Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Use of strontium chromate in the application of paints, primers and specialty coatings containing Strontium Chromate in the construction of aerospace and aeronautical parts, including aeroplanes / helicopters, spacecraft, satellites, launchers, engines, and for the maintenance of such constructions, as well as for such aerospace and aeronautical parts, used elsewhere, where the supply chain and exposure scenarios are identical

ECHA/RAC/SEAC: AFA-O-0000006553-73-02/D

Consolidated version

Date: 9 December 2016

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(s): Strontium chromate
EC No.: 232-142-6
CAS No.: 7789-06-2

for the following use:

Use of strontium chromate in the application of paints, primers and specialty coatings containing Strontium Chromate in the construction of aerospace and aeronautical parts, including aeroplanes / helicopters, spacecraft, satellites, launchers, engines, and for the maintenance of such constructions, as well as for such aerospace and aeronautical parts, used elsewhere, where the supply chain and exposure scenarios are identical.

Intrinsic property referred to in Annex XIV:

Article 57(a) of the REACH Regulation

Applicant:

AKZO Nobel Car Refinishes B.V.
Habich GmbH
Henkel Global Supply Chain B.V.
Indestructible Paint Ltd
Finalin GmbH
Mapaero
PPG Central (UK) Ltd in its legal capacity as Only Representative of PRC DeSoto International Inc. - OR5
PPG Industries (UK) Ltd
PPG Coatings SA
Aviall Services Inc.

Reference number:

11-2120105576-59-0010
11-2120105576-59-0011
11-2120105576-59-0012
11-2120105576-59-0013
11-2120105576-59-0014
11-2120105576-59-0015
11-2120105576-59-0016
11-2120105576-59-0017
11-2120105576-59-0018
11-2120105576-59-0019

Rapporteur, appointed by the RAC:	**Yvonne Mullooly**
Co-rapporteur, appointed by the RAC:	**Rudolf van der Haar**
Rapporteur, appointed by the SEAC:	**Philipp Hennig**
Co-rapporteur, appointed by the SEAC:	**Richard Luit**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On 19 November 2015 AKZO Nobel Car Refinishes B.V., Habich GmbH, Henkel Global, Supply Chain B.V., Indestructible Paint Ltd, Finalin GmbH, Mapaero, PPG Central (UK) Ltd in its legal capacity as Only Representative of PRC DeSoto International Inc. - OR5, PPG Industries (UK) Ltd, PPG Coatings SA and Aviall Services Inc. submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **27 January 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 **10 February 2016**. Interested parties were invited to submit comments and contributions by **06 April 2016**.

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 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 **13 October 2016**.

The applicant sent his written argumentation to the Agency on **27 October 2016**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and/or the environment 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 **16 September 2016**.

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 **9 December 2016**.

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 September 2016**.

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 **2 December 2016**.

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 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 the duration of the review period for the use is recommended to be **seven 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:

Strontium chromate has a harmonised classification as Carcinogenic Cat. 1B – H350.

Based on studies which show its genotoxic potential, the Risk Assessment Committee (RAC) has concluded that strontium chromate 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, Agreed at RAC-27).

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 strontium chromate is the Cr(VI) ion, which is released when strontium chromate 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

This application for authorisation by 10 applicants covers the application of a surface coating of paints, primers and specialty coatings containing strontium chromate to articles in the aerospace and aeronautics industry. This process is typically carried out to protect the part from corrosion and improve adhesion between metal and composite parts and may be carried out during production, maintenance or repair.

The coating material generally contains < 10% hexavalent chromium by weight. The formulated product is delivered to the industrial facility in sealed containers. The size, geometry and area of the article to be coated determine the coating technique to be used. The coating material may be applied to the component by spray application using a spray gun and/or by brush application (local/roller application). The paint is applied either automatically or manually by a trained operator within a designated area. Sometimes a coating may be 'touched-up' during maintenance or repair operations in- or outside a designated facility by small brush.

The tonnage of strontium chromate used is stated to be 200 tonnes per year equating to 50 tonnes per year of Cr(VI) and covers 152-616 downstream user sites.

The applicants presented in the CSR one exposure scenarios (ES) which consists of one environmental contributing scenario (ECS) and 23 worker contributing scenarios (WCS) (see Table 1).

Table 1: Contributing Scenarios related to the application of a surface coating of paints, primers and specialty coatings

Contributing scenario	ERC / PROC	Name of the scenario
ECS1	ERC 5	Application of paints of paints, primers and specialty coatings containing Strontium Chromate in the construction of aerospace and aeronautical parts, including aeroplanes / helicopters, spacecraft, satellites, launchers, engines, and for the maintenance of such constructions, as well as for such aerospace and aeronautical parts, used elsewhere, where the supply chain and exposure scenarios are identical
WCS 1	PROC 1	Delivery and storage of raw material
WCS 2	PROC 5	Decanting, mixing and filling of guns, cups or small containers
WCS 3	PROC 7	Surface treatment by spraying (large parts) in a purpose-designed room
WCS 4	PROC 7	Surface treatment by spraying in spray cabin/spray booth
WCS 5	PROC 7	Surface treatment by spraying outside of paint-booth
WCS 6	PROC 10	Surface treatment by brushing/rolling (small to medium sized parts)
WCS 7	PROC 10	Surface treatment by brushing (very small parts/touch-up)
WCS 8	PROC 26	Drying/self-curing
WCS 9	PROC 26	Drying/heat-curing
WCS 10	PROC 26	Drying/self-curing of large sized parts
WCS 11	PROC 8b	Cleaning of equipment – tools cleaning (closed system)
WCS 12	PROC 8b	Cleaning and maintenance of equipment – tools cleaning (paint cabin)
WCS 13	PROC 8b	Cleaning – paint cabin and ancillary areas
WCS 14	PROC 8a	Infrequent maintenance activities
WCS 15	PROC 21, 24	Machining operations on small to medium sized parts containing Cr(VI) on an extracted bench/extraction booth including cleaning
WCS 16	PROC 21, 24	Machining operations on small to medium sized surfaces containing Cr(VI) on an extracted bench/extraction booth including cleaning
WCS 17	PROC 21, 24	Machining operations in large work areas on parts containing Cr(VI) including cleaning
WCS 18	PROC 21, 24	Machining operations in large work areas on surfaces containing Cr(VI) including cleaning
WCS 19	PROC 21, 24	Machining operations on parts containing Cr(VI) in small work areas including cleaning
WCS 20	PROC 21, 24	Machining operations on surfaces containing Cr(VI) in small work areas including cleaning
WCS 21	PROC 21, 24	Sanding of large surfaces containing Cr(VI) in large work areas including cleaning
WCS 22	PROC 8b	Waste management
WCS 23	PROC 8a	End of Life

Workers exposure

The workers' exposure assessment has been limited to the inhalation of strontium chromate containing dust and/or aerosols since strontium chromate is a non-volatile substance and the dominating health effect resulting from the intrinsic hazardous properties of strontium chromate 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.

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, it can be seen that the duration of exposure per day is not the same as the maximum allowed duration in any one day.

Exposure estimation methodology

According to the applicants, the exposure estimates are conservative. The applicants 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. Minor differences in exposure conditions between facilities and companies occur occasionally and are described in the Exposure Scenarios (ES). In such cases, and according to the applicants, exposure levels take account of the least stringent RMM/OC and greater release parameters to over-estimates the risk.

The ES has been developed based on information provided by the CCST consortium[1] member companies (n=21) and their suppliers. Process descriptions were provided by 19 companies and used to derive draft exposure scenarios, followed by several rounds of discussion of the draft scenarios with nearly 20 consortium member companies plus some suppliers. Additionally, full-day visits of three major aerospace sites (mostly integrated sites) were conducted within the scope of this application to verify that the exposure scenarios mirrored the described processes as accurately as possible.

The results were summarized in order to derive exposure scenarios for the supply chain.

Occupational exposure estimates are based on measured data, qualitative assessment and on modelled data. 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 or qualitative assessment were used.

The applicants mentioned that biomonitoring data was not used because, as noted in Vincent et al. (2015)[2], it does not provide a reliable metric for exposure to Cr(VI).

[1] The CCST (Chromium VI Compounds for Surface Treatment) Consortium applied for five chromium VI containing substances for uses in the in the aerospace industry: dichromium tris(chromate), sodium dichromate, potassium dichromate, strontium chromate, and potassium hydroxyoctaoxodizincatedichromate. Members of CCST are manufacturers and importers of the substances, formulators of the mixtures, and downstream users of the mixtures (large companies and SMEs). The consortium members provided input in all the stages in the application process.

[2] Vincent R, Gillet M, Goutet P, Guichard C, Hédouin-Langlet C, Frocaut AM, Lambert P, Leray F, Mardelle P, Dorotte M and Rousset D (2015). Occupational exposure to chrome VI compounds in French companies: results of a national campaign to measure exposure (2010-2013). *Ann Occup Hyg.* 59(1): 41-51.

Modelling

For the majority of WCSs, modelling inhalation exposure data were presented using the higher tier tool ART 1.5. (see Table 3). The input parameters used for this tool, including operational conditions (OCs) and risk management measures (RMMs), were mentioned by the applicant. No site-specific data were used as input parameters but default values which lead to reasonable worst case exposure estimates using in general the highest exposure duration and the lowest level of personal protection reported. Furthermore in the scenarios a maximum level of the chromate concentration in the mixture was assumed. According to the applicant, in most of the applications the concentration will be much lower.

For the machining activities, the applicants indicated that the solid weight fraction of Cr(VI) considered in these WCS is a worst case concentration based on conservative assumptions regarding the maximum concentration of Cr(VI) in formulation and the maximum surface coating applied to any surface. To determine the maximum exposure estimates, a distinction has been made between tasks that involve either predominantly surface working where dust is generated entirely from the surface coating (Cr(VI) weight fraction < 13%), for example finishing (higher Cr(VI) content), or where dust generated includes a minor contribution from the surface coating (Cr(VI) weight fraction < 0,1%), for example drilling (lower Cr(VI) content). The applicants 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.

On request by RAC the applicants provided supporting comparative modelling scenarios for WCS 4 (Spraying in spray cabin / booth) to corroborate the validity and representativeness of the measured data.

Air monitoring

The applicants requested measurement data from 28 members of the CCST consortium and the latter in turn requested information from a few keys suppliers. The available data that could not be proven to meet certain quality criteria (e.g. outdated, inadequately reported, inadequate sampling or analytical methods) were not included for further analysis. The applicants claimed that is this way the data used are robust and reliable and present the current work situation with their operating conditions and risk management measures

Finally, 31 personal air sampling (TWA 8 hrs) data representing the exposure during the performing of task WCS 4 (Spraying in spray cabin / booth) were used. The measurements were obtained from 7 companies who treat parts for the aerospace sector.

The applicants clarified that GSP or UKAEA sampling head with glass-fibre or quartz-fibre filters were used for the measurements and that they were conducted by an accredited institute according to European regulations and following the general requirements of EN 482:2015. No specific information about the measurements itself was presented by the applicants (detection limit, duration of each measurement, applied method etc.).

The applicant mentioned that the number of sampling data provided by each of the companies varied, 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 90th percentile exposure estimates are used for the risk assessment. On request by RAC more disaggregated exposure data from the individual companies (average exposure concentrations, sampling period) were provided. No information is given about the characteristics of these companies (size, production volume) and its representativeness neither the location within in EU.

Even though the applicant felt that preference should be given to personal measurement data, on RAC's request also 7 static measurement data of one company were made available to RAC. These measurements were realized in the proximity to the paint booth.

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

According to the applicants measurement data not associated with the current practices exposure conditions were not used for the exposure assessment.

The personal and static measurements were taken between 2007 and 2013.

Also personal air sampling data are available for WCS 16 (n=6), and for the combined WCS17 and 18 (n=7) and the combined WCS 19 and 20 (n=11). However the applicants consider that the small sample size does not allow for using them as the basis for exposure estimation. More detailed information about these measurements can be found in Appendix 1.

Qualitative assessment

For WCS 1 the applicants mentioned that a qualitative assessment was performed and purport that there is no potential for exposure because the raw strontium chromate material is delivered in sealed containers.

Description of WCSs and RMMs/OCs applied

Description of WCSs

All activities corresponding are performed indoors except WCS 5 and 7 which also may be performed outside. All personnel are trained and are aware of the hazardous nature of chromate containing material(s). There are Standard Operating Procedures in place to cover all aspects of all handling of chromate containing materials.

WCS 1: Delivery and storage of raw material

The strontium chromate containing paint is delivered in sealed containers and stored in a chemical storage room for dangerous chemicals.

WCS 2: Decanting, mixing and filling of guns, cups or small containers

The container is opened either in a dedicated room or in the spray booth. Mixing can be done automatically or manually, using a handheld tool, to achieve a good consistency in the paint and, occasionally, adding in small quantities of other components, prior to filling into paint guns, cups or small containers. Local exhaust ventilation is present. Manual weighing and decanting of solid chromates is only relevant if small amount are used. This

scenario describes, as worst case scenario, the manual mixing as an open process and without any respiratory protection.

WCSs concerning spraying - the usual application method

The spray technique varies between and within the companies and depends on the particular application. Some spray techniques applied are robotic painting, electrostatic painting and painting with high volume low pressure systems. Also some companies use hydraulic spraying at high material pressure (3 to 500 bar, spray gun with high pressure (around 6 bars) or low pressure (2.6-3.2 bars). Processes are selected to maximise transfer efficiencies and minimise overspray and thereby to minimise the exposure risk and wastage (cost of paint / booth filters maintenance etc.).

WCS 3: Surface treatment by spraying (large sized parts) in a purpose-designed room

The applicant described that large sized parts with surface up to more than 3 000 m^2, e.g. aircrafts, helicopters and wings are sprayed in a specifically designed large paint shop (>150 000 m^3) with restricted access (however, restricted access is not specified as a condition in the ES). Continuous air ventilation is provided from the roof to the floor, including adequate filter systems. Full-face respirators with external air supply, gloves and overalls are worn. This activity can be conducted over a full-shift but then not every day. For the purpose of this exposure assessment, it is assumed that it takes place daily with 4h exposure/day. Spraying is typically done with no or low compressed air and with an application rate of 0.3-3 l/minute. This task is considered highly specialist; workers are specifically trained.

WCS 4: Surface treatment by spraying in spray cabin / spray booth

Small to medium sized parts are sprayed in a spray cabin or spray booth with air extraction systems in place (down-flow spray room). This is not a continuous task during the full-shift. Respiratory protection is always worn during spraying. Spraying is typically done with no or low compressed air and with an application rate of 0.3-3 l/minute.

WCS 5: Surface treatment by spraying outside of paint-booth

Occasionally spraying is conducted on limited surfaces outside a paint booth, e.g. directly on airplanes.

According to the applicant, there are no bystanders during these operations. The area in which the activity is conducted is said to be restricted either physically by means of barriers/signage or through strict procedures during the activity and for a specified time after the application (however, this is not specified as a condition in the ES). RPE is not removed before leaving the area of application. The activity is only carried out on smaller surfaces (components) and only in instances when spraying within a booth is not an option from a practical point of view (i.e. the surface area to be sprayed forms part of a larger object).

For the purpose of this exposure assessment it is assumed that it takes place two times a week, using less than one litre of paint, without exhaust air extraction and using a half-face mask. This scenario also covers as worst-case those situations in which a higher amount of paint is used, but less often and using a full-face masks. Spraying is typically done with no or low compressed air and with a low application rate (<0.03l/minute).

WCSs concerning brushing / rolling or touch-up as an additional application method for medium to very small parts

WCS 6: Surface treatment by brushing/rolling (small to medium sized parts)

For the purpose of this exposure assessment it is assumed that brush application takes place daily with up to 4 hours exposure/day on a yearly average.

WCS 7: Surface treatment by brushing (very small parts/touch-up)

This activity involves painting of small defective surfaces (e.g. surfaces where abrading has been conducted due to tasks such as fitting, earth bonding or minor damage during the manufacturing process) with a pencil or touch-up pen (a touch-up pen looks like a felt tip pen which contains a little amount of chromate (≈ 1g chromate/pen) which can be used for several actions. Before touch-up, the defective surface is normally prepared by sanding (see WCS 16 and 18)

For the purpose of this exposure assessment it is assumed that it takes place daily with 30 min exposure/day on a yearly average. The application may happen indoors and outdoors.

WCSs concerning drying and curing

The applicants indicate that the primary exposure potential relating to curing is transferring and checking objects recently painted**.**

WCS 8: Drying/self-curing

Once coated, the finished part is stored for drying and curing. The part may be cured in the spray booth or in a separate room fitted with extraction. In most cases, no workers are present. In some facilities, however, workers might be around the curing part for a limited amount of time and then the following scenario applies. Distinction is made between performing activities within one meter distance to the drying part (within breathing zone) and more than one meter distance (outside breathing zone) what is done most of the time. As a worst-case, the scenario assumes that no LEV is present (there is no extraction for objects which have been touched-up on the shop floor) and no RPE worn

WCS 9: Drying/heat-curing

The finished part is cured by air drying and then heat cured in an oven at high temperatures. Emissions from the oven are extracted. In most application cases, no workers are present.

In some facilities, however, workers might be around the oven and then this scenario applies.

WCS 10: Drying/self-curing of large sized parts

Once coating of large surfaces is completed, the finished part (e.g. aircraft) remains for drying and curing. In some cases, other, non-spraying, activities like masking or de-masking will be carried out in the same workroom, and then the following scenario applies. These activities are not conducted daily. For the purpose of the exposure assessment, it is assumed that frequency is 2 times per week. Distinction is made between performing activities within one meter distance to the drying part (within breathing zone) and more than one meter distance (outside breathing zone) what is done most of the time. As a worst-case, the scenario assumes that no LEV is present and no RPE worn.

WCS 11: Cleaning of equipment – tools cleaning (closed system)

Tools (e.g. spray guns) are cleaned with solvent in a closed system.

WCS 12: Cleaning and maintenance of equipment – tools cleaning (paint cabin)

Tools (e.g. paint guns, brushes) are cleaned with water or solvent in the spray cabin, paint shop or paint mixing room by the worker who conducted spraying. If maintenance is required, it is conducted in the same step under same conditions.

WCS 13: Cleaning – paint cabin and ancillary areas

Cleaning of the paint shop or booth and of any ancillary areas often is conducted by the workers who conducted spraying, under the same operational conditions. Walls and the floor of the spray area might be covered with protective film/foil before spraying. After spraying this is removed and stored in a tank for contaminated waste. The used model provides, as worst case, exposure estimates for cleaning without air extraction in operation and without respiratory protection. No information is given about the kind of ventilation in place.

