Helsinki, 04/03/2022

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

chromium trioxide use: Chromium trioxide-based functional chrome plating of cylinders used in the rotogravure printing and embossing industry

Submitting applicant

Maschinenfabrik Kaspar Walter GmbH & Co KG

ECHA/RAC/SEAC: AFA-O-0000007070-86-02/F

Consolidated version

Date: 04/03/2022

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	**Maschinenfabrik Kaspar Walter GmbH & Co KG**
Role of the applicant in the supply chain	Upstream ☐[group of] manufacturer[s] ☒importer ☐[group of] only representative[s] ☐[group of] formulator[s] Downstream ☐[group of] downstream user[s]
Use performed by	☐Applicant[1] ☒Downstream users of the applicant
Substance ID EC No CAS No	**Chromium trioxide** 215-607-8 1333-82-0
Intrinsic properties referred to in Annex XIV	☒Carcinogenic (Article 57(a)) ☒Mutagenic (Article 57(b)) ☐Toxic to reproduction (Article 57(c)) ☐Persistent, bioaccumulative and toxic (Article 57(d)) ☐Very persistent and very bioaccumulative (Article 57(e)) ☐Other properties in accordance with Article 57(f) –

[1] The applicant manufactures and sells the galvanic machines/systems, but the company itself does not perform functional chrome plating of cylinders as a commercial activity.

Use title	**Chromium trioxide-based functional chrome plating of cylinders used in the rotogravure printing and embossing industry**
	Other connected uses: Formulation of chromium trioxide-based electrolyte for electroplating process[2]
	Similar uses applied for: Functional chrome plating (CTAC, Use 2)[3]
Number and location of sites covered	117 sites in CZ, PT, ES, FR, BE, DE, IT, EL, PL, AT, SK, HU, HR and RO
Annual tonnage of the Annex XIV substance used total for all sites	160-220 tonnes of CrO_3/year
Function(s) of the Annex XIV substance	Functional chrome plating using chromium trioxide results in a metallic chrome coating that provides a range of desired properties to the coated cylinder: • High hardness • Homogeneous surface with adequate layer thickness • Excellent adhesion of the metallic layer to the substrate • Specific surface morphology enabling adhesive properties • Suitable surface roughness and friction coefficient • Adequate surface topography reproducing the engraved contour • Wear resistance
Type of products (e.g. articles or mixtures) made with the Annex XIV substance and their market sectors	Printing cylinders used in high-quality printing applications required in the packaging, decorative, publication and embossing industry
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	12 years

2 https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/62904/del/50/col/synonymDynamicField_1512/type/asc/pre/8/view

3 https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/14305/del/50/col/staticField_-104/type/desc/pre/4/view

applicant (length)	
Use ID (ECHA website)	0234-02
Reference number	11-2120881009-51-0002

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	15/02/2021
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	10/05/2021
Was the application submitted by the Latest Application Date for the substance and can the applicant and their downstream users 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 Link: Adopted opinions and previous consultations on applications for authorisation - ECHA (europa.eu)
Request for additional information in accordance with Article 64(3)	On 21/06/2021, 31/08/2021 (RAC), 01/09/2021 (SEAC) and 19/10/2021 Link: Adopted opinions and previous consultations on applications for authorisation - ECHA (europa.eu)
Trialogue meeting	Not held – reason: no need for additional information/discussion on any technical or scientific issues related to the application from the rapporteurs
Was the time limit set in Article 64(1) for the sending of the draft opinions to the applicant extended?	☐Yes, by Reason: ☒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: 29/11/2021, agreed by consensus SEAC: 08/12/2021, agreed by consensus

Date of sending of the draft opinions to the applicant	03/02/2022
Date of decision of the applicant not to comment on the draft opinions, in accordance with Article 64(5)	04/03/2022
Date of receipt of comments in accordance with Article 64(5)	Not relevant
Date of adoption of the opinion in accordance with Article 64(5)	RAC: 04/03/2022, adopted by consensus
	SEAC: 04/03/2022, adopted by consensus
Minority positions	RAC: No minority positions
	SEAC: No minority positions
RAC Rapporteur RAC Co-rapporteur	Rudolf VAN DER HAAR Riitta LEINONEN
SEAC Rapporteur SEAC Co-rapporteur	Martien JANSSEN John JOYCE
ECHA Secretariat	Arnis LUDBORŽS Sanna HENRICHSON Tytti MBANI

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
DU	Downstream user
ES	Exposure scenario
ECS	Environmental contributing scenario
LAD	Latest application date
LEV	Local exhaust ventilation
NUS	Non-use scenario
OC	Operational condition
PBT	Persistent, bioaccumulative and toxic
PNEC	Predicted no-effect concentration
PPE	Personal protective equipment
RAC	Committee for Risk Assessment
REACH	European Union regulation on registration, evaluation, authorisation and restriction of chemicals
RMM	Risk management measure
RP	Review period
RR	Review report
SDS	Safety data sheet
SEA	Socio-economic analysis
SEAC	Committee for Socio-economic Analysis
SP	Substitution plan
SSD	Sunset date
vPvB	Very persistent and very bioaccumulative
WCS	Worker contributing scenario

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

THE OPINION OF RAC

RAC has formulated its opinion on:

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

RAC concluded that it was not possible to determine DNEL(s)for the carcinogenicity 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 or their downstream users 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** appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion.

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 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 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, information submitted by interested third parties, as well as other available information. SEAC's evaluation is based on relevant guidance, which comprises the Commission's Better Regulation guidance, the Guidance documents on applications for authorisation and the socio-economic analysis as well as specific guidance related to how SEAC evaluates the applications (e.g. dose response functions, values of health endpoints).

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

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

- Cr(III) electroplating with Cr(III)-based electrolyte
- Polymer coatings.

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 or their downstream users by the date of the adoption of this opinion.
- There is no 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.
- 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 and third parties from a scientific perspective, using standard methodology, and following relevant guidance. Based on the elements listed below, SEAC concludes that the applicant has demonstrated that the societal costs of not granting an authorisation are higher than the monetised risks to human health resulting from the granting of an authorisation.

The expected societal costs of not granting an authorisation are estimated to be at least €51-100 million per year consisting of economic impacts to the applicant and its supply chain and the social cost of unemployment. Additional societal impacts of not granting an authorisation have been assessed qualitatively but have not been monetised and consist of changes in product quality, changes in the market price for end consumers and changes in customer retention and market position. It should be noted that the societal costs relate to both Use 1 and Use 2, given that these are interlinked. SEAC notes that these impacts occur only once if either one or both uses are not granted an authorisation.

The risks arising from granting an authorisation, consider:

- the endpoint relevant for listing the substance in Annex XIV of REACH;
- the 657 directly exposed workers;
- the general population exposed at local scale (approximately 1.17 million persons) and at regional scale (approximately 447.7 million persons);
- that the risk of continued use as assessed by RAC may result in approximately 0.4 expected additional cases of cancer per year;
- the value of these expected additional cases has been monetised based on the willingness-to-pay methodology and corresponds to an estimate of approximately €1.2-2 million per year.

It should be noted that the above monetisation of risks only relates to Use 2 of the application for authorisation. The human health impacts of both uses would be avoided by refusing the authorisation to either one of the uses applied for. Therefore, the societal costs outlined above should be compared with the combined monetised risk of Use 1 and Use 2. The combined monetised risk of the two uses would also be €1.2-2 million per year.

Risks to human health of alternatives have not been assessed.

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

PROPOSED CONDITIONS, MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

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

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

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

REVIEW PERIOD

Taking into account the information provided in the application for authorisation submitted by the applicant and any comments received in the consultation, a **12-year** review period is recommended for this use, i.e. until the end of 2032.

JUSTIFICATIONS

0. Short description of use

The applicant, Maschinenfabrik Kaspar Walter GmbH & Co KG, is a manufacturer of plating equipment for gravure printing and embossing cylinders and supplies customer-specific complete plating systems (plating lines) for different printing segments: packaging, decorative, publication and embossing. The applicant acts as importer, purchases chromium trioxide as raw material from outside the EEA and has the formulations carried out by a third party.

Rotogravure printing is a printing technique based on the transfer of fluid ink from engravings on a printing cylinder to the surface of a substrate, or the material to be printed. Rotogravure is used primarily for long printing runs in applications such as magazines, catalogues, inserts, flyers, gift-wrap, and labels, among many others.

The affected production activity covered in this AfA has been segmented into two uses.

Use 1 corresponds to the formulation of chromium trioxide-based electrolyte for the electroplating process. The formulation is performed by a contracted party (formulator) and the mixture is supplied back to the applicant to be used by its DUs.

In this use (Use 2), the applicant is applying for authorisation for the application of CrO_3-based functional chrome plating of gravure printing and embossing cylinders used in high-quality printing applications e.g., in the packaging, decorative, and publication industry.

Both uses are covered by the CTAC authorisation[4] and the applicant is currently not responsible for the import of the substance nor does it have direct control of the volumes purchased by its DUs. The applicant pointed out that once the authorisation for this application has been granted, the applicant will take over the role of importer and will cover its entire supply chain with the two uses applied for.

A consultant was commissioned to conduct a Downstream User (DU) survey on behalf of the applicant. For more information about the survey, please see the AfA of Use 2 and section 0.4 of this opinion.

The applicant stated that the total foreseen consumption of CrO_3 during the review period is 160-220 t CrO_3/year[5] and is based on information about the annual consumption (as liquid formulation and/or liquid formulation + solid flakes) from 67 DUs (out of 117)[6]. It is noted that the applicant delivers the DUs with liquid formulations. Moreover, the total tonnage was also reviewed and confirmed by the applicant based on its market knowledge and expectation about future demand. The reported minimum and maximum consumption of CrO_3 per DU were 0.00015 t/year and 6.5 t/year, respectively. The applicant considered that the assessed tonnage presents a worst-case estimate. The applicant foresees a gradual reduction of the CrO_3 consumption starting from 2025 and reaching full substitution at the end of the review period (end of 2032).

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[4] Authorisation decision C(2020)8797.
Use 1: ID 0032-01; RAC and SEAC Opinion on an Application for Authorisation for Chromium trioxide use: Formulation of mixtures ECHA/RAC/SEAC: AFA-O-0000006490-77-01/D
Use 2: ID 0032-02; RAC and SEAC Opinion on an Application for Authorisation for Chromium trioxide use: Functional chrome plating ECHA/RAC/SEAC: AFA-O-0000006490-77-02/D

[5] The amount CrO_3 used per year is considered confidential information by the applicant but know to RAC

[6] Information provided from 67 DUs was used to calculate the average consumption of CrO_3 per site and then further used to extrapolate the total consumption.

The applicant pointed out that, although it obtains the ready-to-use liquid formulation from the formulator and sells/provides the mixture to its DUs, some DUs source their mixtures from other formulators/distributors as well.

Based on the applicant's experience, 220 working days per year is considered representative for the industry and set as a default assumption for all DUs[7].

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

The DUs stated, based on the survey, that currently, they receive liquid CrO_3 formulation as well as solid CrO_3 flakes. The majority of the DUs reported using CrO_3 in liquid (47 %) form, 16 % of the DUs reported the use of both liquid and solid form, 12 % depended solely on solid CrO_3 and a quarter did not indicate the form of CrO_3 used[8]. The main reason for DUs to use solids is economic; solid CrO_3 mixtures are cheaper than liquid ones.

The applicant pointed out that **the scope of the CSR and the application is limited to the use of liquid CrO_3**. The applicant stated that they regularly inform the DUs about the ongoing authorisation process and that the DUs who would like to be covered under this AfA have to switch entirely to the use of a liquid formulation. Based on the DU survey, the applicant estimates that many of the remaining users of the solid form will switch in a short time to liquid mixtures.

The applicant also mentioned that they strive to establish the use of automated dosing systems among their DUs as a risk minimisation measure. The use of solid CrO_3 flakes, which have to be added manually, presents a higher risk as regards particle inhalation by the workers. The liquid mixture enables the usage of an automated dosing system.

The electroplating units are closed-loop systems equipped with fixed capturing hoods. The production of the gravure cylinders starts with the degreasing of steel cylinders, followed by copper plating and finishing. The printing pattern is then embedded into the copper coating through either engraving or laser imaging. Regardless of the method applied, the cylinders are then degreased and finally plated with chromium in a 20-minute step carried out in the closed electroplating unit. Following a finishing step, the cylinders are ready for printing. The entire cylinder preparation process takes approximately 210 minutes if the cylinders are engraved and approximately 230 minutes if direct laser imaging is used instead.

WCS 1: Delivery and storage of raw material

CrO_3 is delivered as a solution in an Intermediate Bulk Container (IBC), unloaded and stored in a chemical storage (WCS 1) or the container is directly attached to the automated dosing system. On average, 2.3 workers (90th percentile = 3 workers) per site are usually engaged in this task. The task takes on average 1.3 h (90th percentile = 1.4 h) to complete[9]. The raw material is delivered about 5 times per year[10].

Information on this WCS has been equally provided by DUs using both, solid and liquid or only solid CrO_3.

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[7] A question about the number of working days per year was not included in the CSR or in the AoA/SEA survey.
[8] The DUs that did not indicate the form CrO_3 used correspond to the DUs that did not participate in the survey.
[9] Values based on the responses of 83 DUs.
[10] Value based on the responses of 81 DUs.

WCS 2: Chrome electroplating unit

The chrome plating process in an electroplating unit is designed for automatic and unstaffed chrome plating of rotogravure cylinders. Although the plating process is conducted with a closed hood, the electroplating unit is not an air-tight enclosure[11]. The CrO_3 solution is situated in an enclosed basin below the main tank and is only pumped up to the main tank when the plating process is started and the unit is closed. After the plating process is finished, the solution flows back into the basin and the cylinder is rinsed with water before the unit is opened again for unloading. The rinsing water is collected in the lower basin of the electroplating unit together with the CrO_3 solution. The evaporation of liquid in the course of the electroplating process (temperatures between 60-70 °C) compensates for the additional volume from the rinsing step.

Additionally, the loading and unloading of the electroplating unit are performed via a crane. The crane is controlled either fully automatically according to a pre-defined programme, a process that does not require a worker near the electroplating unit, or manually via remote control, that does require the presence of the worker nearby the electroplating unit (within a distance of ~1 m). During the loading/unloading of the cylinders, the CrO_3 solution is situated in the lower basin of the unit which cannot be accessed from the upper basin, in which the cylinder is (un)loaded.

After extensive use of the printing cylinder, the affected chromium surface can be renewed, enabling further usage of the cylinder. The dechroming of gravure printing and embossing cylinders takes place both electrolytically and chemically in a closed-loop dechroming galvanic unit[12], which is usually part of the plating line. In some cases, the dechroming unit can also be placed next to the plating line, but is always installed inside the galvanic area, and therefore is subject to the safety measures of the area and part of the examined exposure measurements. The entire chromium layer of the cylinder is removed as dissolved Cr(III) salt.

Both the chrome electroplating unit and the dechroming unit are equipped with a local exhaust ventilation system and no wastewater is generated.

The chrome plating and dechroming processes run fully automatically in the respective closed units and are monitored by the software system allowing control of the process parameters. During the processes, no employee is in the immediate vicinity (within a distance of ~1 m) of units.

On average, 4.4 workers (90th percentile = 11.4 workers; based on 79 DU responses) are employed with the loading and unloading (manual, automatic or both) of the electroplating unit.

From the 77 DUs who responded to the question about the use of mist suppressants to prevent mist formation, 68 DUs reported using these agents.

The number of cylinders plated varies among the DUs (min N = 10/month; max N = 4 000/month; mean N = 1 011/month, based on 80 DU responses) and consequently, the time taken for the automatic and manual loading/unloading of the cylinders (mean of 3.2 h/day and

[11] The electroplating unit is not enclosed air-tight because the plating tank takes in air from the outside to balance the exhaust airflow; this is necessary to prevent the creation of an explosive atmosphere within the tank caused by the generation of H_2.

[12] For dechroming, the cylinder is submerged into an acidic electrolyte within a closed-loop dechroming galvanic unit. The process is initially started electrolytically in order to remove the outer passivated chromium layer. To prevent an accumulation of Cr(VI) during electrolytical dissolution, a reducing agent (HelioDeChrome Salt, based on sodium hypophosphite) is used to reduce the electrolytically produced Cr(VI) in-situ to Cr(III). The remaining chromium layer is subsequently chemically dissolved by using sulphuric acid.

