Committee for Risk Assessment

RAC

Opinion related to the request by the Executive Director of ECHA under Art. 77(3)(c) of REACH to the Committee for Risk Assessment to consider a condition in the opinion on the application for authorisation N° AFA-O-0000006655-67-01

ECHA/RAC/ A77-O-0000001412-86-205/F

Adopted

8 June 2018

OPINION

Pursuant to Article 77(3)(c) of 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), the Committee for Risk Assessment (RAC) has adopted an opinion on whether the additional information submitted by the applicant in February 2018 would change the need for a condition in the RAC opinion N° AFA-O-0000006655-67-01 on an application for authorisation submitted by Wesco Aircraft EMEA Limited adopted on 30 November 2017.

I. PROCESS FOR ADOPTION OF THE OPINION

On 18 April 2018[1], the Executive Director of ECHA requested RAC to consider by 30 June 2018 the clarifications provided by the applicant for authorisation and to conclude if the condition in the opinion which reads: *"The scope of the authorisation for the use of chromium trioxide is limited to slurry coating (sacrificial coating and diffusion coating) and chemical conversion coating operations by aerospace companies and their suppliers. Chemical conversion coating by spraying and slurry coating by dipping, brushing, swabbing or roller shall not be covered by the authorisation, if granted."* is still necessary.

Rapporteur, appointed by RAC: **VAN DER HAAR Rudolf**

Co-rapporteur, appointed by RAC: **TOBIASSEN Lea Stine**

In accordance with the mandate from the Executive Director of ECHA, the rapporteurs developed a draft opinion, summarising the justification for removing the condition. The draft opinion together with the revised chemical safety report (CSR) submitted by the applicant and the amended version of the RAC opinion dated 30 November 2017, were then made available for RAC members' written comments on 18 May 2018.

The RAC opinion was adopted by **consensus** on **8 June 2018**.

Consequently, opinion N° AFA-O-0000006655-67-01/F, dated 30 November 2017, is replaced with the amended version in Annex 1, dated 8 June 2018.

[1] https://echa.europa.eu/documents/10162/13641/rac_mandate_wesco_en.pdf/dc3bd58e-f32b-cafe-313b-859f525bf4b8

II. OPINION OF RAC

On the basis of the revised chemical safety report (CSR) of 8 February 2018 provided by the applicant (Annex 2), RAC is of the opinion that the condition: *"The scope of the authorisation for the use of chromium trioxide is limited to slurry coating (sacrificial coating and diffusion coating) and chemical conversion coating operations by aerospace companies and their suppliers. Chemical conversion coating by spraying and slurry coating by dipping, brushing, swabbing or roller shall not be covered by the authorisation, if granted."* **is no longer necessary**.

Therefore, RAC amended the opinion N° AFA-O-0000006655-67-01/F, dated 30 November 2017. Annex 1 presents the amended opinion and its amended justification.

The committee bases its opinions on the information included in the application documents. Thus, in the view of RAC, it is important that applicants unambiguously define the scope of the use applied for, describe in detail the processes covered, and present exposure scenario(s) with a clearly defined set of Operational Conditions and Risk Management Measures for all the corresponding tasks and processes covered by the scope of the use applied for. Lack of such clear information greatly hinders the evaluation of applications for authorisation.

III. JUSTIFICATION

Scope

In its opinion of 30 November 2017, RAC recommended two conditions related to the scope of the requested authorisation (condition 1 and 2 in what follows).

1) *The scope of the authorisation for the use of chromium trioxide is limited to slurry coating (sacrificial coating and diffusion coating) and chemical conversion coating operations by aerospace companies and their suppliers.*

Condition 1 had been introduced to avoid any misunderstanding regarding the scope of the authorisation resulting from the statement that the exposure scenario (ES) includes "but is not limited to" slurry coating (sacrificial coating and diffusion coating) and chemical conversion coating (CCC) operations (on p.22 of the CSR as originally submitted). In their written response of 5 April 2017 to a question from RAC, the applicant agreed that the scope of the authorisation should in fact be limited to these operations and the condition made this unequivocally clear.

The revised CSR of 8 February 2018 provided by the applicant ('revised CSR' in what follows) states that "the ES includes (is limited to)" the said processes and thereby the ambiguity on p.22 has been eliminated, **therefore rendering condition 1 redundant**.

2) *Chemical conversion coating by spraying and slurry coating by dipping, brushing, swabbing or roller shall not be covered by the authorisation, if granted.*

Condition 2 had been introduced because RAC was of the view that no WCSs were presented in the CSR to cover the following coating application types:

- CCC by spraying, and
- slurry coating by dipping, brushing, swabbing, roller or pen-stick application.

However, RAC acknowledged that the above coating application types were mentioned on p.22 of the CSR as originally submitted. RAC also noted that Table 4 of the analysis of alternatives also does not mention spraying of CCC as a coating process covered by the use applied for but did mention slurry coatings by brush and dip processes. As part of the comments on the draft opinion, the applicant requested the above coating processes to be covered by the authorisation. However, as the processes in question were considered not to be covered by the ES, and no supplementary supporting information was provided in the comments on the draft opinion, RAC was of the view that they should therefore not be covered by the authorisation, if granted.

The revised CSR provides missing information and clarifications to support the applicant's view that the CSR as originally submitted intended to cover these processes.

RAC is of the view that with the revised CSR, the ambiguities in the scope have been eliminated. The scope of the use applied for unequivocally covers also chemical conversion coating by spraying, as well as slurry coating by dipping, brushing, swabbing or roller application, and as a result it is also unambiguous that there are WCSs with OCs & RMMs defined for these processes.

RAC therefore considers that condition 2 is no longer needed.

Removal of conditions: assessment of implications to risk assessment

With the removal of condition 1, RAC's interpretation of the scope does not change and thus has no bearing on the exposure and risk assessment. However, lifting condition 2 does mean a change in RAC's interpretation of the scope of the use applied for. RAC assessed any implications that such a change may have on the exposure and risk assessment contained in the justifications to the opinion of RAC of 30 November 2017. Based on this assessment RAC is of the view that the conclusions of the exposure and risk assessment in the justifications to the opinion of RAC of 30 November 2017 remain valid, however, some amendments to the justification are required mainly to reflect the clarifications provided in the revised CSR. This assessment is provided in what follows.

Bath

'Bath application' for slurry coating (WCS 5 Surface treatment by immersion /dipping) is in essence the same as that for CCC and the same OCs & RMMs are applied as defined in the WCS. In practise there are the following differences:

1) The formulations used in the bath: the concentration of Cr(VI) in CCC formulations is less than 1% w/w compared to less than 5% w/w in slurry coatings;

2) The process temperature: up to 30°C for CCC and at ambient temperature for slurries.

The exposure was only modelled with ART. For the concentration of Cr(VI) in the mixture the modelling parameter "Small (1 - 5%)" and "above room temperature" (defined in ART as 25-50°C) were selected. These parameters cover both the baths with CCC and slurries. RAC considers the evaluation of the risk assessment and conclusions in the opinion of 30 November 2017 remain valid, including the remark that *"While the applicant stated that in the modelling scenarios a maximum level of the concentration of chromium trioxide is assumed, the maximum 5% bath concentration is not used as a conservative parameter for modelling but a range of 1-5%."*.

Spraying

Spraying (WCS 6 Substance preparation and surface treatment by spraying in paint booth) with CCC coatings is in essence the same as spraying with slurry coatings and the applicant confirmed that the same OCs & RMMs as defined in the sub-WCSs apply. In practise, there are the following differences:

1) The formulations used: the concentration of Cr(VI) in CCC formulations is less than 1% w/w compared to less than 5% w/w in slurry coatings;

2) Frequency of tasks: the revised CSR states that CCCs operations are carried out far less frequently than for slurry coatings;

3) The sub-WCS "Article curing" is not relevant to CCC coatings.

The exposure to Cr(VI) from spraying was estimated by means of measured data from slurry coating processes. The applicant stated that *"As the concentration of Cr(VI) in CCC formulations is less than 1% w/w (compared to less than 5% w/w in slurry coatings), CCC operations are carried out far less frequently and there are no significant differences in other relevant exposure parameters, the measurement data for slurry coatings can be considered conservatively representative of CCC spraying processes."*. The exposure to Cr(VI) from spraying was also modelled with ART assuming a "Small (1 - 5%)" concentration.

RAC considers that the exposure potential from spraying with the two different coating types is similar, and the measurement and modelled data from spray coating of slurries can be used to estimate exposure from spray coating with CCC. It is likely that other differences that exist between the operations at different sites are more significant in determining the exposure than the coating type (see discussion in Annex 1 concerning the data for slurry coating). RAC considers that the evaluation of the risk assessment and conclusions in the opinion of 30 November 2017 remain valid, including the remark that *"It is not clear to which extent the exposure estimate for WCS 6 is representative across the supply chain of the applicant considering: monitoring data is available from only six sites out of 275; a lack of detailed descriptions of the OCs and RMMs corresponding to the measurements; a lack of information regarding the site characteristics (e.g., size of the room, production volume) corresponding to the monitored data; a lack of details regarding the tasks performed by the workers during the measurement sampling."*.

Touch-up

Touch-up activities with slurry coating (WCS 7 Surface treatment by brushing or pen-stick use (small sized areas)) are in essence the same as with CCC and the same OCs & RMMs are applied as defined in the WCS. The main difference lies in Cr(VI) concentration of the formulations used (CCC formulations is less than 1% w/w compared to less than 5% w/w in slurry coatings). Since the exposure was only modelled with ART with the modelling parameter "Small (1 - 5%)" the exposure estimate covers both the baths with CCC and slurries. RAC therefore considers the evaluation of the risk assessment and conclusions in the opinion of 30 November 2017 remain valid also for this WCS.

Viscosity

Regarding the modelled exposure estimates for WCS 2, 3, 4, 5, 7, 8 and 10 it has been clarified that the viscosities of the formulations in scope of this dossier are characterized as "low viscosity" (like water) in ART, also when the process involves slurries. As this is the option in the ART model which results in the highest exposure estimates, the evaluation of the risk assessment and conclusions in the opinion of 30 November 2017 remain valid.

Combined exposure

Regarding the combined exposure the applicant informed ECHA that *"The term 'multiple processes' as referenced in the AfA refers to more than one surface treatment application (e.g., bath processes, spraying), machining, etc. We confirm that operators performing spraying activities would not also perform bath activities, as these are specialist activities and are very separate processes. As such, there is no need to change the combined exposure section, as the CCC bath example provided is the most conservative (WCS 2-5, 10), and thus conservatively covers slurry bath (slurry bath does not typically include WCS 10)."*. RAC considers that the evaluation of the risk assessment and conclusions in the opinion of 30 November 2017 remain valid.

ANNEXES

Annex 1 Amended opinion (track-changed)

Annex 2 revised CSR (track-changed)

Annex 1

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for the use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers

ECHA/RAC/SEAC: Opinion N° AFA-O-0000006655-67-01/F

Consolidated version

Date: ~~30/11/2017~~8 June 2018

Consolidated version of the

Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis

on an Application for Authorisation

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

Chemical name:	**chromium trioxide**
EC No.:	**215-607-8**
CAS No.:	**1333-82-0**

for the following use:

Use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers

Intrinsic property referred to in Annex XIV:

Article 57(a) and (b) of the REACH Regulation

Applicant:

Wesco Aircraft EMEA Limited[1]

Reference number:

11-2120133105-72-0001

Rapporteur, appointed by the RAC:	**VAN DER HAAR Rudolf**
Co-rapporteur, appointed by the RAC:	**TOBIASSEN Lea Stine**
Rapporteur, appointed by the SEAC:	**GEORGIOU Stavros**
Co-rapporteur, appointed by the SEAC:	**DELCOURT Benjamin**

This document compiles the opinions adopted by RAC and SEAC.

[1] Name of the applicant in the original application: Haas Group International SCM Ltd updated due to a notified legal entity name change.

PROCESS FOR ADOPTION OF THE OPINIONS

On **14/03/2016 Wesco Aircraft EMEA Limited** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **02/11/2016** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **09/11/2016**. Interested parties were invited to submit comments and contributions by **09/01/2017**.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation as well as the responses of the applicant.

The draft opinions of RAC and SEAC take into account the responses of the applicant as well as third parties to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

The draft opinions of RAC and SEAC were sent to the applicant on **24/07/2017**.

The applicant informed on **15/09/2017** that it wished to comment the draft opinions of RAC and SEAC according to Article 64(5) and sent his written argumentation to the Agency on **02/10/2017**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **09/06/2017**.

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of RAC was adopted by consensus on **30 November 2017**. On 18 April 2018, the Executive Director of ECHA requested RAC to consider a condition recommended by RAC in its opinion. The RAC opinion responding to this mandate was adopted by consensus on 8 June 2018 and replaces the opinion of 30 November.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **15/06/2017**.

The draft opinion of SEAC was agreed by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of SEAC was adopted by consensus on **30 November 2017**.

THE OPINION OF RAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

RAC has formulated its opinion on: the risks arising from the use applied for, the appropriateness and effectiveness of the risk management measures described, the assessment of the risks related to the alternatives as documented in the application, the information submitted by interested third parties, as well as other available information.

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

RAC confirmed that there appear not to be any suitable alternatives that further reduce the risk.

RAC confirmed that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements are expected to improve the situation.

THE OPINION OF SEAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC has formulated its opinion on: the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application, the information submitted by interested third parties, as well as other available information.

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

SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant.

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

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

The conditions and monitoring arrangements listed in section 9 of the justifications are recommended in case the authorisation is granted.

REVIEW

Taking into account the information provided in the application for authorisation prepared by the applicant and the comments received on the broad information on use(s) the duration of the review period for the use is recommended to be **7 years**.

JUSTIFICATIONS

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property / properties:

☒ 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) [please specify]:

2. Is the substance a threshold substance?

☐ YES

☒ NO

Justification:

Chromium trioxide has a harmonised classification as Carcinogen Cat. 1A and Mutagen Cat. 1B with H340 and H350 according to CLP. Based on studies which show its genotoxic potential, the Risk Assessment Committee (RAC) has concluded that chromium trioxide should be considered as a non-threshold substance with respect to risk characterisation for carcinogenic effect of hexavalent chromium (reference to the studies examined are included in the RAC document RAC/27/2013/06 Rev.1).

3. Hazard assessment. Are appropriate reference values used?

Justification:

RAC has established a reference dose response relationship for the carcinogenicity of hexavalent chromium (RAC/27/2013/06 Rev. 1), which was used by the applicant.

The molecular entity that drives the carcinogenicity of chromium trioxide is the Cr(VI) ion, which is released when chromium trioxide solubilises and dissociates.

Chromium(VI) causes lung tumours in humans and animals by the inhalation route and tumours of the gastrointestinal tract in animals by the oral route. These are both local, site-of-contact tumours – there is no evidence that Cr(VI) causes tumours elsewhere in the body.

Dose-response relationships for these endpoints were derived by linear extrapolation. Extrapolating outside the range of observation inevitably introduces uncertainties. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be overestimated.

In the socio-economic analysis (SEA) the remaining human health risks are evaluated based on the dose-response relationship for carcinogenicity of hexavalent chromium (RAC27/2013/06 Rev.1).

Are all appropriate and relevant endpoints addressed in the application?

All endpoints identified in the Annex XIV entry are addressed in the application.

4. Exposure assessment. To what extent is the exposure from the use described?

Description:

Short description of the use

The application for authorisation covers the use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers:

- Chemical conversion coating (CCC) is a chemical process applied to a substrate producing a surface layer containing a compound of the substrate metal and other chemical species from the process solution. For conversion coatings, the main form of application is dipping or immersion of parts in a tank or through a series of tanks containing solutions in closed or open systems. The solution containing Cr(VI) additionallyAdditionally, CCC is performed by spraying and is occasionally applied by brush or with a pen-stick, especially to small localised areas. The WCSs do not cover chemical conversion coating by spraying.
- Slurry coatings, more specifically sacrificial coatings (which have a lower electrode potential than the substrate to be protected) and diffusion coatings (process based on the coating material diffusing into the substrate at high temperatures) is), are used for corrosion protection. Slurry coatings are comprised of aqueous slurry of a powdered material (typically aluminium) mixture with chromium trioxide and are applied by standard air atomizing spraying, then dried and cured in air at 260°C or above (chemical modifiers can be added to some coatings to reduce cure temperature to as low as 190°C). The WCSs do not cover application of slurrySlurry coatings are also applied by dipping, in baths as well as application by brushing, swabbing or using a roller.

Chemical conversion coatings and slurry coatings provide various critical functions (e.g. protecting the metal from corrosion, increasing wear resistance, providing an adhesive base, electrical and thermal properties, and chemical resistance).

Chemical conversion coating and slurry coating processes might leave Cr(VI) on the article after the process.

Machining operations, like fettling, drilling, riveting, edging, abrading, or sanding, might be necessary during industrial post-treatment of coated parts. Therefore, exposure to Cr(VI) dust during these activities is possible.

The application for chromium trioxide is submitted by one applicant. An estimated volume of < 2 tonnes chromium trioxide per year is used for surface treatment (equal to 1 tonnes Cr(VI) per year) at an estimated 275 sites.

The applicant presented one exposure scenarios (ES) in the CSR which consists of 1 environmental contributing scenario (ECS) and 16 worker contributing scenarios (WCS), of which one is divided into 7 sub WCSs (see Table 1).

The main processes covered by this application for authorisation include:

- on site formulation;
- bath surface treatment;
- slurryspray coating; and
- machining activities on parts

Table 1: Contributing Scenarios presented in the "Use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers"

Contributing scenario	ERC / PROC	Name of the scenario
ECS1	ERC 6b:	Use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers
WCS 1	PROC 1	Delivery and storage of raw material
WCS 2	PROC 8b	Decanting of liquids
WCS 3	PROC 5	Mixing- liquids
WCS 4	PROC 8b	Re-filling of baths for concentration adjustment liquids
WCS 5	PROC 13	Use of chromium trioxide for chemical conversion coating (CCC) applications by aerospace companies and their suppliersSurface treatment by immersion/dipping
WCS 6	PROC 8b, 7	Use of chromium trioxide for slurry coating-substanceSubstance preparation and surface treatment by spraying in paint booth
WCS 6.1		Mix coating slurry
WCS 6.2		Filling of paint gun
WCS 6.3		Masking and degreasing
WCS 6.4		Spraying in paint booth
WCS 6.5		Article drying
WCS 6.6		Article curing
WCS 6.7		Tools cleaning (spray cabin)
WCS 7	PROC 10	Surface treatment (CCC) by brushing or penstickpen-stick use (small sized areas)
WCS 8	PROC 8a	Maintenance of equipment
WCS 9	PROC 8a	Infrequent maintenance activities
WCS 10	PROC 8b	Sampling
WCS 11	PROC 21, 24	Machining operations on small to medium sized parts containing Cr(VI) on an extracted bench/extraction booth including cleaning.
WCS 12	PROC 21, 24	Machining operations in large work areas on parts containing Cr(VI) including cleaning
WCS 13	PROC 21, 24	Machining operations on parts containing Cr(VI) in small work areas including cleaning
WCS 14	PROC 1	Storage of articles
WCS 15	PROC 8b	Waste management
WCS 16	PROC 8a	End of Life

Worker exposure

The worker exposure assessment has been limited to the inhalation of chromium trioxide containing dust and/or aerosols since chromium trioxide is a non-volatile substance and the dominating health effect resulting from the intrinsic hazardous properties of chromium trioxide is lung cancer due to inhalation. The applicant assumed that all particles are in the respirable size range and thus oral exposure was not assessed.

Exposure estimation methodology

By agreement, the GCCA consortium[2] used the CTAC[3] exposure scenarios as a starting point since the activities in the scope of the GCCA are a subset of those in the scope of the CTAC application.

The CTAC exposure scenarios[4] were developed by the original equipment manufacturers (OEM) from the aerospace and defence industry and formulators that were members of the CCST consortium, with input from companies carrying out surface treatment in the supply chain. The same companies reviewed and validated the ESs and exposure levels by means of an extensive consultation through the completion of a questionnaire, bilateral discussions and site visits.

Each member of the GCCA consortium contacted companies in its supply chain for information (a questionnaire) to refine and augment the CTAC Exposure Scenarios.

According to the applicant, the companies that responded collectively represent the different applications and sectors of application as well as different company sizes. The applicant stated that therefore the ESs presented are unambiguous and demonstrated to be representative for their use of chromium trioxide and of good practice across the industry.

The applicant is of the view that the Exposure Scenarios are conservative, meaning that exposure measurements or estimates represent the upper boundaries of exposure (representing the reasonable worst case). The applicant stated that, due to the specialised and highly regulated nature of activities in the aerospace sector, the uses are well defined and uncertainty associated with the Exposure Scenarios is limited. Where differences in exposure conditions between facilities occur, the exposure levels take account of the least

[2] The GCCA consortium (Global Chromates Consortium for Aerospace) consists of a total of 17 members, including 3 major engine manufacturers, 2 major aerospace and defence organisations, 2 major aerospace companies, companies carrying out maintenance & repair operations and several formulators. To date, the GCCA consortium supported the preparation of applications for four chromium VI-containing substances for uses in the in the aerospace industry: sodium dichromate, potassium dichromate, chromium trioxide, and sodium chromate. There is some overlap in membership of CCST and GCCA.

[3] The CTAC consortium (Chromium Trioxide REACH Authorization Consortium) supported the application for several uses of chromium trioxide in several industry sectors with LANXESS Deutschland GmbH in its legal capacity as Only Representative of LANXESS CISA (Pty) Ltd. as lead applicant. Use 4 of this application covered "Surface treatment for applications in the aeronautics and aerospace industries, unrelated to Functional chrome plating or Functional chrome plating with decorative character". This Use 4 was covered together with Use 5 in one CSR and amongst the process covered were CCC (covered by the generic surface treatment WCSs) and slurry coating (covered by several generic WCSs for surface treatment by spraying).

[4] It is understood from the limited information in the CSR that generally the same principles apply to the development of ESs by the CTAC consortium and subsequent adaption by GCCA, albeit the applicant in its replies to questions regarding the ESs development only referred to the CCST consortium, as an example.

stringent operational conditions (OCs) and risk management measures (RMMs) to over-estimate the risk.

Modelling

For most WCSs the exposure estimates were modelled (ART 5.1) (see Table 2). Input parameters for the model including OCs and RMMs have been provided in the CSR. No site-specific data were used as input parameters but default values which are aimed at deriving reasonable worst case exposure estimates. In general the highest exposure duration and the lowest level of personal protection reported and maximum level of chromium trioxide reported in the supply chain were used to define the WCS and modelling input parameters.

The applicant noted that since the ART model does not cover machining activities on metallic surfaces, the activity class “fracturing and abrasion of solid objects (stone)” is used.

The 90th percentile value full shift exposure estimate is used for the exposure and risk assessment.

Qualitative assessment

For WCS 1 (Delivery and storage of raw material) and WCS 14 (Storage of articles) a qualitative assessment was performed.

Air monitoring

A total of 28 personal air sampling data from 6 sites of 5 different EU countries (IT, FR, HU, UK and PO) are available for ~~WCS 6 (~~slurry coating by spraying (WCS 6). The individual measurement data set is presented in Appendix 1.

Measurements below the limit of detection were accounted with 50% of the LoD, as common practice in occupational exposure assessment. The applicant stated that measurement of inhalation exposure has been conducted using standardized methods.

The measurements results were adjusted for RPE efficiency. Subsequently, since the number of sampling data provided by each of the companies varied, the data were aggregated per site by calculating the mean of the adjusted personal air measurement results in the first instance. Lastly, the applicant calculated the AM, GM and 90th percentile of the means of the 6 sites, thus giving equal weight to each site in the data set independent of the number of measurement per site.

The 90th percentile exposure estimates obtained in this manner are used to estimate the exposure for WCS 6.

Description of WCS and RMMs/OCs applied

Description of WCSs

All activities are performed indoors and at ambient temperature, with the exception of the re-filling of baths (WCS 4) which takes place at above room temperature; chemical conversion coating (WCS 5) with temperatures up to 30ºC; ~~and~~ the drying of spray coated articles at ambient temperature or at around 80-150 ºC (WCS 6); and curing ~~process~~ of ~~the~~ slurry ~~coating (WCS6) with temperatures of 80-150 ºC and~~coatings at 500-650ºC ~~respectively.~~(WCS 6).

WCS 1: Delivery and storage of raw material

Formulations containing chromium trioxide are delivered as aqueous solution in sealed containers and stored in a chemical storage room and therefore the applicant states that there is no potential for exposure. The substance can be delivered just in time or be stocked in designated storage areas. The size of the sealed containers varies between 1 litres to 5 litres.

WCS 2: Decanting of liquids

The formulations containing chromium trioxide may be decanted in (smaller) containers for re-filling of ~~CCC~~ baths or for further ~~pre-~~mixing. This may be conducted under exhaust ventilation or increased mechanical room ventilation but is not considered for the exposure assessment. Decanting is usually a manual process. The applicant addresses this scenario as a manual, open process.

WCS 3: Mixing – liquids

The aqueous solution may be ~~pre-~~mixed before re-filling of ~~CCC~~ baths ~~for concentration adjustment~~.

This task is undertaken at a special place, e.g. under a hood, at a location with dedicated LEV, in mixing room or other isolated location. However, for the exposure assessment it is assumed that no LEV is in place.

WCS 4: Re-filling of baths ~~for adjustment of concentration~~ – liquids

The chromium trioxide solution or slurry is transferred to and manually filled into the ~~CCC~~ bath. In the case of conversion coating, this may be completed for adjustment of the concentration in the bath. In the case of slurry coating, this is completed for refilling of the bath. The applicant stated that this scenario, as worst-case, covers similar activities in which a complete emptying and re-filling of a bath is conducted; in practice, however, such a complete refill is only rarely needed (around one time per year). Complete emptying is done by means of a pump and the bath chromate solution, and afterwards the rinse water, is pumped to a labelled waste container.

WCS 5: ~~Use of chromium trioxide for chemical conversion coating applications~~Surface treatment by ~~aerospace companies and their suppliers~~

~~Use of chromium trioxide for chemical conversion coating applications in the aeronautics and aerospace industries by dipping/~~**immersion**~~ is conducted in sequential process steps within a series of tanks that contain treatment, cleaning and other related solutions. Before~~**/ dipping**

Before CCC treatment, parts are prepared by degreasing, stripping, rinsing in several ~~bathes.~~baths. These pre-treatment steps do not involve use of chromium trioxide. Slurry coatings are occasionally applied by dipping/immersion in a single bath (no pre-treatment). Lifting tools (hoists and racks) are used to move the parts which are placed on tools from one tank to another one. The parts are then placed in the ~~CCC~~ bath through the upper opened surface of the tank and ~~immerged~~immersed. The liquid of CCC baths is tempered up to 30°C. Slurry coating baths are at ambient temperature. Finally, articles are removed from the bath using the lifting tools, drained above the bath during a few seconds and then rinsed in several water tanks. Then articles are dried before they are removed from the tools and demasked.

The ~~CCC~~ baths containing Cr(VI) are equipped with extract ventilation during the treatment process. Baths might be covered or partially covered. However for the modelled exposure estimate it is assumed that the baths are open.

Cleaning of equipment is not a separate task but conducted by those employees working in the bath area as part of their normal working procedure.

~~WCS 6: Use of chromium trioxide for Slurry coating -~~WCS 6: Substance preparation and surface treatment by spraying in paint booth

This WCS consists of a number of different sub-tasks which are described below. These tasks might be repeatedly conducted during one shift. The dimensions of the articles to be treated can vary greatly, but are likely to have a surface area between 1 and 3 m^2. All wastewater, including from cleaning the gun and booth, is segregated. The cured coating contains no Cr(VI).

- **WCS 6.1 Mix coating ~~slurry~~**
  The worker mixes the components of preparation with the ~~convenient~~appropriate ratio (<5% w/w ~~chromium trioxide~~for slurries and <1% w/w for conversion coating). The substances are mixed mechanically using a specific mixer (rolling machine or shaker) to ensure complete homogenization of its constituents. The preparation is made in a special area (e.g. laboratory) near the paint booth.

- **WCS 6.2 Filling of paint gun**
  The worker fills the hand-paint gun after filtration of the mixture with a specific particulate filter mesh, volume of ~~paint~~coating is about 100 ml.

- **WCS 6.3 Masking and degreasing**

  Articles to be coated must be cleaned and have their surfaces prepared by blasting using a media such as aluminium oxide. This process serves to slightly roughen the surface and to remove any oxide layer that may have built up during storage. Before coating application, surfacesparts may be sandblasted and degreased. Surfaces not to be coated are masked by application of a masking tape or other suitable device. This task is performed in the paint booth, or elsewhere. The other parts must be sandblasted and degreased. Most blasting operations are performed manually with the operator reaching into the machine through access ports (as in a “glove box”). Larger parts may be prepared and sandblasted in walk-in cabinets or dedicated booths. In that case, the operator wears air fed RPE. Normally dust does not contain Cr(VI) since sandblasting is performed on bare hardware, prior to coating. However, sometimesWhen sandblasting is performed on parts for rework in OEM and during maintenance, repair and overhaul (MRO) to remove coating. The, the potential for this dust to contain Cr(VI) cannot be discounted. The applicant assumed a concentration of less than 1-5% Cr(VI).