WCS 14: Infrequent maintenance activities

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, it is assumed that this task is performed one time per month with duration up to 4 hours. No information is given about the kind of ventilation in place. This activity might be conducted by the same maintenance workers as in more regular maintenance activities or by different group(s) of maintenance workers, e.g. external operators

WCSs concerning machining activities

Aircraft mechanics tend to concentrate on machining operations e.g. grinding of treated surfaces or drilling of painted parts. Activities can be performed in a different part of the

facility or by an entirely different company. The conditions of use and the respective requirement on the selection of OCs & RMMs depend on the type of machining operations, i.e. if the activity is mainly conducted on the surface of an object (e.g. abrasion) or concerns rather the whole part (e.g. drilling) and if the machining activities take place on a specific work bench / booth or not. Light abrading is typically carried out manually by means of a glass fibre brush or dry abrasive paper and normally takes place in a fully contained booth with laminar down-flow. Abrading tools (e.g. random orbital sanders) are equipped with on-tool extraction or these tools are used with in the proximity of a LEV system such as a vacuum hose. Also wet abrading might be used, when for example there is no possibility to perform the task in a dedicated booth. Drilling can be done either fully automated (e.g. robotic), semi–automated (e.g. automated drilling unit which locks into a drilling jig with single button press operation) or manual drilling. The latter is normally conducted wet, with extraction or both. In Appendix 2 some more detailed information and examples of machining activities are given.

WCS 15: 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 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.

WCS 16: Machining operations on small to medium sized surfaces containing Cr(VI) on an extracted bench / extraction booth including cleaning (PROC 21, 24)

During assembly, maintenance and/or repair, small to medium sized surfaces are fettled, abraded, or sanded 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.

WCS 17: Machining operations in large work areas on parts containing Cr(VI) including cleaning (PROC 21, 24)

Solid parts are manually drilled, riveted, 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.

WCS 18: Machining operations in large work areas on surfaces containing Cr(VI) including cleaning

Surfaces are manually fettled, abraded or sanded 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.

WCS 19: Machining operations on parts containing Cr(VI) in small work areas including cleaning

Parts are drilled, riveted or cut in comparable small work areas (e.g. inside wing tanks). 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 WCS does not specify any localised control. However, the applicants explained that in practise working in confined spaces may require additional RMM such as forced ventilation to provide thermal comfort.

WCS 20: Machining operations on surfaces containing Cr(VI) in small work areas including cleaning

Small surfaces are fettled, edged, abraded or sanded in comparable small work areas (e.g. inside wing tanks). 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. The WCS specifies that wetting at the point should be in place as a primary localised control. The WCS does not specify secondary localised controls.

WCS 21: Sanding of large surfaces containing Cr(VI) in large work areas including cleaning

Large sized parts, e.g. aircrafts, helicopters, wings are sanded in a specifically designed large room with restricted access. Continuous air ventilation is provided from the roof to the floor, including adequate filter systems. Full-face respirators with air supply, gloves and overalls are worn. This activity can be conducted over a full-shift but then not every day (i.e. once per week). For the purpose of this exposure assessment, it is assumed that it takes place daily with 2h exposure/day.

WCS 22: Waste management (PROC 8b)

Waste from paint spraying or brushing is collected as part of cabin/tools cleaning processes and cleaning in machining processes. Waste is collected in closed tanks for contaminated waste which further are collected by licensed waste management companies for treatment, incineration and disposal of incineration residues to contaminated landfill.

The equipment is cleaned by flushing or washing the equipment with water or solvent; all wastewater/waste solvent is collected and treated as hazardous waste. Other waste materials including used paint containers, rags, paper, film, foil, filters, sludge, overalls and protective gloves are treated as a hazardous waste.

This WCS describes the transfer of such type of waste to the storage area. However no description is given about the transfer itself, only the RMMs and OCs in place.

WCS 23: 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.

Description of RMMs/OCs applied

Operating conditions and risk management measures are specified to limit potential worker (inhalation and dermal) exposure to various components in the paint and environmental exposure during application of the coating. According to the applicants these RMMs & OCs reflect good industrial hygiene practice and exclude unacceptable practices and set out the exposure levels that are achievable. Downstream users must ensure that the RMMs & OCs they have in place provide an equivalent or better level of protection than those set out in the ES.

The applicants stated that spray booths with wet or dry filters are used for spray applications of small to medium-sized parts. Large parts are sprayed in specifically designed large paint shops with air extraction units and local exhaust ventilation (LEV). The applicants indicate that access to all areas where spraying is conducted is restricted to authorised personnel, however this is not specified in the ES.

Once the coating has been applied, the equipment is cleaned. Equipment is maintained regularly.

Also the applicants mentioned that workers are skilled, and receive regular training with regards to chemical risk management and how to properly wear the Personal Protective Equipment.

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 solid chromates or in cases in which exposure to airborne chromates can occur (e.g. spraying), personnel are required to wear protective clothing, chemical-resistant gloves, goggles, and adequate respiratory protection (except for RPE these are not specified in the ES).

For machining activities (WCSs 15-20) a value of Cr(VI) content of the surface is given. However no information is provided on which this assumption is made. In case of lower or higher Cr(VI) content, estimated exposure would be reduced or increased in a linear way. In this case the applicants stated that in these situations the OCs and RMMs could be adjusted. However no details about these adjustments are given[3].

The applicants indicated that the presence of devices (e.g., electronic, mechanic, acoustic) and regularly checks are used to control functionality of the LEV systems. Also, on request by RAC, some literature data about LEV efficiency was presented to indicate that the LEP effectiveness mentioned in the ES are in line with these data.

Concerning the OCs and RMMs mentioned for each WCS, the applicants stated that they represent the least conservative conditions that could theoretically be imposed that allow

[3] In response to RAC's request, the applicant has stated that there is no further need to determine the Cr(VI) weight fraction in any particular solid part. The applicant has stated it is the responsibility of the company to define adequate RMMs based on a workplace/task specific risk assessment and these already take into account worst case assumption for Cr(VI) content of the article. If a contractor wishes to refine the Exposure Scenario for any particular article and machining activity that would be possible, but it is not necessary.

companies to meet the high standards of protection. However there may be some differences in OCs and RMMs applied across different facilities, due to facility and operation specific considerations (scale and frequency of the operation, design of the equipment and the particular requirements of the surface treatment operation, which may itself be influenced by the size, geometry and area of the article to be coated). The applicants argued 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 contain minimum OCs and RMMs. For that reason the applicants stated that one facility may be able to implement an automated process because there is a high level of homogeneity in operations, whereas that may not be feasible for another facility that has to maintain a high level of supervision of the process.

Thus, the type of RPE specified in the respective WCS is considered as the minimum level required. Companies must assess based on their workplace/task specific risk assessment whether a type of RPE with higher protection is required, According to the applicant, companies have to base their decision regarding the type of RPE, either half-face or full face masks, and potentially additional RMMs on their own workplace specific risk assessment considering the amount of paint, duration, place of activity and parts to be sprayed.

Local extraction, a mobile local extraction unit or fixed ventilation, may or may not be available.

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

Table 2: Operational Conditions and Risk Management Measures per WCS

Contributing scenario	Duration and frequency of exposure	Physical state & Concentration	LEV used + effectiveness	RPE used + effectiveness	Other RMMs
WCS 1 Delivery and storage of raw material (PROC 1)	< 8 hrs/day, daily	Liquid 5-10% Cr(VI)	Not in place	Not used	• Containment (sealed containers) • General ventilation (ACS 1-3)
WCS 2 Decanting, mixing and filling of guns, cups or small containers (PROC 5)	< 1hrs/day, daily	Liquid 5-10% Cr(VI)	Yes 90% effectiveness (fixed capturing hood)	Not used	• Natural ventilation (no ACS is given)
WCS 3 Surface treatment by spraying (large sized parts) in a purpose-designed room (PROC 7)	< 4 hrs/day, daily	Liquid 5-10% Cr(VI)	Continuous roof to floor ventilation (downward laminar flow booth) 80% effectiveness	Full mask with external air supply. 99.9% effectiveness	• Specifically designed paint shops with restricted access
WCS 4 Surface treatment by spraying in spray cabin/spray booth (PROC 7)	< 2 hrs/day, daily	Liquid 5-10% Cr(VI)	Down-flow spray room (80% effectiveness) or fixed capturing hood (90% effectiveness)	Half mask with P3 filter (96.67%)	• Spray cabin or booth
WCS 5 Surface treatment by spraying outside of paint-booth (PROC 7)	< 30 min; two days/week	Liquid 5-10% Cr(VI)	Not in place	Half mask with P3 filter (96.67%)	• Natural ventilation (No ACS is given)
WCS 6 Surface treatment by brushing/rolling (small to medium sized parts) (PROC 10)	< 4 hrs/day, daily (yearly average)	Liquid 5-10% Cr(VI)	Fixed capturing hood (90% effectiveness)	Half mask with P3 filter (96.67%)	• Natural ventilation (No ACS is given)

Table 2: Operational Conditions and Risk Management Measures per WCS - continued

Contributing scenario	**Duration and frequency of exposure**	**Physical state & Concentration**	**LEV used + effectiveness**	**RPE used + effectiveness**	**Other RMMs**
WCS 7 Surface treatment by brushing (very small parts/touch-up) (PROC 10)	<30 min/day, daily	Liquid 5-10% Cr(VI)	Not in place	Not used	• Natural ventilation (No ACS is given)
WCS 8a Drying/self-curing (PROC 26) (within breathing zone)	<30 min/day, daily	Liquid 1-5% Cr(VI)	Not in place	Not used	• Natural ventilation (No ACS is given)
WCS 8b Drying/self-curing (PROC 26) (outside breathing zone)	<90 min/day, daily	Liquid 1-5% Cr(VI)	Not in place	Not used	• Natural ventilation (No ACS is given)
WCS 9 Drying/heat-curing (PROC 26)	< 8 hrs/day, daily	Liquid 1-5% Cr(VI)	Fixed capturing hood (90% effectiveness)	Not used	• Fully enclosed process • Natural ventilation (No ACS is given)
WCS 10a Drying/self-curing of large sized parts (PROC 26) (within breathing zone)	< 1 hrs/day; two days/week	Liquid 1-5% Cr(VI)	Not in place	Not used	• Natural ventilation (No ACS is given)
WCS 10b Drying/self-curing of large sized parts (PROC 26) (outside breathing zone)	< 5 hrs/day; two days/week	Liquid 1-5% Cr(VI)	Not in place	Not used	• Natural ventilation (No ACS is given)

Table 2: Operational Conditions and Risk Management Measures per WCS - continued

Contributing scenario	**Duration and frequency of exposure**	**Physical state & Concentration**	**LEV used + effectiveness**	**RPE used + effectiveness**	**Other RMMs**
WCS 11 Cleaning of equipment – tools cleaning (closed system) (PROC 8b)	< 1hrs/day; daily	Liquid 5-10% Cr(VI)	Fixed capturing hood (90% effectiveness)	Not used	• Fully enclosed process • Natural ventilation (No ACS is given)
WCS 12 Cleaning and maintenance of equipment – tools cleaning (paint cabin) (PROC 8b)	< 1hrs/day; daily	Liquid 5-10% Cr(VI)	Not in place	Not used	• Specialised room ventilation (ACS > 10)
WCS 13: Cleaning – paint cabin and ancillary areas (PROC 8b)	< 1hrs/day; daily	Liquid 5-10% Cr(VI)	Not in place	Not used	• No data about ventilation
WCS 14: Infrequent maintenance activities (PROC 8a)	< 4hrs/day; 1 time/month	Fine dust 5-10% Cr(VI)	Not in place	Half mask with P3 filter (96.67% effectiveness)	• Natural ventilation (No ACS is given)
WCS 15: Machining operations on small to medium sized parts containing Cr(VI) on an extracted bench/extraction booth including cleaning (PROC 21, 24)	< 3 hrs/day; daily (1)	Solid object <0.1% Cr(VI) (2)	Fixed capturing hood / vacuum cleaner (HEPA filter with 99% effectivity)	Half or quarter mask with P2 filter (90% effectiveness)	• Natural ventilation (No ACS is given)

Table 2: Operational Conditions and Risk Management Measures per WCS - continued

Contributing scenario	**Duration and frequency of exposure**	**Physical state & Concentration**	**LEV used + effectiveness**	**RPE used + effectiveness**	**Other RMMs**
WCS 16: Machining operations on small to medium sized surfaces containing Cr(VI) on an extracted bench/extraction booth including cleaning (PROC 21, 24)	< 3 hrs/day; daily (1)	Solid object <13% Cr(VI) (2)	Fixed capturing hood / vacuum cleaner (HEPA filter with 99% effectivity)	Full mask with P3 filter (99.75% effectiveness)	• Natural ventilation (No ACS is given)
WCS 17: Machining operations in large work areas on parts containing Cr(VI) including cleaning (PROC 21, 24)	< 1 hrs/day; daily (1)	Solid object <0.1% Cr(VI) (2)	Wetting at the point of release/on-tool extraction /vacuum cleaning (90% effectiveness)	Half or quarter mask with P2 filter (90% effectiveness)	• Natural ventilation (No ACS is given)
WCS 18: Machining operations in large work areas on surfaces containing Cr(VI) including cleaning (PROC 21, 24)	< 1 hrs/day; daily (1)	Solid object <13% Cr(VI) (2)	Wetting at the point of release/on-tool extraction /vacuum cleaning (90% effectiveness)	Full mask with P3 filter (99.75% effectiveness)	• Natural ventilation (No ACS is given)
WCS 19 Machining operations on parts containing Cr(VI) in small work areas including cleaning (PROC 21, 24)	< 1 hrs/day; daily	Solid object <0.1% Cr(VI) (2)	Not in place	Full mask with P3 filter (99.75% effectiveness)	• Natural ventilation (No ACS is given)

Table 2: Operational Conditions and Risk Management Measures per WCS - continued

Contributing scenario	**Duration and frequency of exposure**	**Physical state & Concentration**	**LEV used + effectiveness**	**RPE used + effectiveness**	**Other RMMs**
WCS 20 Machining operations on surfaces containing Cr(VI) in small work areas including cleaning (PROC 21, 24)	< 1 hrs/day; daily	Solid object <13% Cr(VI) (2)	Not in place	Full mask with P3 filter and air supply (99.9% effectiveness)	• Natural ventilation (No ACS is given)
WCS 21 Sanding of large surfaces containing Cr(VI) in large work areas including cleaning (PROC 21, 24)	< 2 hrs/day; daily	Solid object <13% Cr(VI) (2)	Continuous roof to floor ventilation (downward laminar flow booth) 80% effectiveness. Wetting at point of release/on-tool extraction/vacuum cleaning (90% effectiveness	Full mask with P3 filter and air supply (99.9% effectiveness)	• Specifically designed room with restricted access
WCS 22 Waste management (PROC 8b)	<30 min/day; daily	Fine dust 5-10% Cr(VI)	Low level containment (90% effectiveness)	Half mask with P3 filter (96.67% effectiveness)	• Natural ventilation (No ACS is given)
WCS 23 End of Life (PROC 8a)					•

1) When machining operations has a longer duration of activity than a higher level of respiratory protection is used, e.g. by using a half-mask with P3 filter (APF 30) or a full face mask with P3 filter (APF 400).
2) In case of lower or higher Cr(VI) content, estimated exposure by ART modelling would be reduced or increased in a linear way

Worker exposure estimates

In Table 3 the exposure estimates are presented as given by the applicant. The applicant used the values marked in bold for the risk assessment. On request by RAC, the applicants provided more detailed information about the monitoring data corresponding to the spraying in spray cabins or booths (WCS 4). A summary of these data can be found in table 4.

The applicants stated that the modelled exposure estimates are based on worst-case situations using in general the highest exposure duration and the lowest level of personal protection reported. In addition, the same approach applies to the Cr(VI) content of the coating material and provision of methods to achieve exposure reduction like automation, enclosure, and extract ventilation.

For the assessment of exposure and risks for workers the effectiveness of respiratory protection was taken into account by the applicant by using company-specific information on the type of mask and filter used or, if not reported, the Assigned Protection Factor (APF) provided by the manufacturer of the RPE. In other cases, the APF provided by the German BG rule "BGR/GUV-R190" from December 2011 was used.