4.2 h/day and 90th percentiles of 8.0 h/day and 9.3 h/day for respectively automatic and manual loading/unloading, based on 79 DU responses). As a worst-case, an exposure of 8 hours (as the duration of a standard working day) has been taken forward by the applicant.

WCS 3: Sampling

To check the composition of the electrolyte, a sample is taken manually using a measuring cup or a ladle and analysed in an in-house laboratory and/or sent to a facility for analysis operated by the applicant. The applicant mentioned that currently a product is being developed with which sampling might also be performed using a valve and pump system. On average, a sample is taken 3 times per month (90th percentile = 8 times per month; based on 80 DU responses) and 2.2 workers (90th percentile = 4 workers; based on 81 DU responses) are employed with the task. The procedure is short and takes about 9 minutes (90th percentile = 15 minutes, based on 81 DU responses).

WCS 4: Concentration adjustment with liquid CrO_3

To maintain the concentration of CrO_3 in the electrolyte, adjustment with either liquid or solid CrO_3 is necessary. The applicant limits the scope of the AfA to the concentration adjustment process using liquid CrO_3.

Liquid CrO_3 is refilled automatically via a container (e.g., an IBC) connected to the electroplating unit. During the concentration adjustment process, no employee is located in the immediate vicinity (within a distance of approximately 1 m) of the plating unit since no intervention of a worker is required.

The exchange of containers with liquid CrO_3 solution presents the only potential for exposure caused by the handling of contaminated objects like the suction lance. The applicant pointed out that they have developed a new removal head connected to a pump via a hose that facilitates the connection/disconnection of CrO_3-containers that prevents contact with CrO_3, the so called “Quick Connect”-system. Also, containers that featured an integrated and fixed immersion tube, thus prohibiting unintentional dripping when reconnecting the removal head are made available by the applicant for their DUs. According to the applicant, and due to the CTAC authorization conditions, the DUs have an increasing interest to upgrade their dosing system with these modern ones, which require a small, one-time investment.

On average, 2.1 workers (90th percentile = 3 workers, based on 59 DU responses) need half an hour (90th percentile = 1 hour, based on 55 DU responses) to exchange the container with liquid CrO_3 at the automatic dosing system. The task is performed 1.4 times per month (90th percentile = 4 times per month, based on 58 DU responses).

WCS 5: Maintenance

At the DU sites, regular maintenance of the plating lines is conducted. This includes daily checks of the extractor systems, the level in supply tanks, cleaning of the spindle seal and clamping cones of bearing brackets. Anodes and the protective shell of the electroplating unit are cleaned weekly and the moving parts are checked weekly for wear. The spindles of the bearing bracket and guide rails of the lid are lubricated monthly. The carbon brushes are checked monthly, too. Quarterly, the tightening of screw connections, cleaning of screen elements in the water installation and lubrication of various parts take place. The screw connections of the power supply system are checked half-yearly. Once a year, the basic maintenance is carried out.

The applicant considered three tasks for this WCS that mark the overall worst-case scenarios

- The *cleaning of the anodes* is performed weekly and takes on average 1.2 hours (90th percentile = 2.3 hours; based on 68 DU responses) by 1.8 workers (90th percentiles = 3 workers; based on 71 DU responses).
- The yearly *complete maintenance* covers a range of tasks (e.g., checking on the electronic works in the electrolyte basin of the bath). On average, 2.6 workers (90th percentile = 4 workers; based on 44 DU responses) need 12 hours (90th percentile = 35.2 hours; based on 43 DU responses) to complete the tasks. As a worst-case (90th percentile), 4 workers need 35.2 hours (i.e. 4.4 working days). The applicant mentioned that not all of the tasks pose the threat of direct contact to CrO_3. The applicant mentioned that, as a worst-case scenario, it is assumed that all tasks imply contact to contaminated surfaces although in practice this is not the case.
- The *exchange of the electrolyte solution* of the bath is an infrequent maintenance task Impurities can be carried over and accumulate (e.g. sulphate impurities originating from the CrO_3 used or other metals such as copper or iron stripped of the cylinder), which interfere with the process of an exchange of the electrolyte should be performed. A partly exchange of the electrolyte is also performed if the CrO_3 concentration in the bath is too high. This task was not the subject of the DU survey since it is performed occasionally and therefore the DU information might not provide useful information. The applicant estimated, as a worst-case, that the task is performed every third year, takes one working day (8 h) and includes 2 workers.

WCS 6: Waste management

Process waste with potential Cr(VI) loads (e.g., waste from repair work or PPE) are stored in closed containers which are collected by licensed waste management companies for treatment, incineration, and disposal of incineration residues at licensed landfills. The collected water from the scrubber is redirected in the process cycle. The electroplating unit is a closed process circle without wastewater production. The exposure potential during disposal of the process waste that is collected into the containers or waste bins is considered negligible by the applicant. It is considered a common practice that waste containers are closed for transportation, and both waste and waste containers are handled in such a way that contamination, e.g. of outer surfaces, is prevented.

Table 1: Contributing scenarios presented in the use

Contributing scenario	**ERC/PROC**	**Name of the contributing scenario**	**Size of the exposed population**(1)
ECS 1	ERC5	Chromium trioxide-based functional chrome plating of cylinders	Regional: 447 7 million Local: 1 170 000
WCS 1	PROC 1	Delivery and storage of raw material	269 (2.3 × 117)
WCS 2	PROC 13	Chrome electroplating unit	515 (4.4 × 117)
WCS 3	PROC 8b	Sampling	257 (2.2 × 117)
WCS 4	PROC 8b	Concentration adjustment with liquid CrO_3	246 (2.1 × 117)
WCS 5a	PROC 28	Maintenance – cleaning of anodes	211 (1.8 × 117)
WCS 5b	PROC 28	Maintenance – complete inspection	304 (2.6 × 117)
WCS 5c	PROC 28	Maintenance – exchange of electrolyte	234 (2.0 × 117)

WCS 6	PROC 8b	Waste management	117 (1.0 × 117)
(1): the total number of workers per WSC was estimated by multiplying the calculated mean number of workers per site based on the survey results with the total of DUs' sites (N = 117)			

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

Although the cylinders of the rotogravure printing and embossing are different, the electroplating process is the same and the key functionalities used to assess the performance of potential alternatives are also the same. Thus, the assessment of alternatives and the substitution timelines are valid for both processes.

In describing the key functions of the chrome (VI) coating the applicant refers mainly to the quality of the printing and embossing technique and the durability of the printing and embossing cylinders produced. The applicant describes that no other technology can provide printing cylinders with a highly wear-resistant coating, which is able to withstand long printing runs, in combination with a high level of colour schemes and highest printing resolutions.

In all rotogravure printing and embossing processes (publication rotogravure, packaging rotogravure and decorative rotogravure printing), the gravure cylinders must have a surface that is homogeneous, scratch-proof, highly wear-resistant, corrosion-resistant and hard (> 900 HV), as interaction with hard ink particles, with the doctor blade and the substrate causes wear to the cylinder's surface. Properties like wear resistance and hardness are considered to be very important. The key functionalities and the requirements are summarized in Table 2.

Table 2: Key performance functionalities and requirements of the functional chrome plating in the applicant's application for authorisation

Key performance functionalities	Requirement
Hardness	900-1500 HV
Layer thickness	6-15 µm
Layer homogeneity	Application of homogenous layer
Adhesion to substrate	High adhesion to substrate
Deposition rate/plating time	20 to 40 minutes
Surface morphology/density of microcracks	200-700 cm^{-2} are required to ensure optimal ink/lubrication distribution
Coefficient of friction / surface roughness (Rz)	0.3-0.5 µm

Wear resistance	Comparable to currently produced cylinders
Corrosion resistance	Resistance over entire service life of cylinder

For most key characteristics the requirements are provided in quantitative units, but further details on the measurement techniques are not provided. The key properties are related to the life span of the cylinders (e.g. adhesion to substrate, wear resistance, corrosion resistance), production time (deposition rate) and correct transfer of ink to the substrate (e.g. layer homogeneity). Cylinders must withstand 1-12 months in storage and must resist printing with solvent-and-water-based inks over their entire service lives. Longer deposition rates may lead to interruptions in printing runs or delays in normal operation.

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

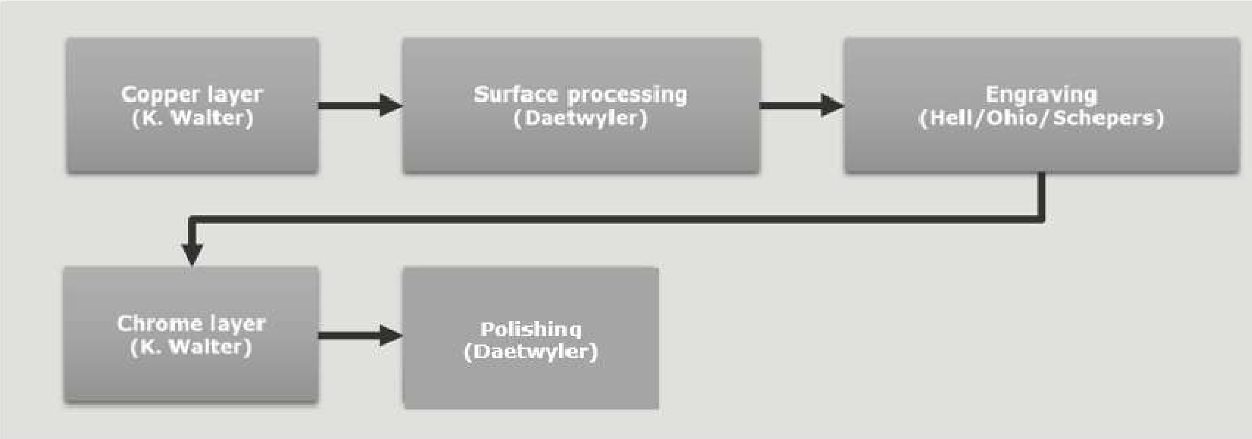
The applicant is importer of chromium trioxide, commissions the formulation of the chromium (VI) electrolyte formulation by a third party and provides the chromium (VI) formulation and the equipment for the functional chrome plating of rotogravure and embossing cylinders that they produce for companies in three printing market sectors:

- Packaging gravure
- Publication gravure and
- Decorative gravure

Thus, the actual chrome plating of rotogravure and embossing cylinders is carried out by the applicant's DUs.

Embossing of substrates plays a role in all the above three sectors. Embossing can increase the value of the print results by adding a 3D-structure and specific haptic to it. Since the same cylinder dimensions are used as in rotogravure printing, it is easy to provide the print with the appropriate structure directly after the printing process within the same process (printing + embossing).

The services that the applicant delivers are carried out in close cooperation with other subsidiaries within Heliograph Holding, who provide services for different manufacturing steps of the rotogravure cylinders (Figure 1).



Note: Bauer offers logistic services for cylinders between the brands of the holding that operate the different manufacturing steps. This brand also provides storage solutions for large quantities of cylinders.

Figure 1. Production flow between the applicant and other members within Heliograph Holding

The market sectors likely to be affected by the authorisation comprise the market sectors of the DUs being served by the applicant, but also the other subsidiaries within Heliograph Holding. These companies provide services to the production of rotogravure printing and embossing cylinders. The application for authorisation also affects the formulator that is commissioned by the applicant and competitive distributors that currently also deliver Cr(VI) formulations or solid Cr(VI) to the applicant's DUs. Upon SEAC's questions, the applicant indicated that it currently has a market share within the EEA of 55-65 % for the formulations covered by Use 1 and of 75-85 % for the plating units or machines covered by Use 2. The exact numbers are known by SEAC but claimed confidential. The DUs of the applicant comprise both:

- intermediate service providers that manufacture gravure printing and embossing cylinders and deliver these to printing companies (type I),
- printing companies that manufacture their own gravure and embossing cylinders (type II), or
- a combination of both (companies manufacturing gravure and embossing cylinders for their own use and for other printing companies) (type III).

The service providers comprise 40 % of the applicant's DUs and are entirely dependent on Cr(VI) plating; 60 % of the applicant's DUs are printing companies that coat their own cylinders. Most gravure printing firms do not have their own plating line in the EEA and are dependent on intermediate service providers.

0.4. Downstream user survey

The applicant collected information from its DUs through two surveys: one related to the CSR and one related to the AoA/SEA. One CSR-related survey was sent per site, while one AoA/SEA-related survey was sent for each registered legal entity. They were distributed as an online survey available in five languages (Spanish, Italian, French, German and English). Additionally, explanatory videos providing instructions on how to complete the survey and explaining the authorisation process were made available to all DUs in the five languages. The responses were collected from February 2020 to April 2020, with two reminders sent out before the deadline.

A total of 117 CSR- and 105 AoA/SEA-related questionnaires were sent, covering all DUs of the applicant in the EEA[13] of which five countries made up 83 % of the sample[14]. A response rate of 75 % was obtained for the CSR-related questions, i.e. a total of 88 responses. For the AoA and SEA-related questions, the response rates were 70 % (74 responses) and 70 % (73 responses), respectively. These results also include partially completed questionnaires with incomplete or missing answers. The DUs whose responses were unclear or incomplete were contacted individually and asked for clarification or further information, even past the response deadline. The DUs were not obliged to fill in all fields, some of the fields were left unanswered or might have not been applicable to a specific site. The applicant indicated that, following the premise to provide a worst-case approach, those values were excluded in order to ensure unbiased descriptive statistics.

The questionnaire was designed based on the knowledge of the applicant, who is in close contact with their clients and know most of their clients' sites (e.g., from yearly maintenance work). Furthermore, five German sites from DUs were visited by the applicant and the contracted consultant before the finalization of the questionnaire to collect feedback on the correct understanding of the questionnaire and to confirm its applicability to the process.

The applicant stated that companies that did not participate are mostly small companies located in Eastern Europe. The processes they use and their general situation in the supply chain are very similar to those of the companies that did participate in the survey. Therefore, the applicant considered that the data obtained through the DU survey is representative for all their DUs.

About 40 % of the applicant's DUs are service providers, companies that only do the plating of the gravure printing and embossing cylinders (Type I). The clients of these service providers (printing companies that commission the plating) were not reached by the survey.

For the CSR, information was collected about:

- the conditions under which the activities connected with the use of Cr(VI) are carried out,
- the duration and frequency of each task;
- the number of workers involved at the different sites;
- information on workplace and emissions to air monitoring data.

For the impact assessment, the applicant aggregated data for all the DUs covered by the use applied for (Use 2) by establishing a model DU to extrapolate the impacts for those DUs that did not respond to the survey. The annual revenue and profits for the model DU were derived by using values below the average revenues and profits of the respondents to avoid overestimation of the impacts. For further sensitivity, lower and upper bound estimates of profits, extrapolated based on the values derived for a model DU, was presented by the applicant. The model DU approach assumed that the average annual revenues related to Use 2 were €0.5-5 million per DU (compared with €7-20 million for those who responded to the survey) while the average profit was assumed to be €0.005-0.5 million per DU (compared with €0.4-3 million for those who responded to the survey).

The assessment of social impacts was according to the applicant based on a conservative approach, meaning that the extrapolations are more likely to result in overestimations on the risk side and underestimation on the job loss side. To derive the average number of exposed

[13] The countries covered were Portugal, Spain, France, Belgium, Germany, Italy, Greece, Poland, Austria, Slovakia, Hungary, Croatia and Romania
[14] Germany (N = 31), Italy (N = 24), Spain (N = 19), France (N = 15) and Poland (N = 8).

workers per DU by type, the total number of exposed workers was divided by the total number of DUs addressed in the survey for socio-economic assessment. As opposed to the approach of using underestimates for revenue and profit, the number of exposed employees was calculated based on a conservative approach to include the maximum risk to these workers. Regarding job losses, according to the model DU, the applicant assumed that the directly exposed workers would be those most likely to be dismissed in case of a refused authorisation, meaning that six directly exposed workers per DU were assumed to be dismissed at the remaining DUs that did not respond to the survey. The applicant considered six dismissals per DU as an underestimation. When asked about the DUs that did not respond to the survey, the applicant responded that these were mainly small companies located in Eastern Europe. The applicant considered that the processes and the general supply chain of these companies are similar to the companies that did respond, maintaining that the data obtained through the DU survey is representative of the applicant's DUs.