- **WCS 6.4 Spraying in paint booth**

  The slurrycoating is sprayed by the worker using a hand-held HVLP spray gun within an open or closed down-flow booth. Specific local exhaust ventilation is installed in the booths, each equipped with HEPA filters. The flow of air through the booth should be evenly distributed and the average cross draft velocity over the horizontal cross section should be no less than 100 feet per minute when the exhaust bank of filters are loaded to the manufacturer's recommended maximum pressure drop. The worker is supplied with a full-face mask with air supply or half-face mask with P3 filter. Paint booths with an open front may furthermore be equipped with a water curtain. The applicant mentioned that while many companies will have mechanical ventilation in the area of the paint booth(s), others, especially with closed booths, will not. The paintcoating is applied in several layers until the specific thickness is reached. Spray applications are performed for small to medium-sized parts. Spraying of large parts (e.g., air frames) outside of spray rooms/spray booths is not in the scope of this application.

- **WCS 6.5 Article drying**

  Articles are allowed to dry off for 15 minutes under ambient conditions or at around 80°C-150°C in a specific oven and then aremay be moved (e.g. by an automatic hoist) from the paint booth to the curing oven.

- **WCS 6.6 Article curing**

  ArticlesFollowing slurry coating, articles are cured at high temperature (500-650°C) in an oven for up to around three hours. The oven may be vented. No workers are present. Articles are moved by an automatic hoist from the paint booth to the oven, and from the oven to the storage area. This task is not relevant for CCC.

- **WCS 6.7: Tools cleaning (spray cabin)**

  Paint guns and tools are cleaned with water or solvent in a specific area of the spray room /booth by the worker who conducted spraying under exhaust extraction. Waste material eliminated in a specific tank for contaminated waste.

WCS 7: Surface treatment (CCC) by brushing or pen stick (small sized areas)

For small sized areas, CCC or slurry coating might be conducted by brushing or by use of a pen-stick. This task concerns localized treatments on surfaces new parts needing a localized treatment, new parts needing a repair due to defects in bath production, or worn parts in service needing to be repaired. It concerns production and maintenance technicians. For the purpose of the exposure assessment, it has been assumed that it will be carried out 1 h/day every day.

WCS 8: Maintenance of equipment

The applicant conservatively assumed that the regular maintenance of the baths and related equipment (e.g. LEV, pumps, panels etc.) occurs for 60 minutes one time every two weeks. Regular maintenance is conducted when the bath solutions are at ambient temperature.

A worst case assumption for potential inhalation exposure for this activity is that these workers would be exposed to the same level of Cr(VI) as workers conducting the CCC, process bath application (i.e. assuming a background concentration of Cr(VI) within the work area equivalent to that present during CCC bath application, even if no surface treatment takes place and that LEV is off.).

This scenario also covers infrequent maintenance activities with longer duration and depending on the exposure potential, RPE is worn additionally.

WCS 9: Infrequent maintenance activities

Maintenance activities on equipment of the paint booth like the exhaust system or the removal and replacement of filters may need more time and might create higher exposure potential. As a worst case, these activities are assumed to be conducted one time per month with a duration of up to 4 hours and with a maximum Cr(VI) powder weight fraction of 1-5%.

WCS 10: Sampling

One or more samples are drawn at the bath(s) with it (their) ventilation extraction functioning but when no surface treatment is conducted. The samples are transferred into a closed flask to the laboratory. It is conservatively assumed that sampling is conducted one time per week.

Machining activities (WCS 11-13)

Cleaning due to contamination during the machining process is included in this scenario because it is conducted under the same operational conditions and risk management measures as the machining activities.

The applicant assumes that Cr(VI) weight fraction of the part is < 0.1 %. In case of lower or higher Cr(VI) content, estimated exposure would be reduced or increased in a linear way (i.e. 0.5 % concentration in the product would lead to an increase of the exposure estimate by a factor of 5). If needed, OCs and RMMs could be adjusted for that different situation.

WCS 11: Machining operations on small to medium sized parts containing Cr(VI) on an extracted bench / extraction booth including cleaning

During assembly, maintenance and/or repair, small to medium sized solid parts are drilled fettled, abraded, sanded or cut on a dedicated work bench fitted with air extraction.

This scenario also covers machining operations with a longer duration of activity but with a higher level of respiratory protection, e.g. by using a full face mask with P3 filter (APF 400).

WCS 12: Machining operations in large work areas on parts containing Cr(VI) including cleaning

Solid parts are manually drilled, fettled, abraded, sanded, riveted or cut outside a booth in large work areas.

This scenario also covers machining operations with a longer duration of activity but with a higher level of respiratory protection, e.g. by using a full face mask with P3 filter (APF 400).

WCS 13: Machining operations on parts containing Cr(VI) in small work areas including cleaning

Parts are drilled, fettled, abraded, sanded, riveted or cut in comparable small work areas (e.g. inside wing tanks).

In small work areas, no air extraction or other localised controls (e.g. wetting, vacuum cleaning) may be available. This scenario assumes the absence of any localised control.

However, the applicant explained that in practise working in confined spaces may require additional RMM such as forced ventilation to provide thermal comfort.

WCS 14: Storage of articles

The finished articles are stored in a separate storage are. There is no potential for inhalation exposure.

WCS 15: Waste management

The applicant states that very low amounts of Cr(VI), if at all, is released from waste water treatment systems. There is no potential of inhalation exposure of workers from the wastewater treatment systems because sampling before discharging to public sewage system is a short-term activity and the concentration of Cr(VI) is very low if detectable at all. Therefore, potential of inhalation exposure and risk is considered negligible and is not further assessed.

Other process waste (e.g. empty containers, canisters, pencils, masking materials) are stored in closed containers which further are collected by licensed waste management companies for treatment, incineration and disposal of incineration residues to licensed landfill. This scenario describes the transfer of such type of waste to the storage area.

The applicant indicated, as worst-case assumption, that process waste from slurry coating like masking material might be collected and transferred on a daily basis.

WCS 16: End of Life

As part of aviation requirements, all aircraft parts must be destroyed at end of life to avoid reuse. At the end of life, parts are collected in designated, secure boxes and sent to a licensed scrap dealer who treats the metals according to EU and national requirements. The aerospace industry has specialist waste contractors familiar with these requirements.

<u>Description of RMMs / OCs applied</u>

According to the applicant the RMMs and OCs represent good industry practice and represent the least conservative conditions that could theoretically be imposed that allow companies to meet the high standards of protection

However the applicant stated that there may be some differences in OCs and RMMs applied across different facilities, due to facility and operation specific considerations.

The applicant also mentioned that downstream users have to ensure that the controls that they have in place provide an equivalent or better level of protection than those set out in the Exposure Scenario, which contains the least stringent RMM/OC and greater release parameters to over-estimate the risk. Downstream users may adapt or improve RMM and OC selection in order to most appropriately and efficiently control worker exposure and maintain compliance with national regulations.

LEV is always used at the baths. The applicant stated that lip extraction is normally in place for bath treatment processes but that alternatively, a push-pull ventilation system can be used, especially for wider baths.

Covering the baths is not included as a minimum requirement in the exposure scenario by the applicant. In their opinion the type of treatment (electroless process) is not likely to generate aerosols and the concentration of Cr(VI) in the baths is low, and therefore they consider that the expected decrease of the exposure potential by covering baths will be very limited. For the same reason the applicant considers that there is no need for additional use of mist suppressants, taking into account also that this RMM is not always technically feasible.

The applicant stated that for spray operations (WCS 6) access to all areas where spraying is conducted is restricted to authorised personnel, that spray booths with wet or dry filters are used for spray applications of small to medium-sized parts and that <u>spraying of large parts (e.g., air frames) outside of spray rooms/spray booths is not in the scope of this application</u>. The applicant clarified that although natural ventilation is mentioned in the conditions of use, many companies will have mechanical ventilation in the area of the paint booth(s) and that others, especially with closed booths will not.

According to the applicant, regular housekeeping and advanced Health and Safety management systems (e.g. training, hygienic conditions) and other management systems are in place for all WCS ensuring high standard of operational procedures and significant reduction in exposure.

When handling chromium trioxide, personnel are required to wear protective clothing, chemical-resistant, impermeable gloves, and goggles.

Workers involved in spraying activities are required to wear as a minimum half-masks with P3 filter. The applicant stated that manipulation of aqueous solutions of chromium trioxide (WCS 2, 3 & 4) are expected to entail only a low potential for generating mists, not requiring the need for respiratory protective equipment (RPE). Equipment is maintained regularly.

Workers are said to be skilled, and receive regular training with regards to chemical risk management and how to properly wear the PPE.

A detailed breakdown of the specific RMMs and OCs applied in each task, frequency and duration of the exposure activity as well as the corresponding exposure assessment is given in Table 2.

Worker exposure estimates

The applicant concluded that there is no potential for exposure in WCS 1 & 16 because the formulations containing chromium trioxide are delivered as an aqueous solution in sealed containers. The final articles are stored in a storage area.

For all other WCS, with exception of WCS 6 for which personal measured data were provided (see appendix 1), the exposure estimates are based on ART modelling and where relevant adjusted for frequency and/or use of RPE (see Table 2).

Table 2: OCs, RMMs and exposure assessment per WCS

Description	Conc. Cr(VI) / State	Duration & Freq.	RMM	Exposure assessment
WCS 1: Delivery and storage raw material(3)	<25% Liquid	< 1 hrs; infrequent	• ACH:1-3(1) • LEV: no • RPE: no • Sealed containers	**0 mg/m³** • Qualitative
WCS 2: Decanting of liquids(3)	<25% Liquid	<15 min 1/week	• ACH: natural • LEV: no • RPE: no • Containment: Handling that reduces contact between product and adjacent air	**0.26 µg/m³** • ART 90th perc. • Freq. adjusted

WCS 3: Mixing-liquids	<25% Liquid	<30 min 1/week	• ACH: natural • LEV: no • RPE: no • Containment: open surface < 0.1 m^2	**0.13 µg/m³** • ART 90^{th} perc. • Freq. adjusted
WCS 4: Re-filling of baths-liquids	<25% Liquid	<10 min 1/week	• ACH: natural • LEV: 90% eff. • RPE: no • Containment: Open process	**0.19 µg/m³** • ART 90^{th} perc. • Freq. adjusted
WCS 5: ~~Chemical conversion coating~~ Surface treatment by ~~dipping and~~ immersion /dipping	1-5% Liquid	<60 min daily	• ACH: natural • LEV: 90% eff. • RPE: no • Containment: open surface 1-3 m^2	**0.023 µg/m³** • ART 90^{th} perc.
WCS 6: ~~Slurry coating~~Coating preparation & spraying~~.~~				
WCS 6.1: Mix coating ~~slurry~~	1-5% Liquid	<5 min daily	• ACH: natural • LEV: yes(4) • RPE: no	**0.27 µg/m³** • personal (n=28) • 6 companies • 90^{th} perc. • RPE adjusted 0.48 µg/m³ • ART 5.1 • 90^{th} perc. • RPE adjusted
WCS 6.2: Filling paint gun (100ml)	1-5% Liquid	<5 min daily	• ACH: natural • LEV: no • RPE: ½mask P3(2)	
WCS 6.3: Masking & degreasing (sanding)	1-5% Liquid	<5 min daily	• ACH: natural • LEV: no • RPE: ½mask P3(2) • Containment: not specified(5)	
WCS 6.4: Spraying in booth	1-5% Liquid	<30 min daily	• ACH: natural • LEV: yes(6). • RPE: ½mask P3(2)	
WCS 6.5: Article drying	residual	<15 min daily	• ACH: natural • LEV: no • RPE: ½mask P3(2)	
WCS 6.6: Article curing	residual	<180 min daily	• ACH: natural • LEV: no • RPE: no	

WCS 6.7: Tools cleaning (cabin)	1-5% Liquid/solid	< 15min daily	• ACH: natural • LEV: yes(6) • RPE: ½mask P3(2)	
WCS 7: Surface treatment by brushing ~~(pencil)~~/ pen-stick	1-5% Liquid	<60 min daily	• ACH: natural • LEV: no • RPE: no • Containment: no	**0.23 µg/m3** • ART 90th perc.
WCS 8: Maintenance of equipment	1-5% Liquid	<60 min 1/2weeks	• ACH: natural • LEV: no • RPE: no • Containment: open surface 1-3 m^2	**0.0023 µg/m3** • ART 90th perc • Freq. adjusted
WCS 9: Infrequent maintenance activities	1-5% fine dust	240 min 1/month	• ACH: natural • LEV: no • RPE: APF30(2) • Containment: no	**0.088 µg/m3** • ART 90th perc • Freq. adjusted • RPE adjusted
WCS 10: Sampling	1-5% Liquid	<30min 1/week	• ACH: natural • LEV 90% eff. • RPE: no • Containment: open surface 1-3 m^2	**0.0022 µg/m3** • ART 90th perc. • Freq. adjusted
WCS 11: Machining (small / medium parts	<0,1% Solid	<60 min daily	• ACH: natural • LEV 99% eff. • RPE: APF 30(2) • Containment: no	**0.013 µg/m3** • ART 90th perc. • RPE adjusted
WCS 12: Machining in large working areas	<0,1% Solid	<30 min daily	• ACH: 10 • LEV 90% eff. • RPE: APF 30(2) • Containment: no	**0.028 µg/m^3** • ART 90th perc. • RPE adjusted
WCS 13: Machining in small working areas	<0,1% Solid	<30 min daily	• ACH: natural • LEV: no • RPE: 400(2) • Containment: no	**0.08 µg/m^3** • ART 90th perc. • RPE adjusted
WCS 14: Storage of articles	Non detectable Solid	<480 min daily	• ACH: 1-3(1) • LEV: no • RPE: no • Containment: no	**0.0 µg/m^3** • Qualitative

WCS 15: Waste management (empty bags, etc.)	1-5% Solid	<15 min daily	• ACH: natural • LEV: no • RPE: no • Containment: no	**0.037µg/m³** • ART 90th perc.
WCS 16: End of Life	Not available	Not available	• Certain parts must be destroyed to avoid re-use as part of aviation requirements • Treatment of scrap according to EU and national requirements	Not available

(1) No type of ventilation indicated

(2) Half mask with P3 filter has a APF of 30; APF 30 = 96,67% / APF 400 = 99,75% effectiveness according to German BG rule 190[5]

(3) Sealed containers: 1 -5 l containers

(4) LEV design efficiency not stated in the WCS. For modelling 90% efficiency was assumed

(5) Minimum requirements for containment are not specified in the WCS. For modelling a medium level of containment was assumed (99.0% reduction).

(6) LEV design efficiency not stated in the WCS. For modelling 80% efficiency (down-flow spray room) was assumed.

Combined exposure

The applicant considered the combination of WCS 2-5 and 10 as a possible combined exposure for activities in relation to CCC in baths. The combined exposure estimate (as the sum of 90th percentile value of model-based exposure distribution for each WCS) of these activities is 0.60 µg/m³ (see also table 3)

Furthermore, a combined exposure estimate of 0.12 µg/m³ for machining activities (WCS 11-13) was presented (as the sum of 90th percentile value of model-based exposure distribution for each WCS).

The applicant stated that activities such as slurry coating, replenishing treatment tanks, operating surface treatment and maintenance are specialist activities for which staff is trained. Multiple processes would typically not be completed by a single employee and the applicant therefore did not consider combinations of tasks other than presented in the CSR (e.g. an operator performing ~~slurry~~spray coating tasks will not perform bath related activities), and thus the exposure during a shift of workers involved in ~~slurry~~spray coating is estimated to be 0.27 µg/m³.

[5] BGR/GUV-R 190 „Benutzung von Atemschutzgeräten“, December 2011, http://publikationen.dguv.de/dguv/pdf/10002/r-190.pdf

The applicant stated that the combined exposure time was determined based on real data. Operators will be potentially exposed to Cr(VI) for only a part of the working day

The applicant finds the combined exposure estimate of 0.60 µg/m³ for all CCC bath related activities, in which the same workers could be involved, reasonably representing worst-case combined exposure.

Table 3: Combined exposure estimates and the corresponding duration of tasks

Bath surface treatment and sampling			Machining activities			~~Slurry~~Spray coating			
WCS	**Exposure estimate (µgCr(VI) /m³) (1)**	**Duration (min)**	**WCS**	**Exposure estimate (µgCr(VI) /m³) (1)**	**Duration (min)**	**WCS**	**Modelled exposure estimate (µgCr(VI) /m³) (1)**	**Measured exposure estimate (µgCr(VI) /m³) (1)**	**Duration (min)**
2	0.26	15	11	0.013	60	6.1	0.029		5
3	0.13	30	12	0.028	30	6.2	0.0019		5
4	0.19	10	13	0.080	30	6.3	0.0533		5
5	0.023	60				6.4	0.4000		30
10	0.0022	30				6.5	/		15
						6.6	/		180
						6.7	0.0002		15
Combined	**0.60**	145		0.12	120		0.4844	0.27	255

(1) 90th percentile inhalation exposure estimate TWA-8h (µg Cr(VI) /m³) (RPE and frequency adjusted)

Discussion of the worker exposure information

All exposure estimates are based on modelling data or use a qualitative assessment (WCS 1 and 16), with the exception of ~~WCS 6 (Slurry~~slurry coating by spraying (WCS 6) for which personal measurement data was provided (see Appendix 1).

The applicant stated that the limited availability of measurement data and corresponding contextual information is due to several reasons such as: the short duration of certain tasks does not support measurement; historic measurement has shown exposure to be low so more recent measurement is not considered necessary; there is no legal obligation to conduct measurements in some Member States; the supplier's reluctance to share sensitive data such as worker exposure measurements and reports and the applicant has no mandate or means to enforce the provision of data in the supply chain.

RAC points out that according to ECHA guidance[6], 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 Agent Directive (98/24/EC) and Carcinogens and Mutagens Directive (2004/37/EC). For SVHCs, the exposure scenario needs to be detailed and conclusive.

Baths

The applicant pointed out that potential exposure to Cr(VI) might occur during bath surface treatment processes when the operators are near the bath (e.g. during bath preparation, parts immersion, parts lifting and all others tasks near the bath treatment line in the workshop). However, the applicant stated that due to the type of coating process, no aerosol development is expected and exposure potential therefore is low.

On request by RAC, exposure data gathered from the literature was also presented. The applicant noted that the published literature is dominated by measurements for electrolytic hard chrome plating processes. Electrolytic hard chrome plating can result in additional aerosol generation as a consequence of the electrical current applied across the bath and leading to higher exposure potential compared to the bath processes covered in this application for authorisation for chromium trioxide. Two studies reported exposure measurements for chrome bath surface treatment other than hard chrome plating: a French health insurance report provided a concentration range of 0.02 – 0.44 µg Cr(VI) /m^3, with an average of 0.13 µg Cr(VI) /m^3 (21 personal samples) and Vincent et al. (2015) reported a concentration range of < 0.02 – 1.71 µg Cr(VI)/m^3 with an average of 0.28 µg Cr(VI)/m^3. The applicant concluded that the available published data support the results of the exposure estimation in this application for authorisation. RAC considers that interpretation and comparison of the literature data with modelled data in the application are difficult, for example because it is not clear whether the concentrations presented in the literature corresponds to the sampling period or are 8h TWA values and because no details of the OCs and RMMs are reported. However, RAC acknowledges that the two referenced literature studies give some credibility to the applicant's combined exposure estimate of 0.6 µg Cr(VI) /m^3 for bath applications.

[6] Section R.14.7.1 of the ECHA guidance Chapter R.12.

On request by RAC, the applicant provided the 90th percentile of measurement data for bath applications reported in the applications for authorization from the CCST consortium. The applicant stated that exposure concentrations from bath processes covered by GCCA are likely lower than for CCST and CTAC, since CCST and CTAC included bath processes like electroplating and baths with a higher Cr(VI) concentration. RAC notes that furthermore the duration and frequency of the bath treatment tasks covered by CCST and CTAC were higher than in this application for authorisation. RAC acknowledges that this context should be kept in mind when interpreting the 90th percentile inhalation exposure estimate of 1.26 µg Cr(VI) /m^3 for bath applications in CCST and 1.25 µg Cr(VI) /m^3 for CTAC.

Spraying

For WCS 6 the exposure estimate is based on personal air ~~measurement. The 28 personal measurements were obtained from 6 different sites, which represent 2.1% of the total of 275 sites covered by this application.~~ measurements for spray coating. Personal measurements corresponding to slurry spraying (n= 28) were obtained from 6 different sites, which represent 2.1% of the total of 275 sites covered by this application. The applicant stated that the concentration of Cr(VI) in CCC formulations is less than 1% w/w (compared to less than 5% w/w in slurry coatings), CCC operations are carried out far less frequently and there are no significant differences in other relevant exposure parameters, the measurement data for slurry coatings can be considered conservatively representative of CCC spraying processes. RAC considers that the exposure potential from spraying with the two different coating types is similar, and the measurement and modelled data from spray coating of slurries can be used to estimate exposure from spray coating with CCC. It is likely that other differences that exist between the operations at different sites are more significant in determining the exposure than the coating type (see discussion above concerning the data for slurry coating).

On request by RAC, the applicant also provided a modelled exposure estimate of 0.48 µg Cr(VI)/m^3 for this WCS, which is more or less in the same order of magnitude as the measured exposure estimate (0.27 ~~ugCr~~µg Cr(VI)/m^3).

Moreover, Vincent et al. (2015) reported an arithmetic mean concentration of 135.5 µg Cr(VI)/m^3 for paint spraying (n= 45 combined personal and static measurements). Although the applicant did not discuss to which extent slurry and CCC spray coating can be compared with paint coating, the process appears to be similar. The applicant concluded that the available published data are difficult to compare with the processes covered by this application for authorisation but generally supports the exposure estimation. However, RAC notes that the mean of 135.5 µg Cr(VI)/m^3 for paint spraying is 27 times higher than the mean of the measurements provided for WCS 6 (prior to correction for RPE) (AM[7] = 5 µg Cr(VI)/m^3). RAC considers that the literature data needs to be interpreted with caution amongst others because working conditions of each of the group of measurements presented in Vincent et al. (2015) are not known[8] and because slurry and CCC spray coating and paint spraying might differ in terms of their exposure potential[9].

[7] Arithmetic mean of the means per site
[8] It is not clear if the presented concentrations correspond to the TWA of the sampling period or to a 8 hours period; personal and static sampling results are combined; no details of RMM/OC are reported.
[9] E.g., there may be differences in ~~viscosity~~properties (liquid versus slurry) which may influence the quantity and size of produced aerosols.

The arithmetic mean of the exposure measurements without RPE adjustment per site shows relatively large differences ranging from 0.10 to 15.7 µg Cr(VI /m^3 (see Table 4). The site with the highest number of measurements (Site F, n=15) also shows a rather high variability, ranging from 0.5 till 43 µg Cr(VI)/m^3 (see Appendix 1). Information that might explain this variability such as differences in the scale of operations, the RMMs/OCs (e.g. kind of spray cabin, sandblasting cabinet/booth and article size) in place at each of the sites was not provided in the application. It is noted that some measurements have relatively high LoD values up to 10 µg Cr(VI)/m^3 (see Appendix 1).

In addition to the 90th percentile of site means of 0.27 µg Cr(VI)/m^3 calculated by the applicant, RAC considers that also a 90th percentile of 0.82 µg Cr(VI)/m^3 for the overall measurement data (see Appendix 1) is relevant to consider for risk assessment, especially since the abovementioned variability is not explained and thus it is not clear if the actual task-content rather than the site may lead to the higher exposure values in the exposure distribution.

Table 4: Arithmetic mean personal measurements per site and total arithmetic mean and 90th percentile without and with RPE adjustment (by applicant and calculated by RAC) (source: Appendix 1)

Site / country	Period	Measurements		Arithmetic mean concentration µg Cr(VI /m^3 (presented by applicant)			Calculated arithmetic mean (µg Cr(VI /m^3) adjusting for RPE with APF 30 (by RAC)
		N°	N°< LoD	LoD (1) adj.	RPE adj.	APF of RPE	
A (Italy)	2015	3	3	0.5	0.017	30	0.017
B (France)	2012-2014	5	2	5.76	0.0058	1000	0.19
C (Italy)	2014	1	1	0.1	0.0100	10	0.003
D (Hungary)	2013	1	1	5	0.0050	1000	0.167
E (UK)	2012-2014	3	3	2.83	0.0028	1000	0.094
F (Poland)	2015	15	1	15.7	0.52	30	0.52
AM				**4.97**	**0.0937**		**0.166**
90th perct				**10.7**	**0.269**		**0.357**

(1)Measurements below the limit detection were accounted with 50% of the LoD, as common practice in occupational exposure assessment

For comparison RAC calculated the exposure concentration applying the minimum required RPE (APF 30) for WCS 6 as prescribed by the ES. The resulting AM and 90th percentile are of the same magnitude as those presented by the applicant what may indicate that the minimum required RPE by the applicant is acceptable.

Machining

The applicant mentioned that ART 1.5 does not have a specific assessment option for machining of metallic objects but only for stone and wood. The applicant considers stone as a worst-case for metallic objects and therefore the model is not ideal, since in the mechanical description of ART it is stated that there are some indications that hardness of the material is important in the potential for dust release.

RAC notes that the CTAC applications for authorisation distinguished between different machining operations such as drilling, riveting or cutting on the one hand and machining operations such as fettling, abrading or sanding on the other hand. The applicant stated that no differentiation needs to be made between these types of operations because the residual Cr(VI) concentration in all surface coatings of the specific applications covered in the GCCA applications for authorisation is very low. The applicant did not further substantiate this difference in approach compared with the CTAC applications for authorisation. RAC notes that no evidence to support the assumption of a solid weight fraction of <0.1% for all machining operations is provided[10]. In particular for fettling, abrading and sanding operations the value might not be an appropriate assumption.

Vincent et al. (2015) presented arithmetic mean air concentrations of 0.46 (n=11) and 38 µg Cr(VI) /m^3 (n=5) for manual sanding from personal and static measurements from 10 companies in the aeronautics industry. The applicant concluded that the available published data are difficult to compare with the processes covered by this application for authorisation but generally supports the exposure estimation. RAC acknowledges that there are limitations to the results provided in Vincent et al. (2015) which makes it difficult to compare the literature data with the modelled exposure estimates[10]. For example, it is not clear if the result of the sampling or the 8h TWA is reported, and no details of the OCs and RMMs are reported. For this reason RAC does not share the applicant's opinion that the literature data supports the modelled exposure estimation.

Other tasks

The applicant clarified that during maintenance activities also contact with solid material might occur (e.g. as precipitated salts in LEV), they clarified that this potential source of exposure is covered by WCS 9 (Infrequent maintenance activities).

[10] The modelled air concentrations during a 8h TWA shift and prior to correction for RPE are respectively 0.38, 0.83 and 32 µg Cr(VI)/m^3 for WCS 11-13, or during the tasks (not 8 TWA) prior to correction for RPE are 3.04, 13.28 and 512 µg Cr(VI)/m^3 respectively.

Combined exposure

~~On~~ Following ~~RACs~~RAC's question if other combined exposures are possible than those presented in the CSR (e.g. a worker performing ~~slurry~~spray coating activities in addition to carrying out bath preparation and bath surface treatment), the applicant gave assurances that no other combinations of WCSs do occur and that the combined exposure time was determined based on real data. Related to ~~this~~the combined exposure time, the applicant confirmed that the combined exposures presented in the CSR do not cover an 8-hrs working period and that the operators will be potentially exposed to chromium trioxide for only part of the working day (see also ~~table~~Table 3). Since the applicant stated that DUs may also perform activities and processes with Cr(VI) that fall outside the scope of the GCCA applications (and are covered by other applications such as CCST and CTAC), it is plausible that operators might be exposed during the other parts of the working day to other Cr(VI) compounds which are covered by other applications.

Uncertainties related to the worker exposure assessment

Exposure estimates

RAC notes that the lack of measured exposure data for all but one WCSs is a key uncertainty in the exposure assessment.

With the exception of two WCSs with qualitative exposure estimates, and one with measured exposure estimate, all other air exposure estimates are modelled (see Table 2). There are inherent uncertainties related to modelled exposure estimates.

The applicant stated that for the modelled exposure assessment a conservative approach has been used since in general the highest exposure duration, the highest Cr(VI) content and the lowest level of personal protection reported were used as input parameters and that this approach also has been applied to other RMMs such as enclosure and extract ventilation. The applicant also mentioned that exposure model provides within the scope of the model rather conservative estimates and that the use of the 90th percentile value as representative for the exposure situation finally adds to the conservatism of the overall approach.