Table 3: Applicant's estimates of exposure to Cr(VI) via inhalation (values in bold are taken forward)

Contributing scenario	Method of assessment	Exposure value TWA-8hrs [µg Cr(VI) / m^3] (90^{th} percentile)	Exposure value corrected for RPE TWA-8hrs [µg Cr(VI) / m^3] (90^{th} percentile)
WCS 1	Qualitative	0	0
WCS 2	Modelled (ART 1.5)	**0.17** (3)	RPE not used
WCS 3	Modelled (ART 1.5)	830	**0.83** (2)(3)
WCS 4	Measured	Not provided	**0.84** (4)
	Modelled (ART 1.5)	10-1500(8)	Not provided
WCS 5	Modelled (ART 1.5)	15.6	**0.52** (2)(3)
WCS 6	Modelled (ART 1.5)	2,28	**0.076**(2)(3)
WCS 7	Modelled (ART 1.5)	**0.28**(2)(3)	RPE not used
WCS 8	Modelled (ART 1.5)	**0.32** (3)(5)	RPE not used
WCS 9	Modelled (ART 1.5)	**0.18** (4)	RPE not used
WCS 10	Modelled (ART 1.5)	**0.10** (2)(3)(5)	RPE not used
WCS 11	Modelled (ART 1.5)	**0.017** (4)	RPE not used
WCS 12	Modelled (ART 1.5)	**0.089** (4)	RPE not used
WCS 13	Modelled (ART 1.5)	**0.17** (4)	RPE not used
WCS 14	Modelled (ART 1.5)	7.5	**0.25** (2)(3)
WCS 15	Modelled (ART 1.5)	1.1	**0.11** (2)(3)
WCS 16	Modelled (ART 1.5)	150	**0.375** ((2)(3)

	Measured	Not provided	0,05 - 0.28[1]
WCS 17	Modelled (ART 1.5)	2	**0.20** [2][3]
WCS 18	Modelled (ART 1.5)	270	**0.675** [2][3]
WCS 17-18	Measured	Not provided	0.50 [6]
WCS 19	Modelled (ART 1.5)	64	**0.16** [2][3]
WCS 20	Modelled (ART 1.5)	830	**0.83**[2][3]
WCS 19-20	Measured	Not provided	0.18 [7]
WCS 21	Modelled (ART 1.5)	1200	**1.2** [2][3]
WCS 22	Modelled (ART 1.5)	5.7	**0.19** [1][3][4]
WCS 23	Not relevant		Not relevant

1. Calculated 90th percentile. Based on 6 measurements (3 measurements for very small parts; 90th of 0.05 µg Cr(VI)/m^3 and 3 measurements for small medium sized parts; 90th of 0.28 µg Cr(VI)/m^3). No information about the number of sites where these measurements were performed. Individual monitoring data were not presented by applicants.
2. Extended value; includes the protection factors for the use of respiratory protection and correction factor for activities which do not take place every day
3. Worst case situation (highest reported exposure duration; minimum reported RMM; lowest personal protection)
4. Based on 31 measurements performed at 7 sites
5. Calculated value based on the modelling result of two sub-activities
6. Calculated 90th percentile. Based on 7 measurements. Representing a mixture of activities described in WCS 17 and WCS 18. No information about the number of sites where these measurements were performed. Individual monitoring data were not presented by applicants
7. Calculated 90th percentile. Based on 11 measurements. Representing a mixture of activities described in WCS 19 and WCS 20. No information about the number of sites where these measurements were performed. Individual monitoring data were not presented by applicants
8. Applicants performed modelling with different kind of spray rooms resulting in different exposure estimates (see also table 4)

Table 4: Summary of exposure measurement data and modelling data (Art 1.5) covering spray application in booth (WCS4) as presented by applicants

Company	Result 90th percentile (µg Cr(VI)/m³)	Arithmetic Mean (µg Cr(VI)/m³)		No of measurements available	Period	Sampling period (min)	Process type / LEV	LoD
Personal monitoring								
Company A	0.03*	0.43	0.01*	7	2011-2012	120	Manual	All values below LoD
Company B	2.40*	831	1.47*	18	2012-2013	19-330	Manual	No values below LoD
Company C	0.32*	645	0.32*	81	2008	47	Manual	No values below LoD
Company D	0.16*	117	0.12*	3	2009	79-126	Manual	No values below LoD
Company E	0.03*	5.45	0.01*	3	2012	379	Manual	No values below LoD
Company F	0.66*	84.25	0.42*	2	2007	30	Manual	2 out of 3 results below LoD
Company G	0.50*	4.81	0.16*	7	2010-2013	120-300	Manual	6 out of 7 results below LoD
Static monitoring (in proximity of paint booth)								
Company F	3.40	1.79		7	2010-2013	120-480	Manual – automatic / with LEV	All values below LoD
Total measurements				26				

Modelled data		
Scenario	**Tittle**	**Result in µg Cr(VI)/m³ (90th percentile) without RPE**
1	Downward spray room	410
2	Cross-flow spray room	1500
3	Downward laminar flow booth	410
4	Downward spray room / booth smaller parts	10

**Values following adjustment for RPE*

Combined exposure

The applicants stated that, taking into account the various details of processes carried on and risk management measures applied by different companies, each of the sub-scenarios represents a worst-case scenario by using the lowest level of OCs 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. According to the applicants 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.

The applicants explained that the operations performed by one worker are determined by the worker's qualification. An aircraft painter usually performs painting operations (mixing, filling, spraying, and cleaning of equipment) meanwhile an aircraft mechanic will concentrate on machining operations (grinding, drilling). However, the applicant stated that machining activities (WCS15-21) are not likely performed without some local coating (brush/pen) activities.

Nevertheless, the applicants have evaluated several possible combinations of tasks. The highest possible combined exposure estimate (as the 90th percentile value of the data or model-based exposure distribution, as mentioned in the CSR is 1.93 µg Cr(VI)/m^3 (see Table 5), estimate finally used by the applicants to derive the excess lifetime cancer risk.

Table 5: Task aggregation with the highest aggregated exposure estimate presented in the CSR

90^{th} percentile exposure estimate TWA-8h (µg Cr(VI)/m^3) (adjusted for RPE)				Aggregated long term inhalation exposure estimates (µg Cr(VI)/m^3) (90^{th} percentile)
WSC2	WSC3	WCS4	WCS12	
0.17	0.83	0.84	0.089	**1.93**

Based on a proposal of RAC the applicants provided aggregated exposure estimate for machining activities. It was mentioned that operators in charge of sanding of large surfaces (WCS21) are not involved in any other machining activities during the respective day and therefore this WCS cannot be part of an aggregated exposure estimate for machining activities

Table 6: Task aggregation for machining activities proposed by RAC and adapted by applicants with the corresponding aggregated exposure estimate

90^{th} percentile exposure estimate 8h TWA (µg Cr(VI)/m^3) (adjusted for RPE)					Aggregated long term inhalation exposure estimates (µg Cr(VI)/m^3) (90^{th} percentile)
WSC16	WSC17	WCS18	WCS19	WCS20	
0.375	0.20	0.675	0.16	0.83	**2.24**

Discussion of the worker exposure information

The main applications of chromates covered by this application for authorisation include on site formulation; coating of parts by spraying or brushing; and machining activities. The information presented in the CSR about the tasks description, ways of exposure, OCs and RMMs in place was supplemented by the applicants on request by RAC. The applicants stated that it proved to be challenging to collect such information.

Exposure is estimated based on personal air measurement data **only for WCS 4**. The data was obtained from 7 companies, which represents between 1% and 10% of the companies covered by the application.

The applicants pointed out that the limited availability of measurement data 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; and the applicant has no legal recourse to obtain exposure and emission data from downstream users. The applicant indicated that all the data received from the CCST consortium members was reviewed and a subset of exposure data was selected that represents data based on current good practice. The applicants state that the industry is receptive to collection of new measurement data, recognising this will take time to collect.

The applicants also indicated that for WCS 7 - Surface treatment by brushing (very small parts/touch-up) - there is no measurement data available because according the applicants, the exposure and release potential is deemed to be negligible.

The 90th percentile of these measurements corresponding to WCS4 has been corrected by the applicants for the use of respiratory protection to derive a 90th percentile exposure estimate of 0.84 µg Cr(VI)/m^3. Detailed calculations on how the adjustments for use of RPE were made were not provided to RAC. Based on the arithmetic mean reported concentrations with and without RPE, RAC calculated the corresponding APF of the used RPE for each company (see Table 7), resulting in APF values, with exception of company G, much higher than the APF factor of 30 corresponding to the minimum required RPE as mentioned in the conditions of use for this WCS. Applying an APF of 30 results in rather high mean exposure estimates and therefore it can be concluded that in most cases a half mask may not be sufficient and that at least full mask with APF 400 is needed (see Table 7).

The modelled exposure estimates for WCS 4 (without RPE adjustment) are in the range 10 – 410 µg Cr(VI)/m^3 (see Table 4)[1]. The measured results (without RPE adjustment) are in the range of 0.4 – 830 µg Cr(VI)/m^3. These data suggest that the modelling supports the measured data.

[1] RAC did not consider the result for crossflow spray room in this comparison since the WCS specifies down-flow spray room.

Table 7: Calculated APF and exposure estimates with RPE-APF 30 by RAC based on the measurements outcomes presented by applicants

	Arithmetic mean (µg Cr(VI)/m³) presented without RPE (presented by applicant)	Arithmetic mean (µg Cr(VI)/m³) presented with RPE adjustment (presented by applicant)	Calculated APF (by RAC)	Calculated arithmetic mean (µg Cr(VI)/m³) adjusting for RPE with APF 30 (by RAC)
Company A	0.43	0.01	43	0.014
Company B	831	1.47	565	27.7
Company C	645	0.32	2016	21.5
Company D	117	0.12	975	3.9
Company E	5.45	0.01	545	0.182
Company F	84.25	0.42	200	2.8
Company G	4.81	0.16	30	0.16

The arithmetic mean of the exposure measurements without RPE adjustment per company (see Table 4) shows relative high differences ranging from 0.43 to 831 µg Cr(VI)/m³. Information that might explain this variability such as differences in the scale of operations, the RMMs/OCs in place at each of the companies was not detailed in the application nor has information on the monitoring methodology and detection limits been provided by the applicants. Related to this latter item, it should be noted also that there is a high variability in sampling duration of the measurements.

Also static sampling measurements nearby spray booths at one company were provided, all below detection limit of the applied method. However the presented arithmetic mean of 1.79 out of 7 measurements indicate that the detection limit of the applied method is relatively high (mean LoD around 3.6 µg/m³) and therefore it cannot be excluded that workers performing other tasks nearby the booths and not using RPE might also be exposed.

In the SEA, the applicant divided workers into different exposure groups according to their average exposure duration per day (see table 8).

Table 8: Corrected exposure times with number of potentially exposed people at the downstream users (data from SEA document).

Workers potentially exposed	Percentage	Total number of workers exposed
less than 1 hour/day	13	3 073
1-3 hours/day	11	2 518
3-6 hours/day	15	3 376
6-8 hours/day	21	4 758
Not regularly exposed (e.g. once a week, month, year)	40	9 226
Total	100	22 951

The applicants used an extrapolation approach where 12 companies replied to a questionnaire and the results were apparently extrapolated to both the formulator companies (Use 1) and the companies performing Use 2. It is unclear if the questionnaire data is from formulators (Use 1) or companies carrying out Use 2, or both.

The applicants decided not to use the monitoring data for machining (WCS 16, WCS 17-18 and WCS 19-20) due to the limited sample size, but to use the modelled exposure estimate for risk assessment. RAC can agree with this approach.

The applicants mentioned that ART 1.5 does not have a specific assessment option for machining of metallic objects but only for stone and wood and therefore the model is not ideal. The applicants are of the opinion that the modelling is conservative, considering the available measurement data for some machining scenarios (WCS 16, 17-18 and 19-20).

RAC acknowledges that the modelled exposure estimates for machining are of the same order of magnitude as the measured exposure. Since the measured data were the same as for machining application in the metal surface treatment applications of the CCST consortium[2] and no contextual information has been provided by the applicants about the work conditions, it is not clear if the measurements corresponds to machining activities on surface treated or painted –coated metal surfaces or both. Painted material has a higher Cr(VI) content.

For the WCSs corresponding to drying and curing (WCS 8, 9 and 10) the activity class "Handling of contaminated objects" is used for the ART modelling. The applicants indicated that this activity class not fully covers the WCS and that the outcomes of the exposure assessment can be considered as conservative. Also for the pen stick application (WCS 7) the applicants consider that, due to the low volatility of the substance and the highly unlikely formation of aerosol in these tasks, the exposure estimate provided by ART 1.5 possibly represent an overestimate of exposure. RAC agrees with the applicants that the modelled exposure estimates for these WCSs are probably overestimated considering that the vapour pressure used for modelling was <0.01 Pa is unlikely to be realistic and the tasks indeed are not likely to result in significant aerosol formation.

Furthermore, the applicants recognized that the selected activity class "Handling of contaminated objects" for the exposure modelling for WCS 8-10 (Drying and curing) only broadly covers these WCSs. It is considered as the most appropriate activity class available to describe of worker exposure potential.

The applicant has indicated that fugitive emissions are limited or even avoided through good handling procedures and where possible, operations are conducted in designated areas such as segregation through physical containment and barriers and good management procedures from the other workforce unless it can be demonstrated through workplace monitoring that exposure to other workers is negligible (i.e., with measurement results below a minimum detection limit of 1 µg/m^3). In response to RAC's concerns in relation to the preparation of empty bags or containers represented a potential exposure fugitive source of exposure to other workers working in vicinity who are not wearing RPE. The applicant indicated that when operators are working with solid chromates there are no other workers in proximity and empty bags are immediately packed away to avoid potential exposure.

[2] Applications for sodium dichromate, potassium dichromate and dichromium tris(chromate).

On request by RAC, aeronautics industry exposure data gathered from the literature was presented. For the paint spraying and sanding activity reference was made to Vincent et al. (2015)[2]. This publication reported arithmetic mean concentrations of 110-172 µg Cr(VI)/m^3 for paint spraying (n= 85 combined personal and static measurements) and 0.46 – 38 µg Cr(VI)/m^3 for manual sanding (n=16 combined personal and static measurements).

According to the applicants, the exposure data for paint spraying are in the same order of magnitude as the measured concentrations presented by the applicant for WCS 4 uncorrected for RPE (paint spraying in paint booth). For sanding, and comparing with the modelled exposure estimates of WCS 21 (sanding of large surfaces), the applicants concluded that these published data are a 10 fold lower. This finding, in the applicants' opinion, supports the conservative nature of exposure models and of assumptions made in modelling to overestimate the results and reflects the general tendency that the modelled machining scenarios drastically overestimate real exposure. However, RAC considers that the data needs to be interpreted with caution amongst others because the working conditions of each of the group of measurements presented in Vincent et al. (2015) are not known[3]. Spray painting, as mentioned by the applicants, mainly concern operations involving painting for which the application procedure was not indicated. In case of sanding, it is doubtful that the measurements corresponding to manual sanding, represent similar operational conditions as described in the WCS 21. Therefore RAC does not share the applicant's conclusion that the modelled machining scenarios drastically overestimate real exposure.

Uncertainties related to the worker exposure assessment:

RAC notes that the lack of measured exposure data for all but one WCSs is a key uncertainty in the exposure assessment. Moreover, some activities have a high exposure potential and the exposure estimates rely on the correct functioning and use of RPE.

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 of the RPE is very much dependent on the individual wearer. 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 if RPE is used for longer time- periods.

Although the applicants, on request by RAC, provided additional information, RAC considers that the description of tasks, how exposure may occur and the RMMs /OCs which should be in place as minimum standards, is still limited.

Also no information is given about minimum requirements for maintenance and efficiency control of the RMMs, an important factor to guarantee reduced exposure levels.

For many WCSs (WCS 2, WCS 5-11, WCS 14) it is stated in the CSR that natural ventilation is in place (see Table 2). RAC considers that to rely on natural ventilation as one of the measures to reduce exposure, is questionable considering that openings like doors and

[3] The applicant acknowledged there were potential problems with the results provided in Vincent et al. (2015), such as: it is not clear if the result of the sampling or the 8h TWA is reported; personal and static sampling results are combined; no details of OC and RMMs are reported.

windows responsible for natural ventilation might be closed for climatological reasons or for product quality reasons as surface treatment could suffer from open doors and windows. On the other hand it is not credible that in small work areas (e.g. inside wing tanks) natural ventilation exists (WCS 19 and 20).

There are inherent uncertainties related to modelled exposure estimates. This is especially true for the modelled exposure estimates for the machining operations since these activities are not covered in the design of ART. The small amount of available monitoring data for some of the machining WCSs suggest that the modelled estimates may be overestimates rather than underestimates. However, the measured data is scarce and not representative. In particular, RAC noted that the same measured data was also used for the metal surface treatment applications of the CCST consortium. It is thus unclear if these data correspond to machining of painted parts which have a higher Cr(VI) surface concentration compared with metal surface treated parts.

The applicants present two aggregated exposure situations of 1.93 µg Cr(VI)/m^3 and 2.24 µg Cr(VI)/m^3. RAC agrees with the applicant's opinion that adding up 90th percentile exposure estimates across different WCS may result in an overestimation. However, the exposure estimates have not taken the frequency of activities into account which also creates uncertainty. RAC considers that this may have a significant effect but it is difficult to quantify without any information on the maximum frequency of the tasks performed.

Although the applicant has insisted that the exposure level estimate covering the WCS 4 is representative across the industry, to RAC it is not clear to which extent this is true considering: the low number of monitoring data from only seven companies corresponding to different time periods; lack of detailed descriptions of the OCs and RMMs corresponding to the measurements; lack of information regarding the process characteristics and production volume of each of the sites covered by the monitored data; and the lack of information on the sampling methods used for these measurements.

On the other hand, the variation in measured air concentrations between the sites (WCS 4) indicates that there is room for implementation of OCs and RMMs other than RPE to lower the exposure to Cr(VI) for those sites with high air concentration levels.

Although the applicants indicated that fugitive emissions are limited or even avoided due to the implementation of control measures, the static sampling does not exclude fugitive emissions nearby the spraying booth. This might be also the case for other Cr(VI) aerosol generating tasks, such as machining activities or waste management (no static measurements provided).

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 considered that for use 2 the ERC 5 is the most appropriate Environmental Release Category.

Humans might be exposed via the environment, either via ambient air (from indirect emissions), and orally via drinking water and food (fish only, in line with the EU RAR for chromate substances (EU RAR 2005). The applicant derived release factors for emission to air and these were used as input in EUSES modelling (v.2.1.2).

According to the applicant hexavalent chromium releases to the environment are carefully

controlled by industry and monitored by regulators. The volume of hexavalent chromium depends on the scale of the facility.

For the coating applications, the production facility is strictly separated from the wastewater stream.

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

Release to water

According to the applicant, controls are in place to deal with wastewater emissions. Water in scrubbers or filters is generally recycled and occasionally replaced, with resulting material being treated as a waste. According to the applicant releases to the wastewater are not relevant. The applicant has indicated that companies reduce emissions to wastewater by treating and/or recycling wastewater. In other cases, wastewater emissions are minimised and treated off-site as a hazardous waste. The applicant noted that where companies do process waste water on-site, releases to the local municipal wastewater treatment facility or, less occasionally, local surface waters are typically in the region of 1 to 50 µg/l. Following response to RAC questions the applicant provided monitoring information for 4 companies that treat Cr(VI) on site and discharge to surface water. The variation in the data ranges 0.03µg/l to 25µg/l (see table 9). The LoD reported is variable but relates to total chromium rather than Cr(VI). The LoD range for Cr(VI) appears to be 1 µg/l to 50 µg/l.

Table 9: Cr(VI) and total Cr concentration in discharge to surface water

Company	Exposure µg/l Cr(VI)	Exposure µg/l Total Cr
1	<0.03	
2	22.5 in one month (5 g per year)	
3	-	25
4	<1	

Therefore the applicants did not incorporate emissions to water into the assessment of indirect exposure to humans via the environment.

Some sites use more than one Cr(VI) substance on site and due to the limited accompanying contextual information on the monitoring data, these data are considered difficult to interpret but in all cases effluent concentrations were <50 µg/l stated upper boundary in the application CSR.

Release to soil

The applicant considered that releases to soil, either at a local or regional level, do not occur.