1. Operational Conditions and Risk Management Measures

The applicant pointed out that the DUs should comply with the OCs and RMMs outlined in the CSR. For that reason, the applicant is providing training and distributing information and has planned to conduct tutorials for their DUs.

These OCs and RMMs are summarized in section 1.1 and section 1.2 related to the exposure for workers and humans via environment respectively.

1.1. Workers

The applicant stated that the sites covered under their supply chain must ensure that the following risk management measures (RMMs) are implemented:

- The chrome plating and dechroming processes take place in closed units, run fully automatically and are monitored by the software system.
- Local exhaust ventilation system located at the chrome electroplating and the dechroming unit.
- Closed automatic system for the CrO_3 concentration adjustment.
- Process design is such that no direct contact with the CrO_3 solution occurs during the loading/unloading of the cylinders.
- Access to the chrome plating unit and the CrO_3 storage area is restricted to authorised and trained personnel only. The specific implemented measures might vary between the individual DUs depending on the working process and conditions at the site and may include barriers such as lockable doors, general access restriction to the production hall, access control to the facilities properties or warning signs.
- The plating unit has measures implemented to prevent unauthorised intervention (e.g. which may include for accessing the lid-opening option for modern systems, a key or a software password is needed).
- Standard Operating Procedures (SOPs) are in place and workers receive regular training regarding chemical risk management and how to properly wear the Personal Protective Equipment (PPE).

- The use of protective clothing, chemical-resistant gloves, and goggles are mandatory for tasks involving the handling of or potential contact with liquid formulations, e.g., during maintenance.
- Specific risk assessments are performed, documented and regularly reviewed and updated.
- Compliance with the company’s rules which are based on several European Directives is controlled by supervisors.
- Requirements to inform on objects containing carcinogens or mutagens, and label them clearly and legibly, together with warning and hazard signs.

Table 3: Operational Conditions and Risk Management Measures (sub-set of Succinct Summary of RMMs and OCs)

Contributing scenario	**Concentration of Cr(VI)**	**Duration and frequency of exposure**	**Engineering controls + effectiveness as stated by the applicant**	**PPE as stated by the applicant**	**Organisational controls** (access control, procedures, training)
WCS 1 Delivery and storage of raw material PROC: 1	≤ 35 %	1.4 h (90th percentile of DUs) and 10 times per year (90th percentile of DUs)	Closed system (closed IBC containers	Protective clothing, safety footwear	Occupational Health and Safety Management System, trained workers
WCS 2 Chrome electroplating unit PROC:13	≤ 20 %	≤ 8 h, daily	LEV (90 % eff.) Natural ventilation (4)	Protective clothing, safety footwear, face protection (e.g. safety goggles, face shield) (1)	Occupational Health and Safety Management System, trained workers
WCS 3 Sampling PROC 8b	≤ 20 %	15 min (90th percentile of DUs); 8 times per month (90th percentile of DUs)	LEV (90 % eff.) Natural ventilation (4)	Protective clothing, safety footwear, face protection (e.g., safety goggles, face shield), chemical resistant gloves	Occupational Health and Safety Management System, trained workers
WCS 4 Concentration adjustment with liquid CrO_3 PROC 8b	10-50 %	60 min (90th percentile of DUs); 4 times per month (90th percentile of DUs)	Natural ventilation (4)	Protective clothing, safety footwear, face protection (e.g., safety goggles, face shield), chemical resistant gloves	Occupational Health and Safety Management System, trained workers
WCS 5a Maintenance (3) – cleaning of anodes PROC 28	≤ 20 %	138 min (90th percentile of DUs); weekly	Natural ventilation (4)	Protective clothing, chemical resistant clothing (e.g., apron) safety footwear, face protection (e.g., safety goggles, face shield), chemical and cut resistant gloves	Occupational Health and Safety Management System, trained workers
WCS 5b Maintenance (3) – complete inspection PROC 28	≤ 20 %	480 min; 4.4 days per year, (90th percentile of DUs; 220 working	Natural ventilation (4)	Protective clothing, chemical resistant clothing (e.g., apron) (2)	Occupational Health and Safety Management System, trained workers

		days/year)		safety footwear, face protection (e.g., safety goggles, face shield) (2), protective gloves, chemical and cut resistant gloves (2)	
WCS 5b Maintenance (3) – exchange of the electrolyte PROC 28	≤ 20 %	480 min; every third year (220 working days/year)	Natural ventilation (4)	Protective clothing, chemical resistant clothing (e.g., apron) safety footwear, face protection (e.g., safety goggles, face shield), chemical resistant gloves	Occupational Health and Safety Management System, trained workers
WCS 6 Waste management PROC 8b	≤ 20 %	< 1 min, daily	Closed system (closed waste containers)	Protective clothing, safety footwear	Occupational Health and Safety Management System, trained workers

(1) Only necessary when in close vicinity to the plating unit (e.g., during program set-up)

(2) Only tasks leading to potential exposure to the electrolyte (i.e. mainly tasks in the upper basin of the bath) require wearing of the complete set of PPE

(3) The PPE is described for the maintenance scenarios reflect tasks with the highest exposure potential. Those tasks hence require a higher level of PPE. Other maintenance tasks that are not covered in this table might need lower protection levels. In the applicant’s manuals and maintenance instructions, detailed information on individual tasks and the corresponding PPE that should be worn can be found.

(4) The applicant stated that the production areas often have additional workplace exhaust systems and the presence of such systems may be viewed as an industry standard. However, good natural ventilation was considered as the worst-case.

1.2. Environment/Humans via the environment

Air

The electroplating units used by the DUs are closed-loop systems with limited potential for exposure. They are equipped with fixed capturing hoods installed at the sides of the Cr(VI) containing plating unit. The exhaust air is then passed through wet scrubbers according to the best available technique. The water from the chrome scrubber is redirected into the process cycle. A sensor monitors the functioning of the exhaust air system. The process stops immediately in any event of disturbance or malfunction.

In the answer to RAC's question concerning the implementation of this technical system in DU sites, the applicant stated that the exhaust monitoring system is offered with all new plating units from the applicant. The applicant estimates that currently 20 % of the units are equipped with such a system. At the same time, the applicant assumes that a large number of machines have been retrofitted or are being retrofitted to comply with Machinery Directive 2006/42/EC and the new ATEX Directive 2014/34/EU. For compliance, these directives require continuous exhaust monitoring for explosion protection in order to extract the hydrogen formed. If the extraction system fails, the chrome plating process must be stopped.

The installation of a chrome scrubber is assumed as a standard industry practice to reduce chrome emissions. The scrubber can be obtained directly from the applicant or other providers and is installed either by the DU itself or by external service providers.

Furthermore, the redirection of water from the scrubber back into the process cycle is supported by the applicant's plating unit and technically presents a simple pipeline connection between the scrubber and the plating unit. It is assumed that all DUs apply this installation since external disposal of CrO_3 containing liquid is expensive and reusage of the scrubber water does not have a negative impact on the process.

The applicant had received information on air emissions from 28 companies in 8 EU Member States. The measurement data was used to calculate the release factor of 0.083 %.

Water

During the chrome plating of cylinders, using the applicant's electroplating unit, no wastewater is produced. Any liquids remain within the system as a closed circuit. When the chromium solution needs to be replaced, it is pumped into an IBC and disposed of via external service providers, who perform the reductive treatment. Any liquids remain within the system and the water used to rinse out the equipment is collected and recycled or disposed of in specialist facilities.

Soil

No release to the soil.

Waste (other than wastewater)

No release from waste. Process waste with potential Cr(VI) loads are stored in closed containers which are collected by licensed waste management companies for treatment, incineration, and disposal of incineration residues at licenced landfills.

Table 4: Environmental RMMs – summary

Compartment	RMM	Stated Effectiveness
Air	Fixed capturing hoods, wet scrubbers.	> 99 %
Water	Closed-circuit, collection, and disposal by specialist facilities.	100 %
Soil	Liquid and solid waste collected by licenced waste management companies.	100 %

1.3. RAC's evaluation on the OCs and RMMs

RAC acknowledges that the DU survey provides detailed information about the OCs and RMMs in place to limit the workers' exposure and exposure via the environment at the DUs' sites.

RAC considers that the OCs and RMMs to limit the workers' exposure in place are adequate (e.g., closed automatic process units, LEV).

However, RAC points out that the information related to the OCs and RMMs are obtained by a DU survey, which has its uncertainties:

- It is not clear to which extent the survey results can be extrapolated to the non-responding DUs, considering that they are mostly small companies located in Eastern Europe.
- Although the overall responses from the applicant's DUs are 75 %, for several WCSs the response rate regarding working hours and the number of workers involved is lower (around 50 %).
- As also mentioned by the applicant, the interpretation and comprehension of the questions may differ among the DUs (e.g., regarding the shift length or the total time needed per all workers vs. the total time needed per individual worker).
- Some responses related to the RMMs and OCs are based on the information provided by DUs that also use solid CrO_3 and therefore might give a distorted picture of the situation, considering that this authorisation is only relevant for the use of liquid CrO_3.

RAC notes that the information of the maintenance task "exchange of the electrolyte solution" (frequency, duration of task, number of workers involved) is provided by the applicant and was not part of the DU survey. RAC points out that, although this is an infrequent task, information from the DUs that perform this task, could corroborate these operational conditions.

RAC takes note that for the exchange of containers with liquid CrO_3 (WCS 4), the applicant has developed new dosing systems that prevent contact to CrO_3 and unintentional dripping and that currently the applicant is developing a valve and pump system for sampling.

The OCs and RMMs regarding release to the environment described in the CSR and in the answer to RAC's questions are appropriate. There are, however, concerns about the OCs and RMMs currently in place within the 117 DUs.

The applicant mentioned that only those DUs that comply with the RMMs and OCs outlined in the CSR are covered by the authorisation. The applicant pointed out that they have close communication with their customers and DUs that would like to be covered within this application.

However, it is not clear if all RMMs and OCs mentioned in the CSR, like the use of mist suppressants, form part of the minimum requirements for their DUs to comply with.

The CSR, which is a part of this application for authorisation does not contain an explicit list of minimum RMMs and OCs, but RAC considers that such a list might be of benefit for the DUs and the national enforcement authorities. Therefore, RAC requests the applicant to update the CSR by including the following list of minimum RMMs and OCs. All the DUs of chromium trioxide covered by this Use have to comply with these minimum requirements. The applicant may add additional RMMs and OCs items to the list if they consider the list below as being incomplete.

List of minimum RMMs and OCs for all the DUs of chromium trioxide within this Use[15].

- The scope of the CSR and the application for authorisation is limited to the use of liquid mixture containing CrO_3. The DUs of the applicant shall comply with the following OCs and RMMs in place to minimize the workers' exposure and the substance releases to the environment.

- Electroplating units / dechroming units are closed-loop systems equipped with fixed capturing hoods and run fully automatically during chrome-plating and are monitored by the software system. Loading and unloading can be done manually. Also, the machine and chrome-plating can be operated manually via the control unit (software-based). In relation to the dechroming activity, any wastewater that could contain Cr(VI) is disposed of separately.

- Mist suppressants[16] are used to minimize any potential worker's exposure to Cr(VI) and environmental releases during the electroplating process. The electrolyte of the dechroming bath shall contain a reducing agent (such as e.g. sodium hypophosphite) which scavenges any Cr(VI)-containing compounds directly as they are formed by reducing them to Cr(III). The reducing agent shall be present in such a concentration that Cr(VI) cannot accumulate in the electrolyte of the dechroming bath at any time. The concentration shall be monitored regularly.

- The exhaust air system of the chrome electroplating units, which is connected to the local exhaust ventilation system, has a sensor that monitors the partial pressure difference. The process stops immediately in the event of disturbance or malfunction. Older electroplating units in which this system is not installed should be retrofitted at the next convenience.

- The plating unit / dechroming unit has measures implemented to prevent unauthorised intervention.

- During standard operation of the processes (electroplating and dechromating), no employee is in the immediate vicinity (within a distance of ~1 m of the units).

- Closed automatic dosing system for the CrO_3 concentration adjustment.

- The design of the units is such that no contact with CrO_3 solution is possible during loading/unloading takes place (the CrO_3 solution is situated in an enclosed basin below

[15] The list is a result of the answers of the applicant to RAC's questions clarifying the OCs and RMMs provided in the application. RAC notes that in addition to the list the OCs and RMMs presented in Table 2 and 3 are evidently also part of the minimum requirements as they have been submitted with the application and represent the conditions, which result the presented worker exposure .

[16] The use of PFOS as mist suppressants is restricted. According to the Commission delegated regulation (EU) 2020/1203 of June 2020, the use of PFOS as mist suppressant for non-decorative hard chromium (VI) plating in closed loop systems is allowed until 7 September 2025

the main tank and is only pumped up to the main tank when the plating process is started and the unit is closed. After the plating process is finished, the solution flows back into the basin and the cylinder is rinsed with water before the unit is opened again for unloading).

- The access to the chrome plating unit, respectively the chrome formulation areas and the CrO_3 storage area is restricted to authorised and trained personnel only.
- The electroplating units and dechroming units are always installed in the same working area and therefore are subject to the safety measures of the area and part of the examined exposure measurements.
- Standard Operating Procedures (SOPs) are in place and workers receive regular training regarding chemical risk management and how to properly wear the Personal Protective Equipment (PPE).
- The use of protective clothing, chemical-resistant gloves, and goggles are the mandatory minimum requirement for tasks involving the handling of or potential contact with liquid formulations, e.g., during maintenance.
- Specific risk assessments whenever considered relevant and appropriate by the national enforcement authorities or by the company, are performed, documented and regularly reviewed and updated by the company.
- The company's rules which are based on several European Directives are presented to all employees involved with the affected tasks. Compliance which these rules is controlled by the company's supervisors.
- Requirements to inform on objects containing carcinogens or mutagens, and label them clearly and legibly, together with warning and hazard signs.
- No Cr(VI)-containing wastewater is released into the environment during the electroplating / dechromating processes (closed-loop processes). Wastewater that does contain Cr(VI) is disposed of separately. Any wastewater that could contain Cr(VI) is disposed of separately.
- In the chrome baths, the exhaust air is passed through wet chrome scrubbers according to the best available technique.
- The water from the chrome scrubber is redirected into the process during standard operation. Exchange of liquids is possible if necessary.
- The replacement of CrO_3 solution is performed in a closed system and collected in a container (typically this is done by attaching a pump onto the bath and pumping the solution into an IBC). The collected waste is disposed of for adequate treatment.
- If necessary, remaining liquids in the electroplating / dechroming units and all rinsing water used for cleaning the equipment is collected and disposed of for adequate treatment.
- Process waste (other than wastewater) with potential Cr(VI) loads are stored in closed containers which are collected and disposed of for adequate treatment.

1.4. RAC's conclusions on the OCs and RMMs

Overall conclusion

The OCs and RMMs implemented for the workers' protection, including the selection of PPE are considered to be appropriate and effective and follow the hierarchy of control principles.

As indicated in section 1.3 above, RAC emphasizes that the scope of the CSR and the application for authorisation is limited to the use of liquid mixture containing CrO_3.

Also, RAC considers that, in terms of environmental release minimisation, the OCs and RMMs are effective and appropriate in limiting the risks to the general population.

However, RAC has concerns related to the inherent uncertainties of the applied survey and the clarity of the minimum required OCs and RMMs for the DUs' compliance as described in the CSR and the applicant's responses to RAC's questions.

RAC takes notes of the existence of dosing systems that prevent contact with CrO_3 and unintentional dripping when changing the containers, the use of mist suppressants by the majority of the DUs and the development of a valve and pump systems for sampling.

The abovementioned concerns lead to conditions for the authorisation (see section 7) and proposed recommendation for the review report (section 9)

Are the operational conditions and risk management measures appropriate[17] and effective[18] 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

2. Exposure assessment

2.1. Inhalation exposure

Occupational exposure estimates for the different WCSs are based on qualitative assessment (WCS 1 and WCS 6), measured data (WCS 2) and modelled estimates (WCS 3, WCS 4 and WCS 5). The corresponding information was provided by the DUs participating in the survey. In cases where the sample size and sampling strategy was adequate, the risk characterisation relied on the measured exposure values. When no measurement results (or no sufficient/adequate measured data) were available, the exposure was modelled based on the

[17] '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.
[18] '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.

information of the process description provided by DUs.