However, RAC considers that for specific exposure scenarios this statement is not always applicable as demonstrated for example in the applications for authorisation prepared by the CCST consortium where the modelled data for conversion coating, sealing after anodizing and etching and pickling was several orders of magnitude lower than the measured data presented in the CCST applications. Also the presented literature data suggest that the modelled exposure estimate for bath treatment do not overestimate the exposure. Therefore, RAC underlines the importance of having also measured exposure data to obtain a more solid and credible risk assessment.

In WCS 5 (~~CCC~~ bath treatment) the tasks of moving articles to and from the bath and cleaning of bath equipment, are both part of the same WCS and covered by only one activity class in the modelling ("activities with relatively undisturbed surfaces (no aerosol formation"), although these two activities are probably quite different in the way exposure occurs. The same argument is valid for machining activities which also include cleaning.

RAC notes that the absence of more detailed information about the operational conditions of several WCSs makes it difficult to interpret the representativeness of the corresponding exposure estimates. For WCS 3 (Mixing –liquids) it is stated that the aqueous solution may be ~~pre-~~mixed before re-filling of CCC baths for concentration adjustment. However no additional information is given about how this task is performed. For WCS 12 no information is given about the reason to perform machining operations outside a booth in large work areas. For the bath treatment the applicant stated that the articles size might vary from a pin to a substantial aircraft component and that the bath size may vary accordingly. ~~No more specified~~More specific dimensions of the articles were not provided. Related to the baths, the applicant mentioned that they are likely to have a surface area between 1 and 3 m^2.

The selected input parameters for modelling do not always reflect the activities covered by the WCS. This is especially true for the exposure estimates for the machining operations on metallic surfaces since this activity is not covered in the design of ART. Also it is questionable if the chosen activity class, "*activities with undisturbed surfaces (no aerosol formation*)", is the most adequate for mixing activities of liquids (WCS 3). Normally, mechanical mixing of liquids falls under activities with agitated surfaces.

Although maintenance of equipment (WCS 8) and sampling (WCS 10) are different activities with probably different exposure potential, the same activity class is used for the modelling of the exposure estimate, namely "*activities with relatively undisturbed surfaces (no aerosol formation)"*.

While the applicant stated that in the modelling scenarios a maximum level of the concentration of chromium trioxide is assumed, the maximum 5% bath concentration ~~for CCC~~ is not used as a conservative parameter for modelling but a range of 1-5%.

The applicant presented two combined exposure situations justifying that multiple processes would typically not be completed by a single employee. RAC agrees with the applicant's opinion that adding up 90th percentile exposure estimates across different WCSs may result in an overestimation of the combined exposure. However, this conservativeness should be placed into the context of the uncertainties related to modelled exposure estimates.

Also, the way the applicant calculated the combined exposure estimate of the subtasks of slurry coating (WCS 6) (0.27 µg Cr(VI)/m^3 as the 90th percentile of the mean measurement values per site) does not reflect the above mentioned conservativeness since the 90th percentile of all the measurements together will lead to 3-fold higher exposure estimate (i.e., 0.82 µg Cr(VI)/m^3, see Appendix 1).

It is not clear to which extent the exposure estimate for WCS 6~~ (slurry coating)~~ is representative across the supply chain of the applicant considering: monitoring data is available from only six sites out of 275; a lack of detailed descriptions of the OCs and RMMs corresponding to the measurements; a lack of information regarding the site characteristics (e.g., size of the room, production volume) corresponding to the monitored data; a lack of details regarding the tasks performed by the workers during the measurement sampling.

RAC notes that no detailed information is provided about the number of downstream users who provided information that was used as a basis to prepare the ES. For this reason RAC considered that there is an uncertainty regarding the representativeness of the ES and thus also regarding the estimated exposure duration for the whole supply chain covered by this application.

RAC considers that, due to the presence of dry-out salts around the treatment bath and equipment used (LEV, tools, instruments) and in the vicinity where machining activities take place, especially those without LEV, surface contamination cannot be excluded. Surface contamination might be a potential source for dermal exposure due to direct contact with contaminated surfaces, or due to inhalation exposure from disturbing of settled dust, especially when workers don't wear PPEs.

Where the use of RPE was included, the applicant used an assigned protection factor (APF) provided by the German BG rule "BGR/GUV-R190" from December 2011 to account for the effect of RPE on exposures. It is noted that other countries allocate lower APFs than the mentioned BG rule. Therefore the exposure estimates may not be sufficiently conservative. In practise, the adequate protection provided by the RPE is very much dependent on the individual wearer. This has special relevance for WCS 6 (slurry coating-substance preparation and surface treatment by spraying in paint booth) for which relative high Cr(VI) in the air have been measured at some sites (see Appendix 1). According to the standard EN 529, RPEs shall be 'fit tested' for each wearer in order to ensure adequate protection. Workers should be adequately trained and supervised for the use and maintenance of the RPE, and their medical fitness should be examined, especially when RPE is used for longer time- periods.

Environmental releases / Indirect exposure to humans via the environment

Summary of applicant's approach to assess environmental releases and indirect exposure to humans via the environment

The applicant stressed that the measures adopted to prevent or limit the release of Cr(VI) to the environment during surface treatment are a matter of best practice for the Cr(VI) industry and that the releases are monitored by regulators.

The applicant used modelled data to estimate releases to air. No measurement data were available in the application. The applicant argued that any measurements would reflect emissions from several activities with different Cr(VI) compounds, and would thus not reflect the contribution from chromium trioxide alone.

Further, the applicant provided information on treatment operations applied to prevent release to the aquatic environment and concluded that exposure via water were negligible. Release to soil as well as via the food chain is also considered negligible, in view of the risk management measures in place at the production facilities.

Air emissions

Emissions to air (via fine dust and particulates) are considered to occur at all DU sites. The CSR indicates that even though chromium trioxide, due to its low volatility, will normally not be present in air, energetic processes will release the compound. Several workspaces are equipped with exhaust ventilation systems to remove residual particulates from workers breathing zone (see Table 2) and exhaust air is passed through the filters or wet scrubbers according to best available technique before being released to atmosphere.

Emissions to the air compartment are modelled with EUSES. An initial release factor of 0.1% was used (default release factor for ERC6b). According to the applicant, a removal efficiency of at least 99% is typical for industry, and this gives a final release factor of 0.001%. EUSES estimates an annual average concentration in air 100 m from a point source ($PEC_{local,air, ann}$), which was 3.8 x 10^{-10} mg/m^3. This value was used for the assessment of risks arising from the indirect exposure of humans via the environment.

Release to water

The applicant states that not all sites will necessarily release Cr(VI) as wastewater as liquid and solid wastes containing Cr(VI) can rather be collected from sites by an external waste management company. Where wastewater releases do occur, wastes are treated before discharge.

The applicant stresses that the production is strictly separated from the wastewater stream at all sites. The applicant states that minimising Cr(VI) losses from surface treatment processes by rinsing through a series of cascading tanks of water and recirculating the rinse water into the treatment system is common practice within the surface treatment industry. As a result, at many facilities there is no waste water from chromate surface treatment systems. Where waste water is generated, the volume is normally limited and the concentration of Cr(VI) within the waste water is typically low (e.g. less than 50 µg/l based on industry experience).

Wastes from scrubber systems can be collected by an external waste management company or disposed as wastewater after appropriate on-site treatment that varies by facility. The most common method for lowering the concentration of Cr(VI) in wastewater involves the reduction of chromium followed by flocculation and precipitation. Alternative techniques are evapoconcentration; use of activated carbon; ion exchange, and adsorption by filtration. Treatment technology (on-site or off-site) to reduce Cr(VI) to trivalent chromium [Cr(III)] in wastewater is considered by the applicant to be generally highly effective, such that residual concentrations of Cr(VI) in treated wastewaters are very low and often non-detectable. The applicant therefore considers that these releases may be considered as negligible.

The applicant informed that monitoring programmes demanded by current regulatory requirements are part of the permits at most sites. The measurement results from such programmes were, however, not provided in the application. In response to a question from RAC, the applicant explained that the data from these measurements from the individual sites are not available to the consortium. Also, the applicant argued that mandatory measurements of releases cover the whole site and not only the Cr(VI) releases resulting from the use applied for in the present application.

Table 5: Summary of environmental emissions

Release route	Release factor / rate	Release estimation method and details
Air	Initial: 1 x 10^{-3} Final: 1 x 10^{-5}	Based on the default release factor of ERC 6b of 0.1% and 99% removal efficiency of filters or wet scrubbers.
Water	Not applicable	Deemed negligible – qualitative estimation
Soil	Not applicable	Deemed negligible – qualitative estimation

Table 7: Summary of indirect exposure to humans via the environment

Protection target	Exposure estimate and details (i.e. methodology and relevant spatial scale)
Man via Environment – Inhalation	Local $PEC_{ann.,air}$: 3.81 x 10^{-7} Cr(VI) µg/m^3
Man via Environment – Oral	negligible
Man via Environment – Combined	= Local $PEC_{ann.,air}$: 3.81 x 10^{-7} Cr(VI) µg/m^3

In summary, the applicant's assessment of exposure via air is based only on EUSES modelling. Exposure via air is the only element included in the assessment of indirect exposure to humans via the environment. Exposure via food and drinking water (oral route of exposure) has been waived on the basis that emissions are "negligible" or that treatment technologies in place at the sites and transformation of Cr(VI) to Cr(III) will occur sufficiently rapidly in the environment to negate the requirement to undertake an assessment of exposure via the oral route.

RAC evaluation of the applicant's approach to assess environmental releases and indirect exposure to humans via the environment

Release to air

RAC considers that the methodology used by the applicant, which is based on generic release factors associated with Environmental Release Categories (ERCs), inherently introduces uncertainty to the assessment. No measured data on releases were provided that could have been used to corroborate the releases estimated using generic release factors and, therefore, reduce this uncertainty.

The applicant considered that the use is consistent with ERC 6b "use of reactive processing aid at industrial site (**no** inclusion into or onto article)" (emphasis added). RAC notes that according to the ECHA Guidance Chapter R.12: Use description (Version 3.0, December 2015), ERC 5 "Use at industrial site leading to inclusion into/onto article" may have been a more appropriate ERC for the bath and spraying processes covered by the use applied for[11] and that machining activities may not be appropriately covered by the same ERC as bath use[12]. The default initial release factors to air for ERC 5 is 0.5, which is significantly greater than the default factor of 0.001 for ERC 6b used by the applicant.

RAC notes that the default release factors associated with ERCs are intended to describe the worst case release potential of a use and, therefore, do not take into account the efficiency of RMMs or the physico-chemical properties substances. As such, default release factors are intended to be modified during the development of exposure scenarios, either to reflect the physico-chemical properties of a substance, operational conditions or risk management measures.

[11] See Table R.12-13 and Figure R.12-5 of the guidance. Among the examples of processes intended to be covered by ERC 5 "Use of metals in coatings applied through plating and galvanizing processes".
[12] ERC12a "Processing of articles at industrial sites with low release" appears to be a more appropriate ERC for machining activities. Indeed, ECHA Guidance Chapter R.12: Use description (Version 3.0, December 2015) exemplifies "Cutting of textile, cutting, machining or grinding of metal or polymers in engineering industries". The default initial release factor is 0.025 for ERC12a.

Whilst RAC notes the uncertainty introduced by the applicant's choice of ERC (ERC 6b), it acknowledges that the release to air of Cr(VI) from this use is likely to be limited by the low volatility of chromium trioxide in aqueous solution and that the operational conditions for bath-related activities are likely to result in a relatively low potential for the formation of aerosols. As such, the use of a default release factor of 0.5 (i.e. assuming that half of the used volume would become airborne) would significantly overestimate the initial releases of Cr(VI) to air for the use of chromium trioxide in the bath process ~~(CCC)~~ covered by this application for authorisation. In contrast, ~~spraying of slurries~~spray coating has a high potential for release. RAC considers that the use of a default initial release factor of 0.001 could potentially underestimate the initial release to air, potentially by one order or at the most two orders of magnitude.

However, this uncertainty is to some extent balanced against the applicant's assumption that 0.05 tonnes Cr(VI) per year are used at every site. RAC considers that this assumption will lead to an overestimation of total releases from the sites undertaking the use by at least an order of magnitude (the applicant estimates 275 sites use a total of <1 tonnes Cr(VI) per year and thus, on average, a site would use 0.004 tonnes Cr(VI) per year). In summary, the initial site-specific release estimated by the applicant may therefore be reasonable, albeit possibly underestimated by one order of magnitude.

In terms of ERC modification to account for the efficiency of risk management measures, the applicant assumed an air abatement efficiency of 99% for all sites, leading to a final release factor of 1 x 10^{-5}. Whilst RAC does not find any reason to disagree with the applicant's conclusions that highly effective systems to control air emissions of Cr(VI) are typical across the sites undertaking this use, the stated minimum efficiency of 99% is not supported with specific evidence. RAC notes that according to ECHA Guidance Chapter R.13 (RMM library) the typical default efficiency (i.e. an estimate of the 50^{th} percentile) for a wet scrubber is 50% for dust and 70% for gas, with maximum achievable efficiencies of 99% and >99%, respectively. Moreover, for operations where the applicant considers that exposure potential is low (i.e. where operations are infrequent using only using small quantities of Cr(VI)) the exposure scenario details that air emission abatement may not be required. The ERC modification undertaken by the applicant could have therefore led to releases being underestimated by a factor of 30 - 50. However, RAC notes that applicants benefiting from an authorisation will nevertheless be expected to comply with the RMMs (including their efficiency) described in the exposure scenario included in an application.

In terms of exposure after release, the default assumption used by the applicant to estimate the $PEC_{local,\ air}$ 100m from a point source is likely to overestimate exposure of the general population via air at the many, if not all, of the sites undertaking the use.

Equally, reduction of Cr(VI) to Cr(III) in air after release, which is not taken into account by the applicant, is likely to further reduce the general population exposure.

Although the generic nature of the application and of the information provided precludes a further estimate of the magnitude of uncertainty introduced by the latter two assumptions on exposure after release, these assumptions may overestimate exposure to the general public living close to sites by at least an order of magnitude and, recognising the dispersion/transformation behaviour or Cr(VI) once it has been released from a site, potentially by several orders of magnitude for those living further away from a site.

In conclusion, considering the uncertainties relating to both release and subsequent exposure via air, RAC considers that the applicant's assessment of indirect exposure of the general population may underestimate exposure for members of the general public that live close to sites (potentially by approximately one or two orders of magnitude), but will overestimate exposure for the general public that live further away from sites. As such, the single estimate of individual risk for humans exposed indirectly via the environment presented by the applicant should be interpreted with caution by SEAC when they evaluate the applicant's estimates of the impacts associated with the use.

Regional exposure of the general population was estimated by the applicant, but is not considered relevant by RAC given that Cr(VI) is rapidly reduced to Cr(III) under most environmental conditions and that any impacts will occur in the area local to releases (as previously detailed in the EU RAR for Cr(VI) substances.

Release to water

With respect to the evaluation of releases to water, no data on potential releases for this use are provided from any sites covered by the application to support the conclusion of the applicant that release to water is negligible. RAC notes that measurements are stated to be available, covering aggregated emission from all Cr(VI) processes also beyond the scope of this application, to meet local regulatory requirements.

RAC does not fully support the applicant conclusion that emissions of Cr(VI) to water are "negligible" without any contextual quantitative information. RAC does therefore not agree with the applicant that it was appropriate to exclude releases to water from the assessment of indirect exposure to humans via the environment at the local scale.

RAC notes that these emissions to water, irrespective of their magnitude, were not incorporated into the applicant's estimates of excess risk for the general population and corresponding impact, upon which a conclusion on negligibility could have been presented more transparently i.e. the relative risks from air and oral exposure (i.e. drinking water and fish) could have been apportioned and discussed in a transparent manner. This was despite the fact that a dose-response relationship for the general population from oral exposure was available to the applicant.

As part of the comments to the draft opinion, the applicant provided information from the literature in support for their conclusion that the oral route of exposure is negligible.

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 via the oral route of exposure. Accordingly, the EU RAR only assessed oral exposure to Cr(VI) as result of exposure from drinking water and the consumption of fish, rather than using the standard food basket approach that also includes contributions to oral exposure from the consumption of arable crops (root and leaf), meat and milk. This approach was considered appropriate on the basis that, whilst treatment to remove Cr(VI) from wastewater was considered to be effective, it was not known how comprehensively this treatment was put into practice by users of Cr(VI) in surface treatment at the time. As such, an acknowledged worst-case approach, where treatment was not considered to be in place, was used as the basis for the assessment of indirect exposure to humans via the environment in the EU RAR. This assessment concluded that the concern for human health via indirect exposure was low for all scenarios. RAC notes that the basis for these conclusions i.e. the underlying dose-response relationship and effects' thresholds for Cr (VI) were different in the EU RAR assessment to those agreed by RAC (RAC/27/2013 Rev 1).

The absence of the oral route of exposure in the applicant's assessment of indirect exposure to humans via the environment for this use is considered by RAC to introduce some uncertainty to the assessment, particularly on the basis that Cr(VI) is a non-threshold carcinogen and the applicant is responsible for justifying that the benefits of use outweigh the risks. However, given that effective measures to prevent the release of Cr(VI) to the environment appear to be in place and that the conversion of Cr(VI) to Cr(III) in the environment is expected to occur rapidly after release under most environmental conditions this uncertainty is not considered to invalidate the assessment of indirect exposure of humans via the environment undertaken by the applicant, although this route of exposure should be more comprehensively addressed in any review report prepared for this application.

Conclusion

Overall, RAC considers that the indirect exposure calculated by the applicant is acceptable for risk characterisation and impact assessment, but that the assessment contains uncertainties.

Uncertainties related to the environmental releases exposure / assessment of exposure to humans via the environment:

RAC acknowledges that release to air of Cr(VI) is generally low due to the low volatility of chromium trioxide and modern abatement technology with high efficiency. In addition, reduction of Cr(VI) to Cr(III) in air is likely to further reduce the general population exposure. However, the estimated $PEClocal_{air}$ is based on EUSES modelled data alone.

RAC has a concern that the exposure scenario described and used in the modelling may not be representing sites where "infrequent surface treatment using small quantities of Cr(VI) where exposure potential is very low" since, according the ES, they may not have air abatement technology in place. Therefore, this leaves an uncertainty in the assessment on indirect exposure of man via environment.

RAC notes that the default assumptions in EUSES for local scale assessment estimate $PEClocal_{air}$ 100m from a point source[13]. This, in general, is likely to overestimate exposure for the majority of the people living in the vicinity of a site (e.g. not everybody that could be affected by a site will live 100 meters from it; some will live further away and be exposed to a lower concentration in air). On the other hand, the default ERC values are not motivated by the applicant and the removal efficiency of 99% is not sufficiently substantiated.

RAC notes that whilst EUSES is the default assessment tool under REACH it is recognised to have limitations that reduce its usefulness within the context of impact assessment (for non-threshold carcinogens)[14]. Alternative assessment approaches could have been used by

[13] Using the release data, EUSES estimates a concentration in air 100 m away from a point source.

[14] ECHA R.16 guidance (environmental exposure assessment) states in section R.16.4.3.9, in relation to the use of the EUSES model for assessing indirect exposure to humans via the environment, that "In light of these limitations, it is clear that a generic indirect exposure estimation, as described by the calculations detailed in Appendix A.16-3.3.9, can only be used for screening purposes to indicate potential problems. The assessment should be seen as a helpful tool for decision making but not as a prediction of the human exposure actually occurring at some place or time."

the applicant to refine the exposure assessment of the general population, such as modelling approaches that estimate the concentration gradient of Cr(VI) in the atmosphere surrounding a point source, or the use of ambient air monitoring.

RAC notes that the applicant's approach is likely to overestimate exposures for the majority of the general population and the modelled exposure estimate should be interpreted with caution.

As noted above, there are uncertainties related to the applicant's statement that wastewater releases are "negligible" and the absence of the oral route of exposure in the applicant's assessment of indirect exposure to humans via the environment introduces some uncertainty to the assessment.

Conclusions

Regarding worker exposure, RAC concludes that:

- The greatest uncertainty in the exposure assessment for workers arises from the fact that only qualitative and modelled exposure estimates were presented by the applicant for all but one WCS.
- The generally conservative character of modelled exposure estimates, as stated by the applicant, is not supported. There are uncertainties inherent in modelled worker exposure estimates and this is especially true for the machining operations on metallic surfaces since these activities are not covered in the design of ART.
- Literature data provides some support to the modelled exposure estimates for bath surface treatment applications. No conclusions can be drawn regarding the literature data for machining and ~~slurry~~spray coating.
- The monitoring data provided for WCS 6 was from 6 sites only and lacks contextual information. The uncertainties could have been reduced by providing more detailed information on the OCs & RMMs for each of the 6 sites and by providing data from more sites, including data for spraying of CCC.
- WCS 6 has a potential for high exposure of workers via air (spraying of ~~slurry~~coatings). The uncertainties related to the exposure reduction resulting from the use of RPE are in addition to the uncertainties due to the measured concentrations of Cr(VI) in air.
- RAC acknowledges that the applicant has introduced some conservativeness ~~for~~in the calculation of the maximum combined exposure estimate by summing up the 90th percentile exposure estimates of the corresponding WCSs.
- The 90th percentile of the overall measurement data for WCS 6 as calculated by RAC is slightly higher (0.82 µg Cr(VI)/m^3) than the combined exposure estimate proposed by the applicant (0.60 µg Cr(VI)/m^3).
- In conclusion, there is uncertainty regarding the appropriate reasonable worst case exposure estimate for risk assessment since the exposure level might be higher than the combined exposure estimate of 0.60 µg Cr(VI)/m^3 in several workers and in several workplaces. However, weighing the evidence as a whole, RAC considers that the combined exposure estimate made by the applicant is sufficient for risk characterization and impact assessment. RAC also notes that the use of the combined exposure estimate for impact assessment needs to be considered in the context of SEA where use of typical (average) exposure values generally is more appropriate[15].

[15] Assuming that all workers are exposed to a reasonable worst-case exposure concentration is likely to overestimate the actual health impacts associated with a use.

Regarding indirect exposure to humans via the environment, RAC concludes that:

- It is acknowledged that releases to air of Cr(VI) during the activities are likely to be low due to the low volatility of chromium trioxide and modern abatement technology with high efficiency.
- The assessment of emissions to air and exposure of the general population through inhalation is based on modelled data. Since no measurement data is available, the representativeness of these estimates is uncertain but, according to the applicant, highly effective systems to control air emissions are typical for the industry with an assumed removal efficiency of 99%. RAC notes that only limited supportive information for such a high efficiency has been provided, also bearing in mind that the ES allows sites where “exposure potential is low” may not have air abatement technology in place. This may lead to underestimation of the exposure. On the other hand, a reduction of Cr(VI) to Cr(III) in air will occur, and $PEC_{local, air}$ estimated 100m from a point source, which may lead to an overestimation of the exposure of man via environment.
- RAC does not fully support the applicant’s statement that wastewater releases are “negligible”. The resulting absence of a quantitative exposure estimate for the oral route introduces some uncertainties.
- Weighing the evidence as a whole, RAC considers that the exposure estimates made by the applicant are sufficient for risk characterisation and impact assessment.
- RAC notes that the applicant’s approach for assessing general population inhalation exposure is likely to overestimate exposures for the majority of the general population and the modelled exposure estimate should be interpreted with caution.
- Regional exposure of the general population was estimated by the applicant, but is not considered relevant by RAC.

5. If considered a threshold substance, has adequate control been demonstrated?

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

RAC has concluded that chromium trioxide should be considered as a non-threshold carcinogen with respect to risk characterisation.

6. If adequate control is not demonstrated, are the operational conditions and risk management measures described in the application appropriate and effective in limiting the risk?

☐ YES

☒ NO

Justification:

Workers

The applicant has estimated cancer risk using the RAC reference dose-response relationship for the carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1). The applicant has conservatively assumed that all chromium trioxide inhaled particles are in the respirable range and contribute to the lung cancer risk. Thus, the calculated excess life-time lung cancer risk is 4 x 10^{-3} per µg of Cr(VI)/m^3.

Evaluation of the Risk Management Measures

According to the SEA up to 275 sites perform chemical conversion and slurry coating applications in the EU. The applicant stated that it is not possible to develop a description of OCs & RMMs applicable to every individual situation due to the variability of these RMMs/OCs between sites and that downstream users must have in place an equivalent or better level of protection than those set out in the ES.

The descriptions of tasks, how exposure occurs ~~and~~, the RMMs/OCs and their effectiveness applicable to all these sites have been described only on a general level.

RAC considers that the approach to define the ESs using the input parameters of ART does not always result in OCs & RMMs that are appropriate and effective in limiting the risk. For example, the ART input parameter "splash loading, where the liquid dispense remains at the top of the reservoir and the liquid splashes freely" for decanting of liquids (WCS 2) and re-filling of baths with liquids (WCS 4) is questionable as a minimum requirement for performing these tasks. In the comments to the draft opinion the Applicant stated that the description used does not adequately describe the process in reality. RAC considers this illustrates the need to distinguish between exposure estimation using modelling and defining WCSs with OCs & RMMs that are appropriate and effective in limiting the risk. Additional information provided by the applicant on request by RAC, was more specific and detailed. RAC suggested to the applicant to include these specified and detailed RMMs/OCs as a condition to the authorisation, when warranted. The applicant pointed out that these more detailed and specified RMMs/OCs are in line with good practice. The applicant is of the view that the users must have the ability to select appropriate OCs and RMMs according to specific risk assessment. The applicant is not aware of situations when these RMMs and OCs could not be applied but cannot completely discount such a possibility for practical or risk management reasons. RAC included these RMMs & OCs as a condition to the authorisation (see section 9, "specific conditions").

On request by RAC to provide a more detailed description of the specific OCs/RMMs at the 6 sites for which measurements data was provided (WCS 6) to allow comparison of the monitoring data between sites and to justify its representativeness, no satisfactory response was given by the applicant.

The applicant clarified that maintenance of LEV equipment is normally carried out at least once a year. However this statement is not reflected in the ES as a minimum requirement.

For many WCSs (WCS 2-11, WCS 13) natural ventilation is in place (see Table 2). RAC considers that to rely on natural ventilation as one of the measures to reduce exposure may not be sufficient (as it might for example depend on meteorological conditions) and generally considers mechanical ventilation is more efficient to minimize exposure levels and more in agreement with the general principles of the hierarchy of control exposure than natural ventilation.

RAC questioned specifically the appropriateness of natural ventilation for machining operations performed in small work areas (WCS13). The applicant acknowledged that in confined space mechanical ventilation is generally in line with good practice and that natural ventilation might not be efficient and that in such situations additional risk management measure might be provided, such as forced ventilation and good control at source (wet methods, on tool extraction systems). The applicant clarified that the reason for having natural ventilation as minimum requirement is that there are situations when mechanical ventilation might not be appropriate, for example in the case of a local spark risk. RAC is the opinion that it is necessary to have mechanical ventilation as minimum requirement and in case that this would lead to additional risks, alternative RMMs should be implemented with the same or even better exposure control efficiency as mechanical ventilation.

The applicant stated that RMMs/OCs in place to prevent fugitive emissions and surface contamination nearby the place where machining, spray coating and waste management activities are undertaken typically include use of containment and/or LEV and/or PPE and/or local designated hazardous waste storage and that each user has their own standard operating procedure. However, RAC considers that it has not been demonstrated that fugitive emissions and surface contamination from such activities are sufficiently controlled.

The applicant stated that each WCS provides a combination of worst-case conditions. It is challenging for RAC to assess whether these worst-case conditions still reflect good industrial hygiene practice and to judge whether they are appropriate and effective in limiting the risks, considering also that only modelled or qualitative exposure estimates were used.

Risk characterisation

Occupational exposure in surface treatment using chromium trioxide has been assessed by using modelled data, qualitative exposure assessment and for one WCS, measurement data. The applicant considered a combined exposure estimate of 0.60 µg/m^3 for all CCC bath related activities, in which the same workers could be involved, reasonably representing worst-case combined exposure. Even though not explicitly stated in the CSR, the applicant used the value of 0.60 µg/m^3 also as a worst-case exposure estimate also for workers performing other tasks (e.g. machining or slurry coating) in the SEA.

The exposure assessment includes uncertainties related especially to the representativeness of the exposure estimates across the wide-range of companies in EU and the assessment of combined exposure. The data provided by the applicant shows that by using appropriate ~~OCS~~OCs & RMMs (which will have to be adjusted on a case-by-case basis for each different facility) it is possible to reach combined exposure levels below 0.60 µg/m^3 chromium trioxide in chromium surface treatment by CCC and slurry coating, as well as machining activities.

RAC also notes that the applicant has conservatively assumed that any chromium trioxide particles present in air are in the respirable range and contribute to the lung cancer risk.