Release to air

Loss of strontium chromate by gas or vapour is not expected due to the physiochemical properties of the substance (non-volatile) instead losses as particulate matter are estimated

Emissions to air (via fine dust and particulates) are considered to occur at all use sites. All workspaces with potential release to air are equipped with exhaust ventilation systems to

remove residual particulates from workers breathing zone and exhaust air is passed through filters (e.g. HEPA) or wet scrubbers according to best available technique (minimum 99 % removal efficiency) before being released to atmosphere. The wet solution from the scrubbers is treated to reduce the Cr(VI) to Cr(III) (see waste water treatment). Wastes from scrubber systems can be collected by an external waste management company or disposed as wastewater after appropriate on-site treatment.

The CSR indicates that Cr (VI) in air exhaust reduces significantly to Cr(III). Point source emission data was provided for 5 sites (see Table 10). These data were used in the EUSES model to estimate, an annual average concentration in air 100 m from a point source ($Clocal_{air, ann}$), which was subsequently used for the assessment of risks arising from the indirect exposure of humans via the environment. RAC notes that this approach is consistent with the default assumptions outlined in ECHA guidance for "local scale" environmental exposure assessment (outlined in R.16 guidance), which assumes that "worst-case" general population exposure could occur at the site boundary, which is typically 100m from a point source.

Individual site measurements were not reported. Measured concentrations below the detection limit were used applying a factor of 0.5 to the reported values. In addition, if the measurement reported the emission as Cr total, a factor of 0.5 as worst-case assumption[4] was used to estimate Cr(VI) emission. Although the aggregated dataset is characterised in terms of its range, arithmetic mean, geometric mean and 90th percentile, no accompanying contextual information describing the sampling regime at each of these sites is provided in the CSR, i.e. the number of samples taken at each of the sites or details of the sampling or analytical method used (e.g. limit of detection).

In addition, no information about RMMs and OCs in place at each of the 5 sites where monitoring was undertaken, was not provided. Release rates or release factors to the environment from the five sites was not provided but the concentration of Cr(VI) in air 100 meters from a point source was estimated (whilst also taking into account regional background concentrations).

Table 10: Reported Cr(VI) exposure concentrations in air, 100 meter from point source

Nº sites	Reporting year	Range $Clocal_{air,ann}$ (mg Cr(VI)/m³)	Artihmetic mean	Geometric mean	90th percentile (mg Cr(VI)/m³)
5	2012-2013	$2.41x10^{-6}$ - $7.38x10^{-9}$	$6.16x10^{-7}$	$1.65x10^{-7}$	$1.61x10^{-6}$

Note: Regional air concentrations, based on modelling with EUSES 2.1.2, are 2.90 x 10^{-14} mg Cr(VI)/m³

[4] In response to RAC's questions, the applicant specified that available data from industry indicates that the majority of chromium emissions from surface treatment facilities are in the form of Cr(III). A facility based example was given with an air exhaust system including an evaporation unit. The Cr(VI) in the air exhaust reduces significantly to Cr(III) in heavy airflow (e.g. total chromium is represented by 97% Cr(VI) in the vicinity of the bath to approximately 20% Cr(VI)) at the chimney end).

On the basis of this information the applicant concludes a $PEC_{local,air}$ for use in the assessment of indirect exposure to humans via the environment of $1.61x10^{-6}$ mg Cr(VI)/m^3.

In summary (see also Table 11 and 12), the applicant's assessment of exposure via air is based on measured data combined with 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 by the applicant on the basis that emissions are "negligible" or that the 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.

Table 11: Summary of environmental emissions

Release route	Release factor / rate	Release estimation method and details
Water	0	Negligible releases
Air	0.5%	Estimated from C_{local}, which is based on measured emission data
Soil	0	Negligible releases

Table 12: 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 exposure 100m from point source – based on 90^{th} percentile of measured releases 1.61×10^{-6} mg Cr(VI)/m^3 Cr(VI) Regional exposure estimated by EUSES 2.1.2. 2.90×10^{-14}
Man via Environment – Oral	Not considered relevant by the applicant
Man via Environment – Combined	Not considered relevant by the applicant

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

The applicants used measured data to estimate exposure in air, and what they felt were conservative assumptions to assess exposure and show that exposure via water, soil and the food chain were 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 from 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 at the time on the basis that whilst treatment to remove Cr(VI) from wastewater was considered to be effective it was not known how comprehensive this treatment was put into practice by users

of Cr(VI). 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. The EU RAR concluded that the concern for human health via indirect exposure was low for all scenarios, although 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.

According to the applicant releases to the wastewater are not relevant. The applicant has indicated that where wastewater is released to the local municipal wastewater treatment facility or to local surface waters, the concentration is in the region of 1 to 50 µg/l. RAC considers the data provided of the discharge to surface water of four sites rather limited. Furthermore, it is not clear if the data has come from sites formulating the mixtures or from sites undertaking surface treatment activities. No contextual information is given by the applicants that could help explain the variation in the data (0.03 µg/l to 25 µg/l).

Based on the data provided and analysis undertaken by the applicant, RAC agrees that wastewaters containing Cr(VI) are either not produced or subject to treatment before discharge to either the municipal sewer or the environment. However, based on the information provided by the applicant, RAC does not support the applicant's general conclusion that emissions of Cr(VI) to water are "negligible" and that it was therefore appropriate to exclude these releases from the assessment of indirect exposure to humans via the environment.

RAC notes that these emissions, 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 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 and RAC requested the applicant to substantiate their conclusion on the negligibility of wastewater emissions. RAC notes that releases to the local municipal wastewater treatment facility or local surface waters in the region of 1 to 50 µg/l do not appear consistent with a conclusion that emissions are negligible.

Equally, the data available on potential emissions to wastewater for this use is limited to sites across the EU reported to undertake this use and no contextual information to assess the representativeness of these sites is available. It is not clear if the data has come from sites formulating the mixtures, from sites undertaking surface treatment activities or both.

Regarding emissions to air and consequent inhalation exposure of the general population living in the vicinity of the plants, the assessment is based on measured data from five sites (from a number of sites up to 616 reported to undertake this use in the EU). However, since no accompanying contextual information is provided in the CSR, the representativeness of these data is uncertain.

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. In addition, reduction of Cr(VI) to Cr(III) in air is likely to further reduce the general population exposure, but that this may not occur so rapidly that emissions to air are not a relevant source of exposure of Cr(VI) to humans via the environment at local scale.

The oral exposure could have been apportioned and discussed in a transparent manner. This was despite the fact that RAC requested for it and that a dose-response relationship for the general population from oral exposure was available to the applicant.

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

Although it is acknowledged that release to air of Cr(VI) are generally low due to the low volatility of strontium chromate and modern abatement technology with high efficiency, estimated $Clocal_{air, ann}$ is based on rather limited number of data which RAC was not fully able to evaluate because of the absence of accompanying contextual information.

There is uncertainty related to releases to wastewater. According to the applicant releases to the wastewater are negligible. However, on the basis of data received releases do occur and RAC considers that these releases should have been more comprehensively addressed in the applicant's exposure assessment. In addition it is not clear to which extent the limited data from 4 sites can be considered as representative for all companies involved.

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 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.

In addition, RAC notes that the applicant's estimate of $PEC_{local,air}$, which is used for general population exposure assessment, was based on a point source emission data from 5 sites (representing <1% of sites reported to undertake this use in the EU). Since no accompanying contextual information is provided in the CSR, the representativeness of these data is uncertain. However, according to the applicant, highly effective systems to control air emissions are typical for the industry. In addition, reduction of Cr(VI) to Cr(III) in air is likely to further reduce the general population exposure.

RAC notes that the applicant's use of a 90^{th} percentile value for estimating releases to atmosphere is likely to overestimate the $PEC_{local,air}$ at many of the sites undertaking this use. The $PEC_{local,air}$ values calculated by the applicant based on either the arithmetic or geometric mean, which could be more appropriate for estimating the impacts from a use across multiple sites, are a factor of ~2-3 lower than the 90^{th} percentile. Median exposure values would also have been useful to present.

In addition, RAC notes that the default assumptions in EUSES for local scale assessment estimate $PEC_{local, air}$ 100m from a point source[5]. 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). RAC notes that whilst EUSES is the default assessment tool under REACH it is recognised to have limitations that limit its usefulness within the context of impact assessment (for non-threshold carcinogens)[6]. Alternative

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

[6] 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."*

assessment approaches could have been used by 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.

Conclusions

RAC concludes that:

- There are uncertainties in the worker exposure assessment due to the fact that for the vast majority of key WCSs, only modelled exposure estimates were used and measured data, either static or personal was not presented by the applicant.
- For only one WCS (WCS 4) exposure was monitoring data provided (from 7 companies). However, the data lacks contextual information. The uncertainties could have been reduced by providing more detailed information on the OCs & RMMs for each of the 7 companies.
- There are uncertainties inherent with modelled exposure estimates and this is especially true for the machining operations since these activities are not covered in the design of ART.
- Aggregated WCSs for machining activities, provided by applicants on RAC's request, may lead to a higher combined exposure estimate (2.24 µg Cr(VI)/m3) than the value the applicant considered a reasonable basis for use in the SEA, a maximum individual exposure value of 1.93 µg Cr(VI)/m^3.
- There are WCSs with potential for high exposure of workers via air (e.g. spraying activities, sanding). These WCSs rely heavily on the correct functioning and use of RPE for the control of high exposure levels in air. The uncertainties related to the exposure reduction resulting from the use of RPE are in addition to the uncertainties due to the estimated concentrations of Cr(VI) in air.
- With regards to the environment, because of the limited data provided, there are uncertainties related to the applicant's claim that wastewater releases are "negligible".
- In the case of air emissions and inhalation exposure of the general population, the assessment of local exposure is based on measured data from five companies (representing <2% of sites reported to undertake this use in the EU). Since no accompanying contextual information is provided in the CSR, the representativeness of these data is uncertain. However, according to the applicant, highly effective systems to control air emissions are typical for the industry. In addition, reduction of Cr(VI) to Cr(III) in air is likely to further reduce the general population exposure. PEC local, air estimated 100m from a point source is likely to overestimate exposure.

Following from the above uncertainties, RAC considers that the exposure estimates made by the applicant for workers should be used with caution for risk characterisation and impact assessment.

RAC notes that for the majority of the general population the applicant's approach is likely to overestimate exposures and 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 strontium chromate 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 strontium chromate inhaled particles are in the respirable range and contribute to the lung cancer risk. Thus, the calculated excess life-time lung cancer risk is 4×10^{-3} per µg of Cr(VI)/m^3.

Evaluation of the Risk Management Measures

According to the SEA up to **616 sites** perform the application of paints, primers and specialty coatings in the EU. The applicant has stated that it is not possible to develop a description of OCs & RMMs applicable to every individual situation in the ES 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 OCs and RMMs and their effectiveness applicable to all these sites have been described only on a general level.

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.

Risk management for the activities described are very much based on the use of SOP's, spray booths/cabins, LEV and RPE. According to the applicant, the operation and use of these RMMs varies between the sites and therefore they have not developed a single description of them applicable to all sites.

On request by RAC to provide a more detailed description of the specific OCs / RMMs in the 7 sites for which measurement data was provided (WCS 4) to allow compare the monitoring

data between the sites and to justify its representativeness, but no satisfactory response was given by the applicants.

Of particular concern are relatively high exposure levels after correction for very high APF factors for RPE. As such, reliance on well-functioning and correct use of RPE is very high for several WCSs (e.g., RPE with APF 1000 for up to 4h per day in WCS 3 with an estimated exposure level (RPE adjusted) of 0.83 µg Cr(VI)/m^3).

RAC notes that restricted access is not specified in any of the WCSs. The applicant claims there is restricted access at downstream users in WCS 3 (spraying in a purpose-designed room) and in WCS 5 (spraying outside of paint-booth) the area in which the activity is conducted is said to be restricted either physically by means of barriers/signage or through strict procedures during the activity and for a specified time after the application. RAC considers that such conditions should be specified in the ES.

RAC considers the RPE specified for WCS 4 and WCS 5 (APF of 30) insufficient and that RPE with at least an APF of 400 is needed.

RAC considers it important to point out that mechanical ventilation is more efficient than natural ventilation to minimize exposure levels and more in agreement with the general principles of the hierarchy of control exposure.

Risk characterisation

Occupational exposure in surface treatment by application of paints, primers and specialty coatings containing strontium chromate has been assessed by using modelled data for WCS 2-3 and WCS 5-22 and measured data from 7 companies for WCS 4. A generalised estimation of maximum combined individual exposure level, 1.93 µg Cr(VI)/m^3, has been derived on the basis of information on most probable combinations of different WCSs and "expert judgement". This value of 3 digits suggests a precision and accuracy which does not corresponds to the reality.

The exposure assessment includes uncertainties related especially to the representativeness of the exposure estimates across the wide-range of companies in EU, the reliance on RPE, and the assessment of combined exposure. The data provided by the applicant shows that using appropriate 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 1.93 µg Cr(VI)/m^3.

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

Taking into account the uncertainties and the broad scope of the use, RAC considers that the exposure estimates 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 applicant's maximum combined exposure level of 1.93 µg Cr(VI)/m^3 as an 8 h average, resulting in an excess risk of 7.72×10^{-3} as the basis of further analyses by SEAC.

It should be noted that this value is proposed by the applicant and its use is for socio-economic purposes by SEAC so it should not be seen as an endorsement by RAC as any safe or acceptable level for this non-threshold substance.

In the CSR, the applicant has not considered the duration and frequency of exposure of different occupational groups, however in the SEA, the applicant presents data collected showing the number of workers according to the average daily exposure duration (see table 8). RAC considers there is no obvious reason to consider that the data are representative since contextual information how the questionnaire was executed was not provided by the applicants. For example, it is unclear if the extrapolation of the questionnaire data is based on formulators (Use 1) or companies carrying out Use 2 or both.

Considering that these data has been used to correct exposure times for human health impact assessment (HHIA) in SEA and considering the mentioned uncertainties about their representativeness across the whole field of industry, RAC suggest to use for the HHIA the worst case approach, which assumes that all regularly exposed workers are exposed up to 8 h per day and infrequently exposed workers are exposed on average up to 1 h/d. This sensitivity analysis adds some margin of safety to the applicants risk calculations for workers.

Table 13: Excess risk estimates for 40 years exposure for workers

WCS	Inhalation route	
	Adjusted exposure (µg Cr(VI) / m³)	Excess risk
total	1.93	7.72×10^{-3}

Indirect exposure to humans (general population) via the environment

The applicant has estimated excess cancer risks based on inhalation exposure of the general population. Risk characterisation was undertaken according to the RAC reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1). The applicant has conservatively assumed that all inhaled strontium chromate particles are in the respirable range and contribute to the lung cancer risk. Thus, an excess life-time lung cancer risk is 2.9×10^{-2} per µg of Cr(VI)/m³ for 70 years of exposure (24 h/day, 7 d/week).

For a local population living in the vicinity of formulation sites the applicant calculated an excess individual life-time lung cancer risk of 4.67×10^{-5}. The applicant also calculated the excess risk related to regional exposure (2.9×10^{-14} mg Cr(VI)/m³) for 70 years of exposure. However, as Cr(VI) is effectively reduced to Cr(III) in the environment, RAC agrees with the conclusions of the previous EU RAR for chromate substances that regional exposure may not be very relevant.

Table 14: Excess risk estimates for 70 years exposure for man exposed via the environment

ECS	Inhalation route	
	Exposure level (mg Cr(VI) / m³)	Excess risk
ECS 1, local exposure	1.61×10^{-6}	4.67×10^{-5}
ECS 1, regional exposure	Not relevant	

This estimate does not take into account further conversion of Cr(VI) to Cr(III) in the atmosphere. On the other hand, the exposure estimate is based on modelling and does not incorporate any risks via oral exposure. 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.

Risks from oral exposure via food or water were not considered relevant by the applicant. RAC considers these risks 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.

Conclusion

RAC concludes that:

- There is a wide variety of sites using Cr(VI)-containing paints and coatings (varying depending on e.g. the treatment type, size of the parts treated, building layout, scale and frequency of surface treatment operations, level of the automation of the process, etc.). This results in variation in the RMMs applied and ultimately the exposure levels. 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 measured data to corroborate the applicant's modelled exposure estimates. Taking also into account these uncertainties and those 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 relatively high exposure levels after correction for very high APF factors for RPE. As such, the reliance on well-functioning and correct use of RPE is essential for several WCSs.
- RAC considers that the exposure estimates 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 applicants estimate for workers of a maximum combined individual exposure level for 8 hours of 1.93 µg Cr(VI)/m^3 (2 µg Cr(VI)/m^3 when rounded[7]), resulting in excess life-time lung cancer risk of 7.72 *10^{-3} (8*10^{-3} when rounded) as the basis of further analyses by SEAC. It should be noted that this value is proposed by the applicant in the CSR and its use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC as a safe or acceptable level for this non-threshold substance.
- According to the data on exposure durations (presented in the SEA), the duration and frequency of exposure of some worker groups may be limited but for a large proportion (>20%) the exposure duration is typically a full shift. However, because

[7] The value of 1.93 µg Cr(VI)/m^3 suggests a precision and accuracy which does not correspond to the reality and thus RAC favours the rounded value. However, considering this is a rounding issue and that the SEA is based on 1.93 µg Cr(VI)/m^3, the value of 1.93 µg Cr(VI)/m^3 can be accepted to be used.

of the uncertainties in the applicant's exposure assessment (related especially to the representativeness of the presented data), also a worst case should be considered in the human health impact assessment. Such a worst case should assume that all regularly exposed workers are exposed up to 8 h per day and infrequently exposed workers are exposed on average up to 1 h/d. This sensitivity analysis would address some of the uncertainties related to the risk calculations for workers.

- 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.
- For the local general population inhalation exposure, the exposure estimate is based on limited data on releases from 5 sites, without contextual data. As described in section 4, highly effective RMMs to control air emissions are typical for the industry.
- RAC considers that the applicant's estimate of general population risk at the local scale is sufficient for further analysis by SEAC, but notes that the applicant's approach is based on several assumptions that are likely to significantly overestimate risks for the majority of the general population. The possible transformation of Cr(VI) to Cr(III) in the atmosphere is also not considered. 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.
- Considering the risks, the uncertainties and the hierarchy of control, 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 the use of strontium chromate in the application of paints, primers, and specialty coatings (hereafter referred to as 'coatings') in the aerospace and aeronautical sectors. The use covers the application of coatings, both in the construction of aerospace and aeronautical parts as well as the maintenance of such parts. This application for authorisation as submitted by the CCST consortium is closely linked to the surface treatment applications submitted by the same consortium. For the corrosion protection of aircraft, surface treatment steps and multi-layered coatings are used together in sequential steps.