Qualitative assessment:

According to the applicant, the exposure potential during storage (WCS 1) and disposal of the process waste into collection containers or waste bins (WCS 6) is considered negligible.

Monitoring

For WCS 2 the exposure assessment is based on static and personal measurements received from the DUs participating in the CSR-related DU survey. Measurements were included, if the provided information on measurement type, sample duration, limit of detection (LOD) etc. were complete and the following criteria were met: (1) LOD ≤ 1 µg Cr(VI)/m^3 and (2) measurement duration ≥ 2 h.

In total, 69 measurements from 31 DUs were included in the assessment (~26 % of all DUs). Of these DUs, 23 use liquid CrO_3, 2 DUs solid CrO_3, 5 DUs both forms and 1 DU did not provide information in the questionnaire. The applicant decided to include all available DU data, independently of the form of CrO_3 used, since the final concentration used for electroplating is the same within the plating unit and therefore no difference in exposure is expected.

Of those measurements, 40 were based on personal sampling and 29 on static sampling. The samples were taken during routine tasks at and around the electroplating unit or galvanic (dechroming) line. 45 of the measurements (16 static and 29 personal measurements) were below the respective LOD, which lay between 0.004 to 1.000 µg Cr(VI)/m^3. For further calculations, half of the detection limit was considered for those measurements.

To weigh the measurements of the different companies equally and avoid overrepresenting the results of single companies who provided more data than others, statistical values were calculated for each company. Therefore, the results from static and personal sampling were partly pooled. Following this approach, an arithmetic mean of 0.29 µg Cr(VI)/m^3 and a 90th percentile value of 0.50 µg Cr(VI)/m^3 could be derived.

The applicant pointed out that the measurements often cover dechroming operators or were located at the plating line. According to the applicant, the generation of Cr(VI)-containing mist during dechroming is significantly lower than during electroplating. Therefore, the applicant assumed that potential exposures during the dechroming process are covered by the presented measurements.

Modelling

The modelled exposure estimates were obtained by using ART version 1.5. for WCS 3, WCS 4 and WCS 5. The corresponding ART reports were provided by the applicant.

For the modelled 8 h TWA exposure estimate, the applicant used the 90th percentile value of the duration of the task.

2.2. Dermal exposure

Dermal exposure was not assessed by the applicant since according to RAC/27/2013/06 Rev.1, there are no data to indicate that dermal exposure to Cr(VI) compounds presents a potential cancer risk to humans.

2.3. Biomonitoring

The applicant did not provide biomonitoring data of their DUs.

Table 5: Summary of exposure information –inhalation

Contributing scenario	Method of assessment	Exposure (8h TWA) µg Cr(VI)/m³	Duration and frequency of exposure	Exposure corrected for frequency µg Cr(VI)/m³
WCS 1 Delivery and storage of raw material	Qualitative	0	1.4 h (90th percentile of DUs) and 10 times per year (90th percentile of DUs)	0
WCS 2 Chrome electroplating unit	Measurements (N = 69)	0.5	≤ 8 h, daily	0.5
WCS 3 Sampling	ART	0.31	15 min (90th percentile of DUs); 8 times per month (90th percentile of DUs)	1.6×10^{-2} (1)
WCS 4 Concentration adjustment with liquid CrO_3	ART	0.91	60 min (90th percentile of DUs); 4 times per month (90th percentile of DUs)	4.6×10^{-2} (2)
WCS 5a Maintenance – cleaning anodes	ART	1.1	138 min (90th percentile of DUs); weekly	0.22 (3)
WCS 5b Maintenance - complete inspection	ART	3.7	480 min; 4.4 days per year, (90th percentile of DUs; 220 working days/year)	7.4×10^{-2} (4)
WCS 5c Maintenance – exchange of electrolyte	ART	12	480 min; once each 3 years (220 working days/year)	1.8×10^{-2} (5)
WCS 6 Waste management	Qualitative	0	< 1 min; daily	0

(1) The estimate was based on the time taken for the task per month (= 120 minutes). In order to adjust for daily exposure, the exposure value was multiplied with a factor of 0.25 (4 weeks of a month) and 0.20 (5 working days a week).
(2) The estimate was based on the time taken for the task per month (= 240 minutes). In order to adjust for daily exposure, the exposure value was multiplied with a factor of 0.25 (4 weeks of a month) and 0.20 (5 working days a week).
(3) The estimate was based on the time taken for the task per week. In order to adjust for daily exposure, the exposure value was multiplied with a factor of 0.20 (5 working days a week).
(4) The estimate is based on a standard working day of 8 h. The total task takes 35.2 hours (= 4.4 working days) per year (220 working days). In order to adjust for daily exposure, the exposure value was multiplied with a factor of 4.4/220.
(5) The estimate is based on a standard working day of 8 h. Since the task is performed every third year, the exposure value was multiplied by (1/3) × (1/220).

2.4. Environmental releases

Exposure and risks for the environment and man via environment described in the corresponding ECS (section 9.3.2 of the CSR) is based on emission measurements from exhaust gases provided by the DUs.

The provided data were included when relevant information to estimate the yearly emissions were available (*e.g.*, CrO_3 tonnage, rate of the exhaust ventilation, emission days). Sufficient information on emissions to air allowing an exposure assessment for man via environment were available from 28 companies in 8 EU States (Austria, Croatia, France, Germany, Italy, Poland, Portugal, and Spain) covering the period 2007-2020. The measurements were available: one measurement data from 2007, one from 2013, one from 2015, one from 2016, 3 from 2017, 5 from 2018, 12 from 2019 and 3 from 2020. The date was unknown for one measurement. The total annual releases ranged from 0.016 to 2.814 kg/a. The average daily releases ranged from 4.44×10^{-5} to 7.71×10^{-3} kg/day.

The estimation of the resulting exposure was performed with Chesar 3.

To derive values for emission to air to be used for the risk assessment, the DUs' data were used to individually calculate the $C_{local\ air\ annual}$. In order to do so, daily releases of Cr(VI) were calculated for each DU in a first step. Subsequently, daily release values were multiplied with the $Cctd_{air}$ (concentration in air at a source strength of 1 kg/d, *i.e.* 2.78×10^{-4} mg/m³)[19] to calculate the local concentration in air during release episode ($C_{local\ air}$).

The resulting values ranged from 1.23×10^{-8} mg/m³ to 2.14×10^{-6} mg/m³ with a mean value of 4.94×10^{-7} mg/m³ and a 90th percentile of 1.42×10^{-6} mg/m³. The maximum value was used in the risk assessment of man via environment and the pathway inhalation. The highest reported annual tonnage of 6.5 t CrO_3 (i.e. 3.38 t Cr(VI) was related to the maximum calculated exposure estimate of 2.14×10^{-6} mg/m³ in Chesar 3. The release fraction was determined as 0.083 %. The local released amount was 2.805 kg/year.

Water

Any releases to the aquatic environment are negligible as CrO_3 is contained within the preparation and the water used to rinse out the equipment is collected and recycled or disposed of in specialist facilities.

Soil

No exposure to soil is expected.

Table 5: Summary of releases to the environment

Release route	**Release factor**	**Release per year** kilograms Cr(VI)	**Release estimation method and details**
Water	0 %	0	Not relevant.

[19] ECHA Guidance on Information Requirements and Chemical Safety Assessment – Chapter R.16: Environmental exposure assessment (Version 3.0)

Air	0.083 %	2.805	Based on measured data.
Soil	0 %	0	Not relevant.
Waste	0 %	0	Not relevant.

The oral route of exposure is relevant for exposure via the food (fish) and drinking water, and a quantitative assessment of exposure and risks is performed. Since no exposure to soil is assumed only oral exposure via water is considered relevant. Taking into account the lack of releases to wastewater only deposition of airborne Cr(VI) particles is considered relevant. The exposure estimates were derived with Chesar 3. The summed estimated daily dose from the consumption of drinking water and fish was 2.44×10^{-7} mg/kg bw/day.

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

Parameter	**Local**	**Regional**
PEC in air (mg Cr(VI)/m^3)	2.14×10^{-6}	1.59×10^{-15}
Daily dose via oral route (mg Cr(VI)/kg bw/d)	2.44×10^{-7}	-

Following the EU RAR 2005, the applicant has applied a reduction factor of 97 %[20] to the estimated dose of drinking water and fish to account for the rapid transformation of Cr(VI) to Cr(III) in the environment. Therefore, **the sum of the estimated dose via drinking water and fish results in** 7.32×10^{-9} mg/kg bw/day instead of 2.44×10^{-7} mg/kg bw/day.

2.5. RAC's evaluation of the exposure assessment

Workers exposure

RAC takes note that that qualitative exposure assessment, measurement data and modelled exposure estimates are taken forward for the risk assessment.

RAC agrees with the applicant's conclusion that for WCS 1 (Delivery and storage of solid CrO_3) and WCS 6 (Waste management) no exposure exists.

RAC considered that the criteria used by the applicant to include the measurements for the exposure assessment of WCS 2 were adequate (LOD ≤ 1 µg Cr(VI)/m³; measurement duration ≥ 2 h). Contextual information of each measurement has been provided by the applicant

[20] This approach was taken in accordance and based on the EU RAR 2005, where on p. 48 it is stated: *"For the risk assessment, it will be assumed that for acidic (or neutral, where high concentrations of reductants for Cr(VI) exist) soils, sediments and waters, Cr(VI) will be rapidly reduced to Cr(III) and that 3 % of the Cr(III) formed will be oxidised back to Cr(VI). The net result of this is that of the estimated Cr(VI) release to the environment, 3 % will remain as Cr(VI) and 97 % will be converted to Cr(III)."*

(sampling period, detection limit, sampling type).

RAC points out that the number of DUs that provided measurement data is limited (26 %) and therefore some uncertainties exist as to what extent the calculated exposure estimate is representative for all DUs.

Although RAC acknowledges that the approach taken by the applicant, to calculate the workers' exposure for WCS 2 based on the measurement data from different DUs, is valid and that the consistency of these data (90th percentile 0.50 $\mu g/m^3$ $\mu g/m^3$, average 0.29 $\mu g/m^3$, standard deviation 0.25 $\mu g/m^3$ [21]) is such, that the exposure estimates as calculated by the applicant can be used for the risk characterisation, RAC points out the following:

- several companies presented measurement data with a relatively high LoD value of 1 $\mu g/m^3$, while other companies presented a 5-to-10-fold lower LoD values. This might indicate that for several DUs the sensitivity of the analytical method can be improved.
- the mean value of each company (DU) is used to calculate the exposure estimate. As a worst-case approach, the applicant could have used the 90th percentile value or the maximum value of each company.
- if instead of half of the LoD, the LoD value would have been used for the exposure assessment, the 90th percentile of the mean values of each company would be 1 $\mu g/m^3$ with an average of 0.44 $\mu g/m^3$ [22].
- Contextual information about the characteristics of each company that provided measurement data is lacking (size, CrO_3 consumption, country). Related to this, RAC notes that 12 companies provided only one measurement result, 3 companies only presented relatively old monitoring data corresponding to the year 2012 and one company measured relatively high exposures, namely 1.7 $\mu g/m^3$.

RAC takes note that the measurement data cover also the potential exposures during the dechroming process.

RAC points out that for most WCSs the exposure estimates are modelled. RAC considers that the lack of measured exposure data that cover all WCSs is a key shortcoming in the exposure assessment. According to ECHA guidance, adequately measured, representative occupational exposure data should be available and should have been submitted in the application. This requirement is consistent with the requirements under the Chemical Agents Directive (98/24/EC) and Carcinogens and Mutagens Directive (2004/37/EC). For SVHCs, the exposure scenario needs to be detailed and conclusive.

RAC acknowledges that the applicant applied a conservative approach for the exposure assessment by taking forward the 90th percentile of the duration and frequency of the tasks of the information provided by the DUs.

RAC agrees that dermal exposure has not been assessed as dermal exposure to Cr(VI) compounds is not expected to present a cancer risk to humans (RAC27/2013/06 Rev 1).

Humans via the environment

Based on the OCs and RMMs presented in the CSR only exposure via air is relevant for humans via environment assessment. The assessment is based on measured values provided by 28 of

[21] Values calculated by RAC.
[22] Values calculated by RAC.

117 DUs. The emission values were calculated for each DU and the maximum local concentration in air was used for risk assessment.

The applicant explained in the answer to RAC's question about the representativeness of air emission data that only 28 companies provided these data. The average annual tonnage of DUs who provided air emission data was in accordance with the average annual tonnage of DUs described in the CSR. Since the sub-sample of DUs providing air emission data is representative in this regard and similar risk minimization measures are assumed, the applicant considers the provided data as representative for the group of DUs.

RAC acknowledges that Cr(VI) will transform rapidly in the environment to Cr(III) under most environmental conditions. This has been previously discussed in the EU RAR for chromate substances (EU RAR 2005) and will reduce the potential for indirect exposure to humans to Cr(VI) via the environment, particularly from the oral route of exposure.

RAC considers that the local PEC_{air} is considered for risk characterisation as a worst-case approach.

2.6. RAC's conclusions on the exposure assessment

RAC identified moderate shortcomings in the exposure estimates for workers, due to the lack of measured exposure data for most WCSs and the limited number of DUs that provided measurement data.

RAC also identified minor shortcomings in the environmental release estimation related to the representativeness of the air emission data.

The abovementioned shortcomings lead to the proposed monitoring arrangements for the authorisation and recommendation for the review period (see sections 8 and 9).

3. Risk characterisation

The cancer risk is estimated according to the RAC reference dose-response relationship for the carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1, agreed at RAC 27)[23].

The applicant has conservatively assumed that all inhaled chromium trioxide particles are in respirable range and contribute to the lung cancer risk and therefore no exposure via the oral route (mucociliary clearance and swallowing of non-respirable fractions) needs to be considered, taking into account also that the excess lifetime risk for intestinal cancer is one order of magnitude lower than that for lung cancer.

3.1. Workers

The applicant presented for each WCS the exposure estimates with the corresponding excess

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

risk (see Table 7).

Since it is not possible to reasonably consider the combination of tasks for each DU, the applicant summed the exposure of all WCS as a worst-case approach. The applicant stated that in reality it can be assumed that the combination of all tasks is not covering an 8-hour working day. Therefore, the applicant concluded that the sum of all values, referred to a period of 8 hours, provides an overestimate of the actual exposure.

Table 7: Combined exposure and risk characterisation

Contributing scenario	Exposed population	Exposure value corrected for frequency µg $Cr(VI)/m^3$	Excess risk*
WCS 1 Delivery and storage of raw material	269	0.0	0.0
WCS 2 Chrome electroplating unit	515	0.5	2.0×10^{-3}
WCS 3 Sampling	257	1.6×10^{-2}	6.2×10^{-5}
WCS 4 Concentration adjustment with liquid CrO_3	246	4.6×10^{-2}	1.8×10^{-4}
WCS 5a Maintenance – cleaning anodes	211	0.22	8.8×10^{-4}
WCS 5b Maintenance - complete inspection	304	7.4×10^{-2}	3.0×10^{-4}
WCS 5c Maintenance – exchange of electrolyte	234	1.8×10^{-2}	7.3×10^{-5}
WCS 6 Waste management	117	0.0	0.0
Total exposure for 8 hours		0.87	3.5×10^{-3}

* Estimated individual risk resulting from exposure

3.2. Humans via the environment

Risk characterization is based on RAC/27/2013/06 (Rev.1) which establishes the reference dose-response relationships for Cr(VI) carcinogenicity via respiratory and oral route for the general population. Based on exposure for 70 years (24 hours/day, 7 days/week), the excess lifetime lung cancer mortality risk factor for the general population is 2.9×10^{-2} per 1 µg of $Cr(VI)/m^3$, the excess lifetime intestinal cancer risk factor is 8×10^{-4} per 1 µg of Cr(VI)/kg bw/day over an exposure duration of 70 years (24 h/day, 7 d/week).

The applicant provided the assessment of indirect exposure to humans via the environment at the local scale based on Chesar 3 calculations.