Taking into account the uncertainties regarding whether the combined exposure estimate represents a reasonable worst shift exposure and the high number of sites covered (n=275), RAC considers that the combined exposure estimate made by the applicant should be used with caution for risk characterisation and impact assessment. The uncertainties need to be carefully considered when using the combined exposure level of 0.60 μg Cr(VI)/m^3 as an 8 h average, resulting in an excess risk of 2.4 ×10^{-3} as the basis of further analyses by SEAC.

Table 8: Excess risk estimates for 40 years exposure for workers

Inhalation route	
Maximum combined exposure (μg/m^3)	**Excess risk**
0.60	2.4 x 10^{-3}

Indirect exposure to humans (general population) via the environment

The applicant has estimated excess cancer risks based on the modelled inhalation exposure of the general population. Risk characterisation has been undertaken according to the RAC reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/6 Rev 1, agreed at RAC 27). Thus, an excess life-time lung cancer risk of 2.9 x 10^{-2} per μg Cr(VI)/m^3 for 70 years of exposure (24h/day, 7d/week) is used.

For a local population living in the vicinity of sites undertaking this use the applicant calculated an excess individual life-time lung cancer risk of 1.1 x 10^{-8}.

The applicant has also calculated the excess individual risk related to regional exposure 5.41 x 10^{-17} for 70 years of exposure, 24 h/day, 7 d/week). However, as Cr(VI) is effectively reduced to Cr(III) in the environment, RAC agrees with the conclusions of the EU RAR for chromate substances that regional exposure may not be very relevant.

Table 9: Excess risk estimates for 70 years exposure for man exposed via the environment

ECS	**Inhalation route**	
	Exposure level (μg/m^3)	**Excess risk**
ECS 1, local exposure	3.8 x 10^{-7}	1.1 x 10^{-8}
ECS 1, regional exposure	Not relevant	

RAC also notes that the applicant assumed that all environmental exposure was associated with particles within the respirable size range. This assumption could have led to an overestimate of risk as only respirable particles are associated with life-time lung cancer risk. Inhalable particles are associated with the dose-response relationship for intestinal cancer, which is approximately an order of magnitude less sensitive than the dose-response for lung cancer. The relative proportion of particles in the respirable and inhalable size ranges in the atmosphere was not discussed by the applicant.

On the other hand, the exposure estimate is based on modelling only with limited substantiation of the efficacy of the air abatement measures and does not incorporate any risks via food or water. RAC considers these risks from oral exposure may be low, but, as discussed in section 4, does not fully support the applicant's conclusion that risks via wastewater can simply be considered to be negligible without a (semi-)quantitative estimation based on emission data.

Conclusion

Regarding worker exposure, RAC concludes that:

- While it is appreciated that it is difficult to define a single, specific set of OCs and RMMs suitable for all these workplaces, RAC would have expected to receive more detailed OCs and RMMs. Furthermore, more measured data, clearly linked to specific OCs and RMMs, with a justification as to how these corroborate the applicant's modelled exposure estimates, would provide more confidence in the appropriateness of OCs and RMMs. Taking this into account and those uncertainties described in relation to the calculated excess cancer risk as described in section 4, RAC considers that RMMs and OCs are not described in sufficient detail to allow the Committee to fully evaluate whether they are appropriate and effective in limiting the risk to workers.
- Of particular concern are the relatively high measured air concentrations at some sites for WCS 6. As such, the reliance on well-functioning and correct use of RPE is essential.
- Some of the more detailed information about the ~~RMMs~~OCs and ~~OCs~~RMMs provided by the applicant on request by RAC is not reflected in the ~~WCSs~~ conditions of use of the WCSs.
- RAC proposes to use the ~~applicant~~ applicant's exposure estimate for workers ~~of~~, which is a maximum combined individual exposure level for 8 hours of 0.60 µg Cr(VI)/m^3~~),~~ ~~resulting~~) and results in an excess life-time lung cancer risk of 2.4 x10^{-3}, as the basis of further analyses by SEAC.

Regarding indirect exposure to humans via the environment, RAC concludes that:

- ~~For~~The exposure estimate for the local general population by inhalation ~~exposure, the exposure estimate~~ is based on modelling data alone, without contextual monitoring data. As described in section 4, highly effective RMMs to control air emissions are typical for the industry. However, demonstration of the efficiency of the air abatement measures in place at the different sites should be documented to allow the Committee to fully evaluate whether they are sufficient to limit the risk to the general population.
- RAC considers that the applicant's estimate of general population risk at the local scale is sufficient for further analysis by SEAC. RAC notes that the applicant's approach is likely to overestimate risks for the majority of the general population (e.g., the possible transformation of Cr(VI) to Cr(III) in the atmosphere is not considered). On the other hand, there is an uncertainty related to the oral exposure of the general population via drinking water due to the applicant's assessment of the releases to the wastewater, which is not fully supported by RAC.
- Regional exposure, which was estimated by the applicant, is not considered to be relevant by RAC due to the transformation of Cr(VI) to Cr(III) that will occur rapidly under most environmental conditions.
- RAC considers that no risks for workers or humans exposed via the environment for reproductive effects are to be expected.

Considering uncertainties relating to the risks, RAC proposes to apply conditions and monitoring arrangements.

7. Justification of the suitability and availability of alternatives

7.1 To what extent is the technical and economic feasibility of alternatives described and compared with the Annex XIV substance?

Description:

Summary of the analysis of alternatives undertaken by the applicant

The use applied for covers two surface treatment processes and steps that may be applied to a number of different metal substrates (e.g. aluminium, steel, magnesium, alloys, etc.) in the aerospace industries. These surface treatment processes typically involve immersion of the metal component in bath or application by brush or spray, depending on the size and geometry of the part as well as the area to be treated. While the applicant did not apply for formulation as a stand- alone use, the downstream users undertake on-site formulation as part of their use.

The applicant states that within the aerospace and aeronautics sector the use of chromium trioxide in surface treatment processes is essential to meet the strict performance criteria necessary for regulatory compliance. Surface treatment based on chromium trioxide is stated to offer substantial advantages over potential alternatives, including outstanding corrosion protection and prevention for nearly all metals under a wide range of conditions, active corrosion inhibition (self-sealing, e.g. repairing a local scratch to the surface), excellent adhesion properties to support application of subsequent coatings or paints and chemical resistance and low electrical resistivity. The process and the chemistry behind chromium based surface treatment is stated to be complex. Typically, numerous steps are involved, including in addition to the main treatment process, important pre- and post-treatment steps. Table 1 gives an overview of the surface treatment process steps that are within the scope of the use applied for (taken from the analysis of alternatives – non confidential report).

Table 10: Overview of surface treatment process

Process			Application	Product / substrate examples
Main process	Chemical conversion coating		Bath Wipe Brush Touch-up pen	- Al - Mg
	Slurry Coating	Sacrificial Coating	Spray Brush Dip	- Steel - Stainless steel

		High Temperature diffusion coating	**Spray** **Brush** **Dip**	- **Cast and Wrought super alloys** - **High temperature alloys**

The applicant states that it is important to understand that chromium trioxide may be specified at different points in the process (e.g. pre-treatment, treatment or post-treatment).

Chemical conversion coating (CCC) is a chemical process applied to a substrate producing a superficial layer containing a compound of the substrate metal and the process chemistry. In general, CCC forms an adherent, fixed, insoluble, inorganic crystalline or amorphous surface film by means of a chemical reaction between the metal surface and the immersion solution.

Slurry coating is a process in which metal components that will be subject to high temperatures and highly corrosive environments are coated with a protective material comprised of a powdered material mixture containing chromium trioxide. Chromium trioxide used in these coatings provides excellent corrosion protections; adhesion; chemical, heat and erosion resistance and active corrosion inhibition. The coatings are applied by different means and heat cured afterwards. The term slurry coating covers both sacrificial coatings and high temperature diffusion coatings:

- **Sacrificial coatings**: a thin protective film comprising metal particles and an inorganic binder. It is used as a corrosion control through the application of thin metal layers that have lower electrochemical potential values than metal substrate for most applications. It builds a barrier throughout the surface being protected, and corrodes in place of the metal surfaces that it protects. Chromium trioxide serves multiple purposes in that it stabilizes the mixture, suppresses the interaction of the liquid with substrates, promotes structural integrity of the cured film and passivates the metal surface. These systems are used for critical structural parts of propellers, as gas turbine engine components, and as power generation components–.

- **High temperature diffusion coatings**: used to protect components that operate above 500°C. These slurries form a protective aluminide layer on cast or wrought super alloys. During the process, the slurries are heated above 870°C at which temperature the metal in the slurries melts and reacts with nickel and cobalt in the super alloy substrate, producing a nickel- or cobalt-aluminide corrosion resistant layer on the component.

According to the applicant, the use of chromium trioxide (or similar chromium compounds) cannot be entirely replaced in the surface treatment process without impacting the technical performance of the final product. They argue that it is important to understand this, as chromium trioxide-free alternatives for some individual steps are available and used by industry. According to the applicant, chromates are always specified in one of the steps within the overall surface treatment system hence no complete Cr(VI)-free treatment system, providing all the required properties to the surface of all articles in the scope of this use applied for is industrially available. Moreover, the applicant states that the concentration of Cr(VI) in only one layer of the system helps realise the aim of reducing the overall use of Cr(VI) in the surface treatment process (and consequently also the level of risk).

The applicant further clarifies that the need to consider the different surface treatment steps as a whole is due to the interactions that exist between the separate processes and coating layers within the typical multi-layer surface treatment system applied in the aerospace industry. For example, while Cr(VI)-free paint primers (which are not included within the scope of this application) are in use for many aerospace applications, their validation was successful as part of a multi-layer system that still contains Cr(VI). If Cr(VI) is removed from the conversion coating, the entire system does not provide adequate corrosion performance.

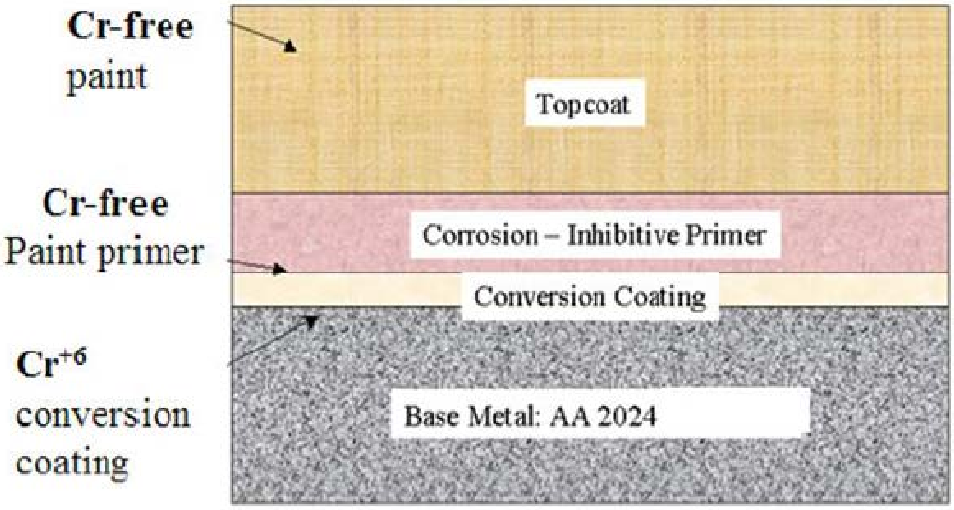

Figure 1: Example of a complete surface treatment

For the analysis of alternatives, the applicant states that extensive literature and test reports were consulted. Furthermore, searches for publically available documents were conducted to ensure that all potential alternative processes to those based on Cr(VI) were considered in the analysis of alternatives. In addition to databases of scientific literature, scientific programmes were also examined, as well as searches of Safety Data Sheets for Cr(VI)-containing and chrome free applications. Information and data from the Chromium Trioxide Authorisation Consortium's ('CTAC') assessment of alternatives were used where relevant. A questionnaire was provided to members of the Global Chromates Consortium for Aerospace ('GCCA', the consortium supporting the preparation of this application for authorisation) to get an overview of/and experience with alternatives, completeness and prioritisation of critical parameters for their specific processes and the minimum technical requirements specific to the use of chromium trioxide. During this survey, alternatives from the CTAC AoA were also reviewed[16]. Two alternatives were identified.

[16] https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/10107/del/50/col/staticField_-104/type/asc/pre/2/view

- Cr(III)-based surface treatments as an alternative for Chromate conversion coating and slurry coatings
- Chromium-free aluminium-based coatings as an alternative for slurry coating

These alternatives are considered as the most promising by the applicant who also screened several other alternatives and rejected them for different reason, as outlined in the table below.

Table 11: Non exhaustive list of screened out alternatives

Potential alternative	Technical findings
Acidic surface treatments	- Corrosion resistance not proved for the range of substrates - Does not cover the broad range of different substrates in general
Organometallics (Zr-, Ti- and Ce-based products	- No reproducible results of corrosion resistance on all kind of substrates - No active corrosion inhibition - Adhesion of coating to substrate not sufficient
Molybdates and molybdenum-based processes	- Corrosion requirement not met - No active corrosion inhibition - No conductive coating (no resistivity) - Difficult process control
Silane/Siloxane and Sol-gel coating	- No stand-alone corrosion protection - No conductive coating (resistivity not sufficient) - Limitations to geometry of parts (no complex parts)
Benzotriazoles-based processes, e.g. 5-methyl-1H-benzotriazol (organic conversion inhibitors)	- Corrosion resistance insufficient
Manganese-based processes	- Corrosion resistance insufficient
Magnesium rich primers	- Corrosion resistance not proved for the range of substrates - No conductive coating (no resistivity)
Electrolytic paint technology	- Process not applicable for assemblies and assembled craft

Technical feasibility

According to the applicant, the use of chromium trioxide delivers specific technical characteristics which are key requirements in the different steps of surface treatment processes within the aeronautics and aerospace industries. The key functionalities offered by chromium trioxide (mainly based on the characteristics of the Cr(VI) compound) that are necessary for the aerospace and aeronautics sectors differ between the processes:

- Chemical Conversion Coating: corrosion resistance, active corrosion inhibition, adhesion promotion and reproducibility
- Slurry coating: corrosion protection, heat resilience, hot corrosion resistance, resistance to humidity and hot water, thermal shock resistance, adhesion and flexibility

As already stated and summarised above, the applicant identified two alternatives which are either considered promising candidates to replace chromium trioxide in the future or which may be suitable for very specific applications. According to the applicant these alternatives show at present major technical deficiencies. The applicant assessed each of these two alternatives against the above mentioned technical criteria, which are indispensable for surface treatment within the aeronautics and aerospace sectors.

Furthermore, the applicant stressed how important it is that the surface treatment process, which consists of numerous steps, is considered as a whole: the steps are almost always inter-related and cannot be separated or individually modified without impairing the overall process or the performance of the treated product. The applicant's overall conclusion is that, although chromium trioxide-free alternatives are available and used by aerospace industry for less demanding applications, currently there are no technically feasible alternatives available for all key applications of the process applied for. Several potential alternative formulations are subject to ongoing R&D, but these do not yet support the necessary combination of key functionalities in order to be considered technically feasible.

- **Cr(III)-based surface treatments** are first assessed by the applicant as an alternative for the chromate conversion coating (CCC) process. Cr(III) is the best candidate alternative for CCC with chromium trioxide and is being implemented at some aerospace companies on selective aluminium alloys and applications. However, test results provided by companies demonstrate that the corrosion resistance has been found to be inferior to Cr(VI)-based CCC for most applications, with the high strength aluminium alloys being the most challenging. Where the applied parts are used for bonding applications, the adhesion properties are currently inconsistent. Several aerospace companies reported that the reproducibility results were inconsistent. On the other hand, the fatigue properties are reported to be equivalent to Cr(VI), thus meeting this requirement of the aerospace industries. Limited success has been achieved for less demanding applications, and the alternative is expected to be implemented for some applications on specific alloys in 2017. Other companies also reported that TRL6 can be reached within the next few years if test requirements are met. The applicant concluded that Cr(III)-based products are not equivalent to Cr(VI) CCC technology and are therefore not technically feasible. SEAC agrees with the applicant that Cr(III)-based product cannot be seen as a general alternative to Cr(VI) for all applications. However, SEAC notes that the scope of the use applied for also covers a limited number of applications for which this alternative is being implemented.

The applicant also assessed Cr(III)-based surface treatments as an alternative for the slurry coating process. The applicant stated that some Cr(VI)-free alternatives have been successfully introduced in a few specific slurry applications. But to date no Cr(VI)-free alternative has demonstrated to match the capabilities of slurries containing Cr(VI) in every instance and application of their current use. There is testing on-going for newly introduced formulations but these remain at a very low maturity level. Based on an assessment of the Cr(III)-based slurry's performance against the key functionalities, the applicant concluded that it is not technically feasible as a general alternative to chromium trioxide. SEAC agrees with the applicant on the importance of meeting the key requirements for aeronautics safety. However, since the applicant stated that commercial Cr(III)-based products are used by some aerospace companies in a limited number of applications, it is not clear to SEAC if these applications are within the scope of the use applied for, introducing uncertainties.

- The second alternative assessed by the applicant is **chromium-free aluminium-based coatings**. The alternative is comparable to the currently used Cr(VI)-based slurry coatings, although it is free of chromium. The alternative comprises aluminium-based components in inorganic binders. After curing, the substrate is provided with additional corrosion resistance due to the sacrificial properties of the deposited aluminium particles of the ceramic coating. Some formulations are commercially available and several have been tested by the applicant. Only one candidate formulation showed equivalent performance for one less demanding application. Performance results were estimated to be insufficient to meet the requirements for substitution for the entirety of applications. The applicant therefore concluded that this alternative is not technically feasible as a general alternative. Testing is currently ongoing for new formulations but still remains at low maturity level, with insertion expected to take more than a decade. SEAC agrees with the applicant's assessment that chromium-free aluminium coatings are not a technically feasible general alternative.

SEAC questioned the applicant on potential other alternatives, including on alternative materials, metallisation techniques and self-assembled monolayer, that were not or only briefly discussed in the AoA. The applicant provided further justifications as to why these would not be applicable to the uses applied for. For example, according to the applicant, magnesium-based materials are susceptible to corrosion and in most cases still require Cr(VI) treatment, carbon composites are not as efficient in dealing with compression loads, while titanium is much more costly and adds significant weight when compared to aluminium, which negatively affects other environmental performance parameters in the aircraft. SEAC found the justifications to be credible.

The applicant concluded that none of the alternatives are technically feasible for all key applications within the use applied for. While several potential alternatives to surface treatments with chromium trioxide, predominantly Cr(III)- based systems and chromium-free aluminium-based coatings, are being investigated, results so far do not support reliable conclusions regarding their performance. The applicant states that, due to its unique functionalities and performance, it is challenging and complex to replace surface treatments based on chromium trioxide or other Cr(VI)-chemistries in applications that demand superior performance for corrosion and/or adhesion to deliver safety over extended periods and extreme environmental conditions.

SEAC notes the importance of the key functionalities (high corrosion resistance, active corrosion inhibition, adhesion promotion, conductivity, reproducibility, layer thickness, etc.) associated with the use of Cr(VI) compounds for the key applications, and had considered the possibility to use these functionalities as a condition to ensure that the scope of applications is fully limited to only those applications for which it has been fully demonstrated that suitable alternatives do not exist. However, SEAC concluded that it would be difficult to implement and enforce any corresponding conditions in practice.

In addition to the need for a technically equivalent alternative, the implementation process of alternatives (qualification – certification – industrialisation) within the aeronautics and aerospace sectors takes time due to high regulatory standards and stringent safety requirements. Figure 3 gives a simplified overview of these processes.

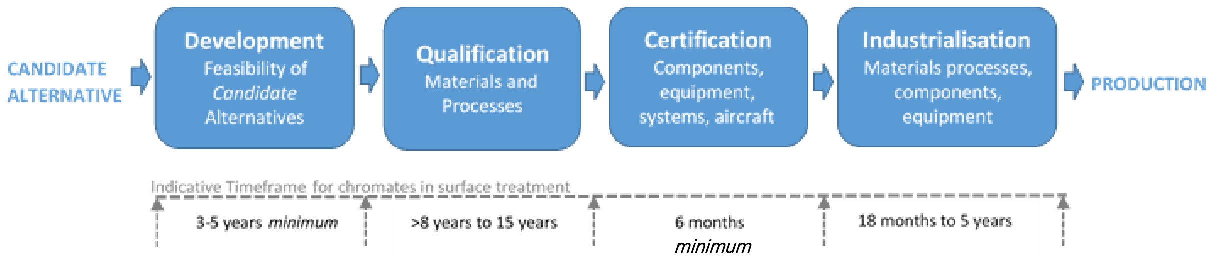

Figure 2: Illustration of the development, quantification, certification and industrialisation process required in the aerospace sector.

The above depicted processes are time-consuming. According to the applicant and based on OEM experience, the time period needed to pass the qualification process is estimated to be in the order of 8 years and can be even longer when major test failures occur. This is one of the main challenges for chromium trioxide replacement. Depending on the materials, processes and criticality of the applications, in-service evaluation and monitoring may be required and can extend the time needed to 15 years or more. The certification step can take as little as 6 months but typically will take several years.

Currently, the applicant considers chromium trioxide to be of significant importance for the aerospace sector. Based on the experience and with reference to the actual status of R&D programs as well as qualification and certification regimes, alternatives to chromium trioxide for all key applications are not foreseen to be commercially available for surface treatment within the aeronautics and aerospace industries before 12 - 15 years after the sunset date.
During the public consultation comments were submitted from actors within the aerospace industry supporting the conclusion of the applicant on the lack of technically feasible alternatives and no information on other alternatives was provided by interested third parties.

The applicant's analysis indicates that some alternatives are being implemented for a limited number of applications. Although it is not clear to SEAC what applications are referred to or what the extent of their implementation and share of the use applied for is, it is clear that the alternatives cannot be considered generally applicable for all key applications, especially when considering the use applied for (chemical conversion coating and slurry coating) as part of a sequence of interlinked process steps in the surface treatment system as a whole.

During the Trialogue and as part of the requests for additional information, the applicant was asked to explain further the possibility to reduce the scope of applications covered by the authorisation, for example by better defining the applications that are within the scope. The applicant clarified that this is not practical due to confidentiality obligations as well as the complexity of aerospace manufacturing and the relationships existing between all parts (e.g. tribology, galvanic reaction, etc.), stating that any attempt to narrow down the scope would require going down to the OEM/engine model/specific part level, as the design can be different for all combinations of these. The applicant also restricted the scope of the use applied for so that it only covers specific surface treatment processes with specific chemical mechanisms (see also 7.2 SEAC's conclusion on technical feasibility). SEAC understands these arguments, but recognises that this introduces uncertainty regarding when alternatives will become available for different applications in different companies.

Economic feasibility

The economic feasibility of alternatives was briefly discussed in the AoA. The applicant stated that due to the fact that all of the above mentioned alternatives show significant technical failures, no quantitative analysis of the economic feasibility was performed. Only broad considerations about whether costs are expected to be higher/lower were included in the application for authorisation. For most alternatives, the applicant concluded that there is no indication that they are not economically feasible. Table 3 below summarises the information provided by the applicant on economic feasibility of the alternatives.

Table 12: Economic feasibility considerations

Alternative	**Economic feasibility considerations**
Cr(III)-based surface treatments	No indication that the alternative is not economically feasible
Chromium-free aluminium-based coatings	No indication that the alternative is not economically feasible

Conclusion

SEAC agrees that the analysis of alternatives is sufficiently detailed to conclude on technical feasibility of the alternatives.

The applicant made a clear distinction between the most promising alternatives and others that were rejected because of major deficiencies. A description of the substance ID & properties and the process was provided. Sector specific assessments (for the aeronautics/aerospace industries) were provided on technical feasibility, followed by a brief discussion about the availability of the alternatives. Moreover, the applicant was asked to provide evidence of results of previous tests and details on other alternatives not referenced in the dossier. Pictures and explanations of test results were provided, which enabled SEAC to better understand the limitations of the alternatives presented. The applicant also provided details on new materials and the difficulty of them being implemented in aircraft (e.g. carbon parts).

For the sectors covered by this application for authorisation, complex airworthiness and approval processes need to be considered, which were described and explained by the applicant. For alternatives to be industrialised and implemented, they must undergo qualification and certification procedures first. SEAC understands that the transition to alternatives can take a significant amount of time due to the need to pass such processes successfully. SEAC notes that the actual time required might vary between various technical applications included in the scope of the use applied for. Moreover, the applicant clarified that any changes at the component level may require re-certification also at the assembly/system level, increasing the time needed for qualification and the complexity of the substitution.

Only a qualitative and very brief discussion on economic feasibility was provided. No assessment was performed allowing e.g. a comparison of the alternatives or any evaluation of the economic feasibility. The applicant stated that this is due to the fact that none of the alternatives are currently regarded feasible from a technical point of view. For both of the most promising alternatives, there is no indication that they are not economically feasible according to the applicant (not taking into account the cost of validation, certification, etc.).

7.2 Are the alternatives technically and economically feasible before the sunset date?

☐ YES

☒ NO

Justification:

Applicant's conclusion on technical feasibility: the applicant states that currently there are no technically feasible alternatives to chromium trioxide used in chromate conversion coating and slurry coatings processes for key applications in the aeronautics and aerospace industries. Based on experience and with reference to the status of R&D programs as well as qualification and certification regimes within these highly regulated sectors, alternatives are not foreseen to be commercially available before 12 years after the sunset date.

Applicant's conclusion on economic feasibility: the applicant states that because the shortlisted alternatives fail significantly when it comes to technical aspects and because costs cannot be known until the technical issues are solved and it is clear which component parts can be covered by the alternative, no quantitative analysis of the economic feasibility was conducted. Economic feasibility is discussed very briefly, only qualitatively and only in broad terms without further substantiation. However, it is reported that for both alternatives there is no indication that they are not economically feasible (see 7.1 for more information).

Conclusion

SEAC's conclusion on technical feasibility: as stated in section 7.1. above, the analysis of alternatives provided by the applicant describes and assesses the technical feasibility of alternatives for chemical conversion and slurry coating applications in the corrosion prevention coating systems. Two promising alternatives were identified and shortlisted. It must be pointed out that the applicant also screened other alternatives that were not shortlisted due to major deficiencies. A large number of research programs were also referenced demonstrating the effort made by the aerospace industries to phase out Cr(VI) compounds. The assessment of alternatives gives a good overview about why certain alternatives were considered further and why others have been excluded from any further assessment. During the public consultation, comments generally supported the conclusion of the applicant on technical feasibility and no information on other alternatives was provided by interested third parties. SEAC concurs that there is no technically feasible alternative on a general level for all key applications and that the certification of the component part and/or the complete system where the part is incorporated could lead to major delay before implementation.

Nevertheless, it is not clear to SEAC when alternatives will eventually become available for specific applications within this use as the feasibility of alternatives is only assessed at a general level for all applications. The applicant assessed alternatives on a surface treatment process basis looking for general alternatives applicable for all key applications across each process. It must be pointed out that the use applied for is described in such a general way that SEAC cannot discount the possibility that there are applications in the scope for which alternatives are in use or will become so during the next years. Indeed, the applicant states that some alternatives are already being implemented for a limited number of applications within individual Original Equipment Manufacturers (OEMs). It must also be recognised that each part has its own interaction with the system (tribology) and that the certification is different for each aircraft leading to differences in timelines for possible implementation. The applicant convincingly described during the trialogue the complexity inherent to substitution within the aerospace industry due to the relationships between parts within an aircraft system/assembly. This is more of an issue for substitution within existing aircraft designs since substitution possibilities on new aircraft may be more easily accommodated during the initial design phase. Moreover, according to the applicant, applications where substitution is already possible are not covered by the application anyhow (answer provided to questions by SEAC). The applicant did, however, not specify such applications or how their related technical requirements differ from those within the scope of the use applied for here. SEAC asked the applicant to further specify the scope of the authorisation, e.g. by narrowing down the use description to one that would not cover any specific applications for which suitable alternatives are already in use or could be used before the sunset date, or by listing specific applications for which there are suitable alternatives and that are out of the scope. The applicant did, however, not specify such applications or their related technical requirements due to confidentiality reasons, but did respond to questions from SEAC stating that due to the fact that even within a single OEM, ostensibly 'similar' components or hardware in different systems / aircraft / engine models have unique design parameters that must be considered individually, as well as part number specific certification requirements, it is not possible to narrow the description any further.

SEAC's conclusion on economic feasibility: SEAC cannot conclude on the economic feasibility of alternatives due to the fact that no such assessment was performed by the applicant. The applicant concluded that overall, there is no indication that alternative processes are not economically feasible (see 7.1). Due to the lack of an appropriate assessment, SEAC cannot conclude on the economic feasibility of alternatives.