A coating is a material that is applied to the surface of a part to form a protective, functional or decorative solid film. According to the applicant, protective coatings containing strontium chromate in concentrations generally between 1 and 25% w/w are used in the production and repair of aeroplanes, helicopters, spacecraft, satellites, launchers and engines, as well as their component parts. The coatings are generally applied in an industrial setting by spray, brush or roller application. The analysis of alternatives provides an overview of a range of corrosion prone areas in various types of aircraft. These areas of use typically differ to a large extent as regards their design and function, the material and the

possibilities for inspection and maintenance (see Analysis of alternatives, section 3.1). Upon questioning by SEAC, the applicant stated that the use applied for is not limited to the corrosion prone areas listed in the analysis of alternatives. Hence, all parts and areas of aircraft that are (at varying levels) treated against corrosion are in the scope of the authorisation applied for (i.e. also lesser corrosion prone areas).

Strontium chromate functions as a corrosion prevention and inhibiting agent in coatings applied to lightweight metals and alloys, including aluminium, magnesium, steel, cobalt, nickel and titanium. Coatings that have to meet specific corrosion performance requirements within the aeronautics and aerospace industries therefore often contain strontium chromate and are specified as part of corrosion prevention and retardation systems for these metals in the manufacture of aircraft and spacecraft.

According to the applicant Cr(VI)-based coatings are specified in the aerospace sector primarily because they provide the corrosion resistance and inhibition necessary for the safe operation and reliability (airworthiness) of aircraft and spacecraft which operate under extreme environmental conditions. The coatings provide outstanding corrosion protection and prevention for nearly all corrosion sensitive metals under a wide range of conditions. The applicant specifically mentions active corrosion inhibition (self-healing, e.g. repairing a local scratch to the surface) and excellent adhesion properties to support application to the substrate and subsequent coating layers. Structures are described as complex in design, containing millions of parts (between 0.4 and 6 million parts per aircraft), many of which cannot be easily inspected, repaired or removed. Structural components (e.g. landing gear, fasteners) and engine parts on aircraft are particularly vulnerable to corrosion. The complexity and a range of environmental conditions that aircraft must withstand makes corrosion prevention a very challenging task. Multiple coatings, such as pre-treatments, primers (non-specialised and specialised), and top coats are specified to achieve the strict performance requirements necessary for regulatory compliance and for public safety in these sectors. The applicant furthermore claims that each coating type and material is different because it must meet individual functionalities and performance standards particular to a specific design.

The applicant distinguishes a wide range of primers and ‘specialty’ coatings in which strontium chromate is used. In total the joint CCST applicants are currently placing on the market at least 50 different product formulations. A list of these formulations, as provided by the applicant, is included as Annex 3 of the opinion document (the applicant notes that the list is not exhaustive and that the products might be subject to reformulation and name changes). In response to questions from SEAC the applicant confirmed that strontium chromate has already been substituted in all sealants and jointing compounds. Hence, these applications are not in the scope of the use applied for. Furthermore, the applicant clarified that the scope of the application for authorisation is intended to include only primers and specialty coatings, whereas "paints" is a generic and non-specific term that covers for example also topcoats which do not require chromates.

All primers and specialty coatings are low viscosity dispersions of solid components in a blend (formulation) of various liquids consisting of three main components: a synthetic resin binder, a catalyst controlling the rate of the curing reaction and a solvent or thinner. The following coatings and primers are included in the overview provided by the applicant: basic primers (largest volume used due to universal applicability aimed at corrosion protection and adhesion, provides typical green colour), adhesive bonding primers (used for joining together two or more metal or non-metal components), structural primers (used for extended corrosion protection of aerodynamic components and structures that protrude

from the fuselage) and fuel tank primers (used for the purpose of corrosion and/or bacterial growth inhibition). The number of parts treated with basic primers amounts to 890 000 and for bonding primers to 35 000. According to the applicant all primers and specialty coatings are bound to a set of quantifiable key functionalities such as corrosion resistance, adhesion of paint, layer thickness, etc. Table 15 below gives an overview of these technical requirements originating from original equipment manufacturer (OEM) specifications. The requirements in the third column are used to assess the use against the key functionality (e.g. a basic primer is considered to meet the corrosion resistance key functionality if it lasts 500-3000 hours on various substrates). According to the applicant, the requirements are not necessarily the same for all companies and furthermore, requirements for individual applications may vary.

Table 15: Key technical functionalities which determine the suitability of alternatives to using strontium chromate in coatings (from: analysis of alternatives section 3.6)

Application	Quantifiable key functionality	Requirements
Primer, specialty coatings	Corrosion resistance	*Basic primer:* • 500-3000 h on various substrates (e.g. Mg alloys, steel, Al/Ti) (ISO 9227) • 3000 h on Al alloys (ISO 9227) • 960-3000 h, length from scratch 0.5-2 mm (Filiform corrosion test, EN 3665) • long-term requirements up to 9000 h on Al alloys, <1.5 mm scratch (ASTM B117, ISO 7253) *-Bonding primer:* • 3000 – 6000 h (ISO 7253)
	Adhesion of paint / compatibility with binder system	GT 0-1 under dry conditions (Cross-cut Test, ISO 2409 / ASTM 3359), most aerospace companies require GT0
	Layer thickness	*Basic primer* 10-30 µm (5 µm for special applications) *Bonding primer* 2-12 µm
	Chemical resistance	No blistering or delamination after 1000 h at 70 °C to hydraulic fluids (ISO 2812, 1200 g)
	Temperature resistance (thermal shock resistance)	No cracks or peeling (GT<1) after 24 h at -55 °C and 150 °C (BS 2X 33, PR EN 4160, HMDC 0097A)
	Compatibility with substrate	Compatibility with all metallic substrates and surface treatments as well as composites (ISO 2409)
	Processing temperatures	Ability to be processed/ implemented at room temperature

The applicant refers to 'corrosion prevention coating systems' as a term describing both pre-treatment steps (surface treatment) and subsequent coatings. Figure 1 provides an overview of the past, current and possible future developments of these coating systems. The applicant states that the use of Cr(VI) cannot be entirely replaced without impacting the technical performance of the final article. The Cr(VI)-free alternatives that are available and used by industry for some individual coating products, according to the applicant are always accompanied by chromates specified elsewhere in the corrosion prevention coating system.

Figure 1 illustrates the applicants' claim that to date Cr(VI) must be applied either in the pre-treatment or in the coating (primer) and no full Cr(VI)-free corrosion prevention coating system exists. In two series of questions and during the trialogue the applicant was requested to describe the use applied for in a sufficiently detailed way as to ensure that only areas of use for which suitable alternatives are not available are included in the use. In response to several questions along this line the applicant explained that the large numbers of part designs made and treated at various sites of OEMs and maintenance, repair and overhaul facilities (MROs) contribute to the complexity of the use description. According to the applicant the only reasonable approach is that the scope of the AfA lists the applications where chromates are needed, defined by sets of critical parameters (rather than by end-product treated) and a product for which the whole set of critical parameters is not relevant is not within the scope of the use applied for. These critical parameters are defined by the applicant in the first two columns in Table 1 (see section 3.6 of the analysis of alternatives).

The applicant was requested to comment on information available in the public domain on chromate-free coating systems available on the market. These systems are advertised by various paint formulators in the aerospace sector. These advertisements, leaflets, journal articles and Safety Datasheets refer to specific chrome (VI)-free pre-treatment and coatings to be used in conjunction. Specific trade names of formulated products are mentioned and on some occasions include references to the Cr(VI)-containing product formulation the marketed alternatives are aiming to replace. The applicant stated that they were familiar with this information but did not find it contradictory to the information provided in the analysis of alternatives. According to the applicant in contrast to the information in the advertisements such Cr(VI)-free primers may meet the technical requirements only when associated with a Cr(VI)-based surface treatment (chemical conversion or anodizing) or with a chromated basic primer beforehand. The applicant also stated that products qualified to Aerospace Material Specification AMS3095 are not recognised as providing sufficient corrosion protection for the design (as defined in OEM and aircraft specific documents) and manufacture of aircraft due to the fact that AMS3095 is a specification for chromate-free external paint schemes used in the MRO/aftermarket.

The applicants specified in their response to SEAC questions that complete Cr(VI)-free solutions (for example, iron based aluminium deoxidizer (pre-treatment), plus sol-gel, plus non-Cr primer (main-treatment) plus non-Cr topcoat (post-treatment) for exterior fuselage application) have been implemented only on a few aircraft models and are still under evaluation for the majority of aircraft models. Therefore, so-called 'backwards compatibility' is required should the in-flight evaluation be unsuccessful and necessitate reverting to the use of Cr(VI) substances. According to the applicant this is the reason why such applications, for which alternatives are already implemented, were not excluded from the scope of the use applied for.

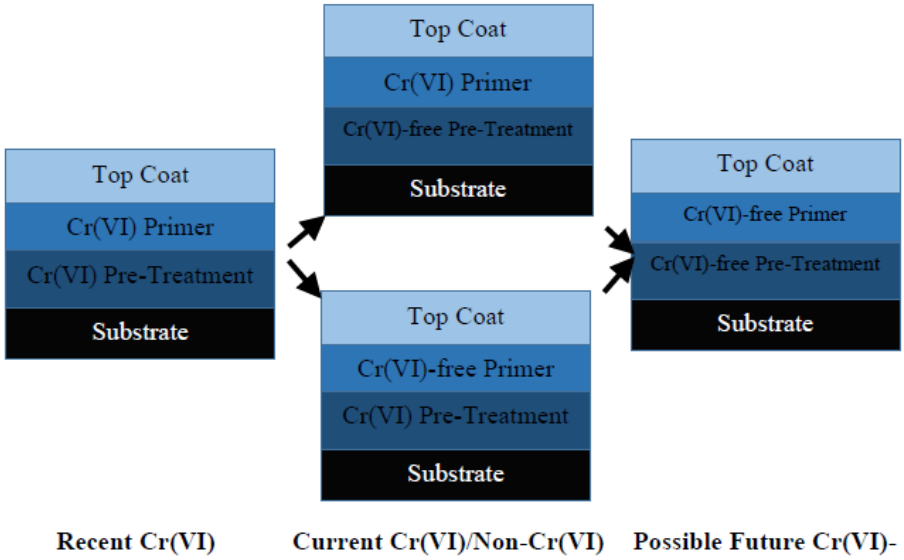

Figure 1. Overview of the development of corrosion prevention coating systems.

The applicant claims that a large amount of research over the last few decades has been commissioned to identify and develop viable alternatives to Cr(VI). Reference is made to numerous research programmes conducted such as those funded by Europe clean sky, programmes funded by United States Air Force and others. Specific reference is made to the Airbus Chromate-Free (ACF) project, launched more than 10 years ago with the aim to progressively develop new environmental friendly Cr(VI)-free alternatives to qualified products and processes used in aircraft production and maintenance. According to the applicant, at a first glance, available performance data for some Cr(VI)-free corrosion inhibitors provided in the alternative assessment indicate interesting results in laboratory scale. However, the applicant notes that the materials mostly have been tested individually and not as part of a complete coating system. Current developments for coating systems incorporate at least one layer of Cr(VI). Complete non-Cr(VI) coating systems are currently under evaluation.

In addition, the applicant performed literature data searches to find evidence on the use of alternatives and provided a questionnaire to all CCST consortia members, verified with bilateral discussions to get an overview of and experience with the alternatives, completeness and prioritisation of critical parameters for their specific processes and the minimum technical requirements. In total 55 'potential' alternatives were identified (See Annex 2 of the analysis of alternatives). The applicant classified those into three categories:

- Category 1: alternatives that are considered most promising, where considerable R&D efforts have been carried out within the aerospace sector. These are:
  Epoxy/polyurethane (PU)-based primers with Cr(VI)-free inhibitors:
  - Cr(VI)-free inhibitors (confidential)
  - Calcium-based corrosion inhibitors
  - Phosphate-based corrosion inhibitors
  - Magnesium-based corrosion inhibitors

  Silane-based processes including Sol-gel coatings

  - Sol-gel coatings

- Category 2: alternatives mainly discussed in literature. In most cases, they are in very early research stages and showed clear technical limitations Epoxy/polyurethane (PU)-based primers with Cr(VI)-free inhibitors:
    - Organic corrosion inhibitors like 5-methyl-1H-benzotriazol
    - Molybdate-based corrosion inhibitors
    - Rare earth-based corrosion inhibitors
    - Zinc-based inhibitors

    Electrocoat primer Sol-gel coatings

    - Various
- Category 3: alternatives, which are -according to the applicant- not applicable for the use applied for (listed in Annex 2 of the analysis of alternatives):
    - 23 alternatives were listed as not relevant for the use applied for since these are actually used in chrome plating, chemical conversion coating and chromic acid anodizing;
    - 13 alternatives were de-selected because of 'clearly insufficient performance';
    - 2 alternatives were described as related to applications within the automotive sector and architecture sector and hence as not relevant for the use applied for;
    - Polysulfide-based primer systems containing Cr(VI)-free inhibitors were disregarded because the matrix-system is not relevant for primer applications within this use (not further specified);
    - Stainless steel was disregarded as a material alternative based on unknown 'material points in a majority of airframe components' (not further specified).

A total of 15 Category 1 and 2 alternatives which were assessed as 10 separate groups were brought forward by the applicant. Table 16 lists the grouped Category 1 and 2 alternatives and their possible application being either as a basic primer, a bonding primer or a structural primer (taken from analysis of alternatives section 6.2). The applicant assessed two of these alternatives separately for their use in basic primers and bonding primers (Cr(VI)-free inhibitors) or for their use in basic primers and structural primers (Magnesium-based corrosion inhibitors). The other alternatives were assessed in a generic way. SEAC noted that for some of the category 3 alternatives the statements for de-selection were provided without any justification. However, as no other information became available (e.g. from the public consultation) challenging the de-selection, this was not followed up further.

Table 16: List of main coating alternatives categorised

Matrix / Process	Cr(VI)-free corrosion inhibitors	Application
Epoxy/polyurethane (PU)-based primers with Cr(VI)-free inhibitors	Cr(VI)-free inhibitors (confidential) (Category 1)	BA, BO
	Calcium-based corrosion inhibitors‡ (Category 1)	BA, BO
	Organic corrosion inhibitors like 5-methyl-1H-benzotriazol (Category 2)	BA
	Phosphate-based corrosion inhibitors ‡ (Category 1)	BA, BO
	Magnesium-based corrosion inhibitors ‡ (Category 1)	BA, SP
	Molybdate-based corrosion inhibitors‡ (Category 2)	BA, BO
	Rare earth-based corrosion inhibitors ‡ (Category 2)	BA, BO
	Zinc-based inhibitors‡ (Category 2)	BA
Electrocoat primer technology	Various ‡ (Category 2)	BA, SP
Silane-based processes including Sol-gel coatings	Sol-gel coatings ‡ (Category 1)	BA, BO, SP

BA (Basic primer); BO (Bonding primer); SP (structural primer)

‡ only some substances in this group may be considered possible alternatives;

Technical feasibility

As already stated and as summarised in the table above, the applicant assessed 10 alternatives in Categories 1 and 2. Category 1 alternatives are considered most promising and the applicant states that some of these replacement substances may already be qualified and used in other industry sectors or for niche applications within aerospace but not as a general alternative to Cr(VI) containing coating systems. Category 2 alternatives are reported as in most cases being in very early research stages and showing clear technical limitations when it comes to the demanding requirements from the aerospace sector.

The applicant assessed each of these 10 alternatives against some of the technical criteria mentioned in Table 15, which are indispensable for coating application within the aeronautics and aerospace sectors. The applicant's overall conclusion is that Cr(VI)-free primers and specialty coatings currently do not represent a general alternative for the replacement of strontium chromate containing formulations as described within the application. All alternatives in Categories 1 and 2 were reported to fail with respect to the necessary corrosion resistance specified by the criteria as presented in Table 15. Eight out of the ten alternatives in addition also fail the criteria for adhesion, chemical resistance, compatibility with substrate and others. The two alternatives that only fail with respect to corrosion inhibition are: Cr(VI)-free inhibitors (both for use in basic and bonding primers) and zinc-based corrosion inhibitors (basic primer use).

The analysis shows there are no technically feasible alternatives to strontium chromate-based coating systems for 'key applications' in the aerospace sector. Several potential alternatives are subject to ongoing R&D, but do not currently support the necessary combination of key functionalities to be considered technically feasible alternatives. The need for a technically equivalent alternative is reflected in the implementation process of alternatives (qualification – certification – industrialisation). This process which takes place within the aeronautics and aerospace sectors takes time due to high regulatory standards and stringent safety requirements. Figure 2 gives a simplified overview of these processes.

Figure 2: Illustration of the qualification, certification and industrialisation processes (analysis of alternatives, section 5).

The above depicted processes are time-consuming. The applicant states that, depending on the difficulty of the technical requirements, the qualification step can easily take 3 – 5 years. The certification step is claimed to need time from 6 months up to some years. Only once these steps are passed through, the industrial production can start. According to the applicant, all components of an aircraft (e.g. seats, galleys, bolts, equipment, materials and processes incorporated in the aircraft, etc.) must be certified, qualified and industrialised. Information supplied in the trialogue explained however that type-certification by a regulatory body only applies to, for instance, the engine of the aircraft or the aircraft structure as a whole and not to every single part. Furthermore, new/alternative materials need to be developed and evaluated prior to these steps. Currently, strontium chromate is claimed to be of significant importance for the aerospace sector and based on experience and with reference to the actual status of R&D programs as well as qualification and certification regimes, alternatives to strontium chromate are not foreseen to be commercially available for surface treatment within the aeronautics and aerospace industries before 12 years after the sunset date.

During the public consultation statements were submitted supporting the conclusion of the applicant on the lack of technical feasibility of alternatives. No comments were received from third parties on any other alternative substances or processes relevant for the use applied for.

Economic feasibility

For all analysed alternatives the applicant states that against the background of significant technical failure of these alternate systems, no detailed analysis of economic feasibility was conducted. For some alternatives it is further stated that based on the literature research and consultations there is no indication that the discussed alternative is not economically feasible. No more information on economic feasibility is provided.

