laboratory work	No. of workers: 1-10
WCS 8	PROC 9	Sampling	No. of workers: 1-10
WCS 9	PROC 1	Liquid Waste Management	No. of workers: 6
Total no. of potentially directly exposed workers			3-30*

**the exact number of potentially exposed workers is known to RAC but claimed confidential by the applicant in order not to allow conclusions on the size/capacity of the plant. Some of the workers may perform combined tasks, for example WCS 2 and 9, WCS 3 and 4, WCS 5 and 6, WCS 7 and 8.*

WCS 2 Delivery, storage and transfer of raw material (PROC 1)

Drums containing Bonderite solution (10-20 % DCTC according to the suppliers' Safety Data Sheet) are stored in a dedicated, dry, covered, cool and secure storage area of the warehouse,

with restricted access through a locked door/gate. Drums are clearly labelled according to CLP and are not opened during delivery and storage. Bonderite drums are transported from the warehouse to the relevant production area using a forklift and stored closed inside a fenced area until use. Empty drums are closed and transferred to the solid waste collection area.

There is no potential exposure for workers to Cr(VI) during normal operating conditions. Maximum one worker per shift is involved in this activity.

WCS 3 Transfer of DCTC in continuous process (PROC 2)

Prior to transfer, a charging lance and a splash guard are manually inserted into the Bonderite drum and the opening to the drum is then sealed. When the reactive rinse bath of the ACC Line needs to be filled, the solution is automatically charged via a dosing pump.

The only potential exposure for workers to Cr(VI) is during the coupling and de-coupling of the lance to the drum (maximum 5 minutes). 1-10 workers (across all shifts) are involved in this activity.

WCS 4 Operation of ACC Line (Reactive Rinse Tank) (PROC 13)

Uncoated parts are manually loaded and unloaded from racks at a separate station area and fed by a conveyor system through the surface treatment system. After the surface pre-treatment and the ACC coating process, the parts are rinsed with de-ionised water misting before passing to the reactive rinse tank[4]. Parts are dipped into the open reactive rinsing bath (containing DCTC) and transported by the conveyor system to the oven where they are dried and cured. Except from the curing step, the process is automated and carried out at room temperature.

The potential exposure for workers to Cr(VI) can occur during the visual inspection of the reactive rinse bath (5 minutes every 2 hours). Workers operating the overall ACC line are located at a distance higher than 3 meters aside from the loading and unloading of the parts. 1-10 workers (across all shifts) are involved in this activity.

WCS 5 Cleaning and Maintenance of equipment - Preventative Maintenance (PROC 28)

Preventative maintenance on the ACC line is carried out annually, during summer shutdown. All equipment, including reactive rinse bath, is drained and cleaned. The waste is collected and disposed of as hazardous waste. Then the equipment is washed and left to dry for 3-4 hours prior to maintenance activities. The wastewater from the rinsing is collected in special containers and sent off-site for treatment in the same way as the content of the reactive rinse bath.

The preventative maintenance tasks that can be carried out - described by the applicant at RAC's request for clarification - consist mainly of:

- visually checking of the dosing pumps (e.g. to identify possible leaks during operation)
- checking the misting zone and the direction of the blow off nozzle, the speed of the conveyor, the correct operation of hydraulic mixing equipment (visually and by assessing the noise during its operation)
- checking the flow rates, rinsing the flowmeters and keeping records
- replacing of the equipment or spare parts in case of breakdown or malfunction (e.g. dosing pump).

[4] The information in the CSR seems to indicate that the rinsing with de-ionised water misting is located between the reactive rinse tank and the curing oven. However, in their response to RAC questions, the applicant clearly states that the reactive rinse tank is the last step and is located just in front of the curing oven.

The estimated exposure time for workers to Cr(VI) is considered to be maximum 30 minutes. 1-10 workers (across all shifts) are involved in this activity.

WCS 6 Cleaning and Maintenance of equipment - Corrective Maintenance (PROC 28)

The corrective maintenance activities arise when maintenance is required to fix an issue that cannot be delayed until the next preventative shutdown maintenance program.

Prior to maintenance all equipment is drained and cleaned (where possible) and the waste is collected and disposed of as hazardous waste, same as described in WCS 5.

The estimated exposure time for workers to Cr(VI) is considered to be maximum 30 minutes, and these tasks are expected to be less frequent than the tasks described in WCS 5, owing to the preventative maintenance programme in place. 1-10 workers (across all shifts) are involved in this activity.

WCS 7 Laboratory work (PROC 15)

The laboratory activity consists of the analysis of quality of the reactive rinse water (containing DCTC). It is carried out in the in-house laboratory, under a fume cupboard. The wastewater generated during this activity is collected in an IBC and directed to the on-site WWTP and the solid waste is disposed of as hazardous waste.

The estimated exposure time for laboratory workers to Cr(VI) is considered to be approximately 5 minutes, one time per month. 1-10 workers (across all shifts) are involved in this activity.

WCS 8 Sampling (PROC 9)

The operator takes a 0.1 L sample from the reactive rinse tank using a beaker on a dipping rod. The sample is directly transferred to a secure closed container and transported to the laboratory within secondary containment, for quality analysis (see WCS 7). After testing, the sample is returned to the bath. 1 mL of sample is disposed of from analysis, so approximately 500 mL per year (assuming 250 days per year of operation) of wastewater containing 20-30 % Cr(VI) are sent to the on-site WWTP.

The estimated exposure time for sampling operators to Cr(VI) is considered to be approximately 1-5 minutes, twice per day. 1-10 workers (across all shifts) are involved in this activity.

WCS 9 Liquid Waste Management (PROC 1)

Wastewater containing Cr(VI) management includes on-site wastewater treatment and/or disposal as a hazardous waste by a licensed contractor according to applicable regulations.

The on-site wastewater treatment plant primarily handles wastewaters from the hard chrome plating activities performed at the site but not covered by this application for authorisation. The wastewaters generated during the laboratory analysis (see WCS 7 and 8) are collected and treated at the on-site WWTP (reduction of Cr(VI) to Cr(III), neutralisation, precipitation and filtering) prior to discharge to surface water. Other liquid wastes are collected and sent off-site for treatment.

The on-site WWTP process is automated and monitored to ensure the minimisation of the chromates concentration in wastewater prior to discharge. Wastewater from the process (e.g. filter press) or treated wastewater containing chromates above the permitted limit are returned to the start of the wastewater treatment process.

There is no potential exposure for workers to Cr(VI) during normal operating conditions. 6 workers are involved in this activity.

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

DCTC is used in the reactive rinsing step to provide corrosion resistance, chemical resistance, and thermal resistance to the shock absorbers. In addition, the reactive rinsing step where DCTC is used strengthens the adhesion between coating and the substrate, enhancing the overall durability of the products.

Shock absorbers must comply with the specifications set up by the automotive industry, as described in section 4.2.

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

Products made with the Annex XIV substance are shock absorbers for automotive vehicles.

Shock absorbers consist of a pressure cylinder, which contains the oil and piston[5]. These devices are used in vehicles to control the impact and the rebound movement of the vehicles' springs[6] and suspension. Therefore, they ensure that the vehicle's tyres are in contact with the road surface at all times.

The applicant supplies different types of shock absorbers to both EU and non-EU customers.

1. Operational Conditions and Risk Management Measures

The overall operational conditions are as follows:

- Annual use amount at the sites: 1-6 tonnes Bonderite (containing 0.5-2 tonnes of DCTC)
- Number of days of release per year: 250 working days
- Concentration used: 10-20 % of DCTC in mixture
- Physical form of the substance: liquid at 20 °C
- Cr(VI) Releases: Water - Local release rate: 6×10^{-12} kg/day; 1×10^{-2} kg/year
  Air - Local release rate: 4.20×10^{-5} kg/day; 1.5×10^{-9} kg/year
  Soil - Local release rate: no releases
- Process temperature: room temperature
- Vapour pressure of substance: 0.01 Pa.

1.1. Workers

The production process is automated, except for some tasks e.g., coupling/de-coupling of the suction lance to the Bonderite drums, loading/unloading of the parts that are performed manually. Auxiliary activities such as sampling, laboratory work, maintenance and cleaning activities include manual tasks.

The operational conditions (OCs) and risk management measures (RMMs) implemented in each

[5] https://www.monroe.com.au/trade-corner/tech-info/shock-absorbers/what-shock-absorbers-do.html
[6] Vehicles springs and shock absorbers are part of the car's suspension system.

WCS, and their effectiveness as described by the applicant, with respect to the hierarchy of control, are summarised in Table 2.

In addition, the following RMMs are implemented:

Technical Risk Management Measures

- General ventilation with an ACH of approximately 3.
- High level of containment, except for short term activities e.g. sampling, coupling/de-coupling of the suction lance during transfer of the Bonderite.
- Restricted access via a locked door.

Organisational Risk Management Measures as described by the applicant

- Relevant good practice guides for Uses of Cr(VI) produced by the CTAC Consortium[7] available
- Good Practice Sheets & Safety Data Sheets (SDSs) available to workers.
- Design closed system to allow for easy maintenance.
- Control staff entry to work area.
- All equipment well maintained.
- Continuous monitoring of the general ventilation (via central control panel) and regular maintenance (twice per year changing of filters and belt pulley inspection, once per year external control of electric regulation system and gas burner).
- Any spill of DCTC during normal operation conditions treated using an appropriate spill kit. All waste resulted is collected disposed of as hazardous waste via a certified company.
- Good standard of personal hygiene.
- Management processes in place to check that the RMMs are correctly used, and OCs are followed.
- Procedures and training for emergency decontamination and disposal.
- Permit to work for maintenance activities.
- Recording of any near miss situations.
- Regular cleaning of equipment and work area.
- Training of staff on good handling practice.
- Adequate supervision.

Personal Protective Equipment (PPE)

The workers are wearing mandatory PPE, according to their activities (see Table 2 below). Standard PPE for all workers consists of:

- Professional work clothing (i.e. trousers, jackets, overalls, arm gauntlets) which are removed after work and are regularly cleaned.
- Safety shoes
- Safety glasses / goggles (sealed to face)
- Protective butyl or nitrile gloves
- Reusable full face or half face mask with ABEK1 + P3R filters. RPE is used in accordance with standard procedures for use and maintenance, including procedures for fit testing of RPE, applied in accordance with relevant standards.

In addition, the applicant mentioned in the CSR and confirmed in their response to RAC's questions, that all workers working with Cr(VI) and personnel at the chrome neutralisation plant (WWTP) participate in a medical surveillance programme, according to national

[7] https://jonesdayreach.com/substances/

requirements. The examinations are performed once per year in terms of urine and blood, every 2 years for ear, nose and throat examination and every 5 years for X-ray heart and lungs examination, by a medical provider in Liberec. The results are confidential and are returned to the on-site physician, who provides a written medical opinion to the applicant's management, including the permit/restriction for work.