The risk assessment for humans exposed via the environment considers both the inhalation of airborne residues of CrO_3 and the oral intake via the food (fish) and drinking water at local and regional level. Taking into account the lack of releases to wastewater only deposition of

For general population: for 70 years of exposure (24 hours/day, 7 days/week)
Inhalation: excess lifetime lung cancer mortality risk of 2.9×10^{-2} per µg $Cr(VI)/m^3$
Oral intake: excess lifetime intestinal cancer risk of 8.0×10^{-4} per µg Cr(VI)/kg bw/day.

airborne Cr(VI) particles is considered relevant for exposure via the food.

The local PEC_{air} value is considered for risk characterisation as a worst-case approach.

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

Parameter	Local	
	Exposed population: 1 000	
	Exposure	Excess risk*
Humans via the environment – Inhalation	2.14×10^{-6} mg Cr(VI)/m^3	6.21×10^{-5}
Humans via the environment – Oral	7.32×10^{-9} mg Cr(VI)/kg bw/day	5.86×10^{-9}
Humans via the environment - Combined	Not applicable	6.21×10^{-5}

* Estimated individual risk resulting from exposure.

3.3. Environment

Not relevant.

3.4. RAC's evaluation of the risk characterisation

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

These shortcomings are addressed and discussed in section 2.5 and summarized in section 2.6.

RAC concludes that these shortcomings are not likely to affect the risk characterisation significantly.

For reference, the current binding Occupational Exposure Limit (BOEL) for this substance as of 17 January 2020 is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025).

3.5 RAC's conclusions on the risk characterisation

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

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

RAC notes that Cr(VI) is effectively reduced to Cr(III) in the environment. In addition, RAC agrees with the conclusions of the previous EU RAR for chromate substances that regional exposure may not be relevant. RAC, therefore, agrees with the applicant to only present the risk characterisation for the local scale.

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 is an importer. The suitability of alternatives is assessed from the perspective of the applicant and from the perspective of the DUs.

The applicant started the search for alternatives a decade ago and it comprised consultation of rotogravure industry associations, external institutions and other companies, data searches and experimental research either in-house or with external parties. The applicant considered two general categories of alternatives for the substitution of chromium trioxide in gravure applications:

i. alternative methods to the use of chromium trioxide in the coating of gravure cylinders but for which the same printing or embossing mechanism is applied, and
ii. alternative printing methods that do not use gravure cylinders in printing applications altogether.

Both categories are briefly described in the AoA, where for the first category three types of alternatives were distinguished: alternative coating technologies, alternative substances to CrO_3 and alternative base material for the cylinders. The reasons for rejecting the various alternatives are briefly described in the AfA and are summarized in Table 9. The short-listed alternatives are underlined.

Table 9: Overview of alternatives considered by the applicant and main reasons for rejection. The short-listed alternatives are underlined.

Alternative	**Main reason for rejection**
Alternative coating technology	
Vacuum processes (Diamond-like carbon (DLC), Roto-hybrid technology, plasma vacuum, PVD processes, CVD processes (CrN))	Production time too long. CVD and PVD require very high surface cleanliness to achieve good adhesion. Extremely high costs for techniques like PVD/CVD (equipment cost for the protection layer is more than 10 times higher than the current cost).
Spray coating	Non-homogeneous and rough/porous surfaces

Cr(III) electroplating with Cr(III)-based electrolyte	None: Short-listed alternative
Alternative substance to CrO_3	
Nickel and nickel alloys and nickel-phosphorus electroplating	Material too soft. Toxicological considerations
Cobalt and cobalt alloys coatings	Material too soft: 600-700 HV. Increasing hardness by heating (1 000-1 200 HV) may result in cylinder deformation and long heating and cooling times
Polymer-coatings	None: Short-listed alternative
Alternative base material for cylinders	
Bronze	Material too soft: 200-600 HV
Anodized aluminium on aluminium embossing cylinders	Material too soft: < 600 HV
Surface modification – nitride steel	Direct imaging on steel not possible within acceptable time. Reuse of base cylinder would not be possible
Alternative printing technology	
Offset printing	Quality and consistency less than achieved by rotogravure. Not possible to print on films or foils
Flexographic printing	Lower ability to print half tones. Quality decreases over long printing runs
Digital printing	High costs because of ink. Only small volumes.

The applicant carried out an assessment of some vacuum processes in collaboration with Fraunhofer Institute between 2010 and 2013 but decided to discontinue further R&D activities on vacuum processes. The applicant collaborated with other companies and external institutions to assess various new coating techniques, such as nickel plating, vacuum technology and polymer coatings between 2012 and 2014, but most of these showed to be not technically feasible (see Table 9). Additional information on the rejections is described in the AoA and answers by the applicant to SEAC's Q13 in the first round of questions. Chromium nitride coatings, brass and zinc coatings and HVOF process were tested in-house or results were directly retrieved from other institutes, whereas other technologies were excluded based on literature data, exchange with customers and tests from other institutions.

The application for authorisation focuses on chromium trioxide-based functional chrome plating of cylinders used in the rotogravure printing and embossing industry. Although alternative printing techniques are not directly a substitute to chrome plating, the applicant has considered such a transition by its DU's as it constitutes a possible partial substitution of gravure printing for some DUs, as they have indicated in the DU survey. Thus, the applicant has considered these technologies in the AoA. For some DUs digital printing was an option either to compensate rotogravure printing fully or to a limited extent. Other DUs mentioned alternative printing technologies such as flexography, offset technology and roto offset printing. The data provided by the applicant are summarised in Table 10.

Table 10: The printing technologies referred to in the applicant's analysis of alternatives

Type of printing	Sector of competition	Disadvantages
Offset	The direct competitor for the publication printing sector is offset printing.	– Not suitable for packaging printing, mainly because impossible to print on films and foils – Not seamless printing (only for decorative) – Quality and consistency are not comparable to rotogravure
Flexographic	The main competition to gravure printing in the packaging sector is flexographic printing.	– Higher wear, decrease printing quality – Printing forms have to be renewed multiple times due to a wear-induced decrease of printing quality – Medium to small volumes
Inkjet/digital	Applicable to decorative printing only for short runs	– Only for short runs – Very small volumes – Higher ink costs main limitation – Not for substrates like films which is the major substrate for printing flexible packaging material

In the AfA the applicant indicates that rotogravure is rather expensive but generates high-quality standard prints and is primarily used for long runs. Flexography has lower initial set-up costs and is used for medium and small volumes requiring medium but overall acceptable quality. Inkjet/digital printing has similar advantages compared to the high initial set-up cost in terms of cylinder costs in rotogravure printing. Digital printing is mostly used for very small volumes and personalized printing due to its higher printing ink costs. No further information on the various printing techniques and the potential to replace rotogravure printing among their DUs was provided in the AfA. However, upon request from SEAC sufficient information was provided by the applicant. The feasibility of Heliograph Holding to switch to other printing techniques was provided as well as the market shares of the various types of printing techniques within the three sectors. The applicant also answered questions on the costs of substituting to an alternative printing technique, the technical feasibility, and provided a comparison of the different techniques. The applicant highlighted that approximately 40 % of its DUs are service providers (not printing themselves) for which only an alternative coating technology using Cr(III) is relevant.

Regarding flexographic printing, which is considered by the applicant as a future competitor to gravure printing, the applicant considers that flexographic printing and gravure technologies will continue to converge in terms of printing press performance. Shorter, one-time print jobs will benefit flexographic printing, multiple-run print jobs, as most of the in-house printing that the DUs (Type II and III) perform, will be more cost-efficient in gravure. However, as the print sizes and the exact cost distribution are confidential data of the DUs (mainly Type II and III), the applicant does not have access to this data and was unable to quantify relevant cost data and, as a result, it was not possible for the applicant to accurately predict which printing method would be more efficient at a certain point. The applicant has described the alternative printing techniques briefly in chapters 4.3.8 to 4.3.10 and concluded that alternative printing methods are available that could substitute rotogravure printing in some niche applications, such as printed electronics[24] and security printing[25]. The applicant indicated that these applications are not delivered by its DUs and thus that the alternatives are not relevant within the scope of the AfA. The applicant further indicated that replacement of rotogravure by other printing technologies, such as offset or flexography, would require DUs to install a whole new printing unit (new printing presses) amounting to approximately €2.5 million per press, as well as new logistics, training of personnel and supply chains (approximately €800 000). Therefore, the total costs of transitioning to an alternative printing technique would be more than twice as high as one of the alternatives offered by the applicant. The applicant attached a letter from one of its DUs in its answers to questions that confirmed that a transfer from gravure to offset would not be economically feasible within the review period applied for due to high investment costs, lower output and higher costs per unit for offset. The applicant did not provide further details on alternatives for embossing in the AfA but indicated in the answers to SEAC that none of the printing techniques mentioned can replace gravure cylinders to emboss or laminate printed products.

As a result of the consultations with experts and its own R&D activities described above, the applicant decided to focus on the development of a Cr(III)-based plating and the development of polymer-based coatings as replacement of the currently used Cr(VI) plating technique. The applicant evaluated the Cr(III) coatings in development by other companies since 2013. Since 2015 the applicant is developing gravure cylinders based on Cr(III) coating with the goal to achieve stable and reproducible electroplating results, optimizing plating parameters, and assessing wear resistance. The development of the polymer-based coatings started in 2014. The applicant reports good progress with many of the technical requirements needed. However, it indicates that further testing is needed at DU sites to ensure the reliability of these technologies. These tests are expected to start in 2021. The applicant also reports that due to the new techniques, new plating lines need to be installed for the Cr(III) plating of the gravure cylinders or new manufacturing lines in the case polymer-coated cylinders are installed at the DUs' sites.

During the consultation, three comments were received. Two of the comments indicated that currently there are no feasible alternatives, whereas one comment indicated the possibility to have a nickel-phosphorus layer deposited together with boron carbide particles as an alternative. In their reply, the applicant indicated that it had investigated such coatings, but received widespread disapproval by their clients because of reasons of exposure to workers and users of the printed material. The applicant further indicated when answering SEAC's question on the topic that the nickel-phosphorus would not be a feasible replacement as the cylinders can currently not be coated in an automated way and that the technology needs to be completely redesigned, which would take much more time than the currently requested review period. The applicant responded on the Roto-Hybrid alternative (Table 9), that DUs may opt for the applicant's own two alternatives due to the long production times and the high energy consumption of the Roto-Hybrid alternative.

[24] See Printed electronics - Wikipedia
[25] See Security printing - Wikipedia

The applicant submitted a comprehensive substitution plan, containing a list of actions and a timetable with milestones, and applied for a 12-year review period comprising three different phases:

1. Technical development,
2. External R&D phase (= testing of the technology at the DUs), and
3. Transition period

These periods last for 2, 5 and at least 8 years respectively. As the phases overlap, a total transition period of at least 12 years is foreseen by the applicant (Figure 2).

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

SEAC notes that the scope of the use and the assessment of alternatives by the applicant are sufficiently described. The steps that have been taken by the applicant since 2012, the investment in research and the subsequent short-listing of alternatives are also clear, as is the importance of the various key functionalities that have been identified to come to the short-list of alternatives. However, SEAC notes that deposition time/plating time, which is now described as a key functionality under the technical feasibility, is rather an economic parameter than a technical one. This is confirmed in chapter 4.3.1 where the applicant indicates that both selected alternatives perform as well as or better than the vacuum processes but at significantly lower costs and faster production speeds. The AfA indicates in several places that the production speed of the cylinders is a very important parameter. Often there is a short deadline between the print order and the print deadline.

Some of the short-listed alternatives (Table 9) were rejected based on literature, but for a number of potential alternatives, in-house research has clearly been carried out and has also been described, which illustrates that the applicant is committed to substitute Cr(VI). This was further elucidated in the answers to SEAC's questions.

The applicant's substitution research mainly focussed on the replacement of the Cr(VI) in the manufacture of rotogravure cylinders. The applicant indicates that its business is based on the manufacture of plating equipment and that alternative printing methods are thus not relevant for its business and substitution activities. However, SEAC is of the opinion that such alternatives are highly relevant and notes that Heliograph Holding, of which the applicant is a subsidiary, does cover such alternative printing techniques through its other subsidiaries that provide services to for instance flexography. On questions by SEAC, the applicant answered that even if the other companies within Heliograph Holding would have the expertise and resources in other printing methods, these cannot replace gravure printing, neither from an economic nor from a technical perspective.

The limited information on alternative printing techniques in the AoA/SEA has been sufficiently supplemented in the answers to questions where e.g. information on trends in the printing industry was provided, which provided a good insight in the market. Based on the additional information on potential alternative printing techniques, SEAC agrees that the transfer to an alternative printing technique does not seem to be a feasible alternative for the applicant's DUs.

The applicant has submitted a concise and clear substitution plan with a list of actions and a timetable with milestones. The longest time is dedicated to the implementation of the alternatives, which sounds plausible to SEAC considering the number of DUs, the complexity of the market and the limitations to the production and installation of new equipment. Questions around the availability of alternatives and the speed of implementation have been sufficiently answered.

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 or its downstream users before the date of adoption of this opinion?

☒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

As described in detail in section 4.1 of this opinion, the applicant and its partners have conducted extensive R&D on several alternatives over the last years. None of these alternatives was found to be suitable, meaning that currently no alternative (substance or technology) is commercially available that ensures the essential combination of the technical key requirements as described in section 0.2 of this opinion. However, two short-listed alternatives were further investigated and developed by the applicant:

i. Cr(III)-based electroplating, and
ii. polymer coatings.

These alternatives were investigated for the key performance functionalities described in section 0.2: hardness, layer thickness, layer homogeneity, adhesion to the substrate, deposition time/plating time, surface morphology/ density of microcracks, friction coefficient/ roughness, wear resistance and corrosion resistance. The applicant has made significant progress in the development of these two alternatives, but they are not yet ready to be implemented. The applicant will further develop these alternatives according to the substitution timeline shown in section 4.4. The applicant considers that both alternatives pose fewer environmental and health concerns than the current Cr(VI) plating of the gravure cylinders. The applicant indicated in answers to SEAC's questions that their technologies are in a more advanced stage of development than other potential alternatives and they are not aware of any competitors that can currently offer Cr(VI)-free alternatives to be applied for rotogravure printing and embossing.

Before 2013 the applicant had started investigating alternative **Cr(III)** formulations developed by third parties (Atotech and Coventya), but these formulations showed to be unsuitable for the gravure cylinders. The Cr(III) coatings based on these formulations contained macrocracks that enabled water and air to reach the underlying copper layer. Thus, an underlying nickel layer would be necessary to prevent corrosion. The Cr(VI) layers currently being used do not exhibit these cracks and can directly be deposited on the engraved copper layer. As indicated in chapter 4.3.2 of the AfA, DUs have concerns about the future regulatory status of nickel and nickel-containing process chemicals because of the health and safety risks of nickel plating. The applicant also considered that such a layer would be a step back for a Cr(III)-based process. The high carbon content of these Cr(III) formulations can also lead to sparking as a result of the mechanical stress and thus potential ignition of the organic solvents of the printing ink. Because of these two shortcomings, the applicant is developing its own Cr(III) technology (HelioChrome® NEO) that does not possess these characteristics and can potentially meet the high tribological demands of gravure cylinders. Since 2013 the applicant aims to develop a safer technology that can produce a metallic chrome surface with comparable mechanical properties and quality as the Cr(VI) equivalent. The applicant indicates that specifically the key parameters of the Cr(III) deposition process are very sensitive and that the formation of Cr(VI) should be prevented. Results of the research activities are briefly described in chapters 4.1.2 and 4.4.1.2. of the AfA. Generally, all key requirements are fulfilled except for the layer homogeneity, the surface morphology/density of microcracks and the wear resistance. For these three characteristics, experimental data are currently only partly available and further R&D is still required.

The applicant is also developing an alternative **polymer-composite coating** with a third party since 2014. This approach is called HelioPearl. The polymer composite can be engraved directly on the surface of the cylinder which allows the direct replacement of both the copper and chromium protective layers. The various key requirements are described in chapter 4.4.2.2. All key requirements meet the criteria set, except for wear resistance where results are not yet sufficient. The lower wear resistance compared to the Cr(VI) cylinders is considered to be the main disadvantage, as it means that cylinders must be re-coated more frequently. This will hinder the use of polymer-coated cylinders for applications with long printing runs as well as decorative rotogravure, where inks containing particles such as titanium dioxide and more abrasive printing substrates might lead to unacceptably high cylinder wear. The applicant describes a number of challenges that had to be solved (development of the polymer coating, engraving by laser ablation instead of diamond stylus) and has already carried out initial printing tests.