Conclusion

In SEAC's view the analysis of alternatives provided by the applicant describes and assesses the technical and economic feasibility of alternatives in a generic way in line with the use applied for. The use applied for in practice encompasses numerous different coating applications (up to 50 formulation types, specific parts to which it is applied, substrate type, place integral in coating system, etc.), in which strontium chromate is used. These coating applications are typically used as part of a coating system consisting of a pre-treatment step (surface treatment), application of a primer and a topcoat. The type of coating depends on many factors such as the type of substrate (aluminium alloy), the specific part of an aircraft to be coated and its technical specificities and the other 'ingredients' of the coating system in which it is applied. The analysis focussed primarily on the use of strontium chromate and its potential alternatives in three groups of coatings: basic primers, bonding primers and structural primers. The analysis focusses only on the technical feasibility. None of the 10 shortlisted alternatives is assessed as being technically feasible.

As stated above, the analysis of alternatives provided by the applicant does not sufficiently differentiate between the various coating applications which is considered by SEAC a shortcoming of the analysis. In total the applicant listed 55 alternatives of which in practice only 32 were of any relevance for the use applied for and 10 grouped alternatives were shortlisted as being most promising (see also Annex 4 – Initial list of potential alternatives). The categorisation into categories 1-3 gives a good overview about why certain alternatives were considered further and why others have been excluded from any further assessment. Nevertheless, the justification for delisting all of the category 3 candidates as alternatives was not fully analysed, but rather only short statements were provided. For those alternatives considered as being promising candidates to be substitutes in the future (category 1 alternatives) or for those that are in very early research stages (category 2 alternatives), a description of the substance ID & properties and the type of coating it may be used for was provided.

For the sector covered by this application for authorisation, complex airworthiness and approval processes need to be considered, which are described and explained by the applicant. In order for alternatives to be industrialised and implemented, these may need to undergo qualification and certification procedures first. SEAC notes that the applicant did not provide sufficient information to distinguish between type-certification by a regulatory body (e.g. of aircraft engines) and other qualification and certification steps. Consequently, SEAC is not able to conclude on the exact time needed for such processes, although SEAC understands that the transition to alternatives takes additional time due to the need to pass such processes successfully. SEAC notes that the qualification step is not a unique characteristic for this sector and the actual time required might vary between various technical applications included in this use applied for.

Only a qualitative and very brief statement on economic feasibility was provided for each alternative. No assessment was performed allowing e.g. a comparison of the alternatives or any evaluation of the economic feasibility. The applicant states that this is due to the fact that none of the alternatives is currently regarded feasible from a technical point of view. Overall, there is no indication that alternative processes are not economically feasible according to the applicant.

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 strontium chromate-based coating systems for key applications in the aerospace sector. Several potential alternatives are subject to ongoing R&D, but do not currently support the necessary combination of key functionalities to be considered technically feasible. Based on experience and with reference to the status of R&D programs, alternatives are not foreseen to be commercially available for all key applications in this sector for at least 12 or 15 years. The applicant's reasoning for this conclusion is given in section 7.1 above.

Applicant's conclusion on economic feasibility: the applicant states that because all of the shortlisted alternatives (category 1+2 alternatives) fail significantly when it comes to technical aspects no quantitative analysis of the economic feasibility was conducted. Only brief qualitative statements on economic feasibility are presented. For some alternatives it is reported that based on the literature research and consultations overall there is no indication that alternative processes are not economically feasible.

Conclusion

SEAC's conclusion on technical feasibility: as stated in section 7.1. above, the applicant has provided an analysis of alternatives in a generic way which is aligned with the broad use applied for covering numerous coating applications (formulation types, specific parts to which it is applied, substrate type, place integral in corrosion prevention coating system, etc.). As stated above, the analysis of alternatives provided by the applicant does not sufficiently differentiate between the various coating applications which is considered by SEAC a shortcoming of the analysis. In total the applicant listed 55 alternatives of which in practice only 32 were of any relevance for the use applied for and 10 were shortlisted as being most promising. The categorisation into Categories 1-3 gives a good overview about why certain alternatives were considered further and why others have been excluded from any further assessment, although SEAC notes that for some Category 3 alternatives the deselection statements were not convincing based on a lack of supporting justification. During the public consultation, comments supporting the conclusion of the applicant on technical feasibility were submitted and no information on other alternatives was provided by interested third parties.

As a consequence of the broadly defined scope of the use applied for, covering many different coating applications containing strontium chromate, and the generic approach of the applicant in the analysis of alternatives, SEAC cannot exclude that there are indeed "coating applications" using strontium chromate, where substitution is already feasible or will become so in the short-term. In the analysis of alternatives the applicant refers to the corrosion prevention coating system as a whole consisting of a pre-treatment, a primer and

a topcoat. The applicants' claim that to date Cr(VI) must be applied either in the pre-treatment or in the coating (primer) and no full Cr(VI)-free corrosion prevention coating system exists is seemingly contradicted by information available in the public domain showing that chromate-free coating systems (chrome (VI)-free pre-treatment and coatings to be used in conjunction) are available on the market. This contradiction is however contested by the applicant who states that such Cr(VI)-free primers may meet the technical requirements only when associated with a Cr(VI)-based surface treatment (chemical conversion or anodizing) or with a chromated basic primer beforehand.

It is not clear to SEAC when alternatives will eventually become available for specific applications within this broad use applied for. SEAC should have been provided with a categorisation of surface treatment/coating applications, along with information on the specific technical requirements, in order to judge about the actual feasibility/infeasibility of alternatives for specific applications within the broad use applied for. 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 does, however, not specify such applications or their related technical requirements. A more precise and use-specific assessment of alternatives would have made clear which uses are covered by the application and which are not. This information allowing differentiation across uses was not provided which is considered a shortcoming of the analysis.

Based on the available information, SEAC concludes that before the sunset date technically feasible alternatives are unlikely to exist for the use of strontium chromate in all coating applications (basic primers, bonding primers and structural primers) in the aerospace sector covered by the use applied for. As a consequence of the broadly defined scope of the use applied for, covering many different coating applications containing strontium chromate, and the generic approach of the applicant in the analysis of alternatives, SEAC cannot exclude that there are 'coating applications' using strontium chromate, where substitution is already feasible or will become so in the short-term. The uncertainties pointed out above are taken into account by SEAC in the recommendation for the review period and the condition for the review report.

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 allowing a comparison of the alternatives on this aspect or any evaluation of the economic feasibility. Economic feasibility is addressed in the application for authorisation very briefly and through qualitative statements only. For assessing the economic feasibility of alternatives, not only production costs, once the technical issues are solved, could be taken into account but also the costs of developing and transitioning to achieve technical feasibility can be considered. None of these costs were however considered by the applicant. For some alternatives, the applicant concludes that overall, there is no indication that alternative processes are not economically feasible. Due to the lack of an assessment on economic feasibility SEAC cannot conclude on the economic feasibility of alternatives.

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

Description:

The applicant has considered three main matrix/process alternatives for the purpose of surface treatment for applications in the aeronautics and aerospace industries. Within the epoxy/PU matrix system eight alternatives with different Cr(VI)-free inhibitors are presented (see table 17).

The use covers a number of surface treatment processes and steps that may be applied to a number of different metal substrates (e.g. aluminium, steel, zinc, magnesium, titanium, alloys and composites with metallic areas). However, the analysis of alternatives shows that actually there are no technically feasible alternatives to the use of strontium chromate in the surface treatment of metal for these key applications. Several potential alternatives are subject to ongoing R&D, but do not currently support the necessary combination of key functionalities to be considered technically feasible alternatives. Therefore, a detailed risk assessment of the alternatives to facilitate a comparison with strontium chromate has not been conducted, the only information provided by the applicant was the hazard classification and labelling of the alternatives and these were compared to the classification of strontium chromate to indicate less or more severe toxicity of the alternatives.

Table 17: List of alternatives

Matrix / Process	**Cr(VI)-free corrosion inhibitors**	**Application**
Epoxy/polyurethane (PU)-based primers with Cr(VI)-free inhibitors	Cr(VI)-free inhibitors (confidential) (Cat 1)	BA, BO
	Calcium-based corrosion inhibitors (Cat1)	BA, BO
	Organic corrosion inhibitors like 5-methyl-1H-benzotriazol (Cat 2)	BA
	Phosphate-based corrosion inhibitors (Cat 1)	BA, BO
	Magnesium-based corrosion inhibitors (Cat 1)	BA, SP
	Molybdate-based corrosion inhibitors (Cat 2)	BA, BO
	Rare earth-based corrosion inhibitors (Cat 2)	BA, BO
	Zinc-based inhibitors (Cat 2)	BA
Electrocoat primer technology	Various (Cat 2)	BA, SP
Silane-based processes including Sol-gel coatings	Sol-gel coatings (Cat 1)	BA, BO, SP

BA (Basic primer); BO (Bonding primer); SP (structural primer)

Cat 1: most promising alternative, where considerable R&D efforts have been carried out within the aerospace sector.

Cat 2: alternative mainly discussed in literature and in most cases in are very early research stages and showed clear technical limitations

Alternative 1: Epoxy/PU-based primers with Cr(VI)-free inhibitors

Epoxy/PU-based matrix systems can be used for bonding and basic primers that can be applied on several substrates. Bonding and basic primer coatings are used on titanium, titanium alloys, aluminium, aluminium alloys and steel parts. In addition, epoxy/PU-based basic primers are applied on composite and stainless steel parts.

Alternative 1.1: Cr(VI)-free inhibitors (confidential)

The exact substance identity and composition of products used is not known as this is confidential business information of suppliers. Since no detailed analysis for a complete epoxy/PU-based formulation could be carried out given the insufficient information, the reduction of overall risk cannot be assessed.

Alternative 1.2: Calcium-based corrosion inhibitors

Based on available information on four strictly confidential calcium-based inhibitors used within this alternative, they are in worst case classified as Eye Dam. 1, Skin Irrit. 2, STOT SE 3, Skin Corr. 1B, Eye Irrit. 2A, Resp. Sens. 1A. Calcium-based primers are also available on the market. Classification and labelling (SDS) of these products is not publically available.

Alternative 1.3: Organic corrosion inhibitors like 5-methyl-1H-benzotriazol

Based on the available information on the substances used within this alternative, in best case inhibitors/products are not classified. As worst case they are classified as Skin Corr. 1B/1C, Eye Dam. 1, STOT SE 3, Acute Tox. 4, Aquatic Acute 1 and/or Aquatic Chronic 1.

Alternative 1.4: Phosphate-based corrosion inhibitors

The exact substance identity and composition of products containing phosphate-based corrosion inhibitors in primers is very often not known as this is confidential business information of suppliers. In a worst case they are classified as Skin Irrit. 2, Eye Dam. 1, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 1, Acute Tox. 4.

Alternative 1.5: Magnesium-based corrosion inhibitors

Based on the available information on two strictly confidential magnesium-based inhibitors, they are in the worst case scenario, the substances classified as Skin Irrit. 2, Eye Irrit. 2 and STOT SE 3. The sacrificial Mg-rich primer is classified as Flam. Liq. 3, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, Aquatic Chronic 2, Acute Tox. 4, Asp. Tox. 1.

Alternative 1.6: Molybdate-based corrosion inhibitors

Zinc molybdate is classified as Skin. Irrit. 2, Eye Irrit. 2 and STOT SE 3. In addition to zinc molybdate, three strictly confidential substances were reported during the consultation which in the in the worst case classified for Aquatic Acute 1, Aquatic Chronic 1, Skin. Irrit. 2, Eye Irrit. 2, Acute Tox. 4 and STOT SE 3.

Alternative 1.7: Rare earth-based corrosion inhibitors (cerium (Ce), praseodymium (Pr))

Publically available information on specific alternative products was evaluated. Based on the available information on the substances used within this alternative,they are in worst case classified as Aquatic Acute 1, Aquatic Chronic 1, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3.

Alternative 1.8: Zinc-based corrosion inhibitors

Zinc compounds that have been tested in paint/primer are in the best case not classified. In the worst case, they have classifications as Pyr. Sol. 1, Water-react. 1, Aquatic Acute 1, Aquatic Chronic 1.

For all above mentioned alternatives, with exception of the alternative 1.1 for which no substance identity and composition has been given, it is concluded that the transition from strontium chromate – which is a non-threshold carcinogen – to one of these inhibitors/products alternatives would constitute a shift to less hazardous substances.

Alternative 2: Electrocoat primer technology

Substance identity and composition of the resins system, pigment paste and anticorrosion paste used in the electrocoating process is not known as this is proprietary of the supplier. Based on the information reported by the supplier during the consultation, substances used within this alternative are classified as Eye Irrit. 2, and Aquatic Chronic 3 as well as Skin Irrit. 2, respectively. As such, transition from strontium chromate – which is a non-threshold carcinogen – to this process would constitute a shift to less hazardous substances.

Alternative 3: Silane-based processes including sol-gel coatings

The exact substance identity and composition of products used in the Sol-Gel process is very often not known as this is confidential business information of suppliers. Based on the available information on substances used within this alternative (see Appendix 3.3 of the Analysis of Alternatives). The worst case is presented by Vinyl trimethoxysilane (VTMS), which is classified as Flam. Liq. 3, Acute Tox. 4, Eye Dam. 1, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Asp. Tox 1, Muta. 1B, Carc. 1B. Additionally VTMS is included in the CoRAP (Community rolling action plan), indicating substances for evaluation by the EU Member States in the next three years.

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

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:

Not relevant as no suitable alternatives have been identified.

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 cancer cases

The estimated number of additional statistical fatal cancer cases has been calculated using the excess life-time lung cancer risk value presented in section 6 and the estimation of the number of exposed people provided by the applicant. Furthermore the differences in the duration of the exposure of workers have been taken into account following the approach used by the applicants in the SEA.

RAC notes that these calculations are based on the estimation of exposed populations as provided by the applicant (see table 18). Even if it is not possible to confirm the exact numbers of workers exposed, nor the allocation of workers between the groups with different exposure durations, RAC agrees that the approach can be used to quantify the estimated statistical cancer cases. However, due to these exposure durations being uncertain and difficult to verify and in order to test the robustness of the cost-benefit ratio, RAC additionally calculated the estimated statistical cancer cases with different (worst case) assumptions, i.e. with only two different values for the duration of exposure (see table 19 below). It is noted that the exposure durations should be considered as part of the CSR, and that it is unclear how the durations have been considered already when deriving the estimates for the combined exposure.

RAC concludes that regional scale assessment of man via environment may not be very relevant, and there is no need to estimate the additional statistical cancer cases from this exposure route. For SEAC, the regional assessment is therefore not regarded being relevant for assessing derived also non-fatal cancer cases using the survival rate based on average mortality rates for lung cancer in the EU-27, namely 82.8% for both sexes.

The applicant the human health impacts man via environment regional. Furthermore, RAC notes that the applicant claims that the exposure of man via environment by air is substantially overestimated, arguing that the assumption of 10 000 inhabitants living at

100 meter from the emission is highly unlikely (surface treatment facilities are often located in industrial areas) and that the local population is not present in the relevant area every day a year for full 24 h (dose response curve is based on the estimation that exposure occurs 365 days a year and 24 h a day). RAC acknowledges this is a likely source of overestimation (see also section 4).

In addition, the applicant pointed out that the highest concentration for PEClocal 100m from the point source of 0.0067µg/m^3 is 15 times lower than the concentration (about 0.1 µg/m3 downwards) from where the ETeSS study (study conducted on behalf of ECHA) states that cancer risks may be negligible. RAC acknowledges that the excess risks in the low exposure range might be overestimated (see section 3).

Table 18: Estimated additional statistical fatal cancer cases for 12 years of exposure (12 is the review period applied for)

	Exposure duration per day (h)	**Exposure 8h adjusted TWA (µg/m³)**	**Excess lung cancer risk**	**Number of exposed people**	**Estimated statistical fatal cancer cases**
					12 years
Workers – Combination of WCS	<1	0.241	0.000965	3 073	0.89
	1-3	0.724	0.00290	2 518	2.19
	4-6	1.45	0.00579	3 376	5.86
	6-8	1.93	0.00772	4 758	11.0
	Not regularly exposed	0.241	0.000965	9 226	2.67
Workers total				22 951	22.6
	Exposure 24h (µg/m³)				**12 years**
Man via environment - Local	1.61×10^{-3}		4.67×10^{-5}	10 000 x 616 sites = 6 160 000	49.3
Man via environment - Regional	Not relevant				
Total					**71.9**

Table 19: Estimated additional statistical fatal cancer cases for 12 years of exposure, based on RAC's alternative approach (12 is the review period applied for)

	Exposure duration per day (h)	Exposure 8h adjusted TWA (µg/m³)	Excess lung cancer risk	Number of exposed people	Estimated statistical fatal cancer cases
					12 years
Workers – Combination of WCS	<8	1.93	0.00772	13 725	31.8
	Not regularly exposed	0.241	0.000965	9 226	2.67
Workers total				22 951	34.5
	Exposure 24h (µg/m³)				**12 years**
Man via environment - Local	1.61×10^{-3}		4.67×10^{-5}	10 000 x 616 sites = 6 160 000	49.3
Man via environment - Regional	Not relevant				
Total					**83.8**

The estimated additional statistical fatal cancer cases reported in Tables 18 and 19 are 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.

As the methodologies used by the applicant (particularly the generic exposure assessment for the general population using the EUSES model) focus on individuals or locations with a high potential for exposure, the overall number of cases is likely to have been significantly overestimated.

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.

Assessment of impacts

The application for authorisation includes a socio-economic analysis (SEA) covering both the formulation (use 1) and the subsequent use of strontium chromate (use 2) described in the application. The geographical scope of the SEA is the territory of the European Economic Area (EEA). The temporal scope of the SEA coincides with the review period requested (12 years) and stretches from 2019 (base year, corresponding to the sunset date of the substance) to 2031.

To assess the impacts of granting or refusing authorisation of the use applied-for, the applicant derives and compares two scenarios: an applied-for use scenario and a non-use scenario. The applied-for use scenario comprises the continued formulation and use of

strontium chromate in primers and specialty coatings in the EEA aerospace industry. The application covers in principle the whole EEA aerospace supply chain and describes the use of strontium chromate at the sites of formulators, distributors, 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 established through consultations with consortium members including formulators, OEMs, suppliers and MROs which reported that they would react to a refused authorisation by shutting down the relevant operations in the EEA and relocating them to a non-EEA country. The relevant operations comprise the formulation of mixtures, the production of parts, components and aircraft requiring strontium chromate as well as the repair and maintenance of such articles using strontium chromate.