The applicant mentioned that the results of the biomonitoring programme were not presented due to confidentiality reasons. The applicant also mentioned that there have been no breaches of the Czech Republic's national limits for Cr(VI) in urine (0.030 mg/g Creatinine/0.065 µmol/mmol Creatinine) and no adverse findings presented by workers during the annual medical assessment within the last 10 years.

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

Contributing scenario	**Concentration of the substance**	**Duration and frequency of exposure**	**Engineering controls** (e.g. containment, segregation, automation, LEV) **+ effectiveness as stated by the applicant**	**PPE** (RPE and Skin protection used) **+ effectiveness as stated by the applicant**	**Organisational controls** (access control, procedures, training)
ECS 1 Use of DCTC in the post treatment (reactive rinse) stage of the ACC Line ERC 6b	10-20 %				
WCS 2 Delivery, storage and transfer of raw material PROC 1	10-20 %	Duration: ≤ 15 min./day Frequency: -	Closed system (minimal contact during routine operations) General ventilation (3 ACH*)	- protective goggles, protective gloves, safety shoes, safety clothing	- raw material delivered in sealed, adequately labelled drums - designated locked storage area - opened drums carefully resealed and kept upright - access restricted to authorised personnel only - safety training - specific hygiene instructions
WCS 3 Transfer of DCTC in continuous almost closed process PROC 2	10-20 %	Duration: Max. 5 min. Frequency: -	Closed system except for the coupling and de-coupling of the suction lance Semi-automated process, suction lance, splash guard to avoid leakages General ventilation (3 ACH*)	- protective goggles, protective gloves, safety shoes, safety clothing/footwear, face mask against splashing, RPE APF 20, 95 % effectiveness	- access restricted to authorised personnel only - safety training - specific hygiene instructions
WCS 4 Operation of ACC Line (Reactive Rinse Tank) PROC 13	10-20 %	Duration: 5 min. (visual inspection) / 480 min.	Automated process except the loading and unloading of the parts Open reactive rinse tank General ventilation	- protective goggles, protective gloves, safety acid-resistant clothing/footwear, RPE APF 20, 95 %	- access restricted to authorised personnel only, - > 3 metres distance from the production line (partial personal enclosure without ventilation (30 %

		Frequency: every 2 hours (visual inspection of the ACC line)/daily	(3 ACH*) Ventilation at the curing oven (500 m^3/h)	effectiveness (during visual inspection only)	effectiveness)) - safety training - specific hygiene instructions
WCS 5 Cleaning and Maintenance of equipment - Preventative Maintenance PROC 28	0.1-0.5 %	Duration: 30 min. Frequency: once per year	General ventilation (3 ACH*)	- protective goggles, protective gloves, safety acid-resistant clothing/footwear, RPE APF 20, 95 % effectiveness	- risk assessment and permit to work in place - access restricted to authorised personnel only, - safety training - specific hygiene instructions
WCS 6 Cleaning and Maintenance of equipment - Corrective Maintenance PROC 28	10-20 %	Duration: 30 min. Frequency: when needed	General ventilation (3 ACH*)	- protective goggles, protective gloves, safety acid-resistant clothing/footwear, RPE APF 20, 95 % effectiveness	- risk assessment and permit to work in place - access restricted to authorised personnel only, - safety training - specific hygiene instructions
WCS 7 Laboratory work PROC 15	10-20 %	Duration: max. 5 min. Frequency: once per month	General ventilation (3 ACH*) Fume cupboard, 99 % effectiveness	- protective goggles, protective gloves, safety acid-resistant clothing/footwear, RPE APF 20, 95 % effectiveness	- access restricted to authorised personnel only, - safety training - specific hygiene instructions
WCS 8 Sampling PROC 9	10-20 %	Duration: max. 5 min. Frequency: once per day	General ventilation (3 ACH*)	- protective goggles, protective gloves, safety acid-resistant clothing/footwear, RPE APF 20, 95 % effectiveness	- access restricted to authorised personnel only, - safety training - specific hygiene instructions
WCS 9 Liquid Waste Management PROC 1	100 %	Duration: ≤ 15 min./day Frequency: -	Closed system (minimal contact during routine operations) Automated process General ventilation (3 ACH*)	- protective goggles, protective gloves, safety acid-resistant clothing/footwear	- access restricted to authorised personnel only, - safety training - specific hygiene instructions

** Calculated based on the air volume recycled by the general ventilation in the production building and the calculate total volume of the building*

In response to RAC's question for clarification on the type of the ventilation over the reactive rinse bath, the applicant explained that there is no exhaust ventilation in place, but there is a ventilation at the curing oven (extraction ventilator, approximately 500 m^3/h removed from the oven), which produces a slight air current above the reaction rinse bath towards the entrance of the oven and reduces the air flow over the sides of the reactive rinse bath.

RAC notes that in case of preventative maintenance, the duration of some tasks can be longer than 30 minutes, in case of malfunction or breakdown. The applicant clarified in a response to RAC's question that such situations are rare, generally do not require long time for repair due to the specifics of the process, and that 30 minutes is a typical duration. The applicant also underlined that worker's exposure to Cr(VI) during these tasks is expected to be low, as the equipment is washed and left to dry for 3-4 hours before any maintenance activity is undertaken.

In addition, a comparison with the OCs and RMMs described in the CSR of the supplier's AfA for DCTC[8] including the relevant differences in the applicant's site was presented for each of the WCSs. The main differences highlighted are:

- for *WCS 3 'Transfer of DCTC in continuous almost closed process'*, open transfer of the liquid mixture was considered by the supplier, and not a contained process as used on the applicant's site,
- for *WCS 5 and 6 'Cleaning & Maintenance of equipment – Preventative Maintenance',* respectively *'Corrective Maintenance',* a duration of 60 minutes and the bath still full was considered by the supplier, comparing with 30 minutes, respectively drained and cleaned bath in the applicant's CSR. The results in the supplier's application include a combination between the worker's exposure during surface treatment using DCTC and the cleaning and maintenance activities, that may lead to an overestimation of the inhalation exposure,
- for *WCS 7 and 8 'Laboratory work/Sampling',* the use of a fume cupboard and of the RPE was not considered in the supplier's CSR, comparing with the applicant's site, and a duration of 30 minutes for the sampling tasks was consider by the supplier, comparing with 5 minutes in the applicant's CSR.

1.2. Consumers

Not relevant.

1.3. Environment/Humans via the environment

Air

The ACC line is not equipped with any dedicated technological system to collect, channel and treat the Cr(VI) emissions produced by the reactive rinse bath during normal plant operation. In the ACC area there is a general ventilation system that achieves 3 air changes per hour (4 716.8 × 3 m^3/h). The electric motors of the main air make-up units are monitored automatically, through the plant's central control panel. The air exchange is verified by calculation of the incoming air from the general ventilation system in place.

[8] The applicant's supplier has submitted an AfA for the use of DCTC but the applicant's use is not covered by that AfA.

Water

The ACC process does not directly generate wastewater. The wastewaters generated during the laboratory analysis (see WCS 7 and 8) are collected and treated at the on-site WWTP, which reduces Cr(VI) to Cr(III) via the addition of sodium bisulphite prior to any discharge. The treatment process results in a factor of 10^4 reduction in Cr(VI) concentrations, up to levels that are below legal and company limits. The treated wastewater from the site is discharged to the Mohelka River. Other Cr(VI) containing liquid wastes are collected and disposed of as a hazardous waste by a licensed contractor.

Soil

The applicant stated that there are no emissions to soil from the use applied for.

Waste (other than wastewater)

Any waste that may contain Cr(VI) is classified as hazardous waste then collected and disposed of by a licenced contractor. Similarly, the sludge containing Cr(VI) which is formed after on-site WWTP processing, is treated with lime, pressed, classified as hazardous waste and shipped off-site for treatment via solidification. Wastewaters generated by rinsing prior to maintenance activities are collected in special containers and sent off-site for treatment. Lastly, the content of the reaction rinse bath is annually shipped off-site for neutralization and disposal as hazardous waste by a licenced waste contractor.

Table 3: Environmental RMMs – summary

Compartment	RMM	Stated effectiveness
Air	N/A	N/A
Water	On-site WWTP	10^4 reduction in concentrations of Cr(VI)
Soil	N/A	N/A

1.4. RAC's evaluation on the OCs and RMMs

Detailed information about the operational conditions (OCs) and risk management measures (RMSs) in place has been presented in the CSR and additional clarification has been provided in responses to RAC's questions.

RAC takes note of the applicant's commitment to replace the ACC line with a new Cr(VI)-free process line by September 2024.

Workers

The RMMs described in the CSR and in the responses to RAC's questions include mainly: automation of the process, restricted access, distance from the bath, and personal protective equipment (PPE) such as the use of RPE (full face or half face mask with ABEK1 + P3R filters for the tasks with high potential exposure to Cr(VI)), safety gloves, safety goggles, safety acid-resistant clothing/footwear, etc. Organisational measures (regularly training, supervising, procedures for fit testing of the RPE, applied in accordance with relevant standards) are also included.

Regarding the RMMs to reduce workers' exposure, RAC has identified shortcomings due to the lack of dedicated local exhaust ventilation or other exhaust system above the reactive rinse bath, and significant reliance on RPE for the tasks with potential exposure to Cr(VI).

Even though the applicant has mentioned that the worker's exposure to Cr(VI) can be

considered low due to the limited interaction with the reactive rinse bath, low energy process, slow horizontal speed of the dipping process (which minimises the aerosol generation), RAC has some concerns regarding the OCs and RMMs in place with respect to the hierarchy of control principles.

Environment

Related to the releases of Cr(VI) to the environment (air), the CSR does not describe any air treatment system. In response to RAC's questions, the applicant confirmed that no such system is in place and justified this by the fact that the bath is operated at room temperature and therefore there is no increased generation of vapour. Again, the static monitoring performed 20 cm above the side edge in the middle of the reactive rinse tank was used by the applicant as an argument to support the appropriateness of the described OCs and RMMs.

RAC noted that in the CSR, the emissions to air that occur from the rinse bath are indicated as fugitive and requested the applicant to further clarify what they meant. The applicant explained that the emissions are described as "fugitive" in the sense that there is no dedicated LEV or other exhaust system over the ACC line. RAC considers it is inappropriate to define the releases as fugitive because they are not 'leaks' or other 'irregular releases of gases or vapours' e.g. from a pressurized containment. **RAC notes that there are no risk management measures in place to guarantee the minimization of the releases of Cr(VI) to the air.**

According to the applicant, the only emissions to water derive from the treatment at the on-site WWTP of wastewaters generated during the laboratory analyses. After treatment these wastewaters are discharged into the Mohelka River. RAC notes that according to the applicant, the WWTP treatment minimizes the levels of Cr(VI) through a reductive process which is reported to decrease the levels of Cr(VI) up to 104 times before any discharge.

Although the applicant elaborated further in their responses to RAC's questions on the shortcomings identified above, RAC considers that the RMMs do not follow the hierarchy of control principles and concludes that RMMs and OCs implemented as presented in the application are not appropriate and effective to guarantee the minimization of workers' exposure and in limiting the risk for humans via the environment (air compartment).