Further R&D is needed until these alternatives are mature enough to substitute chromium trioxide. Cylinders coated with Cr(III)-based technologies or with polymer coatings must be tested with different substrates, inks and doctor blades, which removes excess ink picked up by cylinder, to demonstrate that the printing quality is not compromised. The focus for implementing will initially be on packaging printing because of its lower surface stress and the technology will then be optimised for other application areas in succession, such as publication printing. Decorative rotogravure is more demanding in terms of cylinder wear. Here, particles such as TiO_2 are often added to the ink and more abrasive substrates are used, wearing down the cylinders more quickly.

Table 11: Economic feasibility and economic impacts of the new rotogravure cylinders

	Cr(III)	**polymer**
Applicant development cost	€1.5-2 million	€1.6-2 million
DU investment cost*	€400-500 thousand	€1 million
DU project cost and service*	€10-30 thousand	

*= costs per DU

The applicant foresees higher costs for the DUs that are related to installing new plating systems (Cr(III)) or production units (polymer layer) as outlined in Table 11. For the polymer cylinders also new investments in direct engraving of the polymer coating will lead to higher investment costs as the conventional engraving with a diamond stylus is not feasible in that case. Potential additional costs not included in Table 11 are the plant modifications and disposal of old equipment. In contrast to these statements, the applicant indicates in chapter 4.4.2.2 of the AoA/SEA that the use of the polymer coatings will lead to a reduction in complexity as fewer manufacturing steps are needed, which will lead to lower investment costs for new gravure cylinder manufacturing lines. The applicant also foresees that the cylinder production costs will be reduced as the polymer layer substitutes both the copper and the chromium layer of the current gravure cylinders, and hence the operating costs will be lower than for Cr(VI). In the answers to SEAC's questions, the applicant also clarified that the operating costs for the Cr(III) alternative are expected to be the same as for the current Cr(VI)-based process. The applicant further indicates that according to results from the DU survey the transition to one of the alternatives investigated is economically feasible for most of the DUs. The applicant expects that most of its DUs will transition to one of the two alternatives developed (HelioChrome NEO and HelioPearl), although the applicant is not sure whether 100 % of DUs will transfer to these new techniques. However, changing to another printing technology, if technically feasible, would require an investment of up to €2.5 million per press plus additional costs of approximately €800 000 for e.g. new logistics, training of personnel and supply chains, which is more expensive than the expected costs of transitioning to the alternatives developed by the applicant.

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

SEAC considers the analysis of alternatives to be detailed and clear enough to conclude on the technical and economic feasibility of the alternatives. SEAC concurs with the applicant that currently there is no technically feasible alternative available, taking into account the information provided by the applicant in the AoA/SEA, the responses to SEAC's questions and the information provided in the consultation. According to the applicant, the substitution process is still ongoing, and more time will be needed to determine whether the selected alternatives are technically feasible. SEAC also concurs with the fact that the developed alternatives must prove their feasibility under real printing conditions considering the variation in printing sectors and their requirements.

Although it was difficult to scrutinise the precise state-of-play of the two alternatives under development by the applicant and the limited clarity on the parts of the market where printing could potentially be replaced by other printing techniques (or by Cr(VI)-free alternatives by competitors), SEAC acknowledges that even if alternative printing techniques would be technically feasible, they would be economically infeasible as the installation costs alone are approximately €2.5 million per press, and in addition, there would also be costs of approximately €800 000 related to new logistics, training of personnel and supply chains.

SEAC considers that currently there are no feasible alternatives on the gravure market that can replace the Cr(VI) chrome-plated gravure cylinders. The Roto-Hybrid alternatives, applying a diamond-like carbon layer to the rotogravure cylinders using a vacuum treatment technique and developed by the applicant's competitors (Table 9), are according to the applicant in a less advanced stage than the applicant's alternatives (answer to 1st round of questions, Q14, Q17). The information available to SEAC suggests that there is no printing technique available that can replace the rotogravure printing throughout the whole printing sector. Flexography seems to be the technique that may replace rotogravure in a part of the market, but its feasibility will entirely depend on the type of printing jobs and specifically on the length of the printing runs and whether multiple-run print jobs are required.

4.3. Risk reduction capacity of the alternatives

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

☐Yes ☐No ☒Not applicable

SEAC concluded that currently there are no technically and economically feasible alternatives available for the applicant or their DUs 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 applicant submitted a comprehensive substitution plan and applied for a 12-year review period comprising three different phases:

1. Technical development,
2. External R&D phase (=testing of the technology at the DUs), and
3. Transition period

These periods last for 2, 5 and at least 8 years respectively. As the phases overlap, a total transition period of at least 12 years is foreseen by the applicant (Figure 2).

The applicant is developing two different alternatives, one based on Cr(III) and one based on polymer coatings, both running simultaneously. The aim of the work in phase 1 is to achieve stable process parameters to ensure quality and reproducibility of the new technologies, resulting in the cylinders fulfilling the key functionalities (Table 2). The applicant indicated, based on the development work, that the process control of Cr(III)-based electroplating is much more difficult than that of Cr(VI)-based functional plating. However, many of the technical requirements needed to substitute Cr(VI) in the electroplating of gravure cylinders have already been successfully established by the applicant. Tests currently carried out at the applicant's own site and that of one DU aim to establish a reliable plating process related to abrasion/wear; this is one of the key functionalities that currently not yet fulfil the requirements. The work on phase 1 will continue until the end of 2022.

Phase 2 comprises further testing at DU sites to ensure the reliability of these technologies and will start in 2021 when the first beta tests for both alternatives are scheduled. These tests will be carried out at DU locations under real operating conditions without intervention of the applicant and will have to prove in regular operation that they have the same quality and process stability as the current Cr(VI) systems.

For Cr(III), the applicant has selected one DU for these test runs, whereas a second one still has to be selected. At the DUs' sites, new plating lines for the Cr(III) plating have to be installed as the current plating lines from the applicant are only equipped for Cr(VI)-based electrolytes. The technology should be able to run during three months without any major unplanned change to the plating unit or process that cannot be performed by the DU's staff. In the case of major instabilities, the applicant will re-start the beta tests. If the new technology is not 100 % reliable, downtimes of several days to weeks are to be expected for the DU printing companies. The applicant has supplied additional information on the considerations around the test sites and has also provided their approval criteria for the new technologies.

For the polymer coatings, the first set-up will be located at the applicant's own site (polymer cylinder production) and cylinders will be sent to potential customers for testing. A second beta plant will not be built before the end of 2022 because of interference with the development of the Cr(III) alternative. The beta tests for the polymer-coated cylinders will focus initially on package printing because of its lower surface stress. The technology will then be optimized for other applications (publication, decorative) in succession. The Cr(III) beta tests also starts with packaging printing. The applicant indicates that the timetable is currently only for rotogravure cylinders of type A and C, which correspond with the packaging and publication printing (see Table 1 AoA/SEA). In decorative printing often more abrasive substrates are used, leading to a quicker wear down of the cylinders. The applicant also indicates that the polymer-coated cylinders might not be able to fulfil the performance parameters for decorative printing. The substitution for this application will take 4-5 years, 1-2 years more than the substitution in the packaging industry.

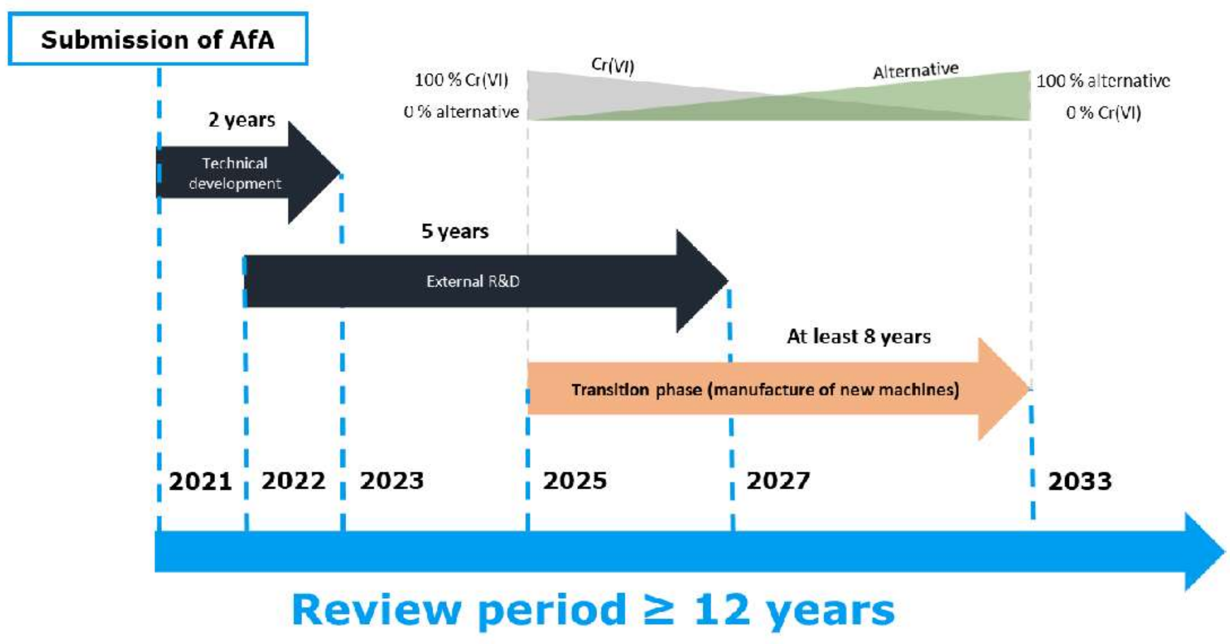


Figure 2. Overview of the R&D plan for the substitution of Cr(VI) by the applicant

Phase 3 is the transition period in which the actual substitution at the DU sites takes place. The applicant expects to start phase 3 two years before the end of phase 2 and indicates that the length of the transition period is determined by how fast these Cr(VI)-based electroplating units can be substituted by the alternative processes. The applicant indicates that the DUs will decide which of the two alternatives better fits their specific applications, mainly considering economic and technical aspects. Because both alternatives use a different technology than the current Cr(VI)-based method, DUs will need to implement new plating lines for the Cr(III) substitution or new manufacturing lines for the polymer-based substitution while replacing the Cr(VI)-based process.

Substitution also depends on how fast the applicant can manufacture the new machines and how fast it can build the know-how required for their service. The applicant estimates a minimum average production rate of 20 machines per year aligned with the current production rate of Cr(VI)-based electroplating machines at full capacity. Based on the 214 currently installed machines in Europe, it will take more than 10 years to reach a 100 % replacement. In a best-case estimated scenario and under the premises of increasing production capacity the applicant assumes that at least eight years are needed for the substitution. On additional questions by SEAC the applicant indicated that the availability of trained personnel who can manufacture these machines and manage their installation and start-up is an important factor limiting the installation capacity. The applicant foresees a gradual decrease of Cr(VI) volume from 160-220 t CrO_3/year currently to none in 2032 due to the substitution process (see also Figure 2). SEAC asked to what extent depreciation of the existing equipment does play a role in the speed of replacement, but the applicant replied that it had no insight into the DUs' considerations to substitute their existing equipment.

SEAC's evaluation of the substitution activities/plan

SEAC evaluated the substitution plan as well as the relevant parts in the AoA/SEA. The description of the potential alternatives and the research that the applicant has carried out over a relatively long period, such as the work on the Cr(III) alternative as well as on the polymer coating, is considered convincing by SEAC. The substitution plan was rather concise and mainly paid attention to the external R&D phase (beta tests) and the transition phase (implementation). The description of the technical development (phase 1) was very short, which may have to do with the fact that it is almost completed. The AoA indicates that both for the Cr(III) substitute and for the polymer substitute a few key functionalities still have to be fulfilled before starting the external R&D phase. The applicant confirmed in answers to SEAC's questions that the review period requested is mainly driven by the applicant's capacities to manufacture and deliver new machines and that, according to its knowledge, no other suitable alternatives can be implemented before the applicant's alternatives. SEAC has no reason to challenge this statement.

The applicant indicates that the technical development must be completed before continuing with the external R&D phase, which is planned to start in 2021. In chapter 4.4.2.2. of the AoA/SEA the applicant describes the results of the initial printing tests with the polymer-based coatings and indicates that these are promising. The description of the tests reports that 100 000 meters have been printed, but elsewhere the applicant indicates that no test printing jobs are yet carried out because these are expensive and time-consuming. SEAC assumes that the printing tests are still part of the technical development, but it is difficult for SEAC to scrutinise where the technical development (phase 1) finishes, and the 5-year external R&D (phase 2) starts.

The new technologies must be tested with different substrates, inks and doctor blades to demonstrate that the printing quality is not compromised. After these have been scrutinized in the external R&D phase (phase 2), the implementation (phase 3) will start with packaging printing because of its lower surface stress and will then be optimized for publication printing. Decorative rotogravure will follow as it is more demanding in terms of cylinder wear. SEAC concurs with this line of reasoning, considering the sequence of substitution.

Although quite crucial in terms of substitution, the AoA delivers limited insight into the considerations of the DUs to substitute and whether the DUs may substitute to the Cr(III) technology, to the new polymer technology or to other printing techniques. The applicant indicated in its answers to SEAC that ultimately it is the applicant's clients who will decide on which technology to use based on their individual requirements. From both the AfA and the answers to SEAC's questions it is clear that, even if technically feasible, the economic feasibility of alternative printing techniques can be questioned as large investments are needed. Furthermore, the applicant's DUs acting as service providers (not printing themselves) cannot implement an alternative printing method. For them, only the alternative coating technology using Cr(III) is relevant. The explanation provided on this topic in the AoA/SEA and the answers to questions seems plausible to SEAC. SEAC can also concur with the reasoning that DUs will not directly substitute 100 % of their process, but will use a Cr(III)-based unit or a polymer coating process in parallel to their current Cr(VI)-based process to minimise risks and gain experience with the new technology as indicated by the applicant.

Finally, almost half (46 %) of the DUs that participated in the survey (70 out of a total of 105 DUs) estimate that they would need between one and four years to implement an already commercially available and technically feasible alternative, while 31 % estimated this transition to take between four and seven years. This time represents the time needed by DUs to conduct all necessary testing and substitution activities in their own processes. According to Table 9 in the AoA, most of the applicant's DUs (40 out of 62) deliver their products to the packaging sector, 13 are dedicated to publication printing and 9 to decorative printing. The considerations by the applicant suggest that replacement for the packaging sector can take place relatively fast compared to the publication and decorative sectors, although this is not further elaborated in the substitution plan. SEAC can concur with the reasoning concerning the stepwise replacement, starting with packaging printing and with the estimation of the time needed for the production of new equipment. The applicant indicates that the production capacity of plating equipment or the production equipment for the cylinders is the main driver that limits the speed of substitution. Other economic considerations, such as the depreciation of already installed equipment, are lacking from the application. Upon additional questions from SEAC, the applicant indicated that the average asset life of the Cr(VI) plating equipment is approximately 20 years. According to the applicant, their customers calculate with a return of investment (ROI) of about 2-3 years and in practice, the depreciation rate is about 10 %. The crucial role of the capacity of trained personnel for manufacturing and installation of the equipment was confirmed in the answer to additional questions. SEAC can concur that these play an important role in the substitution process.

The data presented in 4.5.1. of the AfA indicate that at least 214 Cr(VI) units need to be replaced, based on the applicant's internal knowledge and information from the DU survey. This is the total amount of units installed at the applicant's DUs, of which 70-80 % is delivered by the applicant itself. On SEAC's question regarding whether the old equipment could be retrofitted, the applicant indicated that the Cr(III) plating is extremely sensitive, thus requiring different process parameters, more precise control and monitoring. The applicant considered retrofitting not to be a feasible option. The applicant has estimated that its minimum average production of plating equipment will be 20 machines per year, which would result in more than ten years to achieve a 100 % substitution. In response to SEAC's question the applicant answered that staff currently working on the production of Cr(VI)-dependent technologies will also work on the transition to both alternatives described. Some specialized staff is involved in process development. The applicant also indicated the limitations for extra personnel installing the equipment.