Costs of continued use (HH)

The applicant has conducted a human health impact assessment to characterise the cancer burden for workers and the general population arising from inhalation exposure to strontium chromate in the uses applied for. The dose-response curve established by RAC is used to translate the exposure levels stated in the CSR to excess lifetime risks for fatal cancer which are then adjusted to the duration of exposure corresponding to the temporal scope of the SEA (12 years). As the dose-response curve describes only fatal cases of cancer, the applicant estimated the additional non-fatal cancer cases based on the average mortality rates for lung cancer (82.8%). Valuation of the statistical cancer cases (in terms of impacts on social welfare) is conducted via the Willingness-to-pay values recommended by ECHA guidance (€400 000 for non-fatal cancer cases and €1 052 000 (central value) or €2,258,000 (sensitivity value) for fatal cancer cases) which are adjusted to the base year using a GDP deflator index (1.01517 per year). The assessment for the human health risks to directly exposed workers covers an estimated 616 production sites and assumes that 50% of the workers employed at the sites are exposed to strontium chromate (22 951 workers in total). In addition, risks to indirectly exposed workers and the general population in the direct neighbourhood of the sites as well as risks to the general population in an area of 200 x 200 km around the sites are assessed ("man via environment"). Since the applicant does not have knowledge on the location of all downstream user sites, the number of people living in the area around the sites is assumed to be 512 888 463 (size of the EEA population). The total human health impacts associated with the use applied for (see table 18 and table 10 in the opinion document for use 1) are valued at €215.7 million (present value for the 12 year assessment period) and comprise the following:

- Human health impacts for workers directly exposed at downstream user sites (use 2): €67.4 million
- Human health impacts for indirectly exposed workers and the general population arising from downstream use (use 2): €146.9 million
- Human health impacts for workers directly exposed at formulator sites (use 1): €0.036 million
- Human health impacts for indirectly exposed workers and the general population arising from formulation (use 1): €1.353 million

All of the estimates above represent present values for the 12 year assessment period and are based on the higher (sensitivity) WTP value for fatal cancer cases.

SEAC's view

SEAC finds the approach taken by the applicant with respect to the human health impact assessment to be generally satisfactory. Based on the application documents, SEAC was able to verify that the applicant has applied the dose-response relationship correctly to account for fatal cancers, considered also non-fatal cancers, adjusted the results for the temporal scope of the analysis and chose a suitable and commonly used valuation measure (based on WTP) to describe the human health risks in terms of changes on social welfare attributable to the use applied-for.

The applicant's estimate of exposure, which is used for the exposure assessment of the general population, was based on a modelled concentration located 100 meters from a point source, which is consistent with the default assumptions used in the EUSES model for local scale assessments. RAC considers that the default assumptions used for the local scale exposure assessment in EUSES are conservative and are likely to overestimate the risks and consequently the estimated number of statistical cancer cases for the general population. In addition, SEAC notes that the way the RAC dose-response functions are applied 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, the values presented here are potentially overestimated. Furthermore, the 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.

SEAC has reservations about the presentation of and justification for some of the parameters and assumptions used in the analysis. Based on the information provided, it is not possible to check the plausibility of the input parameters regarding the number of sites using strontium chromate and the number of workers at these sites (this concerns both the number of workers in total and the number of workers exposed to strontium chromate). Responding to a request for additional information, the applicant stated that such data is available from 12 questionnaires received from 16 consortium members using strontium chromate, whereas the SEA covers an estimated total of 616 companies (SEAC assumes that the applicant equates one company with one production site, as these terms appear to be used synonymously). The actual information from the questionnaires completed by consortium members is not included in the application. Also, the number of responses to the applicant's questionnaire seems low in view of the total number of production sites considered in the analysis. The remainder of the supply chain (i.e. the parts of the supply chain formed by actors who are not members of the application consortium) is described based on assumptions (such as the number of sites, percentage of small versus medium size sites, number of employees at the sites, share of employees exposed) which cannot be verified. The applicant assigned the exposed workers to five different groups with respect to the duration of exposure (less than 1 hour per day, 1-3 hours per day, 3-6 hours per day, 6-8 hours per day and irregular exposure) based on the survey conducted among consortium members. As noted by RAC, the representativeness of this data for all downstream users covered by the application is unclear.

In conclusion, although the applicant uses a generally accepted methodology and claims to take a "worst-case" approach to the human health impact assessment, there is uncertainty

as to how accurately the applicant's estimate depicts the social costs of continued use in terms of the cancer burden for workers and the general population. Overall, SEAC notes that the assumptions and methodologies used by the applicant (in particular with respect to the man via environment assessment) may overestimate the human health impacts, although the magnitude of this effect is not known.

SEAC took note of RAC's sensitivity analysis on estimated cancer cases assuming that all regularly exposed workers are exposed for 8 hours daily. Under this assumption, the estimated statistical cancer cases and, thus, the monetised human health risks would increase by less than 20% compared with the applicant's estimate. This would not affect SEAC's view on the applicant's conclusion that the benefits of continued use outweigh the risks.

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

The applicant's assessment of the benefits of continued use is primarily based on social impacts. The applicant assumes that 100% of all jobs at small production sites using strontium chromate in the EEA and 50% of all jobs at medium production sites would be lost as a result of the non-use scenario, amounting to a loss of employment for 19 441 workers currently employed in the EEA. This is based on an assumed 136 production sites and hence considered an underestimate by the applicant (by comparison, 616 production sites are assumed in the human health impact assessment). Using the so-called "salary cost method", the resulting impact is claimed to be €6 515 million (present value) when considering the salary costs for the duration of the review period (12 years). A sensitivity scenario is presented in which the salary costs are considered for one year only, based on a downward rounding of the average duration of unemployment in Europe (15.1 months), resulting in an impact of €618 million.

The applicant generally names a number of economic impacts related to the non-use scenario which are not quantified. Among these, it is stated that relocation of production sites to non-EEA countries would lead to re-certification and re-qualification costs, costs associated with production and maintenance downtime, increased transportation costs and emissions related to importing goods from outside the EEA. Furthermore, some wider economic impacts that would be associated with the relocation scenario are posited, for example the loss of aerospace related know-how within the EEA and the loss of Europe's independent access to space.

It is stressed by the applicant that corrosion inhibition is a key concern in the aerospace industry and that any losses in product quality in this regard would have serious implications for the safety of aircraft operations.

The SEA includes two short annexes broadly outlining possible impacts of a refused authorisation on airlines (Annex E of the SEA) and on the aviation, space and defence industry (Annex F). According to Annex E, approximately 5 000 aircraft inspections and overhauls of 6 100 engine parts and 2 500 aircraft components take place every day in Europe. More than 5 000 aircraft are in operation in Europe. The cost of a grounded aircraft to the operator is between €150 000 and €800 000 per day. Assuming all aircraft were grounded, European airlines would suffer a daily revenue loss of €0.28 billion, amounting to a daily profit loss of approximately €12 million. According to Annex F, the annual turnover of the European Aviation, Space and Defence industries is €197 billion. A refused

authorisation is estimated by the applicant to result in a loss of at least 50% of the turnover (i.e. €99 billion), amounting to a profit loss of €9.9 billion per year.

SEAC's view

SEAC finds that the applicant's assessment of the benefits of continued use in large part lacks a sound methodological basis. The salary costs, whilst interpreted as a benefit by the applicant, represent a cost of continued use. Furthermore, the applicant's treatment of job losses does not follow ECHA's guidance on SEA which states that employment effects that are caused by a given activity, e.g. a production line or company relocating production outside of the EU, should be included as a distributional impact.[8] Nevertheless, SEAC accepts that a redistribution of jobs from the EEA to non-EEA countries in the magnitude claimed by the applicant could have significant social implications for the EEA region. SEAC views the sensitivity scenario presented by the applicant as a more appropriate indicator for the impact on employment in the EEA. This scenario is loosely based on the average statistical duration of employment in Europe and amounts to a total salary cost of €618 million. SEAC cannot ascertain whether the assumed duration of unemployment of 1 year in this scenario is representative for the affected workers in the aerospace sector.

SEAC considers that it would have been useful to analyse the economic impacts which are only qualitatively given by the applicant in more detail. SEAC agrees with the applicant that the relocation of a large part of the aerospace supply chain would likely lead to significant industry-wide impacts which could include substantial costs related to dismantling current production sites, setting up new production sites and taking mitigating measures to reduce the risk of supply disruptions (such as holding reserve inventory of spare parts). However, such impacts are not quantified or elaborated in any meaningful way in the application. With respect to Annexes E and F, although SEAC recognises that economic impacts on airlines and on the aviation, space and defence industry would have been an important aspect to consider when assessing the benefits of continued use, the causal relationship between the estimated profit losses of 100% and 50% (respectively) for these sectors and the non-use scenario described by the applicant (relocation of the use of strontium chromate) remains unclear for SEAC.

To be able to evaluate the overall credibility of the assessment, SEAC would have expected a more thorough justification of the non-use scenario. In this respect, SEAC notes that, according to the applicant, strontium chromate has already been successfully replaced with alternatives in some technical applications in the aerospace sector and that further substitution efforts are ongoing. Therefore, the claim that all production sites currently using strontium chromate would relocate in the case of a refused authorisation would have needed further substantiation. Notably, the SEA lacks an assessment of the economic consequences that would be associated with switching to primers and specialty coatings that do not contain strontium chromate. SEAC points out that such aspects are qualitatively included in the Analysis of Alternatives where it is stated, for example, that using alternatives providing inferior corrosion protection performance would necessitate shorter inspection intervals, with a substantial impact on associated maintenance costs, and that re-equipping aircraft suffering from damage due to inferior corrosion protection would cost hundreds of millions of euros. This information could have been further elaborated to strengthen the credibility of the non-use scenario. This notwithstanding, SEAC agrees with

[8] ECHA 2011, Guidance on the preparation of socio-economic analysis as part of an application for authorisation, p. 82.

the applicant that corrosion protection is of vital importance for aerospace safety and took this aspect into account qualitatively in its opinion.

Although SEAC understands that chromates are used not only during parts manufacturing but also during assembly (i.e. for touch-up or final paint/surface treatment purposes), it would have been useful to analyse in more detail whether relocation would be a likely outcome only for certain production processes rather than for the production sites using strontium chromate as a whole. The assessment included in the SEA is too general for SEAC to be able to comment on the most likely responses of the various parts of the aerospace supply chain and hence on the plausibility of the non-use scenario. Due to this, there are uncertainties about the impacts in the non-use scenario, including the number of jobs which, according to the applicant, would be lost in the EEA if authorisation is not granted.

Benefit-risk comparison

The applicant claims that a granted authorisation would have a net benefit in the amount of €6 299 million (net present value for the 12 year assessment period), based on the monetised risks of continued use to human health (€215.7 million) and the social impacts of a non-granted authorisation (based on salary costs for the whole 12 year assessment period, amounting to €6 515 million). The SEA includes an uncertainty analysis in which the sensitivity of the overall result to some of the assumptions underlying the assessment (number of production sites, value of a statistical life and duration of unemployment) is evaluated. In the most conservative scenario (which assumes the highest health impacts and the lowest social impacts), the ratio between the health impacts and social impacts is 1:5. Based on this, the applicant asserts that the conclusion that the benefits of continued use outweigh the risks to human health and the environment is robust.

SEAC's view

The applicant's approach to impact assessment and benefit-risk comparison fails in many aspects to adequately capture the changes in social welfare resulting from non-use of strontium chromate. SEAC considers that the following estimates provide some indication of the impacts of the applied-for use of strontium chromate from the internal perspective of the EEA:

- Monetised human health impacts: €215.7 million (present value for the 12 year assessment period, taking into account the higher number of production sites)es
- Monetised social implications related to employment: €618 million (salary costs for one year only, taking into account the lower number of production sites), reflecting 19 441 jobs at 136 sites

However, SEAC does not consider that a net impact of continued use of strontium chromate for the EEA can be described based on these estimates. This is because the applicant's approach to assessing the benefits of the use relies solely on indirect impacts on employment. Direct (economic) impacts of the decision to grant or refuse authorisation are not accounted for in the benefits assessment and, hence, not reflected in the comparison of benefits and risks. SEAC regards this as a major shortcoming of the analysis.

According to ECHA's guidance on SEA, the type of non-use scenario selected by the applicant (relocation scenario) requires at least a qualitative consideration of impacts on

regions outside the EEA.[9] The applicant clarified that the human health impacts as well as the jobs associated with the use of strontium chromate would be transferred to non-EEA countries in the non-use scenario. Although the applicant foresees that the risks would increase due to less stringent risk management measures outside of the EEA[10], no information of the net effect on human health and employment is available. As such, SEAC notes that the applicant's analysis primarily shows a redistribution of risks and employment from the EEA to non-EEA countries.

Additional information provided by the applicant

In response to a request from SEAC, the applicant has provided additional illustrative information on some economic impacts arising from a hypothetical substitution scenario and from the relocation scenario described in the application.

Substitution scenario

In the hypothetical case that unproven alternatives or alternatives providing inadequate corrosion protection would be used, a substantial increase in inspections and overhaul of life-limited components of aircraft would be necessary, according to the applicant. Based on an existing system used by the sector to identify the repeat interval of inspection with respect to the stress corrosion rating, protection rating and environmental rating for any component or system, a reduction of the maintenance interval by half is assumed. This would result in additional maintenance costs of €7.5 billion per year. Furthermore, inadequate corrosion protection is expected to have an effect on the economic service life of aircraft. The applicant has estimated the direct cost of replacement associated with the early retirement of European aircraft, assuming that aircraft service lives are reduced from 30 to 15 years on average. The resulting additional cost of replacement is €96 billion per year (comprising €41 billion for commercial aircraft, €55 billion for defence aircraft and €0.3 billion for helicopters).

Relocation scenario

The applicant has presented an illustrative assessment of factory move costs occurring in the event of relocation. An average total move cost of €8 940 per m² (referring to the size of the production site) is assumed. This includes allowances for building floor space, new and re-sited plant machinery, IT, transition cost and cost for decommissioning of old facilities. Factory move costs are estimated for 16 large sites (96 000 m² each), 60 medium sites (36 000 m² each) and 540 small sites (6 000 m² each), amounting to a grand total of €62 billion.

[9] ECHA 2011, Guidance on the preparation of socio-economic analysis as part of an application for authorisation, p. 94.

[10] On a side note, the idea that companies currently operating in the EEA would lower the level of protection for their workers after relocating to a non-EEA country appears rather dubious.

The applicant's estimates of the economic impacts associated with the substitution and relocation scenarios are summarised in the table below:

Substitution scenario	
Type of cost	*Estimate (additional costs per year)*
Maintenance cost	€7.5 billion
Cost of replacement	€96 billion

Relocation scenario	
Type of cost	*Estimate (one-off cost)*
Factory move costs	€62 billion

SEAC's view

Although SEAC was not able to scrutinise all assumptions and calculations in detail, the illustrative cost estimates presented by the applicant provide an indication of the order of magnitude of the potential economic impacts arising from a refused authorisation. SEAC notes that relocation is the lower-cost scenario of the two. The transition and decommissioning costs included in the factory move costs denote an increased consumption of resources in the relocation scenario compared to the status quo (applied-for use scenario) and thus need to be taken into account in a net welfare analysis. It should be pointed out that the factory move costs are based on the higher number of production sites whilst a more conservative approach would be to consider the factory move costs only for the lower number of production sites. Using the ratio between the two (136 / 616 = 0.22), the factory move costs for the lower number of production sites may be roughly estimated to be €13.6 billion (= €62 billion x 0.22). Transition and decommissioning costs represent approximately 25% of the factory move costs and may thus be estimated to be €3.4 billion (= €13.6 x 0.25). Taking into account the transition and decommissioning costs (which represent direct one-off costs resulting from a refused authorisation) for the lower number of production sites only, SEAC accepts that the benefits of continued use of strontium chromate are at least €3.4 billion. These benefits are of interest not only from a private but also from a social perspective as it is likely that a large part of the additional costs incurred by producers and operators of aircraft would be passed on to consumers (including consumers in the EEA), for example in the form of increased passenger fares and freight charges.

Conclusion

Even though there are methodological deficiencies and uncertainties in the applicant's assessment, the quantitative and qualitative information included in the application, in conjunction with the additional illustrative information provided by the applicant, is sufficient to support the applicant's conclusion that the benefits of using strontium chromate outweigh the risk. The avoided transition/decommissioning costs and the monetised human health risks can be used to illustrate the benefits and risks of continued use. In SEAC's view, accepting the transition/decommissioning costs for the lower number of production sites only (resulting in a one-off cost of €3.4 billion) and assuming the worst-case risks as estimated by the applicant (€215.7 million for the 12 year assessment period, based on the

higher number of production sites) is sufficiently conservative and adequately accounts for the uncertainties. The resulting benefit-risk ratio of 16 suggests that the benefits of using strontium chromate exceed the risks by a considerable margin.

In conclusion, SEAC concurs with the applicant that the benefits of continued use of strontium chromate outweigh the risk.

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation by RAC:

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, specific ESs shall be developed for the different types of paint, coating and machining processes and their individual tasks. These shall describe typical 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. The hierarchy of control principles according to Chemical Agent Directive (98/24/EC) and Carcinogens and Mutagens Directive (2004/37/EC) shall be followed in the selection of RMMs described in ESs. The ESs shall be developed and made available to downstream users covered by this application and for the inspection of the enforcement authorities without delay and not later than 3 months after the applicant has been informed that an authorisation is granted for this use.

RAC notes that maximum individual exposure values for workers and release values for the environment were proposed by the applicant based on their assessment. It is inappropriate for RAC to endorse any specific exposure value for a 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

Such ESs shall be validated and verified by the applicant through an analysis of tasks relevant to exposure as well as through representative programmes of occupational exposure and environmental release measurements relating to all processes described in this use applied for. 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

A. Access to the area in which the activities in WCS 3 are conducted shall be restricted by means of access control systems and physical segregation from other work areas.

B. Access to the area in which the activities in WCS 5 are conducted shall be restricted by means of adequate access control systems and in cases where the activity is carried out indoors there shall be physical segregation from other work areas to avoid exposure of workers not performing tasks of WCS 5.

C. At least a full mask with at the minimum APF 400 is required for WCS 4 and WCS 5.

Downstream User Monitoring

Workers

For downstream users covered by this application and where relevant the applicant 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, (II) the operational conditions and risk management measures typical for these tasks and of (III) the total number of workers that are potentially exposed.

In addition to monitoring of paint and coating activities, annual programmes of exposure monitoring shall be performed for machining operations in order to confirm exposure levels in machining activities.