1.5. RAC's conclusions on the OCs and RMMs

Overall conclusion

Are the operational conditions and risk management measures appropriate[9] and effective[10] 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

[9] '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.

[10] '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.

RAC considers that the RMMs do not follow the hierarchy of control principles and is of the opinion that RMMs and OCs implemented as presented in the application are not appropriate and effective in limiting the risks for the workers and for humans via the environment (air compartment).

Additional conditions for the authorisation and monitoring arrangements for the authorisation are proposed. These are listed in sections 7 and 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.

2. Exposure assessment

2.1. Inhalation exposure

For the inhalation exposure assessment, the applicant used qualitative assessment, measured data and modelling using the Advanced REACH Tool (ART, version 1.5).

A qualitative assessment was presented for *WCS 2 'Delivery, storage and transfer of raw material'* and *WCS 9 'Liquid waste management'*, as there is no potential for exposure to Cr(VI) due to closed system with minimal contact for workers.

The qualitatively exposure estimate of 0 µg Cr(VI)/m³ was used for risk characterisation.

Monitoring

No personal measurements are available.

Static air exposure measurements were performed quarterly during 2019 and 2020, at 20 cm above the middle of the reactive rinse bath and were presented by the applicant in an Annex of the CSR. These results are reported in Table 6 below. The sampling time was minimum 6 hours (360 minutes) and the analytical method for hexavalent chromium ID-215[11] with a limit of quantification is 0.2 µg/m^3 was used.

A 90th percentile value of 0.371 µg Cr(VI)/m^3 from 8 static measurements (maximum value 0.42 µg Cr(VI)/m^3), corrected for the use of RPE (effectiveness 95 %) and expressed as 8-h TWA was considered by the applicant for the risk characterisation for WCSs 3, 6 and 8.

The same 90th percentile value of the static measurements was used for risk characterisation in case of WCS 4 '*Operation of ACC Line (Reactive Rinse Tank)',* but no correction for the use of RPE was applied.

For the inhalation exposure assessment based on static measurements only, the applicant mentioned that a worst-case approach can be assumed, due to the following reasons:

- the workers are situated at least 3 meters away from the Cr(VI) emission source and the monitoring point
- the duration of the tasks with potential exposure to Cr(VI) is short (5-30 minutes), and no correction for the frequency of these tasks was made
- the use of RPE was not considered for *WCS 4 'Operation of ACC Line (Reactive Rinse Tank)',* even though RPE is used during the visual inspection along the reactive rinse bath (5 minutes every 2 hours)
- the measured data collected does not distinguish whether the Cr(VI) present in the air comes from DCTC or from CrO_3, so an overestimation of the exposure to Cr(VI)

[11] https://www.osha.gov/sites/default/files/methods/id215_v2.pdf

attributable to DCTC only is probable.

Modelling

The applicant provided modelled data for the WCSs 3-8. The modelled exposure was estimated using ART 1.5 (90th percentile values of the data) as a second-tier model and the results are given as Cr(VI) concentration and expressed as 8 h TWA.

The input data is provided in the CSR and the output of the ART 1.5 model is presented in a separate excel document.

For WCSs 3 and 5-8 the modelled exposure estimate is based on near field emission source, as the tasks are performed nearby the bath.

For WCS 4, the modelled exposure estimate is based on far field emission source, and on activities with relatively undisturbed surfaces (no aerosol formation) as activity class, due to the limited interaction of the workers with the reactive rinse bath (maximum 5 minutes, every 2 hours), the low energy process, and slow horizontal speed of the dipping process.

For WCSs 3-8 the applicant also presented a comparison with the modelled or measured inhalation exposure data provided in their supplier (Authorisation holder) CSR.

The results of the inhalation exposure assessment, also including the comparison with the supplier's modelled and measured data are presented in Table 4. Figures in bold are considered for risk characterisation.

2.2. Dermal exposure

Dermal exposure has not been assessed as exposure to Cr(VI) compounds through the skin is not expected to present a cancer risk to humans (RAC27/2013/06 Rev 1).

2.3. Biomonitoring

Biomonitoring (chromium in urine and blood) is performed annually for all workers with potential exposure to Cr(VI) as part of the medical surveillance programme, by an external medical provider.

The applicant mentioned that the results of the biomonitoring programme were not presented due to confidentiality reasons. The applicant also mentioned that there were no breaches of the Czech Republic's national limits for Cr(VI) in urine (0.030 mg/g Creatinine/0.065 µmol/mmol Creatinine, samples taken at the end of shift at the end of the work week) and no adverse findings presented by workers during the annual medical assessment within the last 10 years.

Table 4: Summary of exposure information –inhalation

Contributing scenario	**Method of assessment**	**Exposure value (8-h TWA) (µg Cr(VI)/m³)**	**Exposure value corrected for PPE (µg Cr(VI)/m³)**	**Exposure value corrected for PPE and frequency* (µg Cr(VI)/m³)**
WCS 2 Delivery, storage and transfer of raw material	Qualitative	0	-	0
WCS 3 Transfer of DCTC in continuous almost closed process	Measured data (n = 8 static) 90th percentile	3.86×10^{-3} (0.371 measured**)	1.93×10^{-4} (RPE factor 0.05[a])	**1.93×10^{-4}**
	Modelled data ART 1.5, 90th percentile	0.520	2.60×10^{-2} (RPE factor 0.05[a])	2.60×10^{-2}
	Comparison to the supplier Modelled data, ART 1.5, 90th percentile	*0.760*	-	**-**
WCS 4 Operation of ACC Line (Reactive Rinse Tank)	Measured data (n = 8 static) 90th percentile	0.371	Not corrected for RPE	**0.371**
	Modelled data ART 1.5, 90th percentile	0.480	Not corrected for RPE	0.480
	Comparison to the supplier Measured data, 90th percentile	*1.26*	-	-
WCS 5 Cleaning & Maintenance of equipment – Preventative Maintenance	Modelled data ART 1.5, 90th percentile	7.60×10^{-3}	3.80×10^{-4} (RPE factor 0.05[a])	**3.80×10^{-4}**
	Comparison to the supplier Measured data, 90th percentile	*1.26*	-	-
WCS 6 Cleaning & Maintenance of equipment – Corrective Maintenance	Measured data (n = 8 static) 90th percentile	2.32×10^{-2} (0.371 measured**)	1.16×10^{-3} (RPE factor 0.05[a])	**1.16×10^{-3}**
	Modelled data ART 1.5, 90th percentile	1.50	7.50×10^{-2} (RPE factor 0.05[a])	7.50×10^{-2}
	Comparison to the supplier Measured data, 90th percentile	*1.26*	-	-
WCS 7 Laboratory work	Modelled data ART 1.5, 90th percentile	0.12	6.0×10^{-3} (RPE factor 0.05[a])	**6.0×10^{-3}**
	Comparison to the supplier Modelled data, ART 1.5, 90th percentile	*0.65*	-	
WCS 8 Sampling	Measured data (n = 8 static) 90th percentile	3.86×10^{-3} (0.371 measured**)	1.93×10^{-4} (RPE factor 0.05[a])	**1.93×10^{-4}**
	Modelled data ART 1.5, 90th percentile	5.1	0.26 (RPE factor 0.05[a])	0.26

	Comparison to the supplier Modelled data, ART 1.5, 90th percentile	*0.65*	-	-
WCS 9 Liquid Waste Management	Qualitative	0	-	0

**: no correction for frequency was made by the applicant*
***: 90th percentile value from 8 static measurements, prior to any correction*
a: respiratory protective equipment adjustment factor (effectiveness 95 %) = 0.05

Combined exposure

According to the applicant, workers can perform some combined site-specific tasks during the lifecycle of DCTC present in the Bonderite mixture, but a simple sum of the monitoring and modelled data for the different WCSs will lead to an unrealistic overestimate of the exposure.

Therefore, the highest exposure estimates based on measured data were used by the applicant for the workers who carry out more than one WCS, to assess the combined exposure. The results are presented in Table 5.

Table 5: Combined exposure data

Contributing scenario	**Route of exposure**	**Worst Case Exposure Estimate (µg (Cr(VI))/m^3)**
WCS 3, 4 Charging/Production Line	Inhalation	0.371*
WCS 5, 6 Maintenance & Cleaning	Inhalation	1.16×10^{-3}
WCS 7, 8 Laboratory/Sampling	Inhalation	1.93×10^{-4}
WCS 2, 9 Storage/WWTP	Inhalation	0

**: no RPE*

2.4. Environmental releases

DCTC and CrO_3 are present in the Bonderite mixture used by the applicant in the reactive rinse bath. The measured data collected by the applicant does not distinguish whether the Cr(VI) present in the emissions comes from DCTC or from CrO_3. Therefore, the emissions estimated are likely to be an overestimation of the emissions of Cr(VI) attributable to DCTC only.

Air

The applicant calculated the emissions to air taking into account the measured concentration 20 cm above the surface of the reactive rinse bath and considering the air changes in the reactive rinse bath (ACC) area guaranteed through the basic general ventilation without any RMMs.

The concentration above the rinse bath is measured every 3 months since 2019; the results are shown in Table 6.

Table 6: Measurements above the reactive rinse bath

Year	Quarter	Location	Result (µg Cr(VI)/m³)	Monitoring method
2019	Q1	Static monitoring - 20 cm above reactive rinse bath	0.34	Hexavalent Chromium Method no: ID-215 (version 2)
	Q2		0.34	
	Q3		0.42	
	Q4		0.35	
2020	Q1		0.34	
	Q2		0.23	
	Q3		0.21	
	Q4		0.23	
		90th Percentile	**0.371**	

Concentrations in air as well as indirect human exposure via the environment are modelled using EUSES 2.1.2. Point source emission data (the 90th percentile of the measured data above the rinse bath) were provided for Hodkovice and these data were used to estimate the average concentration in air 100 m from the point source. This estimate is used for the assessment of Humans via the Environment.

Emissions were calculated with the following equation:

Emission (per hr) = (air volume in ACC area × ACH) × Monitored concentration of Cr (VI) in ACC

Where:

- ACC air volume: 4 716.8 m^3 (32 m × 22 m × 6.7 m)
- 3 air changes per hour (ACH)
- 8 hours operating day
- conc. Cr(VI): 0.371 µg/m^3 (90th percentile of monitored concentration)

A release rate of 4.20×10^{-5} kg/d, resulting from the measured concentration and the air flow rate, was applied to estimate the environmental concentration and exposure of human via the environment with the EUSES model.

The corresponding air concentration at 100 meters from point source is equal to 8.00×10^{-6} µg/m³. This concentration has been used to estimate the exposure of Hodkovice population.

The exposure is also estimated at the regional scale, considering that 100 % of the EU tonnage is used in the region and assuming that there are no releases to water and soil. According to the applicant, the resulting exposure concentration for human via inhalation is 4.58×10^{-12} µg/m^3 (corresponding to a risk level of 1.33×10^{-13}). For the oral route, the resulting level of exposure via food consumption is 7.52×10^{-8} µg/kg bw/day (corresponding to a risk level of 6.02×10^{-11}). This daily dose does not take into account the contribution of drinking

water.