Based on the available information, SEAC concludes that before the sunset date no technically feasible general alternatives exist for all applications of chromium trioxide in surface treatment in the aerospace sector covered by the use applied for. Although it is difficult for SEAC to assess the longer term prospects for developing suitable alternatives, the applicant's previous and ongoing commitment over some decades, along with the time that is necessary to industrialise new developments, is sufficiently indicative that realistic prospects for full substitution of all key applications will only be possible in the next few decades. However, due to the generic approach of the applicant in the analysis of alternatives, SEAC cannot exclude that there are some applications making use of chromium trioxide based surface treatment processes, where substitution is already feasible or will become so in the short-term. The uncertainties pointed out above are considered further by SEAC in the recommendation for the review period.

7.3 To what extent are the risks of alternatives described and compared with the Annex XIV substance?

Description:

Alternative 1: Cr(III)-based surface treatments

As the alternative is not technically feasible, only classification and labelling information of substances and products reported during the consultation were reviewed for comparison of the hazard profile. As worst case scenario, chromium (III) fluoride is classified as Skin Corr. 1B, Eye Dam. 1, Acute Oral Tox. 3, Acute Dermal Tox. 4, Acute Inhal. Tox. 4 and STOT RE 1. As such, transition from chromium trioxide – which is a non-threshold carcinogen – to one of these substances would constitute a shift to less hazardous substances.

Alternative 2: Chromium-free aluminium-based coatings

As the alternative is not technically feasible for most applications, only classification and labeling information of substances and products reported during the consultation were reviewed for comparison of the hazard profile. As worst case scenario, Silicic acid, sodium salt (molar ratio ≤ 1.6) is classified as Met. Corr. 1, Skin Corr. 1B, Eye Dam. 1, Acute Oral Tox. 4, and STOT SE 3 (respiratory effects). As such, transition from chromium trioxide – which is a non-threshold carcinogen – to one of these substances would constitute a shift to less hazardous substances.

7.4 Would the available information on alternatives appear to suggest that substitution with alternatives would lead to overall reduction of risk?

☐ YES

☐ NO

☒ NOT APPLICABLE

Justification:

Use of the alternatives may constitute a shift to less hazardous substances.

7.5 If alternatives are suitable (i.e. technically, economically feasible and lead to overall reduction of risk), are they available before the sunset date?

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

SEAC agrees with the applicant's conclusion that there are no suitable alternatives available before the sunset date.

8. For non-threshold substances, or if adequate control was not demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ YES

☐ NO

☐ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:

Additional statistical fatal cancer cases

The estimated number of additional statistical fatal cancer cases has been calculated using the excess risk value presented in section 6 and the estimation of the number of exposed people provided by the applicant. RAC notes that these calculations are based on the estimation of exposed populations as provided by the applicant.

Table 13 presents the estimated number of additional statistical fatal cancer cases for workers and for the general population for which only the results for the local scale are included, as RAC considered the regional scale (albeit addressed by the applicant) not relevant given that Cr(VI) is effectively reduced to Cr(III) in the environment. For SEAC, the regional assessment is therefore not regarded being relevant for assessing the human health impacts man via environment at regional scale.

Table 13: Estimated additional statistical fatal cancer cases for 12 years of exposure (12 is the review period applied for)

Workers – Combination of WCS	Exposure 8 h (µg Cr(VI)/m³)	Excess lung cancer risk	Number of full-time equivalent exposed workers	Estimated statistical fatal cancer cases (12 years of exposure)
	0.60	2.4 ×10^{-3}	7456	5.36
Man via environment - Local	**Exposure 24h ((µg Cr(VI)/m³)**	**Excess lung cancer risk**	**Number of exposed people**	**12y**
	3.8 ×10^{-7}	1.1 x 10^{-8}	10 000 persons/site x 275 sites = 2 750 000	5.1 x 10^{-3}
Man via environment - Regional	Not relevant			
Total				**5.37**

The estimated additional statistical fatal cancer cases reported in Table 13 is one element of the calculations used to value, in monetary terms, the human health impacts of granting an authorisation. These impacts can then be measured against the expected socio-economic benefits of granting an authorisation.

In the absence of more refined estimates, RAC and SEAC have based their opinion on the assessment presented by the applicant. However, the health impacts presented should not be seen as equivalent to the human health impact that will occur if an authorisation for this use is granted. As such, the re-use of these estimates outside of this socioeconomic analysis is advised against. Further details of the uncertainties and potential overestimation of exposure can be found in section 4 and 6 above.

Assessment of Impacts – General Methodological Considerations

The assessment of impacts conducted by the applicant for this authorisation application includes a comparative quantitative analysis of the monetised impacts associated with the continued use of chromium trioxide ("applied for use" scenario) vs not being able to use chromium trioxide, i.e. assuming authorisation is not granted ("non-use" scenario). The application covers the use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers, as described in the application. The perspective of the analysis is such that it aims to show that the benefits exceed the risks of continued-use within the analytical timeframe considered by the applicant.

The analytical timeframe (temporal scope) of the SEA considered in the applicant's analysis is based on a period of 12 years, stretching from 2017 (base year, corresponding to the sunset date of the substance) to 2029. There is no explicit justification of the 12 year analytical boundary beyond the fact that it coincides with the review period being sought.

As such, whilst it covers the relevant decision-making time horizon, it is not necessarily aligned to the temporal scope of impacts. For example, although the cancer burden risk estimates (see benefits section below) are based on an appropriate adjustment of the exposure duration to the period of the analysis, any latency around exposures and effects is not taken into account. The extent that other impacts are fully manifest within the 12 year review period is also not specified. Nevertheless, the approach is in general consistent with previous practice in authorisation applications and any bias introduced will tend to induce conservatism (overestimation) in the economic burden of health impacts and (underestimation) economic impacts estimated. The discounting period used is consistent with assessing the present value of all impacts at the base year date of 2017. Overall, the approach provides a consistent comparison of benefits and costs over the time period of analysis selected.

The assessment of impacts encompasses those impacts occurring within the EEA and which are incremental to the baselines under the “applied for use” and “non-use” scenarios considered by the applicant. The applicant compares in a consistent way the positive and negative impacts across the “applied for use” and “non-use” scenarios, such that the assessment provides an overall net benefit estimate for the applied for use scenario associated with a granted authorisation.

The applied-for use scenario comprises the continued use of chromium trioxide in chemical conversion and slurry coating applications by aerospace companies and their suppliers in the EEA. The application covers the whole EEA aerospace supply chain and the use of chromium trioxide at the sites of parts and component manufacturers, Original Equipment Manufacturers (OEMs) and Maintenance Repair and Overhaul organisations (MROs). The non-use scenario defines the consequences of a refused authorisation based on the most likely behavioural responses of the affected parts of the supply chain. The applicant states that the non-use scenario was developed with input from multiple sources, primarily consultations with consortium members including OEMs, suppliers and MROs. According to the applicant, the affected parties would react to a refused authorisation by partly or fully shutting down the relevant operations in the EEA and relocating or subcontracting them to a non-EEA country. The relevant operations comprise the production of aerospace products and components (including aircraft and defence products) requiring chromium trioxide, as well as the repair and maintenance of such articles using chromium trioxide. SEAC considers the non-use scenario is plausible, though not always fully motivated and transparently justified across the scope of the use encompassed in the application. Nevertheless, the scenario establishes the most likely general situation for the applicant and their supply chain in the event of not being granted an authorisation. In this respect, the primary motivation is the general lack of suitable alternatives and the ubiquitous need for chromium trioxide use in this sector. Given this, the applicant’s socioeconomic assessment of the “non-use” scenario considers the direct financial costs to their operations (in terms of value-added foregone/loss of profits) in the event of not being granted an authorisation, as well as impacts related to relocation and outsourcing (e.g. investment costs and qualification costs), unemployment, and wider economic impacts.

The assessment of quantitative economic impacts undertaken by the applicant is in general based on an acceptable methodological approach to cost assessment using expenditures related to additional resources having to be transferred from other competing uses, as well as the loss of productive values of resources that are rendered unemployed, as a consequence of the non-use scenario. There are some uncertainties related to the representativeness of the data gathering survey sample (see cost section for details), though these are not considered by SEAC to have any material effect on any of the conclusions derived from the analysis. The analysis of the economic burden of human health impacts is based on established procedures for the calculation of economic welfare changes as a result of human health risk reductions, albeit with the proviso noted above about the time period regarding latent effects associated with cancer exposures. Overall, whilst SEAC identify some issues relating to the exact magnitude by which benefits exceed risks (mainly arising from uncertainties related to the extrapolation of the economic impact [benefits of continued use] data), the analysis is proportionate, taking into account the likely magnitude of risks.

Costs of continued use (HH)

The quantitative analysis of the costs of continued use is based on a human health impact assessment using a methodology following the SEA guidance. The applicant estimates the change in physical health impacts (disease burden) due to changes in exposures as described in the CSR as a result of the "non-use" scenario. The approach is based on linking quantitative relationships between exposure and the health impact of interest. This general procedure is widely used for the assessment of benefits related to pollutants and is considered to be an appropriate methodological approach. In this respect, the applicant makes use of the linear exposure-response relationships for lung cancer as a result of exposure to Cr(VI) compounds, as estimated by and in accordance with the related ECHA paper (ECHA 2013). The quantitative health impact assessment thus estimates the number of avoided cases of lung cancer as a result of the change in exposure to Cr(VI) under the non-use scenario.

Since the ECHA exposure-response relationships are defined in terms of fatal risks only, the applicant also develops estimates of the number of cases of non-fatal cancers, based on the use of average mortality rate for lung cancer in the EU-27 which is 82.8% (IARC, 2012). The number of fatal and non-fatal cases of excess lung cancer has thus been estimated for directly and indirectly exposed workers, as well as the local and regional general population (man via environment). It should be noted that the assessment of human health impacts to directly exposed workers covers an estimated 275 downstream user sites. The number of exposed workers at downstream sites was estimated on the basis of survey questionnaires sent to all companies in the supply chain for this application, along with information on the number of workers employed extracted from EUROSTAT which was used to account for companies who did not respond to the survey questionnaire (see benefits section for more details about the survey). For the latter group, in order to account for the fact that not all workers employed in a company are exposed, the number of exposed workers was estimated using different proportions of the workers employed, the proportions varying according to the business size grouping (micro, small medium, large) the respective companies were in. Although the specific proportions used were not based on any concrete empirical data, the applicant in their written responses to SEAC questions provided a plausible rationale for the proportions selected[17], whilst also including a

[17] The percentages were based on the following plausible considerations: smaller companies are more specialised and a higher percentage of output relies on chromates; the smaller the

sensitivity analysis in which the proportions were varied to assess the impact of any uncertainty associated with the specific values used. SEAC is content that the conclusions regarding the order of magnitude of health impacts are robust to any uncertainty regarding the number of workers exposed arising from the incomplete survey sampling. In addition to the number of directly exposed workers, the applicant estimated the number of indirectly exposed workers and the general population in the direct neighbourhood of sites that would be covered by this authorisation application, as well as the general population in an area of 200 x 200 km around the sites covered who would be exposed through the 'man via environment' route. For the directly exposed workers and general population in the direct neighbourhood of the downstream sites, the number of sites (275) was multiplied by 10,000 to give the total number of people exposed (in line with the relevant default values from the ECHA guidance on chemical safety assessment). It should be noted that although the total number of sites covered in the supply chain was estimated using desk-based research, SEAC considers any uncertainty over the precise number to be limited given the limited number of companies covered by the application. There is likely to be some limited double counting of people within the different population groups covered under the approach taken. Alongside the assumption that the whole local population is exposed to concentrations modelled for 100m distance from the emission source and RAC's conclusion that regional scale exposure is not relevant in this case, SEAC considers the health impacts related to man via the environment to be conservative (overestimated).

Regarding the exposure-response relationships used to estimate the number of cancer cases, SEAC notes that these are based on linear extrapolation using an exposure time period of 40 and 70 years for workers and indirectly exposed ('man-via-environment') workers/general population respectively, and hence the applicant implicitly assumes exposures are 'linearly separable' over time in order to derive the number of cases arising for the 12 year period of analysis. RAC notes that the existing mechanistic evidence is suggestive of non-linearity, such that linear extrapolation outside the range of observation inevitably introduced uncertainties. Such uncertainty is likely to result in an overestimation of risks in the low exposure range. SEAC also notes that further overestimation of monetised human health impacts is also likely to result from the way the RAC dose-response functions are applied, which assumes that the effects (in terms of disease burden/number of cases) occur without delay (i.e. at the beginning of the exposure period). However, any such effects would occur over time as a result of prolonged exposure and hence, the latency around exposures and effects is not accounted for. As knowledge of the time profile of excess incidence along with appropriate discounting is lacking, any values derived are again potentially overestimated. Irrespective, the approach is consistent with existing practice in authorisation applications.

Concerning the estimation of economic welfare losses associated with this number of excess lung cancer cases, the applicant assesses the monetary value using the willingness-to-pay (WTP) values of preventing the intangible 'human' (pain and suffering) costs associated with cancer mortality and morbidity specific health endpoints (intangible costs). The

company the fewer the people employed outside of the chromate-using operations; the larger the company, the bigger the range of products and processes carried out, such that the share carrying out chromate-related operations will decrease with increasing size of company; the larger the company, the more non-production personnel employed. The percentages have been selected as reasonable worst case estimates based on the above considerations.

applicant uses the WTP values recommended by ECHA guidance (€5 million to avoid a fatal cancer case and €396,000 for a non-fatal cancer case), which are adjusted to the base year price level using an appropriate EUROSTAT GDP deflator index. It should be noted that the value of a non-fatal cancer case used in the ECHA guidance in fact relates to a statistical case of cancer (VSCC), rather than the value of cancer morbidity per se. As a consequence, the VSCC may also incorporate the value associated with the probability of death conditional on having cancer, and hence would not necessarily be appropriate to use given the applicant's separation of cancer cases into fatal and non-fatal cases using average mortality statistics (see earlier). However, any error introduced is minor and does not have any material effect on the estimation of health impacts and conclusions thereof.

It should be noted that the opportunity costs associated with the resources spent on medical treatment and health care (treatment costs) as well as for productivity losses and other non-healthcare related costs associated with cancer have not been included by the applicant, though SEAC considers these to be relatively small compared to the intangible WTP values included in the applicant's assessment and would not influence the conclusions.

Accordingly, applying the range of WTP values for fatal and non-fatal cancer to the disease burden estimates of the number of cases, the applicant estimates that the benefits of "non-use" are around €31 million for exposed workers and €30,000 for nearby workers and residents as well as the regional population exposed as 'man via environment'. Given the magnitude of these estimates associated with the 'human' cost of cancer, SEAC considers that the applicant's omission of treatment costs, etc. would have no effect on the overall results, given that they would constitute a relatively minor share of the total unit cost of human health impact values.

In conclusion, SEAC finds that in spite of some minor methodological issues, the general approach and assumptions used to derive the monetised health benefits of "non-use" are on the whole clear, transparent and based on standard assessment practices, such that the estimates derived are considered to be robust and valid for their intended purpose, albeit likely to be somewhat overestimated.

Benefits of continued use (costs of non-use scenario)

The applicant's analysis of the benefits of continued use is based on a "non-use" scenario in which the affected companies of the aerospace supply chain partly or fully shut down the relevant operations in the EEA and relocate or subcontract them to a non-EEA country. The applicant argues that given the complexity of the aerospace market structure, it is difficult to fully discern the characteristics of the non-use scenario. Nonetheless, the applicant sets out their non-use options in terms of a causal chain in which there are no technically feasible alternatives available and the use of a worse performing alternative is not an option in the aerospace sector, in line with the applicant's analysis of alternatives. As such the applicant concludes that the only possible non-use scenario for the companies in the scope of the AfA are the partial or full shutdown of the production of aerospace products and components (including aircraft and defence products), as well as the repair and maintenance of such articles, along with any associated relocation or subcontracting of activities to outside the EEA. The applicant argues that this is the only option open to them which would enable them to maintain production and maintenance/repair activities so as to ensure the continued and smooth operation of the aerospace sector in the EEA. Whilst SEAC finds this most plausible at a general level, the justification sometimes lacks concrete quantitative evidence of the costs of this option relative to other options. So for example, it is not entirely clear to what extent the use of increased inventories of imported articles might be an economically feasible option at least in some areas of operation. Moreover, SEAC notes that according to the applicant, some minor technical applications in the aerospace sector have been successfully substituted and that further substitution efforts are ongoing, such that it is possible to speculate that some limited operations may, at least within the not too distant future, remain within the EEA. Indeed, no information from the companies indicating how many would relocate either fully or partly has been disclosed by the applicant, apparently due to reasons of confidentiality. Certainly some additional evidence examining the specific responses of individual companies in the supply chain could have helped SEAC to better assess the plausibility of the non-use scenario at a more localised level. Nevertheless, given the lack of information in this respect, the extent to which all operations included within scope of the application would not have to cease and relocate outside the EEA is highly speculative and given the assessment of arguments put forward in the analysis of alternatives and for the review period requested (see section 10), SEAC considers that the credibility of the non-use scenario is not in doubt for the general scope of companies included in the application. The applicant in further written responses to SEAC has clarified a number of issues, such as those relating to increased inventories and the extent to which all aspects of repair and maintenance operations can be relocated, these clarifications further supporting the general applicability and validity of the non-use scenario.

In their assessment of the non-use scenario the applicant estimates what are considered to be the minimum socioeconomic impacts in terms of the expenditures related to additional resources having to be transferred from other competing uses, as well as the loss of productive and social values of resources that are rendered unemployed, as a consequence of the non-use scenario. These various impacts are estimated quantitatively, whilst the applicant also provides a brief qualitative description of wider economic impacts. SEAC considers the applicant's approach to assessing the economic and social impacts to be largely based on an acceptable methodological foundation. The approach includes a mixture of impact measures that encompass various financial and economic flows, including revenues, costs and economic transfers. Although the applicant does not fully adjust them to provide a fully correct net economic welfare estimate of impacts, the applicant has provided sufficient information and updated some of the analysis (in response to questions from SEAC), such that a more methodologically appropriate measure of net economic welfare impacts can be determined and assessed. The applicant has used correct procedures for discounting and the adjustment of price levels to the base year where necessary, as well as including only those costs that are incremental to those envisaged under the continued use scenario. The specific cost items and reasons for their inclusion are set out transparently, although it was not possible for SEAC to scrutinise the derivation of all calculations related to the one-off costs of relocation and outsourcing (for example with respect to capital investment and qualification of EEA suppliers).

The main economic impact item considered by the applicant is the value-added foregone that would result from the ceasing of operations under the non-use scenario. SEAC considers that the value-added foregone is strictly speaking not a real economic welfare loss (benefit) measure, but rather indicates the level of economic activity and reflects the sum of wage income and profit generated. In this respect it represents payment to the primary factors of capital and labour, rather than a change in economic surplus equal to the increase in real economic welfare. However, the applicant also provides a measure of the present value loss in profit (producer surplus) over the 12 year decision timeframe, which SEAC considers more appropriate for assessing changes in welfare. The applicant also includes within their sensitivity analysis (see later) a so-called 'recovery' factor in their estimations of value-added foregone. This is to account for the fact that some proportion of the loss of productive values of resources that are rendered unemployed may be re-gained under the non-use scenario as a result of their resources redeployment in other activities unaffected by non-authorisation. Although this recovery factor is not applied to the sensitivity analyses in which profits are used as the measure of economic impact losses, it is straightforward to deduce that the effect is similar as for the case concerning value-added foregone (i.e. that there would be no change in the overall outcome or conclusions therein). The aggregate profits for all companies affected are estimated on the basis of reported revenues/turnovers for those companies who responded to a survey questionnaire conducted by the applicant, as well as EUROSTAT industry sector average revenues/turnovers for those companies who did not respond to the survey. The profits were found by multiplying these revenue estimates by an average industry sector profit margin of 10%. The 10% figure was based on discussions within the Aerospace and Defence Industries Association of Europe, though the figure is supported by sector studies on the global and financial performance of the aerospace sector[18] . Based on these sector study reports, SEAC considers a profit margin figure of 10% to be plausible, though has some concerns regarding the representativeness of the revenue estimates provided by the applicant. As mentioned these are partly based on estimates from a survey questionnaire and also from EUROSTAT statistics. Although the response rate to the survey questionnaire was rather low (~10%), the applicant made good use of data from EUROSTAT statistics combined with desk based research on all the companies affected in the supply chain to ensure a complete set of revenue data was available. SEAC considers the strategy employed by the applicant to attribute revenues to the individual companies for whom data was missing to be appropriate, if somewhat crude in its precision. Whilst SEAC cannot be certain about the accuracy and representativeness of the resulting revenue data, the use of EUROSTAT official statistics for the sector classified according to the main activities carried out is also considered to be an appropriate approach. Moreover, the applicant conducts a sensitivity analysis in which the main input parameters used to derive the economic impact estimates for each of the companies with missing data is varied. This confirms the robustness of the estimates to changes in the parameter. SEAC considers the variation in the parameters used to assess the robustness of the estimates to be sufficiently broad and plausible for the purposes of the sensitivity analysis. In addition and at the request of SEAC the applicant conducted a second sensitivity analysis in which the data (average values) from those companies who did respond to the survey was used to populate the missing data from those companies who did not respond. In this case, it was found that the impact estimates were even larger (i.e. increasing the margin by which benefits outweigh risks). The applicant considers this to be an indication that the respondents to the survey were biased in favour of responses from larger companies, such that they consider the estimates based on the EUROSTAT averages to be more reliable. SEAC concurs with the applicant in this respect, especially given the large sample sizes upon which the EUROSTAT data is based, albeit noting that there will be some loss of precision due to the broadness of the sector codes used to classify the activities included in scope.

[18] See https://www.pwc.com/im/en/publications/assets/shipping-aircraft-space/2014-aerospace-top100.pdf; https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Manufacturing/gx-cip-aerospace-defense-financial-perform.pdf

Regarding the other economic impacts estimated by the applicant, these consider the investment costs related to relocation, one-off costs related to the need to qualify new non-EEA suppliers, other one-off costs to customers and any additional yearly costs to customers. The applicant states that these cost items only included estimates from those companies who responded to the previously mentioned survey questionnaire (i.e. does not include any data for those who did not respond). As such the applicant suggests that there will be a massive underestimation of impacts. While SEAC agree with this latter point, it should be noted that due to confidentiality obligations expressed by the applicant SEAC has not been able to scrutinise the derivation of these impact estimates. As such, although the impact estimate related to these costs is quite significant (around 50% of the PV of profit losses over 12 years), SEAC does not consider this further as a quantitative estimate, but rather notes that such impacts would potentially significantly add to the overall welfare impacts of the non-use scenario.

The applicant also assesses the social impacts associated with the unemployment of workers who would lose their jobs as a consequence of a non-granted authorisation. The figure for the number made unemployed is based on the number of potentially exposed workers at companies, such that the applicant states that this is a conservative estimate. SEAC has already noted the uncertainties related to the number of exposed workers (see costs of continued use section), but accepts that additional employees than just those exposed to chrome VI may be impacted in terms of job losses. At the same time some of the exposed workers may be transferred to other duties, though of course this may still imply some transitional costs. Despite these uncertainties, SEAC considers the estimate for the number of job losses to be plausible and acceptable as an order of magnitude estimate. In monetising the social impacts of unemployment associated with these job losses, the applicant estimates the direct and indirect costs for public finance (payment of unemployment benefits, loss of social contributions and taxation, etc.). Given that these typically reflect transfer payments, SEAC asked the applicant to recalculate the social costs of unemployment on the basis of the approach outlined in the SEAC paper on the Social Cost of Unemployment (ECHA 2016). The applicant provided updated estimates accordingly, which indicate that the social costs of unemployment are in fact around 3 times higher than the original amount estimated by the applicant. Although the applicant did not include their original estimate of these social impacts in their final total impact estimates, SEAC considers it appropriate to do so.

The applicant also considers other wider economic impacts, which are considered qualitatively and cannot be included in the quantitative comparison of benefits and costs. In addition, a number of illustrative case studies indicating significant impacts within the aerospace and defence sector are presented by the applicant. Although not directly included in the quantitative comparison of benefits and risks, SEAC considers that these qualitative impacts and case studies both provide additional evidence that strengthens the conclusion presented by the applicant that benefits outweigh the costs.

Comparison of Benefits and Cost of Continued Use

Based on the monetised risks of continued use to human health (€30 million) and the economic impacts of a non-granted authorisation that were quantified in the application (profits foregone for the whole 12 year assessment period amounting to €3 billion), SEAC considers a granted authorisation would have a net benefit in the amount of at least €3 billion (net present value for the 12 year assessment period) under the assumption that profit losses continue unabated for the full 12 years of the analytical period used. Even under circumstances when this latter assumption is relaxed (see below), SEAC considers that the applicant has clearly demonstrated in a quantitative assessment that economic impacts outweigh the health impacts by a considerable margin. It should also be noted that the applicant's benefit-cost comparison did not take into account the monetised social impacts of unemployment associated with the non-use scenario, which would increase further the margin by which benefits outweigh costs. The additional inclusion of investment and other one-off costs (not considered by SEAC in quantitative terms due to the inability to properly scrutinise their derivation) would also further increase the benefit-cost margin.

The applicant's SEA includes an uncertainty analysis in which the sensitivity of the overall result to some of the assumptions underlying the assessment (number of exposed workers, exposed population from man via environment, percentage of value added impacted at 'missing data' companies) is evaluated. In all the scenarios considered, the conclusion that economic impacts outweigh the health impacts by a considerable margin remains the same (>30 times). The applicant also includes some scenarios in which a 'recovery' factor (see earlier) is included as an additional uncertainty factor, though this is only done for those examples in which economic impacts are measured by value-added foregone. Based on these examples, SEAC is nevertheless still able to deduce that in the case of profits being used as the measure of economic impacts, these would outweigh health impacts by a margin of over 10 times. SEAC considers that such a margin is robust to any other uncertainties related to the applicant's analysis, such as relating to the period over which economic impacts continue to accrue as a result of the non-use scenario (which is assumed by the applicant to be the full term of the authorisation of 12 years), though to some extent this uncertainty is taken into account using the sensitivity analysis incorporating the 'recovery' factor.

SEAC also notes that there is some further underestimation of the quantitative economic impacts as a result of wider economic impacts having only been considered qualitatively, as well as the case studies describing impacts in the sector also not being incorporated into the quantitative analysis. Finally, as noted earlier, SEAC considers that the applicant's benefit cost comparison underestimates the amount by which benefits outweigh costs since it does not take into account the monetised social impacts of unemployment associated with the non-use scenario, as well as the investment and other one-off costs not considered quantitatively by SEAC.

Based on all these considerations, SEAC concludes that the benefits of continued use substantially outweigh the risks to human health and the environment, and that this conclusion is robust to any of the uncertainties related to the assessment.

Conclusion

SEAC considers that the applicant's approach to impact assessment and benefit-risk comparison adequately captures the changes in economic welfare resulting from non-use of chromium trioxide in the EEA. Although there are some minor methodological deficiencies and uncertainties in the applicant's assessment, the analysis is proportionate and the quality of quantitative and qualitative information included in the application is sufficient to support the conclusion that the benefits of using chromium trioxide substantially outweigh the risk. The avoided economic losses and the monetised human health risks are valid and robust enough to indicate the magnitude of benefits and risks of continued use. In SEAC's view, the conservatism incorporated into the economic and monetised health impact estimates, alongside the sensitivity analysis is sufficient to account for any uncertainties, such that the conclusion that the benefits of using chromium trioxide exceed the risks by a considerable margin is robust. In conclusion, SEAC concurs with the applicant that the benefits of continued use of chromium trioxide outweigh the risk.

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation:

Exposure scenarios

Supply chain communication is considered to be a prerequisite to achieve the objective of reducing exposure to workers and humans via the environment. Recognising the applicant's obligation to include representative exposure scenarios (ESs) in their Chemical Safety Report (CSR) as defined in Annex I sections 0.7 and 0.8 of REACH, more detailed WCSs shall be developed. These shall describe detailed Operational Conditions (OCs) and Risk Management Measures (RMMs) to control workers' exposure to the substance as well as emissions to the environment together with resulting exposure levels, include more detailed descriptions of tasks, as well as descriptions of how the tasks should be performed. The hierarchy of control principles according to Chemical Agent Directive (98/24/EC) and Carcinogens and Mutagens Directive (2004/37/EC) including any relevant subsequent amendments shall be followed in the selection of OCs and RMMs described in the ES(s). These ES(s) shall be developed and made available to Downstream Users of this application and for the inspection of the enforcement authorities without delay not later than 3 months after the applicant has been informed that an authorisation is granted for this use.

It should be noted that the maximum combined exposure estimate for workers and release values for the environment proposed by the applicant for the risk assessment analysis should not be seen as an endorsement by RAC as a safe or acceptable level for this non-threshold substance.

The overarching objective should be the progressive reduction of exposures and releases to as low a level as technically and practically possible. Progressive reduction of exposure and releases shall be documented and such reports made available for enforcement authorities.