SEAC does concur with the remark of the applicant that the data on the time needed for substitution submitted by the DUs only reflects the individual time required by each DU to implement an already-available alternative. However, for SEAC it is difficult to scrutinise whether the transition time is only based on technical considerations, such as testing, or whether economic considerations are also important (depreciation, hiring and educating new personnel). SEAC considers the timeline as presented in the substitution plan as being realistic.

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 or their DUs by the date of the adoption of this opinion.
- There is no 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.
- 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 not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

5. Socio-economic analysis

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

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

5.1. Human health and environmental impacts of continued use

The estimated number of additional statistical cancer cases has been calculated using the excess risk value presented in section 3 and the estimation of the number of exposed people provided by the applicant. Furthermore, the differences in the duration of the exposure of workers have been taken into account following the approach used by the applicant in the application or authorisation.

The endpoints assessed by the applicant were lung and intestinal cancers. For lung cancer, the data on workers were gathered by the applicant through a survey of the DUs. The total number of estimated directly exposed workers at the DUs' sites in the EEA is 657. For the general population, i.e. the assessment of the health risk to man via the environment (MvE), the number of people exposed in the proximity of the production site is assumed to be 10 000 for each site (there are 117 DU sites). This equals a locally exposed general population of 1 170 000. For the regional exposure, the entire EU-27 population of 447.7 million was taken forward. For intestinal cancer, only the number of people exposed via the environment was used, where the number of people exposed in the proximity of the production site is assumed to be 10 000 for each site (there are 117 DU sites). This equals a locally exposed general population estimate of 1 170 000.

The applicant assessed the human health impact based on the existing reference dose-response function established for the carcinogenicity of hexavalent chromium (RAC/27/2013/06 Rev.1). The health impacts were monetised by applying the willingness-to-pay values for the reduction of cancer risk from the ECHA (2016) study[26], adjusted to the reference year of 2020 (since the ECHA values are based on year 2012), as shown in Table 12.

Table 12: Monetary values for human health assessment

	Lower bound	**Upper bound**
Value of statistical life for cancer (2012)	€3 500 000	€5 000 000
Value of cancer morbidity (2012)	€410 000	€410 000
Value of statistical life for cancer (2020)	€3 757 639	€5 368 055
Value of cancer morbidity (2020)	€440 181	€440 181

The applicant considered data on the disease latency and fatality rates, as well as inflation adjustment and discount rates of between 2 % (upper bound) and 4 % (lower bound). For the 657 potentially directly exposed workers, the monetised risk was estimated at €1 020 100-1 702 600 over a 12-year review period. For the potentially indirectly exposed workers and humans in the direct neighbourhood, combining MvE (local and regional) for inhalation and MvE (local) for oral, the monetised risk was estimated at €9 934 900-16 582 800 over a 12-year review period.

In total, the applicant estimated monetised potential health impacts for Use 2 of €10 955 000-18 285 300. Annualised, this results in the following monetised risks:

- Exposed workers: €109 600-182 700 per year
- General population: €1 067 900-1 779 600 per year

[26] Valuing selected health impacts of chemicals -Summary of the Results and a Critical Review of the ECHA study. [Online] February 2016. Available at: https://echa.europa.eu/documents/10162/17228/echa_review_wtp_en.pdf/dfc3f035-7aa8-4c7b-90ad-4f7d01b6e0bc

- Total: €1 177 500-1 962 300 per year[27]

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

SEAC considers that the applicant used the appropriate methodologies to estimate the human health impacts and presented a lower bound and upper bound range to account for the uncertainties. SEAC took forward the applicant's ranges in the final analysis, apart from those related to regional exposure as RAC did not consider these relevant. Given that the monetised risk related to regional exposure was €3-5 over 12 years, this has no impact on the rounded-up total values.

Table 13: Summary of additional statistical cancer cases

	Excess lifetime cancer risk[1]	Number of exposed people	Estimated statistical cancer cases (over 12 years)[5]	Value per statistical cancer case	Monetised excess risk (over 12 years)[5]
Workers					
Directly exposed workers[2]	3×10^{-3} (lung cancer)	657	8.13×10^{-2} (non-fatal) 3.51×10^{-1} (fatal)	€0.4-5.4 million	€1 020 100-€1 702 600
Indirectly exposed workers[3]	Included in the general population				
Sub-total					
General population					
Local	Lung cancer: 1.71×10^{-5} Intestinal cancer: 1.61×10^{-9}	1.17 million	Lung cancer: 7.92×10^{-1} (non-fatal) 3.42 (fatal) Intestinal cancer: 1.67×10^{-4} (non-fatal) 1.56×10^{-4} (fatal)	€0.4-5.4 million	Lung cancer: €9 934 600-€16 582 200 Intestinal cancer: €260-590
Regional					
Sub-total					€9 934 900-€16 582 800
Total					**€10 955 000-€18 285 300**
Latency (years)	10 years for lung cancer and 26 years for intestinal cancer				

Notes:

[27] Summary of monetised potential health impacts per year (annuity). Please note that these figures are slightly different than what those in Table 13 divided by 12 would be, as discounting is reflected in the annuity.

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

5.2. Societal costs of not granting an authorisation

Non-use scenario

The impact of the non-use scenario (NUS) for Use 2 depends primarily on how the DUs react in case authorisation is refused, but also on the reactions of, and impacts to, the applicant and its holding companies and subsidiaries.

Most likely NUS for the applicant's DUs

To identify the most likely NUS and understand the possible impacts, the applicant used a questionnaire to survey the DUs' most likely reactions in case authorisation is refused (further details about the questionnaire are provided in section 0.4 and later in this section in *SEAC's evaluation of the societal costs of non-use*).

- NUS A: Switch to an existing printing technology.
- NUS B: Outsource chromium coated gravure cylinders from outside EEA.
- NUS C: Relocation of chromium coated gravure cylinders production to a non-EEA country.
- NUS D: Temporary shutdown of chromium coated gravure cylinders production in EEA until an alternative is implemented.
- NUS E: Permanent shutdown of chromium coated gravure cylinders production in EEA.
- NUS F: None of the above scenarios is applicable.

Additional investment and operating costs and foregone profits were estimated monetarily using data from the survey responses and extrapolated to non-respondents according to the model DU approach described in section 0.4 and evaluated later in this section (please see *SEAC's evaluation of the societal costs of non-use)*.

The applicant distinguished between different types of DUs, referring to them as Type I, Type II, Type III:

- Type I are companies that are intermediate service providers.
- Type II are printing companies with gravure cylinder manufacturing for self-use and rely on the sales of final printed products for their revenue.
- Type III are companies with gravure cylinder manufacturing for self-use and intermediate service providers of self-coated cylinders.

The responses to the possible NUSs can be summarised as follows:

NUS A: Switch to an existing printing technology (11 %, i.e. 7 respondents)

NUS A is a scenario-based on DUs switching to an existing printing technology. 6 Type II DUs and one Type III DU selected this option. Alternative technologies discussed by the respondents included: digital printing, flexography, polymer cylinders and off-set technologies. Limitations of digital printing were described qualitatively by some respondents, including issues related to one-off investment costs, customer acceptance, and reduced production quantities (when compared to rotogravure).

While the survey did not include any questions about the time needed to implement an alternative printing technology in relation to NUS A, the AoA part of the survey included a question about how much time DUs estimate that they would need to implement an alternative in the hypothetical case that such alternative was commercially available and technically feasible. The time estimates were mainly in the range of 1-7 years.

Regarding Cr(VI)-free alternatives, the applicant asked the DUs a general question: "*do you know of chromium trioxide free alternatives for printing cylinders, or can you apply a different printing technology that works without chrome plating of cylinders*." 13 respondents expressed an awareness of a potential alternative or could implement an alternative printing method. 7 respondents specified chromium trioxide-free alternatives that related to those being developed by the applicant (7 respondents listed Cr(III)-based plating and 4 DUs listed polymer-based coatings). Similarly, limitations of alternatives like flexographic and offset printing (among others) were also discussed by the applicant. Regarding Cr(VI)-free alternatives, the applicant acknowledges that they are in a competitive market. The applicant references competitors with Cr(VI)-free alternatives – both in terms of customers switching to alternatives (as a result of potential production bottlenecks on the applicant's side) and also regarding the applicant's research and development processes in which they have evaluated some of their competitors' Cr(VI)-free alternatives. One of the competitors is part of the CTAC application, the other two competitors listed by the applicant are not part of the CTAC application nor have they applied for authorisation to use Cr(VI). In regard to the possibility of the DUs switching to a competitor who would be able to supply Cr(VI)-free alternatives, e.g. a Cr(III) or polymer-based technology, within the EU/EEA, the applicant indicates in its response to SEAC's questions that two competitors were in the process of developing Cr(VI)-free alternatives for the formulation only. The applicant also indicates that competitors are in the process of developing polymer-based alternatives (similar to the approach taken by the applicant in the development of their alternative).

For Cr(VI)-based plating machines, the applicant explains that their equipment and chemistry must match one another and that other plating machines cannot operate with a different electrolyte. The applicant is not aware of any competitors offering plating machines that can operate with a substance other than Cr(VI) that could constitute an alternative to current Cr(VI)-based plating machines. According to the applicant, competitors are not involved in the development of plating machines and equipment for rotogravure

The applicant suggests that the most likely impacts related to the NUS A would be additional investment costs and operating costs to DUs, foregone profits, job dismissals, as well as changes in product quality, market price and market position.

NUS B: Outsource chromium coated gravure cylinders from outside EEA (11 %, i.e. 7 respondents).

NUS B relates to the outsourcing of chromium coated gravure cylinders by DUs from outside the EEA. 5 Type II DUs and 2 Type I DUs selected this option. The respondents indicated a time lag of less than one year, while two respondents mentioned a duration of 1-5 years to find an alternative supplier and qualitatively described a supply chain disruption.

The applicant suggests that the most likely impacts of NUS B would be additional investment costs and operating costs to DUs, foregone profits, job dismissals, as well as changes in product quality, market price and market position.

NUS C: Relocation of chromium coated gravure cylinders production to a non-EEA country (13 %, i.e. 8 respondents).

NUS C relates to the relocation of the DUs' chromium coated gravure cylinders production to a non-EEA country. 4 Type I DUs, 3 Type II DUs and 1 Type III DUs selected this option. The applicant describes that this option mainly relates to larger companies (in terms of revenue), suggesting that smaller (lower revenue) companies may not have the financial resources to pursue this NUS). Respondents estimated the time required for relocation was in the range of 1-10 years, with an arithmetic mean of 3.5 years.

The applicant suggests that the most likely impacts of NUS C would be additional investment costs and operating costs to DUs, foregone profits, job dismissals, as well as changes in product quality, market price and market position.

NUS D: Temporary shutdown of chromium coated gravure cylinders production in EEA until an alternative is implemented (20 %, i.e. 13 respondents).

NUS D relates to a temporary shutdown of the DUs' chromium coated gravure cylinders production in the EEA until an alternative is implemented. 6 Type I DUs, 4 Type II DUs, and 3 Type III DUs selected this option. DUs indicated a supply interruption ranging from less than one year (8 DUs) to 1-5 years (4 DUs). One Type I firm indicated a supply interruption of up to 10 years. In summary, the applicant indicated that the DUs would prefer to temporarily shut down and that this would present a risk to their production continuity. This NUS was linked to the speed of development and production of an alternative by the applicant.

The applicant suggests that the most likely impacts of NUS D would be investment costs, operating costs, foregone profits, job losses, as well as changes in product quality, market price and market position.

NUS E: Permanent shutdown of chromium coated gravure cylinders production in EEA (42 %, i.e. 27 respondents).

NUS E relates to a permanent shut-down of the DUs' Cr(VI) coated gravure production in the EEA. 16 Type II, 7 Type I and 4 Type III DUs selected this option. 24 firms (mainly Type II) responded that this scenario would represent a shutdown of their entire business.

The applicant suggests that the most likely impacts of NUS D would be investment costs, foregone profits, and job losses. The majority of DUs selected an increase in one-off costs (e.g., decommissioning costs). The applicant indicates that with a permanent shutdown of affected production activity, ideally all profits for the relevant period of years would be considered lost, however a minimum of one year is considered by the applicant in this assessment.

NUS F: None of the above scenarios are applicable. 3 %, i.e. 2 respondents replied that none of the above scenarios is applicable.

The most likely NUS for the applicant

In case the authorisation is refused, the applicant would no longer supply the electrolyte and plating machines for coating of rotogravure cylinders to the DUs. For Cr(VI)-based machines, the plating machines and chemistry must match and other plating machines cannot operate with a different electrolyte (i.e. Use 1), thus highlighting the interlinkage between Use 1 and Use 2. As most DUs would either shut down, outsource products, or relocate their production outside the EU, the applicant expects that the rotogravure printing process will no longer be competitive in the EU due to increasing prepress (cylinder) costs. As the applicant would lose the demand for its services related to the use applied for, it would consider relocating its production to outside the EEA where there is a demand for galvanic machines for coating gravure cylinders with chromium trioxide. The applicant would consequently lose its sales of electroplating units in the EEA. The applicant would also lose sales of the electrolyte in the EEA (i.e. Use 1).

The production of gravure printing products would either move out of the EU or be replaced by other printing technologies. Based on the non-EU turnover which would still be a business, the applicant assumes that around 40 % of the employees would have to be dismissed. There would also be additional investment costs for the applicant. The brands of Heliograph Holdings located in the EEA would also relocate outside the EEA, leading to foregone profits, additional investment and operating costs and job dismissals. Heliograph Holding's subsidiaries would shut down, resulting in foregone profits and job dismissals. The formulator would not relocate but would lose the income related to this use.

Economic impacts of non-use

For the calculation of impacts in both uses, the annual earnings before interest and taxes (EBIT) forecasted in the applied for use scenario in 2021 is considered to represent the foregone profits and discounted to the base year of 2020 at a 4 % discount rate. Additional operating costs and foregone profits have only been considered for one year in the assessment.

Formulator

For the formulator, the non-use scenario would imply that all profits pertaining to liquid formulations supplied to the applicant will be foregone. The impact has not been monetised due to a lack of information from the formulator.

Applicant

The applicant estimated that they and their holding companies and subsidiaries would incur foregone profits because of the relocation of production activities outside the EU. For one of the subsidiaries affected foregone profits is taken forward due to a permanent shutdown of the affected activities. The applicant presented (NPV 2020) total foregone profits of:

- €0-1 million for the applicant
- €1-5 million for Heliographic Holding
- €0-1 million for Heliograph Holding's subsidiaries

Downstream Users

To assess the impacts for the DUs, corresponding results from the survey were aggregated for each most-likely NUS.

The following *additional investment and operating costs* were estimated for the DUs:

- For NUS A (Switching to an existing printing technology), 11 % of DUs considered this their likely NUS and they estimated (using pre-established ranges in the questionnaire) additional investment costs and operating costs of €5.1 million to €6 million (lower and upper public range).
- For NUS B (Outsourcing chromium trioxide coated gravure cylinders), 11 % of DUs considered this their likely NUS and they estimated (using pre-established ranges in the questionnaire) additional investment costs and operating of €3.4 million to €7.3 million (lower and upper public range).
- For NUS C (Relocation of chromium trioxide coated gravure cylinders production to a non-EEA country), 13 % of DUs considered this their likely NUS and they estimated (using pre-established ranges in the questionnaire) additional investment costs and operating costs of €6.5 million to €11.1 million (lower and upper public range).
- For NUS D (Temporary shutdown of chromium trioxide coated gravure cylinder production in the EEA until an alternative is implemented), 20 % of DUs considered this their likely NUS and they estimated (using pre-established ranges in the questionnaire)

additional investment costs and operating costs of €2.9 million to €11.5 million (lower and upper public range).

- For NUS E (Permanent shutdown of chromium trioxide coated gravure cylinder production in the EEA until an alternative is implemented), 42 % of DUs considered this their likely NUS and they estimated (using pre-established ranges in the questionnaire) additional investment costs and operating costs of €8.3 million to €10.8 million (lower and upper public range).

The above additional investment and operating costs add up to a total additional investment and operating cost of €26.2-46.7 million in 2021 for the survey respondents. When discounted to 2020, this gives an NPV of €25.3-44.9 million.

For those DUs that did not respond to the survey, the applicant extrapolated the investment and operating costs to the non-respondents, by using the model DU approach outlined in section 0.4, i.e. values below the average values derived from the DUs (64) that responded to the survey.

The extrapolated data was for the 41 DUs that did not reply and was presented as a range of additional costs of €16.4 million to €28.7 million (public range).