Water

There are no wastewaters generated by the normal operation of the coating process. However, the wastewaters generated during the laboratory analyses are collected and treated in the on-site WWTP before being discharged into the Mohelka River.

The on-site wastewater treatment plant primarily handles wastewaters from the hard chrome plating activities performed at the site (not covered by this application for authorisation). Direct measurements of the Cr(VI) concentration in the wastewaters released are provided for the years 2018, 2019 and the first half of 2020. The 90th percentile value calculated for the Cr(VI) concentration in the data set was 0,04 mg/L. The applicant indicated approx. 20 000 m^3/year the total discharge from the WWTP. The resulting discharge rate of Cr(VI) into water is around 0.06 kg/year. At RAC's request, the applicant provided further information on the quantity of Cr(VI) released annually attributable to the use applied for. According to the applicant's calculations approximately 2.5 × 10^{-6} % of the Cr(VI) emissions are attributable to the AAC activities i.e. a total of 1.5 µg Cr(VI) per year. The applicant considers that these releases can be considered negligible and therefore no assessment of humans via the environment due to emissions of wastewater has been carried out for the applied for use.

Soil

No soil emissions are reported.

Table 7: Summary of releases to the environment

Release route	**Release factor**	**Release per year** kilograms Cr(VI)	**Release estimation method and details**
Air	1.31 × 10^{-3} %	0.01	Based on measured data
Water	N/A	1.5 × 10^{-9}	Based on measured data
Soil	N/A	0	N/A

Table 8: Summary of exposure to the environment and humans via the environment

Parameter	**Local**	**Regional**
PEC in air (mg Cr(VI)/m^3)	8.00 × 10^{-9}	2.05 × 10^{-15}
Daily dose via oral route (mg Cr(VI)/kg bw/d)	Not relevant	7.52 × 10^{-11}

2.5. RAC's evaluation of the exposure assessment

Workers exposure

RAC notes that the inhalation exposure assessment is based on a qualitative assessment for WCSs 2 and 9, and on static measurements and modelling using ART 1.5 for the other WCSs. No personal measurements were made available.

RAC agrees with the applicant's conclusion that for *WCS 2 'delivery, storage and transfer of raw material'* and *WCS 9 'liquid waste management',* no exposure is expected due to the nature of the activities.

Workers can be exposed to Cr(VI) from DCTC and CrO_3 that are present in the Bonderite

mixture used by the applicant in the reactive rinse bath. Regarding potential exposure from other sources of Cr(VI), the applicant clarified at RAC's request that no interaction with the hard chrome plating line located in the same building is possible, as no employees work on both the AAC and the hard chrome plating lines. In addition, the hard chrome plating line is enclosed and requires limited worker's presence.

RAC notes that the exposure assessment is mainly based on static air exposure measurements, performed at 20 cm above the reactive rinse bath.

The 90th percentile value of the static measurements (0.371 µg Cr(VI)/m^3), expressed as 8-h TWA, and corrected for the use of RPE (effectiveness 95 %) was considered for the risk characterisation for WCSs 3, 6 and 8.

For WCS 4 '*Operation of ACC Line (Reactive Rinse Tank)'* the 90th percentile value of the static measurements was also used but the correction for the use of RPE was not applied by the applicant, to provide a worst-case assumption for the worker's exposure.

The applicant considers the use of static measured data as a worst case because in practice, workers are exposed to the monitored level of Cr(VI) for short periods of time while for the rest of the shift they are situated at least 3 meters away from the Cr(VI) emission source (and the monitoring point)

The applicant also presented modelled exposure estimates to support the measured data. The results of the modelling were not used for the risk characterisation, although higher values were estimated for WCSs 3, 4, 6 and 8.

The measured data (static measurements) were considered representative and preferred by the applicant as they are assumed to reflect actual conditions and exposure at the plant.

Generally speaking, the use of measurement data is also in line with the ECHA guidance on occupational exposure estimation, where it is explained that preference should be given to measured exposure data over modelled exposure estimates that have inherent uncertainties.

For *WCS 5 'Cleaning & Maintenance of equipment –Preventative maintenance'* and *WCS 7 'laboratory work'* the applicant presented only modelled data and this data was used for the risk characterisation.

In response to RAC's question for clarification, the applicant mentioned that no additional measurements (static or personal) were performed at the ACC production line. The applicant considers that a regular exposure monitoring programme is already in place (quarterly static measurements).

However, the applicant is committed to undertake a monitoring programme based on personal sampling for the workers who perform visual inspection of the reactive rinse line (1 worker per shift, 5 minutes every 2 hours).

RAC considers that the applicant's approach to use the 90th percentile value of static measurements above the reactive rinse bath is not representative for the range of tasks undertaken where exposure to Cr(VI) is possible and introduces uncertainties to the exposure assessment. Personal measurements performed in the worker's personal breathing zone should address these uncertainties.

In response to a SEAC question regarding the potential early implementation of a Cr(VI)-free alternative based on spray coating for part of the production, the applicant mentioned that the workers' exposure and emissions to air would not be reduced because the same DCTC concentration needs to be maintained in the reactive rinse bath. The only changes this would bring is a decrease in the number of workers involved in WCS 3 and 4 as well as a decrease of

the amount of DCTC used to refill the bath.

RAC takes note of the applicant's explanation and considers that there would not be significant differences in the emissions of Cr(VI) in the working hall and air, in the event that the coating of part of the production is shifted to spray coating line.

Regarding the comparison made by the applicant with modelled or measured inhalation exposure data of the supplier/Authorisation holder, RAC notes that values are lower in case of the applicant, due to the significant differences in the OCs and RMMs, as described in section 1.1 above.

Although the applicant has implemented annual biomonitoring campaigns, the biomonitoring data were not provided due to confidentiality reasons and not used in the exposure assessment. RAC considers that the data obtained or the general statement from the medical provider that chromium values are below the local applicable limit values should be included in any subsequent review report.

Humans via the environment

The applicant provided detailed information and justifications to substantiate their claim that the use applied for does not generate meaningful amounts of releases to water and that no assessment of humans via the environment due to emissions of Cr(VI) to the water compartment is necessary.

RAC acknowledges that the Cr(VI) emissions attributable to the AAC activities as calculated by the applicant (i.e. a total of 1.5 µg Cr(VI) per year) are indeed very small and that it can be assumed they are unlikely to have a meaningful impact on the general population. However, RAC is of the opinion that the applicant should continue the monitoring of emissions to water from the site (although mostly unrelated to the use applied for) to ensure that the assumption made holds and that the on-site WWTP functions appropriately.

The applicant used the results of the static air exposure measurements performed at 20 cm above the reactive rinse bath as the starting point to estimate the releases to the air. Chesar (EUSES) was then used to calculate the $PEC_{air,local}$ for the general population.

RAC considers that in the absence of measurement of actual releases to air, this approach allows a general estimation by proxy of the releases and that from this perspective, the assessment is based on site specific information. However, RAC is of the opinion that this approach is not necessarily representative of the actual releases from the site.

The applicant also provided an assessment of the exposure at the regional scale obtained with EUSES. RAC notes that the oral exposure level presented takes into account food consumption but that the contribution from drinking water is not considered. RAC also notes that the estimate of the exposure at the regional scale has been calculated with EUSES by using assumptions that are not well documented and thus cannot be verified. However, RAC notes that the EU risk assessment report (RAR) for Cr(VI) substances[12] states that "*releases of Cr(VI) from any sources are expected to be reduced to Cr (III) in most situations in the environment (…)*" and "*the impact of Cr(VI) as such is therefore likely to be limited to the area around the source*". Therefore, it seems reasonable to assume that the regional exposure is not particularly relevant.

2.6. RAC's conclusions on the exposure assessment

RAC considers that the workers' exposure assessment contains shortcomings due to the use

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

of 90th percentile value of static measurement data for the risk characterisation for most of the WCSs and the absence of personal measurement data. Personal measurements performed within the worker's personal breathing zone should address these shortcomings.

RAC considers that the exposure assessment of human via the environment contains shortcomings mainly due to the lack of measurement of actual releases to air.

RAC considers from the data provided in the CSR and the applicant's responses to RAC's requests, that it is difficult to conclude on the representativeness of the exposure assessment (for workers and HvE).

RAC acknowledges that the measured data collected by the applicant does not distinguish whether the Cr(VI) present in the air comes from DCTC or from CrO_3. Therefore, the exposure assessment for workers and human via the environment is likely to contain an overestimation of the exposure to Cr(VI) attributable to DCTC only.

The concerns in the exposure assessment lead to the proposal by the Committee to require further engineering controls and monitoring arrangements for the authorisation, as presented in sections 7 and 8.

3. Risk characterisation

To calculate the Excess Lifetime Risk (ELR) for lung and intestinal cancers, the applicant used the dose-response relationship derived by RAC for the carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1, agreed at RAC 27)[13].

3.1. Workers

The applicant conservatively assumed that all inhaled chromium trioxide particles are in the respirable range and contribute to lung cancer risk. Thus, an excess life-time lung cancer risk of 4×10^{-3} per µg Cr(VI)/m^3 for 40 years of exposure (8 h/day, 5 d/week) for workers was considered for the risk assessment.

In Table 9 the excess cancer risk estimation for workers is presented based on the exposure data in Table 5.

Table 9: Combined exposure and risk characterisation

Contributing scenario	Exposed population	Route	Exposure value corrected for PPE µg Cr(VI)/m^3	Excess risk*
WCS 3,4 Charging/Production Line	1-10	Inhalation	0.371	1.48×10^{-3}
WCS 5,6 Maintenance & Cleaning	1-10	Inhalation	1.16×10^{-3}	4.64×10^{-6}
WCS 7,8 Laboratory/Sampling	1-10	Inhalation	1.93×10^{-4}	7.73×10^{-7}

[13] For workers: excess life-time lung cancer risk of 4×10^{-3} per µg Cr(VI)/m^3 for 40 years of exposure (8 h/day, 5 d/week). For general population: excess lifetime lung cancer mortality risk of 2.9×10^{-2} per µg Cr(VI)/m^3 for 70 years (24 hours/day, 7 days/week).

** Estimated individual risk resulting from exposure*

3.2. Humans via the environment

The risk assessment for human exposure via the environment takes into account the inhalation of airborne residues of Cr(VI) at the local and regional levels. The applicant also presented risk level at the regional scale for the oral intake only accounting for food consumption.

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

Parameter	**Local**		**Regional**	
	Exposed population: 2 960		**Exposed population:** 7 089 623	
	Exposure	**Excess risk***	**Exposure**	**Excess risk***
Humans via the environment – Inhalation	8.00 × 10^{-6} µg Cr(VI)/m³	2.32 × 10-7	4.58 × 10^{-12} µg Cr(VI)/m3	1.33 × 10^{-13}
Humans via the environment – Oral	N/A	N/A	7.52 × 10^{-11} mg Cr(VI)/kg bw/day	6.02 × 10^{-11}

** Estimated individual risk resulting from exposure.*

3.3. Environment

Not applicable.