Validation of Exposure Scenarios

At the latest 2 years after the authorisation has been granted for this use, and thereafter yearly, the applicant shall validate and verify the ESs through an analysis of the tasks as well as through the representative programmes of occupational exposure and environmental release measurements described below.

Where the validation and verification indicates that exposures and releases are not reduced to as low a level as technically and practically possible, the applicant shall revise the ESs.

Specific conditions

1. The scope of the authorisation for the use of chromium trioxide is limited to slurry coating (sacrificial coating and diffusion coating) and chemical conversion coating operations by aerospace companies and their suppliers. Chemical conversion coating by spraying and slurry coating by dipping, brushing, swabbing or roller shall not be covered by the authorisation, if granted.
2. 1. The area in which the WCS 6 activities are undertaken, is restricted either physically by means of barriers /signage or through strict procedure during the activity and for a specified time after the operation.
3. 2. Mechanical ventilation shall be used for machining activities in small work areas (WCS 13), unless in cases where mechanical ventilation would introduce risks (e.g. local spark risk) or would otherwise not be technically and practically possible.
4. 3. Effective cleaning practises shall be implemented to prevent surface contamination around treatment baths and other equipment, in the vicinity where machining activities take place, and where solid chromates are handled.

Downstream User Monitoring

Workers

Downstream users covered by this application shall implement at least annual programmes of occupational exposure measurements relating to the use of the substance described in this application. These monitoring programmes shall be based on relevant standard methodologies or protocols and be representative of (i) the range of tasks undertaken where exposure to the substance is possible (i.e. the programme shall include both process and maintenance workers), (ii) the operational conditions and risk management measures typical for these tasks and (iii) the total number of workers that are potentially exposed.

The applicant shall prepare recommendations and guidelines (e.g., regarding the use of relevant standards and good practices) to assist downstream users in implementing the annual programmes of occupational exposure measurements, and shall develop a report template for submission of monitoring data by downstream users.

In addition to monitoring of surface treatment activities, annual programmes of exposure monitoring should be performed for machining operations in order to confirm exposure levels in machining activities.

The reports presenting the results of the monitoring and of the review of the RMMs and OCs shall be maintained and be available to national enforcement authorities. Detailed summaries of the results with the necessary contextual information shall be included in any subsequent authorisation review report submitted.

LEV and RPE efficiency are key control measures. Therefore, LEV and RPE shall be checked and tested periodically (including fit testing of RPE). Records of these periodical checks and tests shall kept and made available for national enforcement authorities.

Environment

Emissions of Cr(VI) to wastewater and air from local exhaust ventilation shall be measured at individual sites, apportioning (when relevant) the use of other Cr(VI) sources than those covered by the present application. The results of monitoring shall be made available to enforcement bodies on request. Measurement programmes should be undertaken according to standard sampling and analytical methods, where appropriate. The results of monitoring programmes shall be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted.

The applicant shall prepare recommendations and guidelines (e.g., regarding the use of relevant standards and good practices) to assist downstream users in implementing the annual programmes of environmental exposure measurements, and shall develop a report template for submission of monitoring data by downstream users.

Continuation of monitoring requirements

The information gathered in the monitoring programmes shall be used by the applicant and the downstream users covered by the application to review and where relevant adjust the risk management measures and operational conditions, as indicated above.

Whilst monitoring programmes are essential for the development and verification of ESs by the applicant, it is not the intention that all DUs of this application should continue monitoring programmes for the duration of the validity of the authorisation granted.

Where, following implementation of the OCs and RMMs in the ESs, the DU can clearly demonstrate that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible and where it is demonstrated that OCs and RMMs function appropriately, the monitoring requested for this authorisation may be discontinued.

Where the monitoring programme has already been discontinued in accordance with the above, any subsequent changes in OCs or RMMs that may affect the exposure at a downstream user's site shall be documented. The downstream user shall assess the impact of such changes to worker exposure and consider if further monitoring needs to be undertaken to demonstrate that exposure to humans and releases to the environment continue to be reduced to as low a level as technically and practically possible in the changed worker setting.

Description of conditions and monitoring arrangements for review reports by RAC:

In any subsequent review report, in order to facilitate the assessment of the exposures resulting from the use, the applicant shall provide,

- the representative measured exposure data for workers and environment referred to above;
- the exposure scenarios for typical, representative facilities, clearly describing the relationship between the OCs and RMMs and the resulting exposure levels;
- a justification as to why the selected OCs and RMMs are indeed representative for the use;
- a justification that the chosen OCs and RMMs follow the hierarchy of control principles and are appropriate and effective in limiting the risks;

- better detailed task descriptions, including how exposure occurs for the different exposure routes;
- a refinement of the assessment of indirect exposure and risk to humans via the environment beyond the default assumptions outlined in ECHA guidance and the EUSES model; and
- an assessment of all reasonably foreseeable routes of exposure to humans via the environment (i.e. the oral route of exposure should be fully assessed).

Justification for the additional conditions and monitoring arrangements by RAC:

The level of detail in applicant's exposure scenario (ES) presented in CSR could be improved with due consideration in Annex I section 0.7 of REACH. While Section 0.8 indicates that an ES may cover a wide range of processes, the level of detail is dependent on the use, the hazardous properties and the amount of information available. In the view of RAC, such information is available, and bearing in mind the intent of the REACH regulation and the hazard of a non-threshold carcinogen such as Cr(VI), the lack of exposure measurement data, as well as a lack of information on the relationship between OCs and RMMs and exposure levels, are a significant source of uncertainty in this application.

There are significant uncertainties related to air concentrations of Cr(VI), therefore monitoring is required to confirm worker exposure estimates for all WCSs with exposure potential. Because the applicants share responsibility in generating data in their supply chain it is appropriate to require that they communicate recommendations, guidelines and templates down the supply chain.

The applicant's assessment of the exposure, risk and impacts for humans via the environment is based on a series of default assumptions that result in uncertainties to the health impacts. The lack of measured data of releases to air and quantitative information on releases to water contribute to the uncertainty. These uncertainties should be addressed in any review report.

~~To avoid any misunderstanding regarding the scope of the authorisation resulting from the statement "but is not limited to" on p.22 of the CSR, a condition has been included to make unequivocally clear that the scope of the authorisation for the use of chromium trioxide is limited to slurry coating (sacrificial coating and diffusion coating) and chemical conversion coating operations by aerospace companies and their suppliers. In response to a question from RAC, the applicant agreed that the scope of the authorisation should in fact be limited to these operations. Moreover, no WCS covers chemical conversion coating by spraying nor slurry coating by dipping, swabbing or roller application even though these application types were mentioned on p.22 of the CSR. Table 4 of the analysis of alternatives also did not mention spraying as a process covered by the use applied for but did mention slurry coatings by brush and dip processes. As part of the comments on the draft opinion, the applicant requested these processes to be covered by the authorisation. However, as the processes in question are not covered by the ES they should therefore not be covered by the authorisation, if granted.~~

10. Proposed review period:

☒ Normal (7 years)

☐ Long (12 years)

☐ Short (…. _years)

☐ Other:

Justification:

In identifying the review period SEAC took note of the following considerations:

RAC's advice:

Considering that

- there are uncertainties in the exposure assessment, which may result in underestimation of the risk to workers;
- RMMs and OCs are not described in sufficient detail to allow the Committee to conclude that they are appropriate and effective in limiting the risk to workers;
- RAC confirmed that there are risk-control concerns, i.e., operational conditions and risk management measures described in the application do not limit the risk; and
- as a result, additional conditions and monitoring arrangements are proposed with the intention of reducing the abovementioned concerns;

RAC recommends that the review period should be no longer than seven years.

Other socio economic considerations

In establishing its recommendation on the Review Period, SEAC has taken into account the following considerations:

- The applicant has requested a review period of 12 years (and preferably more) and provided information to justify this request. The review period of 12 years has been requested on the basis that this coincides with estimates by the aerospace industry of the schedule required to industrialise alternatives to chromium trioxide for all applications within the scope of the use applied for.
- There are no technically and economically feasible alternatives to substitute chromium trioxide in all key "applications" by the sunset date.
- However, SEAC notes that chromium trioxide free alternatives for some individual steps in the surface treatment processes are available and currently in use by the aerospace industry. Where this is the case, it is noted by the applicant that chromium (VI) substance is specified in one of the other steps within the overall surface treatment system. Nevertheless, it is still unclear to SEAC whether, given the broad scope of the use applied for, there are indeed some applications that would be covered under the use, for which completely chromium VI-free alternatives are already, or would within a normal review period be, suitable and implemented.
- Furthermore, the applicant remarks that "Completely Cr(VI)-free industrially available solutions exist for a few applications for aerospace components where corrosion risk is

low". However, according to the applicant these are not in scope of the use applied. Indeed the applicant maintains that where alternatives have been successfully developed, they are implemented whenever it is possible within the constraints of having to meet the relevant airworthiness regulations and industrialise the process. Whilst this does not necessarily provide assurance that the scope of uses applied for is suitably narrowed, SEAC agrees that where alternatives for applications have been successfully developed and certified as airworthy, then reverting to Cr(VI) based solutions would be illogical.

- The applicant defines the technical feasibility and suitability of alternatives in terms of their ability to "provide all the required properties to the surfaces of all articles in the scope of the application". Accordingly, the analysis of alternatives considers the extent to which alternatives have the relevant functional properties or not, and where they do not then they are considered to be not suitable. This leads to the question of whether all applications in scope of the use applied for require all those functional properties and whether one can conclude from the AoA that the applicant has demonstrated sufficiently that they do. The applicant has stated that suitable alternatives for less demanding "applications" have been implemented by aerospace companies, though it is unclear what is meant by "less demanding" and whether this implies that some (or all) of the functional properties associated with chromium (VI) were not required in those particular circumstances, or that the degree to which some (or all) of the functional properties were required could be achieved by the alternatives. Irrespective, the applicant has made clear that there will be specific design parameters for very specific applications where a variety of factors will determine the functional properties required and whether they can be achieved by alternatives. Hence, it is not clear to SEAC at what point, for any alternative and application, it is possible to generally state that the achievement of the functional property requirements are not (or cannot be) met. As such, it is not clear to SEAC to what extent the scope of the use applied for can be narrowed to exclude cases for which suitable alternatives are (or will within a normal review period be) available. SEAC recognises that where suitable alternatives for less demanding applications have been implemented by aerospace companies, these will have been in the context of very specific applications with very specific design parameters at single companies. The applicant has clearly demonstrated that a generally applicable suitable alternative is not available or will become so within the timeline of a long review period. Although a question remains for SEAC about the extent to which the applicant has fully demonstrated that there are "no suitable alternatives" for all possible applications that could be covered within the broad scope of use applied for, it nevertheless is a requirement of authorisation to be continuing efforts to substitute throughout the review period and to implement alternatives as soon as possible.
- Following on from the previous point SEAC notes that in this application for authorisation the term "application" refers to a set of specific aerospace design parameters. Therefore, an "application" refers to a single component in a single system for a single OEM's specific hardware, as each OEM is responsible (according to airworthiness regulations) for its own qualification, validation and certification. Within a single OEM, even ostensibly 'similar' components or hardware in different systems / aircraft / engine models have unique design parameters. These parameters include, but are not limited to: base alloys; mating surfaces, including alloys, coatings, lubricants; exposure temperatures; structural stress and strain environment; fluid exposure; external environment (e.g., humidity, wind/rain erosion, etc.). Moving away

from the use of Cr(VI) requires defining and then assessing performance of potential alternatives against the specific set of design parameters associated with each “application”. In this respect, SEAC understands that given the potential combinations of design parameters, it is almost never possible to broadly apply alternatives without a full detailed assessment of each unique set of design parameters associated with each “application”. Whilst the applicant considers that it would, in principle, be possible to provide such a detailed evaluation, it is argued that because each OEM has unique “applications” for which they have validation and certification responsibility, the practicality of such an undertaking is infeasible, for reasons of scale and confidentiality. In any case, although a detailed analysis on any specific component within a specific company could be undertaken, it would be impossible to generalise across companies' components due to each component's and company's unique design parameters. It is not possible to distinguish completely in terms of some general substitutable characteristics, those “applications” in which a completely Cr(VI)-free industrially available solution has been possible to implement, from those where it is not possible. SEAC asked the applicant to provide information on previous substitution for applications in the scope of the authorisation application (as defined in the use name) in order for SEAC to understand the granularity of “application” substitution possibilities better. However, the applicant responded that it was not able to provide detailed examples of specific applications where Cr(VI) substitution has taken place, for reasons of commercial confidentiality between members of the AfA consortium. It is also unknown to what extent previously successful substitutions might be relevant for the surface treatment processes covered in this application, nor what share of all “applications” have been successfully substituted over the past few decades. The applicant has highlighted that even where successful substitutions have been undertaken in any one application by one OEM, this does not imply that this is then a generally applicable alternative to other OEMs. SEAC thus recognises the difficulty, given the definition of ‘application’, to refine the scope of use to fully reflect the lack of possibilities to substitute across all possible ‘applications’ within the scope.

- According to the applicant Cr(VI)-free alternatives have only been introduced on a case by case basis, usually after significant investment in each application. Such investment has not always resulted in success. Although it may be possible to describe when substitution has been successful at the component level, this has not meant that any particular substitution is transferable / repeatable for other applications. As an example, the applicant describes the case of high strength steel bolts protected by electroplated cadmium with a dichromate surface treatment, which have, in some cases, been replaced with lower strength, larger, corrosion-resistant alloy bolts in new designs. Such replacement has been undertaken where it is possible to test the ramifications of such a change, such as galvanic influences and proper torque / tension relationships early in the development process. However, even such a simple example is difficult to generalise, though the applicant acknowledges that it is easier to replace Cr(VI) uses in new model designs because one is able to more readily address all aspects of the part or assembly design.
- As described in their analysis of alternatives, the applicant describes the efforts they have undertaken in order to identify an alternative through information collection and data searches, consultation with experts and industry, collaborative research and development programmes in conjunction with other aerospace companies and stakeholders, as well as describing the considerable general aviation industry research and development activities over the last several decades, costing upwards of €100

million, in seeking alternatives to chromium trioxide and chromium (VI) compounds in general. This indicates that in spite of these extensive activities, these efforts have yielded limited alternatives, such that alternatives for all applications will not be available for at least 12 years. The applicant's analysis indicates that for the breadth of the use applied for, there is no realistic prospect for replacing chromium trioxide within the normal review period. At the same time, as per the discussion above, it cannot be ruled out that the use applied for also covers specific applications for which alternatives have already been implemented or will be implemented sooner. As already mentioned, it is not clear from the applicant's assessment what the specifics of these "applications" are, or what share of all "applications" is within the use applied.

- The applicant has provided a detailed description of the qualification, certification and implementation/industrialisation to comply with airworthiness requirements and flight security standards and procedures to ensure safety of use. All components, equipment, materials and processes incorporated in an aircraft fulfil specific functions and must be certified, qualified and industrialised. If a substance used in a material, process, component or equipment need to be changed the approval process has to be followed. Although the airworthiness regulations do not specify material or substances to be used, they set performance specifications to be met and for which any change in material or substance would have to be assessed against. Consequently, the approval of the suitability of an alternative for the coating of aircraft components, make the exchange of suppliers, technologies or changes in the production process both very time consuming and costly. The applicant has shown that there are no alternative substances or technologies for whom the timescale for developing and validating their use as technically feasible alternatives for all key applications would be possible within a normal review period of 7 years.
- The analysis is robust and the socio-economic benefits of authorisation substantially outweigh the costs for the remaining risk, even when using SEAC's preferred measure of economic welfare change - the loss of profits - instead of the valued-added foregone as proposed by the applicant. As a simple indicator of the robustness, SEAC notes that even the social costs of unemployment alone arising under the non-use scenario is considerably greater than the sum of discounted monetised health impacts.
- The applicant also states that long-term business certainty is vital for the aerospace sector to function. While SEAC considers that potential business uncertainty arising from the length of the review period could be relevant and that the length of review period may not have any effect on the rate of implementation of alternatives in the sector as a whole, it does not have any specific evidence in this respect, beyond some rather general statements from the applicant regarding this issue..
- No information was forthcoming from the public consultation indicating that alternatives were suitable or likely to become so within a long review period for any (or even some) of the applications within the scope of the use applied for.
- The aerospace industry is driven by long investment cycles, as well as very long in-service times for aircraft. New product designs and launches are infrequent and require significant technical and capital investment by each individual company, for each unique product. Any design modification for products already in production are also constrained by airworthiness requirements, requiring significant investments for recertification as well as implementing the requisite manufacturing process changes. At the same time, SEAC notes that the broad scope of the use applied for covers both

new models at the beginning of the investment cycle and older models that are closer to the end of the investment cycle.

- The approach to substitution in the aerospace sector has as a paramount issue of concern the safety and security of aircraft. SEAC recognise that the need to balance worker protection concerns with aviation safety and security concerns adds a significant layer of complexity and cost in the search for alternatives, which in terms of scale is beyond anything comparable in other sectors in which authorisations have been applied for. Implicit in the cost of searching for alternatives that maintain the high standards of safety and security within the aviation sector is the value placed on life and limb associated with such standards. SEAC acknowledge that these issues of safety and security underlie the highly conservative approach to substitution and the search for alternatives adopted by the sector, and which need to be considered in light of the practicality of demonstrating that no suitable alternatives exist across the broad scope of the use applied for.

In summary, SEAC conclude that the application does not fully support a 12 year review period. Although all five criteria for a long review period are either fully (magnitude which benefits exceed costs; long certification timelines) or partly met (long investment cycles; R&D efforts did not lead to alternatives available within normal review period) or not applicable since it has not been possible to analyse (cost of alternatives are very high), there is nevertheless a lack of clarity about the broadness of scope of use, in particular with respect to the nature of applications potentially covered, and the related uncertainties about the already implemented alternatives. When considered alongside the other factors noted above and the advice from RAC, SEAC can only recommend a review period of 7 years.

11. Did the Applicant provide comments to the draft final opinion?

☒ YES

☐ NO

11a. Action/s taken resulting from the analysis of the Applicant's comments:

☒ YES

☐ NO

☐ NOT APPLICABLE

Justification:

Some changes were made to clarify aspects in the justification, chiefly:

– ~~The scope for which the authorisation is recommended to be granted is clarified further in section 4, 7.1 and 9.~~
– A deadline for the first validation of the ESs is introduced and the relationship with the monitoring programmes clarified in section 9.
– It is clarified in section 9 that the monitoring required shall be conducted by Downstream Users but that the applicant shares responsibility in generating data in their supply chain that is of good quality, consistency and detail.

- Clarifications and additional considerations in section 10 to further highlight the issues concerning the unique challenges faced by the aerospace companies and the possibilities for them to overcome those challenges. The text referring to the criteria for a long review period was revised to clarify that the criterion regarding the high costs of alternatives was not applicable, and the criteria relating to having a demonstrably long investment cycle and R&D efforts not leading to alternatives being available within a normal review period were partly met.

The responses of RAC and SEAC to the applicant's general comments on the draft opinions are available in the attached Support document.

Appendix 1: Measurement data for slurry coating process in WCS 6 ~~provided by the applicant~~

Site	Country	Year	Duration of sampling (min)	Measurement result (µg Cr(VI)/m³) (by applicant)					Average, adjusted for RPE with APF 30 (by RAC)	Company specific average (by RAC)
				Not LoD adjusted	LoD adjusted	APF of RPE	Adjusted for RPE efficiency	Company specific average		
Site A	Italy	2015	no details	< 1	0.5	30	0.0167	0.0167	0.0167	0.0167
Site A	Italy	2015	no details	< 1	0.5	30	0.0167		0.0167	
Site A	Italy	2015	no details	< 1	0.5	30	0.0167		0.0167	
Site B	France	2012	321	< 1.3	0.65	1000	0.0007	0.0058	0.0217	0.1920
Site B	France	2012	350	< 1.3	0.65	1000	0.0007		0.0217	
Site B	France	2014	>360	2.5	2.5	1000	0.0025		0.0833	
Site B	France	2014	>360	5	5	1000	0.005		0.1667	
Site B	France	2014	>360	20	20	1000	0.02		0.6667	
Site C	Italy	2014	120	< 0.2	0.1	10	0.01	0.01	0.0033	0.0033
Site D	Hungary	2013	120	< 10	5	1000	0.005	0.005	0.1667	0.1667
Site E	UK	2012	134	< 1	0.5	1000	0.0005	0.0028	0.0167	0.0944
Site E	UK	2013	191	< 8	4	1000	0.004		0.1333	
Site E	UK	2014	156	< 8	4	1000	0.004		0.1333	
Site F	Poland	2015	>360	1	1	30	0.0333	0.5218	0.0333	0.5218
Site F	Poland	2015	>360	20	20	30	0.6667		0.6667	
Site F	Poland	2015	>360	16	16	30	0.5333		0.5333	
Site F	Poland	2015	>360	16	16	30	0.5333		0.5333	
Site F	Poland	2015	>360	1.9	1.9	30	0.0633		0.0633	
Site F	Poland	2015	>360	35	35	30	1.1667		1.1667	
Site F	Poland	2015	>360	14	14	30	0.4667		0.4667	
Site F	Poland	2015	>360	43	43	30	1.4333		1.4333	
Site F	Poland	2015	>360	9	9	30	0.3000		0.3000	
Site F	Poland	2015	>360	14	14	30	0.4667		0.4667	

Site F	Poland	2015	>360	41	41	30	1.3667		1.3667	
Site F	Poland	2015	>360	< 1	0.5	30	0.0167		0.0167	
Site F	Poland	2015	>360	12	12	30	0.4000		0.4000	
Site F	Poland	2015	>360	9	9	30	0.3000		0.3000	
Site F	Poland	2015	>360	2.4	2.4	30	0.0800		0.0800	
				AM	9.95		**0.28**	**0.09**	**0.33**	**0.17**
				GM	3.68		**0.04**	**0.01**	**0.12**	**0.07**
				90th percentile	24.50		**0.82**	**0.27**	**0.82**	**0.36**

CHEMICAL SAFETY REPORT

Use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers

Substance Name: chromium trioxide

EC Number: 215-607-8

CAS Number: 1333-82-0

Registrant's Identity: Haas Group International SCM Ltd

Table of Contents

List of Abbreviations

ACH	Air Changes per Hour
AfA	Application for Authorization
APF	Assigned Protection Factor
ART	Advanced REACH Tool
CCC	Chemical Conversion Coating
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
CTAC	Chromium Trioxide REACH Authorization Consortium
ELR	Excess Lifetime Risk
ERC	Environmental Release Category
ES	Exposure Scenario
EUSES	European Union System for the Evaluation of Substances
GCCA	Global Chromates Consortium for Aerospace
LEV	Local Exhaust Ventilation
LOD	Limit of Detection
Min	Minutes
NOAEL	No Observed Adverse Effect Level
NTP	National Toxicology Program
OEL	Occupational Exposure Limit
OSHA	Occupational Safety and Health Administration (USA)
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PPE	Personal Protective Equipment
PROC	Process Category
RAC	Committee of Risk Assessment
RCR	Risk Characterisation Ratio
REACH	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 (REACH)
RMM	Risk Management Measure
RPE	Respiratory Protective Equipment
SEA	Socio-Economic Analysis
SpERC	Specific Environmental Release Category
TWA	Time Weighted Average
WCS	Worker Contributing Scenario

9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.0. Introduction

This exposure assessment aims to provide reliable estimates of current work place exposure levels relating to the import into the EU of a few proprietary products containing chromium trioxide. These products are imported because they are specified for use in surface treatment to provide anti-corrosive properties in the production, maintenance and/or repair of parts for the aerospace industry and derivative applications. Two types of surface treatment activity are covered by this application: conversion coatings and slurry (diffusion) coatings, the latter including high temperature slurry diffusion coatings and sacrificial coatings. In that respect, the Exposure Scenarios are identical to those for similar processes in other parts of the aerospace industry. Here we refer to the Exposure Scenarios presented in relation to aerospace use as part of the CTAC application. Since the uses are identical, the Exposure Scenarios developed for CTAC have been used, by agreement, as the basis for this application. The aerospace companies represented by this application have reviewed the Exposure Scenarios provided in the CTAC application and confirmed that they are representative of the uses covered by this application. Further context and information has been added as appropriate. For clarity, aerospace companies are principally engaged in carrying out the design, development, manufacture, maintenance, modification, overhaul, repair, or support of civil or military aerospace and defence equipment, systems, or structures, plus any derivative uses (e.g., marine propulsion or power generation using products originally designed for aerospace or defence use).

This exposure assessment sets out detailed Exposure Scenarios, including clear and enforceable Risk Management Measures (RMM) and Operational Conditions (OC), for specific activities within the scope of the Application for Authorisation.

The Exposure Scenarios are based on extensive input and data held by aerospace companies and affiliated industries. The same companies and facilities have reviewed and validated the Exposure Scenarios, including RMM and OC, in detail. The Exposure Scenarios presented are therefore unambiguous and demonstrated to be representative of good practice across the industry.

The Exposure Scenarios are conservative, meaning that exposure measurements or estimates represent the upper boundaries of exposure (representing the reasonable worst case). Due to the specialized and highly regulated nature of activities undertaken by aerospace companies and their supply chain (as explained in the AoA), the uses are well defined and uncertainty associated with the Exposure Scenarios is limited (this finding is supported by the data presented in the document). Minor differences in exposure conditions between facilities and companies occur occasionally and are described in the Exposure Scenarios. In such cases, exposure levels take account of the least stringent RMM/OC and greater release parameters to over-estimate the risk.

This exposure assessment provides reliable estimates of current work place exposure levels across the EU. Occupational work place exposure to hexavalent chromium [Cr(VI)] is regulated in most European countries. National Occupational Exposure Limits (OELs) across Europe respect a range of 8 hour *Time Weighted Average* (TWA) values between 1 $\mu g/m^3$ and 50 $\mu g/m^3$. The US *Occupational Safety and Health Administration* (OSHA) OEL is at 5 $\mu g/m^3$. In 2014, France introduced a new OEL of 1 $\mu g/m^3$. This is one of the most stringent OELs currently in place anywhere in the World and industry has invested substantial research and investment to continually reduce exposure to this level. Measurement data presented within the CSR are necessarily aggregated across several companies and over a period of several years. For countries in which the national OEL is lower than the exposure estimates shown in the following exposure scenario, companies are expected to comply with the national legislation by improved technical or personal Risk Management Measures (RMMs) or by demonstrating through work place exposure measurement data that they meet the national requirements.

The Carcinogens and Mutagens Directive (2004/37/EC) (hereafter referred to as Directive 2004/37/EC) requires each Member State to ensure employers reduce and replace use of Cr(VI) substances, and the introduction of a new OEL in France provides one clear example of regulation by Member States to effect a reduction in potential workplace exposure to Cr(VI). Industry is proactively engaged in delivering continuous reduction through the development and implementation of appropriate RMMs. Lip extraction on baths is one example of a type of Local Exhaust Ventilation (LEV) now commonly implemented to manage potential exposure to Cr(VI) across industry.

Best practice across the industry is continually improving, driven by general awareness of workplace hygiene and increasingly stringent regulatory requirements. This commitment to reducing exposure also reflects the widespread recognition that the use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers is critical for several industries and that alternatives are not available in the near-term. Potential workplace exposure to Cr(VI) has progressively reduced in recent years as the effectiveness and implementation of risk management measures has improved.

For this reason, the exposure assessment, based on both measured and modelled data, considers prevailing (rather than historic) practices so far as possible.

Operations in the use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers are very similar in nature, as can be seen from the Exposure Scenarios developed based on input from operators across the European industry. Even so, individual operators may implement different RMMs over various timeframes for their own reasons, reflecting considerations such as (but not limited to) the layout (and age) of the facility; the scale, frequency and duration of operations; the number of operators; the type of articles; and expenditure required.

9.0.1. Overview of uses and Exposure Scenarios

Tonnage information:

Assessed tonnage: 2.0 tonnes chromium trioxide/year based on:

- 2.0 tonnes chromium trioxide/year imported [containing approximately 1.0 tonne Cr(VI)]

The following table lists all the exposure scenarios (ES) assessed in this CSR.

Table 6. Overview of exposure scenarios and contributing scenarios

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
ES1 - IW1		Use at industrial site – Use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers. (ERC 6b) - Delivery and storage of raw material (PROC 1) - Decanting of liquids (PROC 8b) - Mixing - liquids (PROC 5) - Re-filling of baths~~- for concentration adjustment~~ (PROC 8b) - ~~Use of chromium trioxide for chemical conversion, sacrificial and slurry coating applications by aerospace companies and their suppliers~~ Surface treatment by immersion/dipping (PROC 13) - ~~Use of chromium trioxide for Slurry coating~~ Substance preparation and surface treatment by spraying in paint booth (PROC 8b, 7) - Surface treatment ~~(CCC)~~ by brushing/or pen-stick use (small areas parts) (PROC 10) - Maintenance of equipment (PROC 8a) - Infrequent maintenance activities (PROC 8a) - Sampling (PROC 8b) - Machining operations on small to medium sized parts containing Cr(VI) on an extracted bench/extraction booth including cleaning (PROC 21, 24) - Machining operations in large work areas on parts containing Cr(VI) including cleaning (PROC 21, 24) - Machining operations on parts containing Cr(VI) in small work	2.0 [1.0 Cr(VI)]

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
		areas including cleaning (PROC 21, 24) - Storage of articles (PROC 1) - Waste management (PROC 8b)	
Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)			

9.0.2. Introduction to the assessment

9.0.2.1. Environment

Scope and type of assessment

The current Chemical Safety Report (CSR) and the associated exposure scenarios (ES) are tailored to support the Application for Authorization (AfA) to continue use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers after the sunset date in September 2017. As described in the AoA, the specialty formulations covered by this application for authorisation of chromium trioxide are proprietary products manufactured by non-EU formulators and imported into the EEA for use on aerospace components. The supply chain for these products is not covered by other applications for authorizationt.