The total additional investment and operating costs across all the 105 DUs would hence be (NPV 2020) €41.7 million to €73.60 million (public range).

Another category of impacts relates to *foregone profits*.

For the 73 DUs that responded to the questions related to foregone profits, lower and upper bound ranges were presented, with a NPV (2020) of €24 million to €206 million (public range).

For those DUs that did not respond to the survey, the applicant extrapolated the foregone profits and presented lower and upper bound estimates (NPV, 2020) of €0.15 million to 15.38 million (public range).

Combining the foregone profits from the DUs who responded and those for which extrapolated data was used, the total foregone profits for DUs due to a refused authorisation was hence estimated at €24.15 million to €221 million (public range).

Combining the additional investment and operating costs and the foregone profits, the total impacts to the DUs were presented (NPV 2020) at a range of between €66 million and €295 million. Additionally, the foregone profits related to the applicant, the holding company and associated subsidiaries bring the total economic impacts to an NPV (2020) of €67 million to €302 million (public range).

Social impacts related to job losses

To estimate the social impacts, the applicant used responses from the DU questionnaire and Dubourg (2016)[28] to estimate the social cost of job losses, updated to the year 2020 using inflation rate data from Eurostat. Similar to the estimation of economic impacts, the applicant used the model DU approach to extrapolate social costs of unemployment to the DUs that did not participate in the survey. The applicant estimated that the total number of job losses and the associated social costs would be:

- The applicant: 30-50 job losses, at a social cost of €1-5 million.

[28] Available at: https://echa.europa.eu/documents/10162/17086/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554?t=1476111468417

- Heliograph Holding (30-50 job losses) and its subsidiaries (30-50 job losses) at a social cost of €1-10 million.
- DUs: 5 239 job losses at a social cost of €501 million.

The applicant considers that the assumed average 6 job dismissal per (extrapolated) DU can be regarded as an underestimation.

Job dismissals at the formulator are unknown since no information was available to the applicant.

Combining the total impacts to the different actors, this gives a total social cost of unemployment of €503-515 million.

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

In general, SEAC notes the following considerations that are relevant to the evaluation of the applicant's NUS and socio-economic analysis:

- SEAC considers that the use of a questionnaire survey to reveal the reactions of the DUs is an appropriate instrument to derive the NUS and estimate possible socio-economic impacts while acknowledging the general and one-shot nature of the survey instrument. In terms of the design of the survey instrument used to solicit the DUs, SEAC considers the applicant's approach to the questionnaire design and methodology to be reasonable.
- SEAC considers that there are some shortcomings with regard to the NUSs, for example, the limited discussion about the extent of the financial constraints of the NUSs on the DUs and the lack of distinction between the size of the DU companies (e.g., large versus SME). In general, it has not been possible for SEAC to evaluate whether the DU impacts relate to SMEs or larger companies. This could affect the distribution of the impacts in the EEA. Specifically for NUS E, while the applicant provided generic information on capital asset life and depreciation of plating machines, the absence of information on the resale or scrap value of capital assets is a shortcoming in the analysis. In general, while SEAC considers time lags and supply chain disruptions as plausible (NUS D), the applicant's limited discussion on the extent to which the time lags could be shortened, or supply chain disruption mitigated by the DUs is a shortcoming. In general, SEAC considers that it is plausible that in the short run competitors would be unable to absorb the demand by the DUs (for plating units and electrolyte).
- SEAC considers that the responses by the DUs to the various NUSs suggests that there is a market demand by DUs and their customers for rotogravure plating technology and that the limitations associated with the alternative technologies (e.g., flexography which is considered the closest alternative technology to rotogravure-based printing technology) is reflected in the hesitation of the DUs to switch to the alternative technologies, as implied by the DUs' responses to NUSs B to E. Given this context, SEAC acknowledges the applicant's qualitative explanation regarding the transition to alternative technologies (i.e., flexography). While considering such a transition as possible, in the absence of detailed quantitative data on the likelihood, timing and costs associated with such a possible transition vis-à-vis rotogravure-based printing technology, SEAC was unable to scrutinize the full extent of the possible socio-economic impacts. However, given the general hesitation of the DUs to switch to the alternative technologies, SEAC considers that the outcome of such an analysis would not significantly affect the overall conclusion of this opinion.

- SEAC considers that the applicant seems to have made an active effort to increase the response rate and the quality of the responses. For those DUs that did not respond to the questionnaire, the applicant developed a model DU to extrapolate the social and economic impacts, using estimates of social and economic impacts below the average values reported by DUs in the survey, to derive total estimates. SEAC considers that extrapolated data used to estimate impacts for non-respondents is a reasonable approach, in the absence of detailed cost data from all individual DUs to scrutinise. However, SEAC notes that the use of extrapolated data may generally lead to an underestimation or overestimation of the impacts. At the same time, SEAC notes that the profits assumed for the model DU are below the average values of the respondents, meaning that the extrapolations may be less likely to result in overestimations. SEAC also notes that the assessment of social impacts was based on a conservative approach, meaning that the extrapolations are more likely to result in overestimations. When asked about the DUs that did not respond to the survey, the applicant responded that these were mainly small companies located in Eastern Europe. Given that the applicant considers that the processes and the general supply chain of these companies are very similar to those of the companies that did respond, they maintain that the data obtained through the DU survey is representative of the applicant's DUs.
- For the economic impacts, SEAC considers the estimates as overall plausible. SEAC notes that the formulator has not been included in the analysis due to a lack of information. This shortcoming could possibly lead to an underestimation of the social and economic impacts. However, given that the formulator only represents one actor at one site, SEAC considers that such an underestimate is likely to be relatively small. SEAC also notes that in relation to estimating the investment costs related to the implementation of an alternative (NUS A), the applicant did not take into account that some investments to replace equipment might have occurred anyway. However, given that the investment costs are a small percentage of the overall costs (see Table 14), and the applicant requested the DUs to provide net costs over and above the business as usual, SEAC concludes that this is likely to have a minor impact on the overall costs. SEAC concurs with the methodology used, and the application of the methodology, to estimate foregone profits to the applicant and holding companies and subsidiaries. The applicant assumes that there would also be changes in product quality, changes in the market price for end consumers and changes in customer retention and market position. However, these impacts were referred to by the applicant qualitatively and, as a result SEAC, while considering such impacts as plausible, was unable to scrutinize the full extent of the impacts.
- SEAC notes that the applicant based the producer surplus loss on one year of profit losses. Since the application was submitted, SEAC agreed on an updated approach to the assessment of producer surplus loss[29]. SEAC notes that, given that the applicant has considered profit losses for a shorter time period than suggested in the new approach, the applicant's estimates of economic impacts can be considered an underestimate.
- SEAC questioned the asset life and depreciation of the capital equipment (plating machines) and the applicant responded that in practice the depreciation rate for chrome plating machines supplied by the applicant to the DUs is typically about 10 % per year and that the machines' asset life is approximately 20 years (assuming maintenance). However, information on the current stage of depreciation of capital equipment at the DUs was not a question in the survey.

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

- In terms of the social costs, the impacts on jobs were assessed in line with current SEAC practices.

Taking all of this into account, SEAC overall agrees with the applicant's assessment and has taken forward the ranges presented by the applicant. Over the 12-year review period applied for these are:

- Economic impacts: €67-302 million
- Social cost of unemployment: €503-515 million

The annualised values are shown in Table 14.

Table 14: Societal costs of non-use

Description of major impacts	Monetised/quantitatively assessed/qualitatively assessed impacts
1. Monetised impacts	**€ per year[1]**
Economic impacts due to investment and/or additional production costs related to the adoption of an alternative	0.5-0.6 million
Producer surplus loss due to ceasing the use applied for	1- 30 million
Relocation or closure costs	0.7-1.2 million
Economic impacts due to investment and/or additional production costs related to outsourcing	0.4-0.8 million
Loss of residual value of capital	
Other costs (e.g., additional investment and operating costs extrapolated for the remaining 41 DUs that did not answer the survey)	1.7-3.1 million
Social cost of unemployment	50-60 million
Spill-over impact on surplus of alternative producers	Not quantified
Other monetised impacts (please specify)	Not quantified
Sum of monetised impacts	**€51-100 million**
2. Additional quantitatively assessed impacts	
Number of patients treated	Not applicable
Avoided CO_2 emissions	Not quantified
Other quantitatively assessed impacts (please specify)	
3. Additional qualitatively assessed impacts	
Consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity)	Changes in product quality, market price for end customers, customer retention and market position for DUs due to switching to an existing alternative technology/ relocation of production / outsourcing of

	production / temporary or permanent shutdown of production activities
Other qualitatively assessed impacts (please specify)	

Notes:

1. Per average year during the time horizon used in the analysis (public range)

5.3. Combined assessment of impacts

The applicant summarised all the societal costs of non-use to compare them with the risks of continued use. Based on this comparison, the applicant concluded that the benefits of continued use outweigh the risks.

SEAC's evaluation of the combined assessment of impacts

Table 15: Societal costs of non-use and risks of continued useSEAC notes that Use 2 (functional chrome plating of cylinders) is interlinked with Use 1 (formulation of chromium trioxide-based electrolyte). For the Cr(VI)-based plating machines, the plating machines and chemistry must match and other plating machines cannot operate with a different electrolyte (i.e. Use 1). The applicant has included the economic impacts to DUs and the social cost of unemployment related to the functional chrome plating of cylinders in the assessment of both uses applied for. SEAC notes that these impacts occur only once if either one or both uses are not granted an authorisation.

Furthermore, the human health impacts of both uses would be avoided by refusing the authorisation to either one of the uses applied for. Therefore, SEAC has also taken forward the combined monetised risks from both Use 1 and Use 2 in the combined assessment of impacts (i.e., the combined monetised risks outlined in section 5.1 of the two opinions).

SEAC notes that the applicant's impact assessment does not take into account the applicant's current authorisation situation, implying that impacts would occur immediately after a refused authorisation even if the applicant would in reality be covered by the CTAC authorisation until September 2024. SEAC, therefore, asked the applicant to provide qualitative or semi-quantitative information about how the human health and socio-economic impacts would be affected if the current CTAC coverage was considered. The applicant responded that the impacts would then be realised after September 2024 instead of when the decision about this current application for authorisation is made. This is because the applicant and its DUs would not be able to substitute the use of chromium trioxide by 2024. Thus, an additional timeline of three years would mean that both the costs and the benefits would have to be adjusted similarly to bring to the present day. It would not change the nature of impacts that would occur in 2024 compared to when a decision is made on this current application. SEAC agrees with this explanation.

Table 15 presents the societal costs of non-use and risks of continued use taken forward by SEAC. Based on the comparison of costs and benefits, SEAC concludes that the societal costs of not granting an authorisation are higher than the monetised risks to human health.

Table 15: Societal costs of non-use and risks of continued use

Societal costs of non-use		**Risks of continued use**	
Monetised impacts (€ per year[1])	€51-100 million	Monetised excess risks to directly and indirectly exposed workers (€ per year[2])	€0.11-0.18 million
Additional quantitatively assessed impacts (per year)	not available	Monetised excess risks to the general population (€ per year[2])	€1.09-1.81 million
Additional qualitatively assessed impacts (per year)	Changes in product quality, changes in the market price for end consumers and changes in customer retention and market position	Additional qualitatively assessed risks (per year)	not available
Summary of societal costs of non-use	€51-100 million per year	**Summary of risks of continued use**	€1.2-2 million per year

Notes:

1. Annualised to a typical year based on the time horizon used in the analysis.
2. Per average year during the time horizon used in the analysis.

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

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

This conclusion of SEAC is made on the basis of:

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

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

6. Proposed review period

☐Normal (7 years)

☒Long (12 years)

☐Short (4 years)

☐Other: … years

☐No review period recommended

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

- SEAC considers that the applicant's research and development of alternatives since 2012 indicates an ongoing commitment to research and development to implement alternatives for Cr(VI).
- SEAC concurs with the applicant that currently there are no technically and economically feasible alternatives as demonstrated by the analysis of alternatives, the answers to SEAC's questions, the responses from the DUs and the input from the consultation.
- The applicant presents a substitution plan that is consistent with the duration of the review period that is proposed. According to the substitution timelines presented by the applicant, the time needed to complete substitution requires more than a normal review period of 7 years.
- The applicant indicated that the useful life of the plating equipment mostly goes beyond the general asset life of 20 years. Thus, the investment cycle is demonstrably very long making it technically and economically meaningful to substitute only when a major investment or refurbishment takes place.
- Due to the speed of production and installation of new equipment to replace the current Cr(VI) equipment and the adjustment by the DUs, SEAC finds it credible that it would not be possible for the applicant and all its DUs to substitute within a normal review period.
- SEAC has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the risks to the environment associated with the continued use of the substance.

Taking into account all of the above points, a **12-year** review period is recommended for this use, i.e. until the end of 2032.

7. Proposed additional conditions for the authorisation

Were additional conditions proposed for the authorisation?

☒Yes ☐No

7.1. Description

RAC

Proposed additional conditions

All the DUs of chromium trioxide covered by this Use shall comply with the minimum RMMs and OCs listed in Section 1.3.

In addition, the applicant shall:

- prepare and provide their DUs with the OCs and RMMs provided in the CSR by additional means, e.g., detailed guidance for the DUs on the OCs and RMMs,
- promote the use of a new connection system ("Quick Connect"-system) that includes a new removal head connected to a pump via a hose and containers that featured an integrated and fixed immersion tube, measures that prevent contact to CrO_3 and unintentional dripping when changing the containers,
- promote the use of a valve and pump system for sampling once this product is being developed.

7.2. Justification

RAC

Although RAC is of the opinion that the OCs and RMMs are appropriate and effective in limiting the risk for the workers and the general population via the environment, RAC considers that the standard DU and the national enforcement authorities may benefit from the list of minimum RMMs and OCs provided in section 1.3. This information is expected to be communicated as per Article 31 of the REACH Regulation.

Awareness among the DUs about the OCs and RMMs to be implemented for the authorisation and the implementation of new dosing and sampling systems will further minimise the workers' exposure and environmental releases.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements proposed for the authorisation?

☒Yes ☐No

8.1. Description

RAC

1. The DUs shall implement at all their sites the following monitoring programmes:

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

  (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure;

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

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

  (iv) be representative of:

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

    b. the operational conditions and risk management measures typical for each of these tasks;

    c. the number of workers potentially exposed;

  (v) include contextual information about the tasks performed and their frequency during measurements;

(b) Environmental releases:

  (i) the DUs shall conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process;

  (i) the monitoring programmes for 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 DUs' sites.

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

3. The DUs shall ensure that the application of RMMs is in accordance with the hierarchy of control principles.

4. 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 paragraph 2, shall be documented, maintained, and be made available by the DUs, upon request, to the competent national authority of the Member State where the DU is located.

8.2. Justification

RAC

Although RAC considers the operational conditions and risk management measures described in the application in relation to both workers and humans via the environment to be generally appropriate and effective in limiting the risk from exposure through the inhalation and oral routes, the exposure assessment contains shortcomings due to:

- the lack of measured exposure data for most WCSs,
- the limited number of DUs that provided measurement data for workers' exposures and for air emissions to the environment.

Although RAC considers that clarification of these shortcomings would not be expected to lead to significantly higher exposure estimates compared to those considered for the risk characterisation, the applicant shall address these shortcomings by obtaining representative measurements for workers' exposure and air emissions referred to in section 8.1, paragraph 1 of their DUs.

9. Recommendations for the review report

Were recommendations for the review report made?

☒Yes ☐No

9.1. Description

RAC

In relation to the concerns about the inherent uncertainties of the applied survey the applicant should

> perform a new survey among their DUs two years before the end of the review period, a survey that should be designed in such a way that a maximum and representative response is obtained.

The results of the new survey and the measurements referred to in section 8.1 paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 3, should be documented and included in any subsequent authorisation review report.

9.2. Justification

RAC

A new survey before the end of the review period will provide relevant and updated information about the RMMs and OCs in place at their DUs' sites.

Provision of the results of the representative monitoring results would allow for a better evaluation of the actual and future situation at the DUs' sites and would further confirm the appropriateness and effectiveness of RMMs and OCs as described in the application.

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 – the applicant did not comment.

10.3. Reasons for not introducing changes

Not applicable – the applicant did not comment.