3.4. RAC's evaluation of the risk characterisation

RAC notes that the shortcomings related to the absence of personal measurement data for workers and of measurement of actual releases to air for human via the environment which have been discussed and addressed in the relevant sections above, are not likely to affect the risk characterisation significantly.

For human via the environment at the regional scale, considering that the regional exposure is not particularly relevant (as explained in section 2.5), the excess risks presented are such that they do not need to be further considered.

RAC notes that the likely overestimation acknowledged for the exposure assessment will lead to an overestimation of the risk levels.

3.5. RAC's conclusions on the risk characterisation

RAC considers that the application includes all relevant tasks and routes of exposure as well as endpoints and populations.

RAC notes that the highest calculated excess risk estimate for worker's combined exposure is **1.48 × 10^{-3}**. The excess cancer risk calculated for humans via the environment at the local scale, is **2.32 × 10^{-7} (lung cancer),** and at the regional scale **6.02 × 10^{-11} (intestinal cancer).**

There are no significant uncertainties in the characterisation of risks.

The identified shortcomings have been remedied by appropriately conservative assumptions in the calculation of the individual excess risk values.

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

4. Analysis of alternatives and substitution plan

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

The applicant has been searching for an alternative since 2019, to find a replacement to chromium trioxide (CrO_3) and, by extension, to DCTC.

In the analysis of alternatives, the applicant described the functionalities which need to be met by an alternative and these are reported in section 4.2 of the opinion. The applicant described both the standards that the final products need to meet and the tests which are used to verify products' compliance with those standards. The applicant also described a number of process parameters against which the alternatives were assessed, such as the curing temperature and efficiency of the process (e.g. no need to mask the parts which do not need to be coated).

In first place the applicant assessed the feasibility of the already operating spray line to coat the shock absorbers, which are currently treated in the ACC line. However, as detailed in section 4.2, due to both technical and economic reasons, as well as capacity related issues, this alternative was not finally included by the applicant among the shortlisted ones.

To identify potential alternatives, the applicant contacted suppliers of alternatives and performed desk research.

The applicant concluded that it was unlikely to find a drop-in chemical alternative and so decided to focus its efforts on two alternative technologies:

1. one new spray coating technique and

2. one dipping coating application.

According to the applicant, the preliminary laboratory tests performed on the two short listed alternatives were promising (notably with regard their ability to provide corrosion resistance to the shock absorbers).

In terms of economic feasibility, the initial analysis conducted by the applicant indicated that the operating costs of the two alternatives were similar to the ACC line, but that their implementation would, however, require substantial capital costs, as described in section 4.2 of the opinion.

While alternative 1 seems to be more promising when compared to alternative 2, the applicant indicated that it has not decided what the most preferable technology is. This was also confirmed by the applicant in the responses to SEAC's questions.

As explained by the applicant, once the preferred alternative is selected, the substitution activities to implement will commence, with the aim to complete the substitution by 21 September 2024[14].

Finally, the applicant has also assessed the technical and economic feasibility of the already operating spraying line which is located in the second building. However, based on both

[14] The applicant's timeline to replace DCTC is fully synchronised with the timeline for replacing chromium trioxide considering that both substances are used in the reactive rinse formulation.

economic and technical factors – described in section 4.2 – the applicant decided to drop this alternative from the list of shortlisted alternatives and so to focus its assessment on other alternative technologies based on the use of epoxy-based resins.

The applicant also presented a substitution plan, according to which the implementation of the selected alternative will be completed in approximately 3 years. However, SEAC notes that at this stage it is still not clear which of the above two alternatives will be finally selected by the applicant.

Once the alternative is selected, the applicant will implement the substitution plan in four phases. In the first one the applicant will conduct the validation of the new process. The applicant will negotiate with alternative's suppliers and install the new coating line, in the second and third phase respectively. In the final step, the shock absorbers coated with the new process will be validated to ensure their compliance with customers' specifications.

No information was provided during the third-party consultation on alternatives.

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

SEAC considers acceptable the applicant's methodology for assessing the potential alternatives as well as the described activities in the substitution plan.

In SEAC's view, the applicant has appropriately described the shortlisted alternatives and the technical criteria against which they need to be assessed. Therefore, SEAC finds credible the applicant's assessment of the economic feasibility of the two shortlisted alternatives, considering that the applicant has examined both the operating variable and fixed costs associated with the implementation of the two technologies.

SEAC also considers that the applicant has thoroughly described in the substitution plan the different planned activities, as well as indicated the time required for the implementation of each of them. SEAC considers the approach to the substitution plan to be appropriate.

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 at the date of the submission of the application for authorisation?

☒Yes ☐No

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

☒Yes ☐No

The applicant is using DCTC – together with chromium trioxide (CrO_3) – in the active rinsing step to provide several functionalities to the shock absorbers, notably in terms of corrosion, chemical, and thermal resistance. In addition to providing these functionalities, the active rinsing step is critical for strengthening the adhesion between the coating (of the coated parts) and the substrate and so contributing to the overall durability of the products during their service life.

The applicant explains that the above functionalities are critical for safety reasons. If the shock absorbers are not resistant to corrosive agents, chemicals and high temperature, their function would be compromised or could fail completely.

The applicant has been active in the assessment of the alternatives since 2019 to find an alternative to chromium trioxide (CrO_3) and so, by extension, to DCTC. The applicant's efforts are therefore focused on simultaneously replacing the use of both substances in the active rinsing step.

To be acceptable to the applicant, a technically feasible alternative need to:

1. provide corrosion and chemical resistance to the shock absorbers to ensure their durability through their whole service life,
2. ensure a good adhesion between the coating and the substrate, so that the coating remains attached to the substrate, and
3. prevent the deterioration of the coating from exposure to high temperature (thermal resistance).

Even though some Original Equipment Manufacturers (OEMs) might have some specific requirements, corrosion, and chemical resistance of the final products, as well as the adhesion functionality, are verified according to a number of standard tests, such as: Mercedes SAE's DBL 7381.12 ("*Coating of major passenger car components/body panels and other functional parts with high corrosive stress*")[15].

Regarding thermal resistance, the coating should be able to resist high temperatures[16], otherwise a poor thermal resistance would lead to the deterioration of the coating and so compromise the products' resistance to corrosive agents and chemicals.

Moreover, the applicant explained that the suitable alternative should not require the masking of components that do not need to be coated. According to the applicant, this is important to minimise the handling of the products and so avoid any possible risk to damage them during the coating process.

Finally, the alternative process should have a low curing temperature to avoid any damage of the heat sensitive components of the shock absorbers.

The applicant stated that a process which does not require masking of parts that do not need to be coated and which has a low curing temperature is faster, with less risk of damaging the products, and finally, less complex.

To identify a possible alternative, the applicant consulted the suppliers of potential alternative substances and technologies, performed literature review, and consulted ChemSec's Marketplace for alternatives to hazardous chemicals.

The applicant has also considered the possibility to temporarily replace DCTC with chromium trioxide (CrO_3) – which has an authorisation until September 2024. This option has been excluded by the applicant because of the hazardous properties of chromium trioxide (CrO_3) and because the switch to this "*short-term*" alternative would require the revalidation of all the products – to ensure that the new process using only chromium trioxide (CrO_3) meets the customers' requirements. According to the applicant this process would take at least one year, with little benefits considering that the applicant would have to repeat the validation a second time for all the products, once one of the two shortlisted alternatives to the mixture is

[15] https://atslab.com/wp-content/uploads/2019/03/MERCEDES-SAE-Automotive-Spec.pdf
[16] In the confidential version of the AoA the applicant provided the exact temperature to which the coating of shock absorbers is normally exposed to during the service life.

implemented.

After evaluating the potential alternatives, the applicant concluded that it was unlikely to find a drop-in chemical alternative and so focused its development efforts on two alternative technologies, based on the use of epoxy-based resins:

1. A spray coating technique and
2. A dipping coating application (KTL technology).

In the process involving the use of the first potential alternatives, a number of pre-treatment steps are followed before proceeding with the spray coating process. The coated articles are then usually cured in ovens at a temperature sufficient for the coating to create the necessary bonds that increase its adhesion to the substrate. In the confidential version of the application the applicant provides more details on how this process is conducted.

In terms of technical feasibility, the applicant has tested the alternative to assess whether it is able to provide the necessary technical functionalities. According to these preliminary laboratory tests, the alternative meets the critical parameters in terms of corrosion resistance and adhesion. Moreover, the curing can be carried out at a relatively low temperature. As reported in the AoA, this is an important factor because it means that an eventual implementation of this alternative technology would allow the applicant to the keep the current process sequence and so coat the already assembled shock absorbers. This also means that no major modifications to the current equipment would be required. However, the applicant explains that this technology requires the masking of parts that do not need to be coating and this makes the process lengthier and more complex, with more risk of damaging the products.

In terms of economic feasibility, the applicant explains that the operating costs of this alternative would be either lower or equivalent to the current method. However, the implementation of the alternative would require capital costs in the range of €5-15 million for the new equipment. The applicant also explains that the cost would be much higher if they decide to build a new plant to avoid any loss during the downtime needed for the installation of the alternative process. However, the applicant does not indicate that this required investment would make the alternative not economically feasible.

Finally, the applicant explains that this alternative process does not require the use of hazardous chemicals and that the materials used in this process are epoxy-based resins. Therefore, the applicant concluded that – in their view - the switch to this alternative would lead to an overall risk reduction.

The second shortlisted alternative is a dipping coating application (KTL)[17]. Preliminary tests performed by the applicant show that alternative is able to provide high corrosion resistance to the final products. However, the applicant has identified two major disadvantages associated with this process:

1. shock absorbers of vehicles of large dimensions (such as heavy trucks) are not compatible with this process due to their design and

2. the temperature applied during the curing process is higher than the acceptable value[18]. This means that the applicant could not continue to coat the already assembled shock absorbers (the integrity of some components would be compromised) but would have to modify the whole manufacturing process to accommodate the coating step of the cylinder, before the assembly of the final product.

[17] In the confidential version, the applicant provides more details on the process.
[18] Value reported in the confidential version of the application.

The applicant estimates that the implementation of this alternative would require investments in the range of €5-15 million. However, the applicant does not indicate that this required investment would make the alternative not economically feasible. The operating costs of this alternative are expected to be similar to the current process.

Finally, according to the applicant, the switch to this alternative would reduce the overall risk to human health compared to the current process, considering that eliminates the use of Cr(VI) substances and mainly relies on the use of epoxy-based resins.

The applicant is still to select the final alternative. However, as explained in the analysis of alternatives, Alternative 1 appears to be the most promising one between the two, considering that it can be used to coat already assembled shock absorbers and so requires less extensive modifications to the current equipment.

However, Alternative 1 is not yet available for commercial production because the applicant still needs to go through the necessary validation process to confirm that the products meet the customers specifications.