Chromium trioxide has been included in Annex XIV to Regulation (EC) No 1907/2006 ('REACH') due to its intrinsic properties as being carcinogenic (Carc. 1A) and mutagenic (Mut. 1B).

Following REACH, Article 62(4)(d), the CSR supporting an AfA needs to cover only those potential risks arising from the intrinsic properties specified in Annex XIV. Accordingly, only the potential human health risks related to the classification of chromium trioxide as a carcinogenic and mutagenic toxicant are considered in the current CSR. The dominating health effect resulting from the intrinsic hazardous properties of chromium trioxide is lung cancer due to inhalation of dust and/or aerosols. Intestinal cancer following ingestion is also identified as a potential risk: however, the dose-response relationship is lower than that for lung cancer, and ingestion is generally not considered an important exposure route for workers.

Evaluation of any potential hazards to the environment is not required within the framework of this authorisation application. Health hazards may potentially relate to Cr(VI) exposure of the general population via the environment, and are considered accordingly.

Measures to prevent or limit release of Cr(VI) to the environment are provided as best practice at facilities carrying out operations using chromium trioxide. During industrial surface treatment operations, prevention of releases of substances to the aquatic environment is a matter of good practice. Treatment technology (on-site or off-site) to reduce Cr(VI) to trivalent chromium [Cr(III)] in wastewater is generally highly effective, such that residual concentrations of Cr(VI) in effluent are very low and often non-detectable, and may be considered negligible. Solid and liquid waste containing Cr(VI) is collected and treated as hazardous waste where residual Cr(VI) can be effectively safely treated. In view of the risk management measures in place at the production facilities, emissions to the aquatic environment associated with industrial surface treatment operations are effectively prevented. Therefore, any potential risk for carcinogenicity due to exposure to chromium trioxide via the food chain is considered negligible.

Due to its low volatility, chromium trioxide will not normally be present in air. Nevertheless, energetic processes can release chromium trioxide into air. Except in case of very low content of Cr(VI) during occasional release (e.g. infrequent surface treatment using small quantities of Cr(VI) where exposure potential is very low), all workspaces with potential release to air are equipped with exhaust ventilation systems to remove residual particulates from workers breathing zone: exhaust air is passed through filters or wet scrubbers according to best available technique (minimum 99 % removal efficiency) before being released to atmosphere. While emissions to air are therefore very low, they have been considered in this assessment as a factor potentially contributing to Cr(VI) exposure of humans via the environment. The scope and type of the assessment of the pathway “man via the environment” is discussed in section 9.0.2.2 below.

Cr(VI) is neither directly nor indirectly released to soil and releases to soil are therefore considered negligible.

Table 7. Type of risk characterisation required for the environment

Protection target	Type of risk characterisation	Hazard conclusion (see section 7)
Freshwater	Not required	Not relevant
Sediment (freshwater)	Not required	Not relevant
Marine water	Not required	Not relevant
Sediment (marine water)	Not required	Not relevant
Sewage treatment plant	Not required	Not relevant
Air	Not required	Not relevant
Agricultural soil	Not required	Not relevant
Predator	Not required	Not relevant

<u>Comments on assessment approach:</u>

In accordance with REACH, Article 62(4)(d), potential risks to the environment need not be considered.

9.0.2.2. Man via environment

<u>Scope and type of assessment</u>

As discussed in 9.0.2.1., humans may potentially be exposed to chromium trioxide via the environment. Since strict emission control measures are implemented, releases to the aquatic environment (and also to soil), if any, are negligible, and the only relevant potential exposure path is inhalation of fine dust or particulates emitted from the facilities to air (see also “comments on assessment approach” below).

Within the current CSR, local concentrations (Clocal) from emissions to air from industrial use are modelled with EUSES 2.1.2., and expressed as Cr(VI).

The regional concentrations are reported in section 10.2.1.1 (see Table 40, “Predicted regional exposure concentrations (Regional PEC)”) based on modeling with EUSES 2.1.2., and expressed as Cr(VI).

Table 8. Type of risk characterisation required for man via the environment

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion (see RAC/27/2013/06 Rev.1)
Inhalation: Local long-term	Quantitative	Lung cancer: ELR = 2.9E−02 per 1 µg Cr(VI)/m³ for 70 years
Oral: Local long-term	Not needed. Assume all inhaled material is respirable (worst case).	Intestinal cancer: ELR = 8.0E−04 per 1 µg Cr(VI)/kg bw/d for 70 years

<u>Comments on assessment approach:</u>

The risk assessment for humans exposed via the environment is restricted to inhalation of airborne residues of chromium trioxide. The oral route (swallowing of the non-respirable fraction) does not need to be explicitly considered since:

(i) the exposure calculations (airborne concentrations) do not provide different particle size fractions (inhalable/thoracic/respirable);

(ii) the excess lifetime risk (ELR) for intestinal cancer is one order of magnitude lower than that for lung cancer. The assessment of health impacts is therefore dominated by the risk of lung cancer due to inhalation of Cr(VI);

(iii) the document on a reference dose-response relationship for Cr(VI) compounds (RAC/27/2013/06 Rev.1) states that "*in cases where the applicant only provides data for the exposure to the inhalable particulate fraction, as a default, it will be assumed that all particles were in the respirable size range.*"

Therefore, in accordance with the above findings and provisions on the risk assessment for humans exposed via the environment, since it is assumed that all particles are in the respirable size range hence no exposure via the oral route needs to be considered.

This constitutes a worst case approach, since the potential lung cancer risk is an order of magnitude higher compared to the potential intestinal cancer risk, based on the dose-response relationships agreed by RAC.

9.0.2.3. Workers

Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table based on the hazard conclusions presented in section 5.11.

Table 9. Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see RAC/27/2013/06 Rev.1)
Inhalation	Systemic long-term	Not needed	Not relevant
	Systemic acute	Not needed	Not relevant
	Local long term	Quantitative	Lung cancer: ELR = 4.0E−03 per 1 µg Cr(VI)/m³ for 40 years
	Local acute	Not needed	Not relevant
Dermal	Systemic long term	Not needed	Not relevant
	Systemic acute	Not needed	Not relevant
	Local long term	Not needed	Not relevant
	Local acute	Not needed	Not relevant
Eye	Local	Not needed	Not relevant

Comments on assessment approach related to toxicological hazard:

Chromium trioxide has been included into Annex XIV to Regulation (EC) No 1907/2006 ('REACH') due to its intrinsic properties as being carcinogenic (Carc. 1A) and mutagenic (Mut. 1B).

Following REACH, Article 62(4)(d), the CSR supporting an AfA needs to cover only those potential risks arising from the intrinsic properties specified in Annex XIV. The dominating health effect resulting from the intrinsic hazardous properties of chromium trioxide is lung cancer due to inhalation of dust and/or aerosols.

Exposure estimates generated by ART 1.5., or measured values are given in terms of Cr(VI) and are expressed as 8 hour Time Weighted Average (TWA).

The oral route (mucociliary clearance and swallowing of the non-respirable fractions) is not taken into account for the same reasons as already explained in the context of "man via environment" (section 9.0.2.1 above). In accordance with the RAC document on the dose-response relationship (RAC/27/2013/06 Rev.1) it has to be assumed that all particles are in the respirable size range. Hence no exposure via the oral route needs to be considered.

Comments on assessment approach related to physicochemical hazard:

Not relevant – physicochemical hazards are not subject of this CSR.

General information on risk management related to toxicological hazard:

Potential exposure of worker handling chromium trioxide during industrial use is restricted to the lowest possible level.

Aqueous solutions of chromium trioxide are expected to entail only a low potential for generating mists, not requiring Respiratory Protective Equipment (RPE). Nevertheless, protective clothing, chemical-resistant gloves, and goggles are mandatory for those tasks involving handling of the liquid formulation. When the formation of aerosols is likely in the chemical conversion and slurry coating processes and the covering of baths and LEV is not sufficient to minimize Cr(VI) exposure, adequate respiratory protection (e.g. half-face equipped with A2P3[1] filters) is worn additionally.

General information on risk management related to physicochemical hazard:

Not relevant – physicochemical hazards are not subject of this CSR.

9.0.2.4. Consumers

Exposure assessment is not applicable as there are no consumer-related uses for chromium trioxide.

9.1. Exposure scenario 1: Use at industrial site - Use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers

Use of chromium trioxide by aerospace companies and their suppliers within the scope of this document include chemical conversion and slurry coating applications. These coatings provide various critical functions (e.g. protecting the metal from corrosion, increasing wear resistance, providing an adhesive base, electrical and thermal properties, and chemical resistance).

Specifically, ~~it~~ the ES includes (~~but~~ is ~~not~~ limited to):

- Chemical conversion coating (CCC), which is a chemical process applied to a substrate producing a surface layer containing a compound of the substrate metal and other chemical species from the process solution.
- Slurry coatings including sacrificial coatings (which have a lower electrode potential than the substrate to be protected)) and diffusion coatings and paints (process based on the coating material diffusing into the substrate at high temperatures) for corrosion protection.

For conversion coatings, the main form of application is dipping or immersion of parts in a tank or through a series of tanks containing solutions in closed or open systems. The solution containing Cr(VI) additionally is applied by spraying and occasionally, by brush or with a pen-stick, especially to small localised areas.

Paint-type slurries used in slurry sacrificial and diffusion coatings are applied by standard air atomizing spraying, by dipping, swabbing or roller, then dried and cured in air at 260°C or above (chemical modifiers can be added to some coatings to reduce cure temperature to as low as 190°C).

Concentrations of Cr(VI) in the surface coating may be below or above detection levels. Machining operations, like fettling, drilling, riveting, edging, abrading, or sanding, might be necessary during industrial post-treatment of coated parts. Therefore, exposure to Cr(VI) dust during these activities is possible.

Operating conditions and risk management measures are specified to limit worker (inhalation and dermal) exposure to various components in the treatment solution and environmental exposure. LEV and coverage of baths during treatment are technical means to minimize concentrations of Cr(VI) and other components of treatment solutions in the workplace air. Personal Protective Equipment (PPE) is also specified to minimize potential inhalation and dermal exposure. Equipment is maintained regularly.

Workers are skilled, and receive regular training with regards to chemical risk management and how to properly wear the Personal Protective Equipment (PPE). Regular housekeeping is also in place and generally speaking, management systems are in place ensuring high standard of operational procedures.

Environment contributing scenario(s):	
Use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers	ERC6b
Worker contributing scenario(s):	
Delivery and storage of raw material	PROC 1
Decanting – liquids	PROC 8b
Mixing – liquids	PROC 5
Re-filling of baths – for concentration adjustment	PROC 8b
Use of chromium trioxide for chemical conversion, sacrificial and slurry coating applications by aerospace companies and their suppliersSurface treatment by immersion/dipping	PROC 13
Use of chromium trioxide for Slurry coating – Substance preparation and surface treatment by spraying in paint booth	PROC 8b, 7
Surface treatment (CCC) by brushing/or pen-stick use (small areas parts)	PROC 10
Maintenance of equipment	PROC 8a
Infrequent maintenance activities	PROC 8a
Sampling	PROC 8b
Machining operations on small to medium sized parts containing Cr(VI) on an extracted bench/extraction booth including cleaning	PROC 21, 24
Machining operations in large work areas on parts containing Cr(VI) including cleaning	PROC 21, 24
Machining operations on parts containing Cr(VI) in small work areas including cleaning	PROC 21, 24
Storage of articles	PROC 1
Waste management	PROC 8b

Subsequent service life exposure scenario(s):
Relevant for some applications only, as set out in Exposure Scenarios

Explanation on the approach taken for the ES

Occupational exposure estimates are based on measured data and/or on modelled data. Inhalation exposure has been estimated using the exposure model '*Advanced REACH Tool 1.5' or 'ART'*[2]. ART is a second tier model calibrated to assess exposure to inhalable dust, vapours, and mists; this Exposure Scenario is within the scope of ART. The figures obtained by modelling are considered to be worst-case estimates: supportive evidence for the conservative character of the modelled estimates is provided by comparison with relevant measured exposure data (measured concentrations of particulate residues of Cr(VI) in air), where available; such analysis indeed indicates that ART is a reasonable but conservative tool for estimating exposure of Cr(VI) in the scope of this assessment. Appropriate values for each model parameters haves been selected in close cooperation with directly

[2] The use of ART for workers exposure assessment under REACH is described in ECHA's updated Guidance on Information Requirements and chemical safety assessment R.14, Vers. 2, May 2010. Background information for ART are provided in: Fransman W., Cherrie J., van Tongeren M., Schneider T., Tischer M., Schinkel J., Marquart H., Warren, N.D., Spankie S., Kromhout H., Tielemans E. Development of a mechanistic model for the Advanced REACH Tool (ART). Version 1.5, January 2013.

involved companies from the aerospace and affiliated industries, as indicated elsewhere in this document.

Where the sample size and sampling strategy is adequate (i.e. personal sampling data), the risk characterisation relies on the measured exposure values; in other cases the results of the exposure modelling were used as adequate measurement data was not available.

The detailed Exposure Scenario has been developed based on information provided by multiple companies involved in this activity. Companies provided details of the conditions under which the activity was carried out as well as the duration and frequency of each task. This information was verified during visits of facilities carrying out the surface coating activities described here.

The frequency of a specific activity in the worker sub-scenarios is expressed as daily activity unless otherwise stated. As long-term exposure is the relevant period for long-term health effects, the duration of exposure per day as set out in the ES is expressed as average duration per day over a longer period (e.g. 2 hours each day are equal to 4 hours every second day). Therefore, the duration of exposure per day is not the same as the maximum allowed duration in any one day.

All sub-scenarios which are based on modelled values provide worst-case estimates using in general the highest exposure duration and the lowest level of personal protection reported. Therefore many companies will stay below the estimated exposure.

In view of the strict separation of the production facility from the wastewater stream any releases to the aquatic environment are essentially negligible. Chromium trioxide is contained within the preparation and the water used to rinse out the equipment and the treated article is collected and recycled or disposed of in specialist facilities. Additional on-site treatment of any waste containing Cr(VI) [reduction to Cr(III), vacuum evaporation], additionally ensures negligible release of Cr(VI) to water. This is reflected in the environmental contributing scenario below.

9.1.1. Environmental contributing scenario 1: Use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers

Cr(VI) releases to the environment are carefully controlled by industry and monitored by regulators.

Except in case of very low content of Cr(VI) during occasional release (e.g. infrequent surface treatment using small quantities of Cr(VI) where exposure potential is very low, air emissions relating to LEV or extraction systems are filtered (e.g. HEPA filter) or passed through wet scrubbers to remove particulates prior to release to atmosphere. Information from facilities indicates that removal efficiency of at least 99% is typical for industry. Companies regularly monitor and report Cr(VI) emissions as part of permit conditions. Releases are often beneath detection limits.

For the applications in the use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers described here, wastewater releases from the production facility are strictly controlled, i.e. there is only very low release of Cr(VI) to the aquatic environment, if any. Water in scrubbers or filters is generally recycled and occasionally replaced, with resulting material being treated as a waste in accordance with relevant waste management regulations.

Facilities may have on-site wastewater treatment facilities that act by vacuum evaporation or by reduction of Cr(VI) to Cr(III). The solids are precipitated and the supernatant is discharged from the site. These treatment processes are very efficient and concentrations of Cr(VI) in treated water is usually below detection limits.

Waste materials containing Cr(VI) are classified and treated as hazardous wastes according to EU and national regulations.

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
▪ Daily use at site: <= 0.0002 tonnes/day [as Cr(VI)]
▪ Annual use at a site: <= 0.05 tonnes/year [as Cr(VI)]
▪ Percentage of tonnage used at regional scale: = 33 %
Technical and organisational conditions and measures

▪ Air emission abatement: at least 99% efficiency. For operations where exposure potential is low [i.e. operations are infrequent using only small quantities of Cr(VI)] air emission abatement may not be required. ▪ Negligible discharge of Cr(VI) in wastewater from the site ▪ All solid and any liquid waste is collected and either the collected waste is directly forwarded to an external waste management company, or Cr(VI) in wastewater is reduced to Cr(III) on-site, or treated by vacuum evaporation. The treated wastewater is discharged to municipal sewage system. Any solid or slurry waste is either recycled or forwarded to an external waste management company (licenced contractor) for disposal as hazardous waste
Conditions and measures related to sewage treatment plant
▪ Not applicable – negligible discharge of Cr(VI) in wastewater from the site
Conditions and measures related to treatment of waste (including article waste)
▪ Collection of all solid and liquid waste, elimination of Cr(VI) from waste water, reuse disposal as hazardous waste by an external waste management company (licenced contractor)
Other conditions affecting environmental exposure
▪ When needed, exhaust air is passed through filters or wet scrubbers according to best available technique (minimum efficiency 99 %).

9.1.1.2. Releases

For the use of chromium trioxide containing formulations for chemical conversion and slurry coating applications by aerospace companies and their suppliers' activities, no specific air emission data (i.e. measurement of release to the atmosphere) were available. Facilities conducting these activities also have different other uses of chromium trioxide and chromates at the same facility and it is not possible to estimate the likely small contribution of chemical conversion and slurry coating applications on the total air emissions of the facilities. For that reason air emissions are conservatively estimated based on modelling with EUSES 2.1.2.

Significant loss of the substance as a gas or vapour will not occur as chromium trioxide has a high melting point and is of low volatility. Loss of the substance as a particulate is likely to be minimal as it is non-dusty. The ERC 6b release factor of 0.1% was selected as initial release factor representing an absolute worst-case and likely unrealistic assumption.

Air emissions relating to local exhaust ventilation (LEV) or extraction systems are filtered or passed through wet scrubbers to remove particulates prior to release to atmosphere. Information from facilities indicates that removal efficiency of at least 99% is typical for industry.

Therefore the final release factor is set to 0.001%. The maximum local tonnage estimate used for the local release rate is 0.2 kg/day; this is considered very conservative with respect to information provided by industry regarding annual tonnage used per site and the total tonnage of chromium trioxide in this use.

Table 10. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Air	Release factor	**Initial release factor:** 0.1% **Final release factor:** 0.001% **Local release rate:** 2E-6 kg/day

9.1.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 11. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	Not relevant	-
Sediment (freshwater)	Not relevant	-

Protection target	Exposure concentration	Risk characterisation
Marine water	Not relevant	-
Sediment (marine water)	Not relevant	-
Predator (freshwater)	Not relevant	-
Predator (marine water)	Not relevant	-
Top predator (marine water)	Not relevant	-
Sewage treatment plant	Not relevant	-
Air	**Local PEC:** 3.808E-10 mg/m³	-
Agricultural soil	Not relevant	-
Predator (terrestrial)	Not relevant	-
Man via Environment – Inhalation	**Local PEC:** 3.808E-10 mg/m³	Based on the dose-response relationship derived by the RAC, considering a 70 year exposure time (24h/day, 7d/week), the following excess lifetime risk up to age 89 is derived he general population is derived based on the estimated exposure: 1.1E-05 per 1000 exposed
Man via Environment - Oral	Not relevant	-

Conclusion on risk characterisation

The modelled $PEClocal_{air,ann}$ of 3.808E-10 mg Cr(VI)/m³ mg/m³ is estimated as sum of $Clocal_{air,ann}$ and $PECregional_{air}$ and used as the basis for risk characterisation for man via the environment.

Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 70 year exposure time (24h/day, 7d/week), the following excess lifetime lung cancer mortality risk for the general population is derived based on the estimated exposure:

1.1E-05 per 1000 exposed.

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

9.1.2. Worker contributing scenario 1: Delivery and storage of raw material (PROC 1)

Formulations containing chromium trioxide are delivered as aqueous solution in sealed containers and stored in a chemical storage room. There is no potential for worker exposure.

9.1.2.1. Conditions of use

	Method
Product (article) characteristics	
▪ Substance as such/in a mixture Concentration of Cr(VI): < 25%	Qualitative
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 1 hour ▪ Frequency of activity: infrequent	Qualitative
Technical and organisational conditions and measures	
▪ General ventilation: Basic general ventilation (1-3 air changes per hour)	Qualitative

	Method
▪ Containment: Closed system (minimal contact during routine operations)	Qualitative
▪ Local exhaust ventilation: No	Qualitative
▪ Occupational Health and Safety Management System: Advanced	Qualitative
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	Qualitative
Other conditions affecting workers exposure	
▪ Place of use: Indoor	Qualitative
▪ Process temperature (for liquids and solids): Room temperature	Qualitative

9.1.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 12. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	**0 µg/m^3**	Based on the dose-response relationship derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime risk up to age 89 is derived based on the estimated exposure: 0 per 1000 exposed workers

Conclusion on risk characterisation

There is no potential for exposure. The qualitatively determined exposure estimate of 0 µg Cr(VI)/m³ is used as the basis for risk characterisation.

An excess lifetime risk of 0 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship.

9.1.3. Worker contributing scenario 2: Decanting of liquids (PROC 8b)

The formulations containing chromium trioxide may be decanted in (smaller) containers for re-filling of ~~CCC~~ baths or for further ~~pre-~~mixing. This may be conducted under exhaust ventilation or increased mechanical room ventilation but is not considered for modelling.

9.1.3.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: < 25%	ART 1.5
▪ Process temperature: Room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low[3]	ART 1.5

[3] The viscosities of the formulations in scope of this dossier are characterized as low viscosity. In addition, this is the most conservative (worst case) option in the ART model.

	Method
Activity emission potential	
▪ Duration of activity: < 15 min ▪ Frequency of activity: 1 time/week (reduction factor of 0.2 applied	ART 1.5 ART 1.5 (extended) [4]
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Falling liquids	ART 1.5
▪ Situation: Transfer of liquid product with flow of 1–10 l/min	ART 1.5
▪ Containment level: Handling that reduces contact between product and adjacent air.	ART 1.5
▪ Loading type: Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.3.2. Exposure and risks for workers

[4] The exposure model ART 1.5 does not include protection factors for the use of respiratory protection and no option to account for activities which do not take place every working day. Because these are important factors to be considered in the assessment of long-term exposure, the ART model has been extended by incorporating both parameters in the calculation of the final exposure estimate, where appropriate.

Table 13. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		
ART model output	1.3 µg/m³ (90th percentile value)	
Further adjusted for frequency	**0.26 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure 1.04 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.26 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure[5].

An excess lifetime lung cancer risk of 1.04 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

9.1.4. Worker contributing scenario 3: Mixing - liquids (PROC 5)

The aqueous solution may be ~~pre-~~mixed before re-filling of ~~(e.g. CCC)~~ baths.

9.1.4.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: < 25%	ART 1.5
▪ Process temperature: Room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low[3]	ART 1.5
Activity emission potential	

[5] These include:

- highest reported exposure duration for each task (whereas the exposure duration is normally lower)
- highest reported frequency of exposure for each task (whereas the frequency is normally less)
- minimum reported RMM (e.g. automation, enclosure, extract ventilation, use of mist suppressant) to reduce exposure
- lowest level of personal protection reported
- use of the 90th percentile value as representative for the exposure situation.

	Method
▪ Duration of activity: < 30 min ▪ Frequency of activity: 1 time/week (reduction factor of 0.2 applied)	ART 1.5 ART 1.5 (extended)
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Activities with undisturbed surfaces (no aerosol formation)	ART 1.5
▪ Situation: Open surface < 0.1 m²	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.4.2. Exposure and risks for workers

Table 14. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		
ART model output	0.64 µg/m³ (90th percentile value)	
Further adjusted for frequency	**0.13 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.51 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.13 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.51 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

9.1.5. Worker contributing scenario 4: Re-filling of baths ~~for concentration adjustment~~ (PROC 8b)

The chromium trioxide solution or slurry is transferred to and manually filled into the ~~CCC~~ bath. In the case of conversion coating, this may be completed for adjustment of the concentration in the bath. In the case of slurry coating, this is completed for refilling of the bath. This scenario covers as worst-case similar activities in which a complete emptying and re-filling of a bath is conducted (without LEV) - only rarely needed (less than 1 time per year).

9.1.5.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: < 25%	ART 1.5
▪ Process temperature: Above room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low[3]	ART 1.5
Activity emission potential	
▪ Duration of activity: < 10 min ▪ Frequency of activity: 1 time/week (reduction factor of 0.2 applied)	ART 1.5 ART 1.5 (extended)

	Method
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Falling liquids	ART 1.5
▪ Situation: Transfer of liquid product with flow of 10 –100 l/min	ART 1.5
▪ Containment level: Open process	ART 1.5
▪ Loading type: Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: Fixed capturing hood (90.00 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.5.2. Exposure and risks for workers

Table 15. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		
ART model output	0.95 µg/m³ (90th percentile value)	
Further adjusted for frequency	**0.19 µg/m³** (ART 1.5 prediction, 90th percentile value)	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.76 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.19 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.76 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

9.1.6. Worker contributing scenario 5: ~~Use of chromium trioxide for chemical conversion coating, sacrificial and slurry coating applications by aerospace companies and their suppliers~~ Surface treatment by immersion/dipping (PROC 13)

Use of chromium trioxide for chemical conversion coating applications~~, for example,~~ by aerospace companies and their suppliers by dipping/immersion is conducted in sequential process steps within a series of tanks that contain treatment, cleaning and other related solutions.

Before treatment, parts are prepared by degreasing, stripping, rinsing in several bathes. Lifting tools (hoists and racks) are used to move the parts which are placed on tools from one tank to another one. There is no direct exposure to Cr(VI) but workers could be exposed as they are stand up near the CCC bath during parts preparation.

The parts are then placed in the CCC bath through the upper opened surface of the tank and ~~immerged~~immersed. The liquid is tempered up to 30°C. Workers are potentially exposed to Cr(VI) as they are near the bath during parts CCC process. However, due to the type of coating process, no aerosol development is expected and exposure potential therefore is low.

Finally, articles and tools are removed from the bath using the lifting tools, drained above the bath during few seconds and then rinsed in several water tanks. Then articles are dried before to be removed from the tools and demasked. Workers are potentially exposed to Cr(VI) as they are near the bath during removals tasks. However, due to the type of coating process, no aerosol development is expected and exposure potential therefore is low.

~~Cleaning of equipment is not a separate task but conducted by those employees working in the bath area as part of their normal working procedure. For very small baths, a special vacuum cleaner is used each time in the normal process.~~

The CCC baths containing Cr(VI) are equipped with extract ventilation during the treatment process. Baths might be covered or partially covered.

Slurry coatings are occasionally applied by dipping/immersion in a single bath containing the coating formulation at ambient temperature. The process involving chromium trioxide for slurry coating is the same as that for CCC; there is no pre-treatment for slurry coating, but as these pre-treatment steps do not involve use of chromium trioxide this difference is not significant in terms of this AfA. The articles are placed in and removed from the bath using lifting tools, as is the case for conversion coating. The baths containing Cr(VI) are equipped with extract ventilation during the treatment process. As described above, workers are potentially exposed to Cr(VI) as they are near the bath during removal tasks. However, due to the type of coating process, no aerosol development is expected and exposure potential therefore is low. There are no substantive differences in this process when it is completed for chemical conversion and slurry coating.

For both slurry and CCC, cleaning of equipment is not a separate task but conducted by those employees working in the bath area as part of their normal working procedure. For very small baths, a special vacuum cleaner is used each time in the normal process.

9.1.6.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: Small (1 - 5%)	ART 1.5
▪ Process temperature: Above temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low[3]	ART 1.5
Activity emission potential	

	Method
▪ Duration of activity: < 1 h	ART 1.5
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Activities with relatively undisturbed surfaces (no aerosol formation)	ART 1.5
▪ Situation: Open surface 1 - 3 m²	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: Fixed capturing hood (90.00 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.6.2. Exposure and risks for workers

Table 16. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	0.023 µg/m³ (ART 1.5 prediction, 90th percentile value)	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.092 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.023 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.092 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

9.1.7 Worker contributing scenario 6: ~~Use of chromium trioxide for Slurry coating -~~ Substance preparation and surface treatment by spraying in paint booth (PROC 8b, 7)

Slurry coatings (and occasionally CCC) are applied by HVLP spray gun. Following mixing/agitation of the sealed drum containing the proprietary slurry (<5% w/w chromium trioxide) or conversion coating (<1~~5~~% w/w chromium trioxide), the paint gun is filled and the coating applied by spraying. The activity is carried out in a paint spray booth that is supplied with exhaust ventilation. The flow of air through the booth should be evenly distributed and the average cross draft velocity over the horizontal cross section should be no less than 100 feet per minute when the exhaust bank of filters are loaded to the manufacturer's recommended maximum pressure drop. The worker is supplied with a full-face mask with air supply or half-face mask with P3 filter. The article is cured in an air circulating oven at high temperature. The oven may be vented and all wastewater, including from cleaning the gun and booth, is segregated. The cured coating contains no Cr(VI). This application might be repeatedly conducted during one shift.