In addition to considering the above alternatives, the applicant has also mentioned in the AoA the possibility to switch to the SVHCs free spray coating line, which is already operating in the second building on the same site. Even if part of the production is validated on both lines, the applicant has finally excluded the spray coating line - operating in the second building - from the list of short-listed alternatives on the following grounds:

1. The technical suitability of the spray coating line is limited only to a share of the production and could not be used to coat shock absorbers which are exclusively validated on the ACC line because it is unable to meet some important customers specifications. For example, the applicant stressed that ACC line provides important advantages in terms of corrosion protection of weld areas compared to the spray coating line.
2. The production costs for each single shock absorber which is coated on the spray coating line are 10-50 %[19] higher when compared to the ACC line.
3. The spray coating line has a limited capacity and so would be able to take up only a fraction of the shock absorbers which are currently coated on the ACC line and which are also validated on this spray coating line.

No comments on the alternatives were received during the third-party consultation.

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

SEAC has assessed the information provided in the application and in the responses to the SEAC's questions and considers the analysis comprehensive and clear.

SEAC acknowledges that the applicant has already identified two promising alternatives and that the preliminary results confirmed their ability to provide sufficient corrosion resistance to the shock absorbers. The applicant has assessed the pros and cons of the two short listed alternative technologies and described possible solutions to overcome the technical challenges associated with each of them as well as the financial implications linked to their implementation. SEAC notes that although the implementation of the alternatives would require an investment, the applicant does not consider that this would result in them being economically infeasible.

[19] The applicant provided the exact percentage in the confidential version of the responses.

SEAC however notes that a fraction of the production currently coated on the ACC line is also validated on the spray coating line, which is in a different building and which serves the production line of that specific building. SEAC has therefore asked an extensive number of questions to the applicant on the feasibility of this spray coating line for a limited share of production, as well as evaluated the possibility to introduce a condition to limit the scope of the authorisation to those shock absorbers:

a) the coating of which cannot be shifted from the ACC line to the spray coating line because they are exclusively validated on the ACC line and

b) that are validated on both lines but cannot be coated on the spray coating line because of its limited capacity.

The shock absorbers falling in the above two categories account altogether for approximately 10-50 %[20] of the total production.

To understand the feasibility of the above alternative technology for the applicant in a more limited scope of the use applied for and so the implications of the above condition, several specific questions were addressed to the applicant.

In response, the applicant provided a significant number of arguments explaining why in their view this condition is not proportionate and associated with prohibitively high risks and costs from their perspective.

In their responses, the applicant explained that:

1. The spray line has much higher operating costs per unit when compared to the ACC line (e.g. overall cost per unit coated on the spray line is 10-50 %[21] higher when compared to a piece coated on the ACC line). Considering that under this condition a significantly higher number of shock absorbers (1-5 million) would have to be coated on this[22] line (compared to the continued use scenario), there would be a significant increase in the overall operating costs, which the applicant estimated to be in the range of €50 000-500 000 per year.

2. The condition would have high logistic and storage costs. The implementation of the condition would require significant changes in the process and the applicant would not be able to continue its lean manufacturing process which implies that products are coated as soon as they are ready, so with minimal storage costs. The products that would be shifted to the second line, would have to be shipped to external warehouse during the week and then brought back for coating on the spraying line in the weekends[23]. The applicant estimated additional storage costs in the range of €100 000-500 000 per year.

3. If the condition is introduced, 6-25 employees – currently working at the ACC line – will become redundant and lose their jobs. The applicant explained that the additional production in the spray coating line can be achieved with the existing number of shifts,

[20] The applicant has provided the exact percentage in the confidential version of the responses.
[21] The exact percentage is available to SEAC in the confidential version of the responses.
[22] Because the applicant would be allowed to use the ACC only for the remaining share of the production (10 %-50 %).
[23] This because the applicant will need to make sure that the spray line is available before shipping products for the coating step.

meaning that it would not be possible to reassign the above employees – currently working at the ACC line – to the spray coating line. The applicant estimated the corresponding social costs in the range of €100 000-500 000.

4. The use scenario with the condition in place would require more handling of the products between the different steps (manufacturing and coating) which is expected to lead to more defective products being delivered to the customers and so more risks for the applicant.

5. The applicant explained that customers' approval would be needed before moving the coating of any product from the ACC line to the spray coating line. This is because they will need to accept this change in the process, which would imply more handling of the products[24] considering that the shock absorbers will be produced in one building and only later will be coated in a second building. In response to the SEAC's questions, the applicant stressed that it is not certain that an approval from the customers can be obtained.

6. The condition would be associated with high business risks, considering that the spraying line would have to work almost on its full capacity. This means that the applicant would have very little flexibility in the production schedule and difficulty in accepting any new order from current clients or any new client. The applicant stressed that they might lose current clients if any unpredictable event occurs or might not be able to accept new clients, considering that the spray coating line would have to work to almost its full capacity.

7. The ACC line would need to continue to operate anyway all the time during the production to proceed with the coating of the relevant shock absorbers (that would be covered by the conditional authorisation[25]) as soon as they are ready. So according to the applicant, even if the condition is implemented, the overall process will continue emitting the same amount of Cr(VI) from the reactive rinse step as in the continued use scenario without the condition. Considering that the concentration in the bath will have to be same, the applicant claims that the emissions would be the same with or without the condition being implemented.

The applicant has estimated that the overall increase in operating costs (production costs and storage costs) of the above condition would represent approximately 34 % their annual profit[26].

RAC has also taken note of the applicant's explanation (under point 7) and considers that there would not be significant differences in the exposures and emissions of Cr(VI) in the working hall and air.

Considering the applicant's response, SEAC's view is that the spray coating line - operating in the second building - is not feasible for the applicant for the use applied for and that the above considered condition to limit the scope of the authorisation to a fraction of the production would be disproportionate, with high negative economic impacts for the applicant and no significant differences in the exposures and emissions of Cr(VI). SEAC also notes that the

[24] With possible impacts on products' quality
[25] Those which are exclusively validated on this line, as well as of those which are validated on both lines, but which could not be coated on the second line because of its capacity constraints.
[26] SEAC has verified applicant's calculations – provided in the confidential version of the response documents – and finds applicant's estimate plausible.

applicant committed to finalise the substitution by 21 September 2024 and not submit a review report for DCTC.

SEAC has also asked the applicant to provide information on whether the 6 competitors in the EU are using an alternative. The applicant indicated that they do not have this information.

However, the applicant noted that it might be possible that some of the competitors in the EU are using the spray coating or KTL technology. According to SEAC, the response from the applicant might mean that suitable alternatives are available in the EU. But SEAC was not able to corroborate this information.

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 with the same function and similar level of performance. Therefore, RAC did not evaluate the potential risks of the alternatives.

4.4. Substitution activities/plan

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

The application included a substitution plan, according to which the applicant will switch to one of the two most promising alternatives by 21 September 2024.

At the moment of submitting the application, the applicant indicated that the management was still to identify the most preferable alternative among the two. This was also confirmed by the applicant in response to one of SEAC's question.

In the submitted application, the applicant indicated that once the most suitable alternative has been selected the following substitution activities will be implemented:

1. process validation, during which the applicant's engineers will optimise the manufacturing process (between 5-10 months)[27]

2. quotation and negotiation with the supplier of the new coating line (between 5-10 months)

3. installation of the new coating line and fine tuning of the process (between 10-20 months)

4. validation of products coated with the new line to ensure that the coated shock absorbers meet all customers qualifications (5-15 months). During this step the applicant will conduct a series of production runs to produce the validation lots, which will be tested against customers'

[27] The time required by each phase is considered confidential by the applicant. Upon SEAC's request the applicant agreed to provide public ranges for each phase.

specifications. Once the tests are run the results will be presented to the customers for their approval.

5. launch of the commercial production after the approval of customers is received.

The production line with the new technology will also be part of the validation documentation so any future lots to be provided to the customers will need to be produced on that line.

Based on the time required for each phase, the applicant estimated that by 21 September 2024 the switch to an alternative will be completed.

SEAC's evaluation of the substitution activities/plan

In SEAC's view the substitution plan submitted is consistent with the analysis of alternatives and SEAC finds plausible that the applicant will be able to switch to one of the two shortlisted alternatives by September 2024.

The applicant has described each phase of the substitution plan and provided a reasonable timing for their completion. In particular, SEAC notes that the validation of all products needs to be finalised before the commercial production can be launched with the new technology.

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 at the date of submission of this application for authorisation.
- There is information available in the application for authorisation indicating that there might be alternatives available that are technically and economically feasible in the EU. However, RAC is unable to conclude on whether these alternatives are safer.
- The applicant submitted a substitution plan. The substitution plan was credible for the review period requested and consistent with the analysis of alternatives and the socio-economic analysis.

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 and the environment?

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

5.1. Human health and environmental impacts of continued use

DCTC was included in Annex XIV due to its mutagenic and carcinogenic properties (Category 1A carcinogen).

The applicant notes that as DCTC is used together with chromium trioxide in the reactive rinse mixture and workers are potentially exposed to hexavalent chromium from both substances. The exposure levels and so the monetised risks reflect the use of the mixture and not only DCTC. The coated articles produced at the plant do not contain DCTC or Cr(VI), so there are

no emissions during their service life.

The main exposure routes for hexavalent chromium are inhalation and oral. Inhalation exposure has been associated with lung cancer, while oral exposure with intestinal cancer. The applicant's health impact assessment assumes that between 3-30 (exact number claimed confidential but known to SEAC) workers are at risk of potential exposure to hexavalent chromium via inhalation. The applicant has assumed work exposure via oral exposure to be zero, as no food consumption is permitted in the areas at risk of hexavalent chromium exposure. Also the local population (2 960) faces exposure risk through inhalation, while as reported in section 2.5, it seems reasonable to assume that the regional exposure is not particularly relevant.

The applicant has estimated the additional statistical cancer cases associated with the use of DCTC on the basis of the exposure levels, duration of the exposure, number of people exposed using RAC's reference dose response relationship for hexavalent chromium for fatal lung and intestinal cancer. Non-fatal cancer cases have also been estimated by the applicant.

The health impacts have been monetised by the applicant applying ECHA upper bound WTP values for value of statistical life (VSL) of €5 million and value of cancer morbidity of €0.41 million and uprating them from 2012 to 2019 prices using GDP deflator (figures shown below).

Table 11: WTP values (VSL and VCM)

WTP values	**2012**	**2019**
Value of Statistical Life (VSL)	€5 000 000	€5 380 710
Value of Cancer Morbidity (VCM)	€410 000	€441 218

The applicant has assumed no latency period in their human health impact assessment and chosen not to discount the values of statistical life and cancer morbidity.

The applicant's total monetised excess cancer risk from continued use is calculated at approximately €1 160-10 000 over the whole requested review period (to 21 September 2024). The annualised monetised risk is approximately €350-3 000.

In response to questions, the applicant provided SEAC with spreadsheets for the human health impacts. The applicant also confirmed that they had chosen not to apply discounting to the human health calculations.