9.1.7.1 Conditions of use

9.1.7.1.1 Mix coating ~~slurry~~

The worker mixes the components of the preparation with the ~~convenient~~ appropriate ratio, as applicable. The substances are mixed mechanically using a specific mixer (e.g. see Fig. 1). The preparation is made in a special area (e.g. laboratory) near the paint booth.

Fig. 1: Preparation and mixing of substances.

	Method
Product (article) characteristics	
▪ Substance in a mixture ▪ Concentration of Cr(VI): < 1-5 %[6]	Measurement data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 5 min	Measurement data
Technical and organisational conditions and measures	
▪ General ventilation: Good natural ventilation	Measurement data
▪ Local exhaust ventilation: Yes	Measurement data
▪ Occupational Health and Safety Management System: Advanced	Measurement data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	Measurement data
Other conditions affecting workers exposure	
▪ Place of use: Indoor	Measurement data
▪ Process temperature: Room temperature	Measurement data

[6] Concentration of Cr(VI) is <5% and may be <1%. For the purpose of modelling, a concentrations range of 1-5% was selected to be conservative.

9.1.7.1.2 Filling of paint gun

The worker fills the hand-paint gun after filtration of the mixture with a specific particulate filter mesh, volume of ~~paint~~ coating is about 100 ml (compare Fig. 2).

Fig. 2: Filling of the hand-paint gun.

	Method
Product (article) characteristics	
▪ Substance in a mixture Concentration of Cr(VI): < 1-5 %[5]	Measurement data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 5 min	Measurement data
Technical and organisational conditions and measures	
▪ General ventilation: Good natural ventilation	Measurement data
▪ Local exhaust ventilation: No	Measurement data
▪ Occupational Health and Safety Management System: Advanced	Measurement data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: Yes, at least half-face mask with P3 filter	Measurement data
Other conditions affecting workers exposure	
▪ Place of use: Indoor	Measurement data
▪ Process temperature: Room temperature	Measurement data

9.1.7.1.3 Masking and degreasing

Before ~~paint~~ application, surfaces not to be ~~painted~~ coated are masked by application of a masking tape. During maintenance or repair (as opposed to production), ~~T~~the ~~other~~ parts ~~must~~ may be sandblasted and degreased to remove existing surface coating. The worker is outside the closed sandblasting cabin. The worker could be exposed to ~~paint~~ dust during the opening and closure of cabin doors. Also see the following picture (Fig. 3).

Fig. 3: Preparation of the ~~painting~~ coating process: Masking and sandblasting.

	Method
Product (article) characteristics	
▪ Substance in a mixture Concentration of Cr(VI): < 1-5 %[5]	Measurement data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 5 min	Measurement data
Technical and organisational conditions and measures	
▪ General ventilation: Good natural ventilation	Measurement data
▪ Local exhaust ventilation: No	Measurement data
▪ Occupational Health and Safety Management System: Advanced	Measurement data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: Yes, at least half-face mask with P3 filter	Measurement data
Other conditions affecting workers exposure	
▪ Place of use: Indoor	Measurement data
▪ Process temperature: Room temperature	Measurement data

9.1.7.1.4. Spraying in paint booth

The ~~paint~~ coating is sprayed by the worker using a hand-held gun within an open or closed booth. The picture below shows an example of an open paint booth which is in a work area segregated from other areas. Mechanical exhaust ventilation is present in the workshop (area). Specific local exhaust ventilation is installed in the booths, each equipped with HEPA filters. Paint booths with an open front are furthermore equipped with a water curtain. Open paint booths are in a separate area, accessible through a door. The ~~paint~~ coating is applied in several layers until the specific thickness is reached. The ~~painting~~ coating process is shown in the picture below (Fig. 4).

Fig. 4: Manual ~~painting~~ application of several coating layers in open paint booth.

	Method
Product (article) characteristics	
▪ Substance in a mixture Concentration of Cr(VI): < 1-5 %[5]	Measurement data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 30 min	Measurement data
Technical and organisational conditions and measures	
▪ General ventilation: Good natural ventilation	Measurement data
▪ Local exhaust ventilation: Yes	Measurement data
▪ Occupational Health and Safety Management System: Advanced	Measurement data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: yes, at least half-face mask with P3 filter	Measurement data
Other conditions affecting workers exposure	
▪ Place of use: Spray room/Paint booth	Measurement data
▪ Process temperature: Room temperature	Measurement data

9.1.7.1.5 Article drying

Articles are allowed to dry off for 15 minutes under ambient conditions or at around 80°C-150°C in a specific oven and then ~~are~~ may be moved (e.g. by an automatic hoist) from the paint booth to the curing oven.

	Method
Product (article) characteristics	
▪ Substance in a mixture Concentration of Cr(VI): residual	Measurement data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 15 min	Measurement data
Technical and organisational conditions and measures	
▪ General ventilation: Good natural ventilation	Measurement data
▪ Local exhaust ventilation: No	Measurement data
▪ Occupational Health and Safety Management System: Advanced	Measurement data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: Yes, at least half-face mask with P3 filter	Measurement data
Other conditions affecting workers exposure	

	Method
▪ Place of use: Indoor	Measurement data
▪ Process temperature: High	Measurement data

9.1.7.1.6 Article curing

Following slurry coating, ~~A~~articles are cured at high temperature (500-650ºC) in an oven for up to around three hours. No workers are present. Articles are moved by an automatic hoist from the paint booth to the oven, and from the oven to the storage area. This task is not relevant for CCC.

	Method
Product (article) characteristics	
▪ Substance in a mixture Concentration of Cr(VI): residual	Measurement data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 180 min	Measurement data
Technical and organisational conditions and measures	
▪ General ventilation: Good natural ventilation	Measurement data
▪ Local exhaust ventilation: No	Measurement data
▪ Occupational Health and Safety Management System: Advanced	Measurement data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	Measurement data
Other conditions affecting workers exposure	
▪ Place of use: Indoor	Measurement data
▪ Process temperature: High	Measurement data

9.1.7.1.7 Tools cleaning (spray cabin)

Paint guns and tools are cleaned with water or solvent in a specific area of the spray room /booth by the worker who conducted spraying under exhaust extraction. Waste material eliminated in a specific tank for contaminated waste.

	Method
Product (article) characteristics	
▪ Substance in a mixture Concentration of Cr(VI): < 1-5 %[5]	Measurement data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 15 min	Measurement data
Technical and organisational conditions and measures	
▪ General ventilation: Good natural ventilation	Measurement data
▪ Local exhaust ventilation: Yes	Measurement data
▪ Occupational Health and Safety Management System: Advanced	Measurement data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: Yes, at least half-face mask with P3 filter	Measurement data
Other conditions affecting workers exposure	
▪ Place of use: I Spray room/Paint booth	Measurement data
▪ Process temperature: Room temperature	Measurement data

9.1.7.2 Exposure and risks for workers

Twenty-eight personal sampling data from 2012-2015 in five EU countries are available from six companies (see Annex A). These data relate to slurry coating processes. These measurement data cover the whole process, including all the steps described above. The exposure assessment is based on these data. In five of the six companies, all measurement results were below the LOD of the respective measurement. As the concentration of Cr(VI) in CCC formulations is less than 1% w/w (compared to less than 5% w/w in slurry coatings), CCC operations are carried out far less frequently and there are no significant differences in other relevant exposure parameters, the measurement data for slurry coatings can be considered conservatively representative of CCC spraying processes.

Individual company data have been comprehensively evaluated. The number of sampling data provided by each of the companies varied (e.g. different number of measurements conducted, different number of years reported), so the data were aggregated per company in the first instance. In a second step, data were aggregated across all the companies that provided data, giving equal weight to each company in the data set.

The estimation below therefore considers already the effectiveness of local exhaust ventilation (reflected by the measured values).

All estimations do not account for varying duration of exposure and frequency of exposure through the different companies but assume to reflect full-shift exposure on a daily basis as worst case.

The effectiveness of respiratory protection was assessed using the company information on type of mask and filter used and, if available, the APF provided by the manufacturer of the RPE. In a few cases the protection factors (APFs) for the RPE were not provided by the manufacturer. Here the APF determined according to the *German BG rule "BGR/GUV-R190"* from December 2011 have been used[7].

The exposure concentrations and RCR are reported in the following table.

Table 17. Exposure concentrations and risks for workers – inhalation, local, long-term

	N*	NC**	Arithmetic Mean (NC)	Geometric Mean (NC)	90th Percentile (NC)	RCR
Measurement results	**28**	**6**	**5.09 µg/m³**	**2.04 µg/m³**	**11.06 µg/m³**	
Accounting for RPE	**28**	**6**	**0.09 µg/m³**	**0.01 µg/m³**	**0.27 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 1.08 per 1000 exposed workers

* N = number of data from personal sampling data
** NC = number of **aggregated** company data (see text)

Conclusion on risk characterisation

The 90th percentile value of the personal sampling data adjusted for respiratory protection of 0.27 µg Cr(VI)/m³ is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 1.08 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

9.1.8. Worker contributing scenario 7: Surface treatment ~~(CCC)~~ by brushing or pen-

[7] The BGR/GUV-R190 rule was selected because it is published, transparent and provides a robust basis for respiratory protection assessment and, if so necessary, adaptation.

stick use (small sized areas) (PROC 10)

For small sized areas, CCC or slurry coating might be conducted by brushing or by use of a pen-stick. This task concerns localized treatments on surfaces with electrical current or not (new parts needing a localized treatment, new parts needing a repair due to defects in bath production, or worn parts in service needing to be repaired). It concerns production and maintenance technicians. For the purpose of the exposure assessment, it has been assumed that it will be carried out 1 h/day every day.

9.1.8.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: Small (1 - 5%)	ART 1.5
▪ Process temperature: Room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low[3]	ART 1.5
Activity emission potential	
▪ Duration of activity: < 60 min	ART 1.5
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Spreading of liquid products	ART 1.5
▪ Situation: Spreading of liquids at surfaces or work pieces < 0.1 m² / hour	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.8.2. Exposure and risks for workers

The exposure concentrations and RCR are reported in the following table.

Table 18. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	**0.23 µg/m³** (ART 1.5 prediction, 90th percentile value)	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.92 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.23 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.92 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate .

9.1.9. Worker contributing scenario 8: Maintenance of equipment (PROC 8a)

Worker in the maintenance department are responsible for maintenance (incl. control) and repair. For more regular maintenance of the baths and related equipment (e.g. LEV, pumps, panels etc.), it is conservatively assumed that it will happen for 60 minutes one time every two weeks. Regular maintenance is conducted when the bath solutions are at ambient temperature. Worst case assumption for potential inhalation exposure for this activity is that these workers would be exposed to the same level of Cr(VI) as workers conducting the CCC processes (i.e. assuming a background concentration of Cr(VI) within the work area equivalent to that present during CCC (see WCS 5), even if no CCC takes place) and that LEV is off. Adequate PPE is always worn (protective clothing, chemical-resistant gloves, goggles).

9.1.9.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: Small (1 - 5%)	ART 1.5
▪ Process temperature: Room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low[3]	ART 1.5
Activity emission potential	
▪ Duration of activity: < 60 min ▪ Frequency of activity: 1 time/2 weeks (reduction factor of 0.1 applied)	ART 1.5 ART (extended)
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Activities with relatively undisturbed surfaces (no aerosol formation)	ART 1.5
▪ Situation: Open surface 1 - 3 m²	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.9.2. Exposure and risks for workers

Table 19. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		
ART model output (WCS 5)	0.023 µg/m³ (90th percentile value)	
Further adjusted for frequency	**2.3E-3µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 9.2E-3 per 1000 exposed workers

__**Conclusion on risk characterisation**__

The modelled exposure estimate (ART 1.5) of 2.3E-03 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 9.2E-03 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

9.1.10. Worker contributing scenario 9: Infrequent maintenance activities (PROC 8a)

Maintenance activities on equipment like the exhaust system or the removal and replacement of filters may need more time and might create higher exposure potential. As worst case for these activities, the model below provides exposure estimates for the removal and replacement of filters that is assumed to be conducted one time per month with a duration up to 4 hours. The model also applies a maximum concentration level of chromium trioxide [and so Cr(VI)]. In most cases, the concentration will be much lower.

9.1.10.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Powders, granules or pelletised material	ART 1.5
▪ Dustiness: Fine Dust	ART 1.5
▪ Moisture content: Dry product (< 5 % moisture content)	ART 1.5
▪ Powder weight fraction [Cr(VI)]: Small (1 - 5%)	ART 1.5
Activity emission potential	
▪ Duration of activity: 240 min	ART 1.5
▪ Frequency of activity: 1 time/month (reduction factor of 0.05 applied)	ART 1.5 (extended)
▪ Activity class: Handling of contaminated solid objects or paste	ART 1.5
▪ Situation: Handling of objects with visible contamination (object covered with fugitive dust from surrounding dusty activities)	ART 1.5

	Method
▪ Handling type: Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner.	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: Yes [Respirator with APF 30] [Effectiveness Inhal: 96.67%] *During maintenance activities at least half-mask with A2P3 filter (APF 30 according to German BG rule 190) is worn*	ART 1.5 (extended)

9.1.10.2. Exposure and risks for workers

Table 20. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		
ART model output	53.0 µg/m³ (90th percentile value)	
Further adjusted for frequency and RPE	**0.088 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.35 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.088 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.35 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

9.1.11. Worker contributing scenario 10: Sampling (PROC 8b)

One or more samples are drawn at the bath(s) and then transferred in a closed flask to the laboratory. It is conservatively assumed that sampling is conducted one time per week.

9.1.11.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: Small (1 - 5%)	ART 1.5
▪ Process temperature: Room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low[3]	ART 1.5
Activity emission potential	
▪ Duration of activity: < 30 min ▪ Frequency of activity: 1 time/week (reduction factor of 0.2 applied)	ART 1.5 ART 1.5 (extended)
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Activities with relatively undisturbed surfaces (no aerosol formation)	ART 1.5
▪ Situation: Open surface 1 - 3 m²	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: Fixed capturing hood (90.00 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.11.2. Exposure and risks for workers

Table 21. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		
ART model output	0.011 µg/m³ (90th percentile value)	
Further adjusted for frequency	**2.2E-3 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 8.8E-3 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 2.2E-3 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 8.8E-3 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

9.1.12. Worker contributing scenario 11: Machining operations on small to medium sized parts containing Cr(VI) on an extracted bench/extraction booth including cleaning (PROC 21, 24)

This scenario only applies to such surface treatment applications which result in the presence of residual Cr(VI) concentrations on the final product.

During assembly maintenance and/or repair small to medium sized solid parts are drilled, fettled, abraded, sanded or cut on a dedicated work bench fitted with air extraction. Cleaning due to contamination during the machining process is included in this scenario because it is conducted under the same operational conditions and risk management measures as the machining activities.

This scenario covers also machining operations with a longer duration of activity but with a higher level of respiratory protection, e.g. by using a full face mask with P3 filter (APF 400).

The Cr(VI) weight fraction of the part is assumed to be < 0.1 %. In case of lower or higher Cr(VI) content, estimated exposure would be reduced or increased in a linear way. If needed, OCs and RMMs could be adjusted for that different situation.

9.1.12.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Solid object	ART 1.5
▪ Solid weight fraction: < 0.1 %	ART 1.5
▪ Solid material: Stone (as worst-case for metal)	ART 1.5
▪ Moisture content: Dry product (<5 % moisture content)	ART 1.5
Activity emission potential	
▪ Duration of activity: < 60 min	ART 1.5
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Fracturing and abrasion of solid objects	ART 1.5
▪ Situation: Mechanical treatment / abrasion of small sized surfaces	ART 1.5
▪ Containment level: Open process	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Equipment level: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: Fixed capturing hood /Vacuum cleaner (HEPA filter with at least 99.00 % reduction)	ART 1.5 (extended)
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: Yes [Respirator with APF 30] [Effectiveness Inhal: 96.67 %] *At least half or quarter mask with P3 filter (APF 30 according to German BG rule 190) is worn if workplace monitoring data do not confirm negligible exposure clearly below 1 µg/m³ (e.g. < 0.1 µg/m³)*	ART 1.5 (extended)

9.1.12.2. Exposure and risks for workers

Table 22. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		
ART model output	0.38 µg/m³ (90th percentile value)	
Further adjusted for RPE	**0.013 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.05 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.013 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.05 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate .

9.1.13. Worker contributing scenario 12: Machining operations in large work areas on parts containing Cr(VI) including cleaning (PROC 21, 24)

This scenario only applies to such surface treatment applications which result in the presence of residual Cr(VI) concentrations on the final product.

Solid parts are manually drilled, riveted, fettled, abraded, sanded or cut outside a booth in large work areas. Cleaning after machining is included in this scenario because it is conducted under the same operational conditions and risk management measures as the machining activities.

This scenario covers also machining operations with a longer duration of activity but with a higher level of respiratory protection, e.g. by using a full face mask with P3 filter (APF 400).

The Cr(VI) weight fraction of the part is assumed to be < 0.1 %. In case of lower or higher Cr(VI) content, estimated exposure would be reduced or increased in a linear way. If needed, OCs and RMMs could be adjusted for that different situation.

9.1.13.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Solid object	ART 1.5
▪ Solid weight fraction: < 0.1 %	ART 1.5

	Method
▪ Solid material: Stone (as worst-case for metal)	ART 1.5
▪ Moisture content: Dry product (<5 % moisture content)	ART 1.5
Activity emission potential	
▪ Duration of activity: < 30 min	ART 1.5
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Fracturing and abrasion of solid objects	ART 1.5
▪ Situation: Mechanical treatment / abrasion of small sized surfaces	ART 1.5
▪ Containment level: Open process	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Large workrooms only	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: Wetting at the point of release/on-tool extraction (90.00 % reduction)/ vacuum cleaning	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: 10 air changes per hour (ACH)	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: Yes [Respirator with APF 30] [Effectiveness Inhal: 96.67 %] *At least half or quarter mask with P3 filter (APF 30 according to German BG rule 190) is worn if workplace monitoring data do not confirm negligible exposure clearly below 1 µg/m³ (e.g. < 0.1 µg/m³)*	ART 1.5 (extended)

9.1.13.2. Exposure and risks for workers

Table 23. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		
ART model output	0.83 µg/m³ (90th percentile value)	
Further adjusted for RPE	**0.028 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.11 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.028 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.11 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate**.**

9.2.14. Worker contributing scenario 13: Machining operations on parts containing Cr(VI) in small work areas including cleaning (PROC 21, 24)

Parts are drilled, riveted, fettled, abraded, sanded or cut in comparable small work areas. Cleaning after machining is included in this scenario because it is conducted under the same operational conditions and risk management measures as the machining activities.

In small work areas, no air extraction or other localised controls (e.g. wetting, vacuum cleaning) may be available. This scenario assumes the absence of any localised control.

The Cr(VI) weight fraction of the part is assumed to be < 0.1 %. In case of lower or higher Cr(VI) content, estimated exposure would be reduced or increased in a linear way. If needed, OCs and RMMs could be adjusted for that different situation.

9.1.14.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Solid object	ART 1.5
▪ Solid weight fraction: < 0.1 %	ART 1.5
▪ Solid material: Stone (as worst-case for metal)	ART 1.5
▪ Moisture content: Dry product (< 5 % moisture content)	ART 1.5
Activity emission potential	

	Method
▪ Duration of activity: < 30 min	ART 1.5
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Fracturing and abrasion of solid objects	ART 1.5
▪ Situation: Mechanical treatment / abrasion of small sized surfaces	ART 1.5
▪ Containment level: Open process	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Small workrooms only	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: Yes [Respirator with APF 400] [Effectiveness Inhal: 99.75%] *Full face mask with P3 filter (APF 400 according to German BG rule 190) is worn if workplace monitoring data do not confirm negligible exposure clearly below 1 µg/m³ (e.g. < 0.1 µg/m³)* ▪ Dermal Protection: Yes [Protective clothing, chemical-resistant, impermeable gloves (e.g. nitrile rubber gloves with a minimum layer thickness of 0.11 mm and a break through time of at least 480 min), goggles]	ART 1.5 (extended)

9.1.14.2. Exposure and risks for workers

Table 24. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		
ART model output	32 µg/m³ (90^{th} percentile value)	
Further adjusted for RPE	**0.08 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.32 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.08 µg Cr(VI)/m³ is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure (see footnote 5).

An excess lifetime risk of 0.32 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

9.1.15. Worker contributing scenario 14: Storage of articles (PROC 1)

The finished articles are stored in a separate storage area. There is no potential for inhalation exposure.

9.1.15.1. Conditions of use

	Method
Product (article) characteristics	
• Concentration of substance Cr(VI) in article: Non detectable or very low	Qualitative
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	Qualitative
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	Qualitative
• Local exhaust ventilation: No	Qualitative
• Occupational Health and Safety Management System: Advanced	Qualitative
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No	Qualitative
Other conditions affecting workers exposure	
• Place of use: Indoor/outdoors	Qualitative
• Process temperature (for solids): ambient	Qualitative

9.1.15.2. Exposure and risks for workers

The exposure concentrations and RCR are reported in the following table.

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	**0 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0 per 1000 exposed workers

Conclusion on risk characterisation

There is no potential for exposure. The qualitatively determined exposure estimate of 0 µg Cr(VI)/m³ is used as the basis for risk characterisation.

An excess lifetime lung cancer risk of 0 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

9.1.16.1. Worker contributing scenario 15: Waste management (PROC 8b)

Very low amounts of Cr(VI), if any, are released from wastewater treatment systems. There is no potential of inhalation exposure from the wastewater treatment systems because sampling before discharging to public sewage system is a short-term activity and the concentration of Cr(VI) is very low if detectable at all. Therefore, potential of inhalation exposure and risk is assessed as negligible and is not further assessed.

Other process waste (e.g. empty containers, canisters, pencils, masking material) are stored in closed containers which further are collected by licensed waste management companies for treatment, incineration and disposal of incineration residues to licensed landfills.

The scenario below describes the transfer of such type of waste to the storage area.

9.1.16.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Powders, granules or pelletised material	ART 1.5
▪ Dustiness: Firm granules, flakes or pellets	ART 1.5
▪ Moisture content: Dry product (< 5 % moisture content)	ART 1.5
▪ Powder weight fraction [Cr(VI)]: Small (1 – 5%)	ART 1.5
Activity emission potential	
▪ Duration of activity: < 15 min	ART 1.5
▪ Activity class: Handling of contaminated solid objects or paste	ART 1.5
▪ Situation: Handling of objects with limited residual dust (thin layer visible)	ART 1.5
▪ Handling type: Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner.	ART 1.5

	Method
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Any size workroom	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.16.2. Exposure and risks for workers

Table 25. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	**0.037 µg/m³** (ART 1.5 prediction, 90th percentile value)	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.15 per 1000 exposed workers

Conclusion on risk characterisation

The modelled exposure estimate (ART 1.5) of 0.037 µg/m³ Cr(VI) is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.15 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

9.1.17. Worker contributing scenario 16: End of Life

All aircraft parts, at end of life, must, as part of aviation requirement (AMC 145.A.42; AMC M.A. 504 (d)(2) and AMC M.A. 504 (e)) to avoid suspect unapproved parts, be destroyed to avoid reuse. At the end of life, parts are collected in designated, secure boxes and sent to a licensed scrap dealer who treats the metals according to EU and national requirements. The aerospace industry has specialist waste contractors familiar with these requirements.

All other parts, at end of life, are collected and sent to a licensed scrap dealer or waste contractor who treats the metals according to EU and national requirements.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

Workers in the process of use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers could conduct some combinations of tasks (sub-scenarios). The core activities will be the sequential process steps of the application in baths and the slurry coating processes.

For most ancillary activities, exposure estimates have been prepared by modeling. By nature, the exposure models used provide worst-case estimates in order to be assuredly conservative and to apply across a broad range of activities and situations. Accordingly, modeling may provide results that are so over-conservative as to be rather unrealistic, depending on the basic assumptions of the model and the specificity, the quality and the currency of the underlying model database.

Furthermore, taking into account the various details of processes carried out and risk management measures applied by different companies, each of the sub-scenarios represents a worst-case scenario by using the lowest level of operational conditions and RMMs reported for that one specific activity. Summing exposure estimates across sub-scenarios further amplifies the impact of conservative or worst-case assumptions across activities, resulting in potentially substantial over-estimates of potential exposure. As a clear example, summing up all exposure estimates from the worker sub-scenarios in section 9.1. would result in an unrealistic individual exposure duration.

Therefore, simply combining data and model-based exposure estimates for different tasks in the ES will necessarily lead to an unrealistic worst case overall exposure estimate.

A possible combination of sub-scenarios is the combination of WCS 2-5 and 10, activities in relation to the CCC application in baths. The combined exposure estimate (as the 90th percentile value of model-based exposure distribution) of these activities would be 0.60 µg/m^3.

A further possible combination of activities would be the machining activities (WCS 11-13). The combined exposure estimate (as the 90th percentile value of model-based exposure distribution) of these activities would be 0.121 µg/m^3. In general, and as mentioned in the respective CSR WCSs, the ART 1.5 model does not have a specific assessment option for metallic objects but only for stone. The model is therefore not ideal, however, it is conservative. There are measurement data available for comparable substances and these data show that model estimates in all cases considerably overestimated worker exposure. Therefore, any combination of model-based values would result in unrealistic values.

In summary, the applicants find the combined exposure estimate of 0.60 µg/m^3 for all CCC bath related activities, in which the same workers could be involved, reasonably representing worst-case combined exposure.

In this case, an excess lifetime lung cancer risk of 2.4 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

10.1.2. Consumer

Not relevant as there is no consumer use.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Regional exposure

Environment

The regional predicted environmental concentration (PEC regional) and the related RCRs when a PNEC is available are presented in the table below.

The PEC regional have been estimated with EUSES.

Table 26. Predicted regional exposure concentrations (Regional PEC)

Protection target	Regional PEC	Risk characterisation
Freshwater	Not relevant	Not relevant
Sediment (freshwater)	Not relevant	Not relevant
Marine water	Not relevant	Not relevant
Sediment (marine water)	Not relevant	Not relevant
Air	1.867E-18 mg/m³	Not relevant
Agricultural soil	Not relevant	Not relevant

Man via environment

The exposure to man via the environment from regional exposure and the related RCRs are presented in the table below. The exposure concentration via inhalation is equal to the PEC air.

Table 27. Regional exposure to man via the environment

Route	Regional exposure	Risk characterisation
Inhalation	1.867E-18 mg/m³ mg/m³	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 70 year exposure time (24h/day, 7d/week), the following excess lifetime lung cancer mortality risk for the general population is derived based on the estimated exposure: 5.41E-14 per 1000 exposed.
Oral	Not relevant	Not relevant

10.2.2. Local exposure due to all wide dispersive uses

Not relevant as there are not several wide dispersive uses covered in this CSR.

10.2.3. Local exposure due to combined uses at a site

Not relevant as there are no combined uses at a site.

Annex A

Details of slurry coating process measurement data for WCS 6: ~~Use of chromium trioxide for Slurry coating -~~ Substance preparation and surface treatment by spraying in paint booth

Site	Year	Measurement Result (µg/m3)	Adjusted for RPE efficiency (µg/m3)
Site A	2015	< 1	0.0167
Site A	2015	< 1	0.0167
Site A	2015	< 1	0.0167
Site B	2012	< 1.3	0.0007
Site B	2012	< 1.3	0.0007
Site B	2014	2.5	0.0025
Site B	2014	5	0.0050
Site B	2014	20	0.0200
Site C	2014	< 0.2	0.0100
Site D	2013	< 10	0.0050
Site E	2012	< 1	0.0005
Site E	2013	< 8	0.0040
Site E	2014	< 8	0.0040
Site F	2015	1	0.0333
Site F	2015	20	0.6667
Site F	2015	16	0.5333
Site F	2015	16	0.5333
Site F	2015	1.9	0.0633
Site F	2015	35	1.1667
Site F	2015	14	0.4667
Site F	2015	43	1.4333
Site F	2015	9	0.3000
Site F	2015	14	0.4667
Site F	2015	41	1.3667
Site F	2015	< 1	0.0167
Site F	2015	12	0.4000
Site F	2015	9	0.3000
Site F	2015	2.4	0.0800