Table 12 summarises the excess cases and associated monetised costs.

SEAC's evaluation of the impacts on human health and the environment

SEAC notes the applicant's methodological approach and assumptions. SEAC also notes the applicant has used ECHA's 2016 report on valuing selected health impacts of chemicals and has inflated the values from 2012 prices to 2019 using the GDP deflator.

SEAC consider that the applicant's estimated economic burden reflects the welfare loss in the continued use scenario due to the increased mortality and morbidity. SEAC notes that WTP values do not incorporate the increased costs on the healthcare system and other types of indirect costs (such as decrease in labour productivity) associated with cancer. SEAC therefore concurs with the applicant's methodology, while noting that 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 the applicant considers the estimated human health costs reflect a "*worst case*", calculation, that no latency period has been included in the applicant's monetisation calculations and the estimated costs have not been discounted. SEAC considers it appropriate to apply discounting but has not recalculated the results. Doing so would not substantially alter the results, given the relatively short period involved (three years 2021-24).

Overall, SEAC concludes that the applicant's figures provide a reasonable estimate of the monetised human health costs.

Table 11: Summary of additional statistical cancer cases

	Excess lifetime cancer risks	**Number of exposed people**	**Estimated statistical cancer cases (per year and over RP)**	**Value per statistical cancer case**	**Monetised excess risk (per year and over RP)**
Workers					
Directly exposed workers	1.48×10^{-3}-7.73×10^{-7}	3-30 (public range)	4.05×10^{-5}- 4.05×10^{-4} (annual) 1.22×10^{-4} - 1.22×10^{-3} (over RP) (lung cancer)	€5.4 million €0.44 million	€300-3 000 (per year) €1 000-10 000 over the RP
Indirectly exposed workers	Included in the general population				
Sub-total					€300-3 000 (per year) €1 000-10 000 over the RP
General population					
Local	2.32×10^{-7} (inhalation)	2 960	1.19×10^{-5} (per year) 3.5×10^{-5} (over RP)	€5.4 million €0.44 million	€50 (per year) €160 (over RP)
Regional	Not relevant[28]				
Sub-total					€50 (per year) €160 (over RP)
Total					**€350-3 000 pa €1 160-10 000 over the RP**
Latency (years)	no latency period assumed in human health impact assessment and no discounting applied to the values of statistical life and cancer morbidity.				

5.2. Societal costs of not granting an authorisation

Non-use scenario

As previously reported, the applicant currently operates two coating lines, located in different buildings at their manufacturing plant in Hodkovice. One line (the ACC line) using DCTC, while the other is Cr(VI)-free spray coating line.

The applicant ruled out attempting to transfer production to a non-EU facility because the ACC

[28] As reported in section 2.5 of the opinion.

line in the Hodkovice plant is the only one in the applicant's manufacturing network that uses this technique.

In the absence of an authorisation, the applicant would no longer be able to use the reactive rinse containing DCTC, and states that they would stop coating in the ACC line and try to move the coating of some shock absorbers – currently coated in the ACC line – to the spray coating line so to avoid that whole production currently relying on the ACC line is lost.

As described in section 4, the applicant considers moving coating of some shock absorbers to the spray coating line in the Hodkovice plant to be problematic for a number of reasons:

i. The ACC line is in the same building as the shock absorber manufacturing lines. Moving the coating step to the other coating line would require transport of the assembled shock absorbers to a different building. This could cause logistical issues and delays in production, due to the need for loading the transported dampers to the coating line, instead of this being done through an automated process. This option would also result in additional handling and potential weather impacts to the products, increasing the risk of defects.

ii. The applicant states that they try to maintain versatility in their manufacturing process with most of their products being validated for production in both coating lines. However, some products currently coated in the ACC line are only validated for that particular process.

iii. The applicant also states that the second coating line does not have enough free capacity to coating all the shock absorbers that the ACC line currently handles. The Hodkovice plant operates on a three-shift basis, six days a week, with little room for production increase in either of the two coating lines. If ACC were to stop operating, only a share of its input would be taken by the second line. The applicant states they would have to readjust production schedule and prioritise jobs and customers this would lead to delays in deliveries and, ultimately, complete stoppage for some products.

iv. The spray coating line has substantially higher operating costs when compared to the ACC line.

The applicant estimates that in the best-case scenario this non-use scenario would entail a loss of 10-50 % in the shock absorbers' production. As indicated in section 4.2 this share of the production includes those shock absorbers the coating of which cannot be shifted to the spray line because they are exclusively validated on the ACC line, as well as the share that is validated on both lines but cannot be coated on the spray line because of its limited capacity. As stressed by the applicant, this is the best-case scenario because it assumes a swift shift of the remaining shock absorbers to the spray coating line and customers' approval, which– as explained by the applicant - is not certain at this stage.

A portion of jobs proportional to the reduced production is expected to be lost in the plant in this case. The applicant considers this to be the most likely and conservative NUS.

The applicant notes that if supply of shock absorbers stops for some of the products, the relevant vehicle manufacturers may face supply shortages and could be at risk of stopping production. Usually, manufacturers have multiple certified suppliers for parts used in vehicle assembly, to ensure security of supply. The applicant expects the vehicle manufacturers to seek to source parts from other suppliers (the applicant's competitors), some of whom are not located in the EU. The applicant therefore considers the overall impact on downstream users

of the applicant's products to be small, but the EU trade balance for such products could be negatively affected.

The worst-case scenario assumes that the customers would not accept the shift of the remaining shock absorbers to the second spraying coating line. Under this scenario, the applicant assumes that they would lose the whole production of shock absorbers currently coated on the ACC line, not just those shock absorbers that cannot be coated on the spray coating line because of capacity and technical constraints.

The applicant states that they also considered an alternative NUS option involving a short-term "patch" to substitute DCTC in the reactive rinse, until an alternative for the whole process can be implemented. However this was either technically difficult or would not reduce the risk at all, as the most likely drop-in substitute for DCTC in the reactive rinse would be chromium trioxide (another Cr(VI) substance, also on the Authorisation List). While the applicant states they are covered by another authorisation for the use of chromium trioxide, it was not considered a viable option to pursue because, as indicated in section 4.2, the switch to this *"short-term"* alternative would require the revalidation of all the products – to ensure that the process using only chromium trioxide (CrO_3) meets the customers' requirements. The applicant stressed that the implementation of this alternative process would take at least one year and would not bring benefits in terms of workers' exposure. Based on these considerations the applicant concluded that temporary shift to use only chromium trioxide would not be their likely response to a refused authorisation.

On the basis of the information provided by the applicant, (including the potential availability of alternative suppliers to downstream users), SEAC agrees that stopping coating on the ACC line and possibly (if approved by customers) moving the coating of some shock absorbers to the spray coating line located in a different building appears credible as the most likely NUS.

Economic impacts of non-use

Continued use would avoid the impacts of the non-use scenario (stopping coating on the ACC line). The applicant's analysis considers total benefits to be worth at least €195 000-1 900 000. The applicant obtained this monetised range based solely on the costs of disposal of unused materials from the site (€105 000-550 000) and social costs of unemployment (€90 000-1 350 000).

The applicant has produced monetised estimates of other impacts, including lost profits and fines due to contract breaches. These are examined below. However, having set out non-confidential ranges for various potential impacts, the applicant has chosen to exclude most of them when calculating the overall socio-economic assessment. The applicant's assessment considers that most of the estimated monetised impacts are likely to represent transfers (zero-sum costs) rather than economic costs, since the applicant has assumed that their customers are able to readily switch to other suppliers to obtain the parts currently produced by the applicant and therefore the applicant's loss of profit will become a profit gain for their competitors, rather than a net loss to society as a whole. SEAC notes that there are uncertainties in this assumption, as switching supplier is likely to involve some extra costs (although ones difficult to quantify, since it will depend on the extent of competition in the market and also ease of entry/exit). Additionally, some of the applicant's competitors are based outside the EEA, resulting in potentially switching supply to non-EU manufacturers.

SEAC accepts that the applicant has therefore adopted a conservative approach in considering

most of the impacts to be transfers (i.e. essentially distributional in nature). Using only the cost of disposal of chemicals and social costs associated with unemployment therefore provides a conservative (minimum) estimate of the socio-economic costs.

The applicant's assessment of potential economic impacts covered the following: (**NOTE** items marked with* were subsequently **excluded by the applicant** when calculating the overall SEA).

- Loss of profits: * (low €1-10 million and high forecasts €10-50 million)
- Decommissioning (disposal of unused chemicals) (€105 000-550 000) (included by applicant)
- Depreciation /unutilised investment:* €0.75-4.5 million
- EU-based raw material supplier's revenue losses*: low €7.5-35 million and high forecasts €22.5-112.5 million
- Fines due to contract breach with customers* €100 000-1 million per customer per day

  Giving a total cost range of €105 000-550 000. (using the figures included by the applicant)

Social costs of unemployment at the plant in the NUS were also assessed and valued by the applicant at €90 000-1 350 000.

The applicant's monetised impacts were calculated over the period (approximately mid) 2021 to (September) 2024 to reflect the requested review period and discounted to 2021 using a 4 % annual discount rate.

These impacts are assessed in more detail below.

- **Loss of profits:**

  The applicant calculated low and high profit loss estimates. The "*low*" lost profits figure of €1-10 million is for the entire requested review period and based on lost sales of shock absorbers from the ACC line. This assumes an "*optimistic*" NUS from partial loss of sales, where the applicant would lose only 10-50 % of the production for the reasons presented in sections 4.2 and 5.2) The applicant's high "*worst case*" reflects loss of all shock absorbers at the ACC line (€10-50 million). The applicant noted that losses would extend beyond the requested review period, as they will not recover market share immediately. However, the applicant also noted that, without an authorisation, their customers would be expected to switch to alternative suppliers as quickly as possible and therefore the applicant's profit losses would be gains for their competitors. The applicant has therefore not included their profit loss figures in the overall SEA.

  SEAC notes the applicant has conservatively assumed that their customers are able to readily switch suppliers, (essentially at zero cost), resulting in the applicant's estimated lost profit in the NUS being offset (or transferred) to become profits for other suppliers. SEAC accepts the applicant's reasoning (based on customers in this market being able to readily switch to other suppliers) and recognises this to be a conservative approach, for the reasons already outlined above.

- **Decommissioning (disposal of unused chemicals)**

  The applicant states that in the "optimistic" NUS, which assumes a successful shift of part of the production from the ACC to the spray coating line, they do not intend to

decommission the ACC coating line but will need to dispose of unused processing aids and other chemicals used in the process. This is estimated to cost €105 000-550 000. The figure is included by applicant in the overall CBA.

SEAC considers it reasonable to include costs linked to disposal in the analysis and accepts the applicant's estimate.

- **Depreciation /unutilised investment**

The applicant states that recent investment to increase capacity at the plant will be unutilised in the NUS and since the equipment has a planned depreciation over 10 years, approximately 7.5 years of the life of the assets would remain undepreciated in the accounts. This is stated to be worth approximately €0.75-4.5 million (in its accounting "book value") but the applicant has not used this figure in the cost-benefit calculation.

It is unclear to SEAC if the equipment could potentially be put to an alternative use, but since the applicant has not included the figure in the overall cost-benefit, SEAC notes the applicant's approach to be conservative. In any case SEAC notes that the depreciation costs should not be considered if profit losses are already accounted for.

- **EU-based raw material suppliers' revenue losses**

The applicant provides a range of forecast potential revenue losses to its raw material suppliers of €7.5-35 million (low) and €22.5-112.5 million (high), whilst also noting that actual losses are likely to be lower, if the applicant's competitors purchase raw materials from these same suppliers. The figures have therefore been excluded by the applicant from the CBA.

SEAC notes any loss of raw material sales would likely be a transfer if the supply of shock absorbers were readily picked up by other suppliers. It would therefore risk overstating or double counting the impacts. SEAC therefore agrees with the applicant's decision to exclude the raw material figures from the overall CBA, whilst noting the potential for distributional impacts, depending on where future purchases of raw materials are made.

- **Fines due to contract breach with customers**

The applicant provided a non-confidential range of between €100 000-1 million per customer per day for compensation clauses within contracts if the applicant fails to meet its agreed supply of parts. The applicant however regards this cost as a zero-sum cost (a transfer from one party to the other) and has excluded it from the CBA.

SEAC notes that such fines could involve significant financial consequences for the legal parties involved in a contract. SEAC also notes that where contractual penalties include punitive damages, such costs may largely represent transfer payments rather than true economic costs. SEAC considers it unclear what relationship the contract penalties faced by the applicant may bear to actual economic losses potentially arising from a supply failure. In the absence of such information, SEAC agrees with the approach taken by the applicant. SEAC considers it appropriate to note the issue of potential contract fines qualitatively and to not include the fines in the CBA.

Other socio-economic impacts:

Direct unemployment impacts

The applicant claims that shutting down the ACC coating line would result in 10-50 job losses at the plant (exact number claimed confidential). This range includes both those working directly on the line and some personnel working indirectly (e.g. upstream or in sales). The applicant has used the valuation methodology described in the paper endorsed by SEAC: "*Valuing the social costs of job losses in applications for authorisation*")[29] to calculate the social costs of unemployment, using the applicant's average labour costs and data for unemployment durations in Czechia.

SEAC has recalculated the social costs of unemployment based on the estimates provided in the paper for the Czech Republic. On the basis that the total costs are approximately €30 000 per job lost, the social costs of unemployment have been estimated by SEAC to €300 000-1 500 000 euro. Noting that some of the applicant's assumptions are more conservative, SEAC considers the applicant's overall monetised estimate of €90 000-1 350 000 for the cost of unemployment impacts in the NUS to be reasonable and has included them in its analysis.

Wider economic Impacts

The applicant briefly notes that they are among the largest manufacturers of shock absorbers in the EU and that, if forced out of the market, this would result in a smaller number of suppliers which could reduce the degree of competition in the market and potentially cause shock absorber prices to rise.

The applicant also noted that any shortfall in supply caused by them being forced to stop production would be filled by a mix of EU and non-EU suppliers, potentially weakening the EU's overall position in this market. Successful implementation of an alternative could lead to pioneering new technology to improve EU manufactured supply, in a safer manner for human health and the environment.

SEAC notes these qualitative remarks.

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

SEAC's detailed views on the continued use and non-use scenario, economic impacts and social impacts can be found above. SEAC agrees with the non-use scenario and the applicant's decision to limit the monetised impacts used in the overall analysis to the assessment to chemical disposal costs and the socio-economic costs related to job losses in the NUS. This approach is consistent with the applicant's assumption that their customers will be able to readily switch to other suppliers, mitigating some of the other potential impacts of the NUS. SEAC therefore agrees that, in these circumstances, it is appropriate (and conservative) to regard the identified lost profits, impacts on raw material supplies and contractual penalties facing the applicant in the NUS as distributional in nature, rather than true economic costs.

SEAC therefore agrees with the approach adopted by the applicant in assessing the overall

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

economic impact, limiting the monetised elements to decommissioning (disposal of unused chemicals) and potential job losses at the plant.

SEAC notes the applicant's comments concerning their role in the EU market for shock absorbers and the potential benefits of successfully adopting alternative production techniques.

SEAC notes the applicant's request for a review period until 21 September 2024.

SEAC's assessment, based on the applicant's information, is set out below. The results are given in NPVs to reflect the information as provided by the applicant. A rough approximation of annual cost has also been produced by SEAC dividing the NPVs by the number of years in the analysis / applicant's requested review period.

Table 12: Societal costs of non-use

Description of major impacts	Monetised/quantitatively assessed/qualitatively assessed impacts
1. Monetised impacts	**€ over 3 years and per year**
Economic impacts due to investment and/or additional production costs related to the adoption of an alternative	Not applicable[30].
Producer surplus loss due to ceasing the use applied for	*assessed but regarded as transfer
Relocation or closure costs (disposal of unused chemicals (only))	€105 000-550 000 NPV over RP, Annualised approx. €35 000-180 000
Loss of residual value of capital	*assessed but not included
Other costs (e.g. additional costs for transportation or quality testing)	Not applicable.
Social cost of unemployment	€90 000-1 350 000 NPV Annualised approx. €30 000-450 000
Spill-over impact on surplus of alternative producers	Not available.
Other monetised impacts (please specify)	Not applicable.
Sum of monetised impacts	€195 000-1 900 000 over RP Annualised approx. €65 000-630 000

For the purpose of its evaluation, SEAC has included the disposal of unused chemicals and direct job losses at the applicant's plant in the overall SEA (the same elements that have been incorporated in the applicant's overall monetised assessment).

Other elements, comprising loss of profits, depreciation /unutilised investment, EU-based raw material supplier's revenue losses, fines due to contract breach with customers have been noted but not included in the overall monetised SEA, for reasons outlined above.

SEAC also notes that other elements (increase in operating costs and storage costs) have been described by the applicant in the responses to the SEAC's questions but not included among the impacts of the NUS.

SEAC therefore considers the overall approach taken in the SEA to be conservative and that

[30] In response to SEAC's questions, the applicant provided information about the additional costs associated with a possible adoption of the spray coating line for part of the production. However, these operating costs – accounting for approximately 34 % of the applicant's annual profit – were not considered among the impacts of the non-use scenario by the applicant.

the estimates give a minimum value of socio-economic benefits of €195 000-1 900 000. (which roughly approximates to €65 000-630 000 per year over the requested review period).

SEAC's evaluation of the combined assessment of impacts

The table below summarises the monetised elements included in SEAC's assessment.

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

Societal costs of non-use		**Risks of continued use**	
Monetised impacts (€over 3 years and per year)	• €105 000-550 000 NPV • Annualised approx. €35 000-180 000	Monetised excess risks to directly and indirectly exposed workers (€over 3 years and per year)	• €1 000-10 000 NPV • €300-3 000 per year
Additional quantitatively assessed impacts (€over 3 years and per year)	• €90 000-1 350 000 NPV • Annualised approx.€ • 30 000-450 000	Monetised excess risks to the general population (€over 3 years and per year)	• €160 NPV • €50 (per year)
Additional qualitatively assessed impacts (€over 3 years and per year)	Not applicable.	Additional qualitatively assessed risks (€over 3 years and per year)	Not applicable.
Summary of societal costs of non-use	• €195 000-1 900 000 NPV • Annualised approx. €65 000-630 000	**Summary of risks of continued use**	• €1 160-10 000 NPV • €350-3 000 pa

5.3. 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 and environment 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 and the environment.

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

6. Proposed review period

☐Normal (7 years)

☐Long (12 years)

☐Short (4 years)

☒Other: until 21 September 2024

☐No review period recommended

When recommending the review period SEAC took note of the following substitution and socio-economic considerations:

- The benefits of continued use are higher than the risks by a considerable degree (more than 20 times[31]).
- 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 at the date of submission of this application for authorisation.
- There is information available in the application for authorisation indicating that there might be alternatives available that are technically and economically feasible in the EU. However, RAC is unable to conclude on whether these alternatives are safer.
- The applicant submitted a substitution plan. The substitution plan was credible for the review period requested and consistent with the analysis of alternatives and the socio-economic analysis.

Taking into account all of the above points, review period until **21 September 2024** is recommended for this use.

7. Proposed additional conditions for the authorisation

Were additional conditions proposed for the authorisation?

☒Yes ☐No

7.1. Description

RAC

In line with the hierarchy of control principles, the applicant shall introduce engineering controls such as local exhaust ventilation and wet scrubbers at relevant locations where Cr(VI) is emitted to reduce workplace exposure and emissions to the environment to as low a level as technically and practically feasible.

The applicant shall, within 6 months after the granting of an authorisation, use the information gathered via the measurements and related contextual information referred to in Section 8.1 to review the RMMs and OCs in place.

[31] Based on the upper bound of monetised risk and lower bound for the societal costs of the NUS.

7.2. Justification

RAC

RAC is of the opinion that the RMMs described in the application do not follow the hierarchy of control principles and that the RMMs and OCs implemented are not appropriate and effective to limit the risk for workers and for humans via the environment (air compartment).

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements proposed for the authorisation?

☒Yes ☐No

8.1. Description

RAC

1. The applicant shall implement the following monitoring programmes for Cr(VI):
   - (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall:
     - (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI);
     - (ii) be based on relevant standard methodologies or protocols;
     - (iii) comprise personal sampling for workers (for WCSs 3-8) and static inhalation exposure sampling;
     - (iv) be representative of:
       - a. the range of tasks undertaken where exposure to DCTC is possible;
       - b. the OCs and RMMs typical for each of these tasks;
       - c. the number of workers potentially exposed;
     - (v) include contextual information about the tasks performed during sampling.
   - (b) Environmental releases:
     - (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater;
     - (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process;
     - (iii) the monitoring programmes for wastewater and air emissions shall:
       - a. be based on relevant standard methodologies or protocols; and
       - b. be representative of the OCs and RMMs used at the applicant´s site.

2. The applicant shall conduct the first monitoring campaign within 3 months after the granting of an authorisation.

3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with section 7.1, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.

4. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI).

8.2. Justification

RAC

RAC also notes that, even if an overestimation of the exposure to Cr(VI) is probable due to the presence of DCTC and CrO_3 in the mixture, it is difficult to conclude on the exposure assessment for workers and humans via the environment based on static measurements at one point only, albeit very close to the main DCTC emission source.

RAC is of the opinion that the applicant should address these shortcomings by obtaining representative measurements for workers' exposure and environmental releases.

The proposal is in line with the applicant commitment to undertake a monitoring programme based on personal sampling.

An annual biomonitoring programme is already in place at the applicant's site.

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 sections 7 and 8, as well as the outcome and conclusions of the review and actions taken in accordance with same sections, should be documented and included in any subsequent review report.

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 site and would confirm the appropriateness and effectiveness of OCs and RMMs.

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

The applicant did not comment the opinion.