For workers undertaking tasks covered by WCSs 3-5 and WCS 15-21, annual programmes of inhalation exposure monitoring through personal sampling shall be undertaken in combination with post-shift biomonitoring. Where results of the biomonitoring indicate that exposure has not been reduced to as low a level as technically and practically possible, the frequency of biomonitoring shall be increased and OCs and RMMs revised with the aim to achieve exposure to as low a level as technically and practically possible.

The reports presenting the results of the monitoring and of the review of the RMMs and OCs, especially the RPE and LEV as key control measures, 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 be 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. Measurements should be representative for the operational conditions and risk management measures typical for the industry and 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.

Continuation of monitoring requirements

The information gathered in the monitoring programmes shall be used to review 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 downstream user 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(s) shall provide the exposure scenarios for typical, representative facilities, listing OCs and RMMs with their maintenance and efficiency control program, together with resulting exposure levels. A justification as to why the selected scenarios are indeed representative for the use shall be provided along with a justification that the OCs & RMMs follow the hierarchy of control principles and are appropriate and effective in limiting the risks. Furthermore, better detailed task descriptions related to exposure shall be provided with a discussion and justification regarding the choice of OCs & RMMs.

The assessment of indirect exposure and risk to humans via the environment should be refined beyond the default assumptions outlined in ECHA guidance and the EUSES model. All reasonably foreseeable routes of exposure to humans via the environment shall be included in the assessment (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 the applicant's exposure scenario (ES) presented in the CSR could be significantly 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 general nature of current ES (lacking clear information on the relationship between OCs and RMMs and exposure levels) is 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 in all WCSs. In addition, WCSs 3-5 and WCSs 15-21 have a high potential for elevated air concentrations and rely heavily on the correct use and well-functioning of RPE to control exposure. In such cases, in combination with personal air measurements (CrVI and total Cr), biomonitoring offers a useful tool for assessing exposure of workers to chromium[11]. Elevated biomonitoring results can aid to identify that exposure control may not be adequate[11].

The applicant's assessment of the exposure, risk and impacts for humans via the environment is based on a series of default assumptions that are likely to result in a significant overestimate of health impacts. This introduces considerable uncertainty to the applicant's assessment, which should be addressed in any review report.

Description for additional conditions for the authorisation by SEAC:

1. Strontium chromate may only be used for the application of primers and specialty coatings and where the following key functionalities are required: Corrosion resistance, adhesion of paint / compatibility with binder system, layer thickness, chemical resistance, temperature resistance (thermal shock resistance), compatibility with substrate and processing temperatures (key functionalities are further described in the application).
2. Strontium chromate may only be used for the application of primers and specialty coatings in the aerospace sector.

Description of conditions for review reports by SEAC:

3. In case the applicants submit a review report, a more specific assessment of alternatives for the various technical applications of the substance in primers and specialty coatings covered by the use applied for is required.

Justification for the additional conditions by SEAC:

1. The conditions recommended by SEAC are necessary because of the broad description of the use applied-for and to be consistent with the scope of the application for authorisation. The applicant informed SEAC that only primers and specialty coatings are in the scope of the application for authorisation, whereas "paints" (as included in the use title) is a generic and non-specific term. The applicant expressly excluded jointing compounds and sealants from the scope of the application for authorisation.
2. The use title submitted by the applicant refers to "aerospace and aeronautical parts, used elsewhere, where the supply chain and exposure scenarios are identical". The applicant did not provide information about such uses, thus SEAC recommends excluding them if an authorisation is granted.
3. Any subsequent review report should identify and assess potential alternatives for the relevant technical applications within the scope of the use applied for. The applications should be defined in a meaningful and sufficiently detailed way, based on the requirements of, for example, types of primers or coatings being applied,

[11] C. Keen, E. Tan, J. McAlinden, P. Woolgar and P. Smith (2013). Exposure to hexavalent chromium, nickel and cadmium compounds in the electroplating industry. SK17 9JN. UK Health and Safety Executive, Derbyshire, 2013.

types of parts/components to be treated or types of end-uses (such as manufacturing or repair).

Any subsequent review report should distinguish between steps within a broader use (e.g. certain layers of a coating system consisting of multiple layers) where substitution is feasible and steps where it is not. An alternative should not be generally dismissed because it is not applicable in all steps of a broader use or not applicable sector-wide.

Any subsequent review report should include information about research and development activities for each application, including (where relevant) timelines and steps to be undertaken to achieve substitution. If there are applications for which a suitable alternative is available to replace strontium chromate (either in the whole surface treatment or coating system or in individual steps or layers thereof), such applications should be clearly identified in the review report.

The conditions for review reports are necessary because of the uncertainties arising from the approach taken in the analysis of alternatives in connection with the broad description of the use applied-for. In case a review report is submitted, SEAC considers that a more use-specific assessment (which does not summarily dismiss substances or technologies that are not a *general* alternative or that are not yet implemented sector-wide) is needed for the evaluation of the technical and economic feasibility of potential alternatives.

10. Proposed review period:

☒ Normal (7 years)

☐ Long (12 years)

☐ Short (4 years)

☐ Other:

Justification:

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

RAC's advice:

Considering that

- there are uncertainties in 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 fully evaluate whether they are appropriate and effective in limiting the risk to workers;
- several WCSs have a high potential for elevated air concentration in the workplace environment and rely heavily on well-functioning and correct use of RPE to control elevated exposure levels; therefore, 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;
- additional conditions and monitoring arrangements are proposed;

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

Other socio economic considerations

The applicant requests a 12 year review period, highlighting a substitution process ongoing for several decades in the aerospace sector, the large number of parts covered by the application and the need for sector-wide applicability (including qualification and certification) of potential alternatives. SEAC notes that the brief description of the research & development activities provided as part of the analysis of alternatives is rather vague and contains few commitments and little verifiable evidence of substitution (such as concrete examples of successful replacement of chromates with alternative substances or technologies in the aerospace sector). Overall, SEAC considers the information provided too unspecific to justify a 12 year review period. Although substitution efforts in the aerospace industry are outlined in general terms, the applicant fails to clearly define steps and timelines to achieve substitution of strontium chromate in specific applications, including those areas of use where alternatives are already implemented in parts of the sector.

SEAC has established its recommendation on the review period based on the following considerations:

1. The applicant has requested a review period of 12 years, and provided information to justify this request.

2. RAC has given advice to not recommend more than seven years.

3. Some criteria for a short review period could be regarded as fulfilled. They are:

    - *Criterion for a short review period:* The Analysis of Alternatives is not thorough enough in demonstrating that no suitable alternatives will become available during the “normal” period or if the applicant has not made an effort to demonstrate why potential alternatives on the market would not be suitable and available for him.

      SEAC’s view: SEAC finds this criterion is fulfilled for parts of the broad use applied-for. Alternatives which replace hexavalent chromium only in some steps or layers of the coating process (e.g. chromate-free primers requiring a chromate-containing pre-treatment) are not considered suitable by the applicant. Likewise, alternatives which are implemented in parts of the sector but not yet sector-wide (e.g. alternatives used by MROs but not by OEMs or alternatives used by some OEMs but not yet by others) are not considered suitable by the applicant. This approach to the analysis of alternatives introduces uncertainty and leaves open the possibility that there could be technical applications in which substitution of strontium chromate may be possible within the normal review period.

    - *Criterion for a short review period:* The socio-economic benefits, as demonstrated by the applicant, are only slightly higher than the remaining risks and there are uncertainties about these estimates.

      SEAC’s view: SEAC finds that only the second part of this criterion (referring to uncertainties) is fulfilled. There are uncertainties about the impacts of using

strontium chromate, owing in particular to the generic non-use scenario assumed for all production sites and the assessment of the benefits of continued use, which are quantified exclusively in terms of indirect effects on employment in the application. As noted by RAC, there are also uncertainties with respect to the human health impacts of continued use, related for example to the representativeness of the worker exposure durations and the assumptions made in the risk assessment for the general population. However, having considered these uncertainties and seeing the quantitative assessment together with the qualitative arguments (e.g. the safety aspects) and the additional illustrative information provided by the applicant, SEAC concurs with the applicant that the socio-economic benefits are considerably higher than the risks.

4. Some criteria for a long review period could be regarded as fulfilled. They are:

- *Criterion for a long review period:* The applicant can demonstrate that research and development efforts already made, or just started, did not lead to the development of an alternative that could be available within the normal review period.

  SEAC's view: SEAC finds this criterion is fulfilled for parts of the broad use applied-for. The applicant's assessment gives strong indications that, despite ongoing R&D efforts in the sector, there are no realistic prospects for replacing hexavalent chromium within the normal review period in especially demanding applications (such as protection of aircraft operating in marine environments, treatment of internal structural parts, treatment of highly corrosion prone substrates etc.).

- *Criterion for a long review period:* The possible alternatives would require specific legislative measures under the relevant legislative area in order to ensure safety of use (including acquiring the necessary certificates for using the alternative).

  SEAC comment: SEAC finds this criterion is likely fulfilled. Aircraft designs must be certified to determine compliance with the applicable airworthiness regulations. Although the application contains a generic description of the certification process, the applicant did not provide sufficient information or examples which would have enabled SEAC to assess whether the replacement of strontium chromate with an alternative substance or technology in a given surface treatment or coating process would trigger a legal requirement to recertify an aircraft or component by a regulatory body. Irrespective of the certification question, an alternative would generally need to be qualified by OEMs prior to industrialisation in order to assure that it meets the relevant performance and safety requirements.

Taking into account these points and presuming the additional conditions and monitoring arrangements recommended in section 9 are put in place, SEAC recommends a normal (7 years) review period. This recommendation is a result of SEAC's evaluation of the socio-economic factors. It is consistent with RAC's advice not to recommend a review period of more than 7 years.

The surface treatment processes on the one hand and the primers and specialty coatings on the other hand, as covered by the different applications submitted by the CCST consortium members, may be used as steps or layers of one and the same corrosion prevention coating system. Therefore, new information on alternative substances or technologies could affect multiple substances and uses applied for. Furthermore, the substances have different sunset dates. SEAC notes that to ensure that all relevant information is available at the time of the review of the authorisation, the expiry date of the review period for this use should coincide with the expiry date of the review period for the other aerospace related uses submitted by the CCST consortium.

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 edits were made to clarify aspects in the justification, chiefly:

- additional clarification for the reasons the applicant provided for the limited exposure and emission data from downstream users in the application;
- a statement on backwards compatibility was added;
- a more explicit statement that corrosion protection is of vital importance for aerospace safety was added;
- the periodicity of measurements for machining operations and biomonitoring in the proposed additional conditions and monitoring arrangements was specified.

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

Annex 1: Measurement data for machining activities

Activity	No[1]	90th perc. µg Cr(VI)/m3	AM µg Cr(VI)/m3	Comment
Mechanical machining on very small parts. WCS 16	3	0.05	0.05	Without RPE. All measurements below LOD 1 µg/m^3
Mechanical treatment on small- medium parts. WCS 16	3	0.28	0.27	Corrected for RPE (presumably corrected using APF 400 specified in WCS 16)
Machining in large work areas. WCS 17-18	7	0.5	0.39	Corrected for RPE (presumably corrected using APF 10 specified in WCS 17 and/or APF 30 specified in WCS 18)
Machining in small work areas. WCS 19-20	11	0.18	0.28	Corrected for RPE (presumably corrected using APF 400 specified in WCS 19 and/or APF 1000 specified in WCS 20).

1) Number of measurements
2) AM = Arithmetic mean

Annex 2: Examples of machining activities

Light abrasion for bonding and repair

Light abrading of small localised areas with Alocrom coating[12] is typically carried out manually by means of glass fibre brush and/or dry abrasive paper for the purpose of bonding or for localised re-coating (repair and touch up). These activities are typically carried out in a fully contained booth with laminar down-flow (however, this is not specified in the ES). Abrading tools (typically random orbital sanders) are equipped with on-tool extraction.
For small parts activities are typically carried out in a contained dry-stripping cabin, with LEV such as a vacuum hose applied adjacent to the abrading activity. A portable booth may be available.

Where work cannot be done in a ventilated booth, tailored risk management requirements are used. For example re-touch to landing gear or sanding nacelles. In the first case, there are two stages to the work: sanding/grinding and refinishing with an airbrush. The grinding procedure requires use of wet cleaning (wipes), LEV (e.g. vacuum), RPE and gloves. If the activity is mechanical, a tool with integrated suction and filter will be preferentially used. If the action is manual, downdraft with limitation loss will be used.

In case of repairs, abrading is done directly on the aircraft (where there is no possibility to move it to a dedicated booth). Here a wet method and/or on-tool extraction (e.g. 2'' abrasive disc with extracted shroud) might be used. In the case of adjustments to the shape of a component to ensure fit, paint removal may be carried out in a contained shot blasting booth, on an extracted workbench or using on-tool extraction or wet abrading when the component to be fitted cannot be moved. The applicants states that in confined work area (e.g. wing tank) forced ventilation may also be used as this benefits thermal comfort.

Dry stripping

Separately, dry stripping to remove primer (15% Cr(VI) maximum concentration in primer) of aircraft and aircraft parts is carried out e.g. by means of polymer media blasting. This activity may be carried out on large, medium or small sized parts. The activity is segregated from other activities using, e.g. a contained dry-stripping cabin. RPE and gloves are worn.

Drilling

Drilling is required at every stage of the aircraft assembly process. At one company, drilling is generally done either fully automated (e.g. robotic) or semi-automated (e.g. Automated drilling unit which locks into a drilling jig with single button press operation) with on-tool extraction and lubricants. In this company, some manual drilling may be conducted for a limited number of holes e.g. pilot holes for fitting the automated drilling templates – manual drilling is conducted wet or with extraction or both. In this company, drilling holes for rivets is occasionally carried out during repair work. Such work is carried out in the field. According to the applicant, no RMMs are specified and no measurement data are available for the company as the exposure assessment indicated a low potential for exposure.

[12] **Alocrom** is a chromate conversion **coating** chemically applied to aluminium

Annex 3: Non exhaustive list of formulations containing strontium chromate placed on the market by CCST applicants

Formulator	Product name	Product type
Akzo Nobel	10P4-2NF	Structural Primer
Akzo Nobel	10P8-10NF	Structural Primer
Akzo Nobel	AW 2001	Structural Primer
Akzo Nobel	37092	Structural Primer
Akzo Nobel	20P1-21	Structural Primer
Akzo Nobel	37035A	Structural Primer
Akzo Nobel	463-12-8	Structural Primer
Akzo Nobel	10P4-3NF	Structural Primer
Akzo Nobel	S15/90 / 37214	Structural Primer
Akzo Nobel	S15/60	Structural Primer
Akzo Nobel	Aeroshield LV 2410	Structural Primer
Akzo Nobel	Aerodur 67273	Structural Primer/Topcoat
Akzo Nobel	10P8-12	Structural Primer
Akzo Nobel	463-12-18	Structural Primer
AkzoNobel	10P30-1	Fuel tank coating
AkzoNobel	10P20-44 Base	(Exterior) basic primer
AkzoNobel	10P20-44MNF	Primer
CAAP	CAAP FP–70–HSC	Specialty coating
Cytec	Cytec BR-127	Basic primer
Cytec	Cytec BR-6747-1	Bonding Primer
Cytec	Cytec BR154	Structural primer
Henkel	Loctite EA 9258.1 AERO	Primer
Henkel	Hysol EA 9257	Bonding primer
Indestructible Paint Ltd	588-0066-2	Primer
Indestructible Paint Ltd	IP3-6362-	Primer
Indestructible Paint Ltd	IP9064-1405	Low Temp. Touch-up for Khaki Ipseal
Indestructible Paint Ltd	IP9064-6362	Strontium Chromate Primer Base
Indestructible Paint Ltd	IP9064-9226	2-Pack Epoxy Chromate Primer
Indestructible Paint Ltd	IP9253-R2	PL219 Equivalent H/H Resistant Coating
Indestructible Paint Ltd	IP9310	Primer
Indestructible Paint Ltd	LR1079	Primer
Indestructible Paint Ltd	LR1165	Primer
Indestructible Paint Ltd	LR1256	Primer
Indestructible Paint Ltd	LR1387	Chromate Jointing Compound
Indestructible Paint Ltd	LR1783-040	Primer
Indestructible Paint Ltd	LR1984-048	Khaki Chromate Seal

Formulator	Product name	Product type
Indestructible Paint Ltd	LR2009-076	Primer
Indestructible Paint Ltd	LR2027-088	Primer
Indestructible Paint Ltd	LR2444	Primer
Indestructible Paint Ltd	LR3113	Primer
Indestructible Paint Ltd	LR3215-CR	Primer
Indestructible Paint Ltd	IP1757-R1	Primer
Mankievicz	SEEVENAX Grundbeschichtung 113-22	Primer
Mankievicz	SEEVENAX Grundbeschichtung 113-82	Primer
Mankievicz	SEEVENAX Primer 313-01	Primer
Mankievicz	SEEVENAX Primer 313-81	Primer
Mankievicz	SEEVENAX-Low VOC Cr-Primer 113-07	Primer
Nittoku	Nihon Tokushu - Sky-Hullo Primer Base No. 1005	Basic primer
PPG	02GN058	Primer
PPG	02Y040A	Primer
PPG	09Y002	Primer
PPG	44GN011	Primer
PPG	44GN024	Primer
PPG	44GN036	Primer
PPG	44GN057	Primer
PPG	44GN049 EPOXY PRIMER BLACK-GREEN	Primer
PPG	44GN060	Primer
PPG	44GN061	Primer
PPG	44GN072	Primer
PPG	44Y022	Primer
PPG	44Y030	Primer
PPG	44Y032	Primer
PPG	44Y101	Primer
PPG	513-003 Super Koropon Fluid Resistant Primer	Primer
PPG	513X332 Epoxy Primer	Primer
PPG	513X377	Primer
PPG	513X384 Urethane Compatible Primer	Primer
PPG	513X390 Pigmented Epoxy Resin Yellow	Primer
PPG	513X408B Waterborne Epoxy Primer	Primer
PPG	513X419 DeSoto HS Epoxy Primer	Primer
PPG	515-005 Super Koropon Interior Primer	Primer
PPG	515X330 Super Koropon Fluid Resistant Primer	Primer
PPG	515X333 Super Koropon Fluid Resistant Primer	Primer
PPG	515X346 Room Temperature Bonding Primer	Primer

Formulator	Product name	Product type
PPG	515X349 URETHANE COMPT IMPACT RESIST PRIMER	Primer
PPG	515X386 Waterborne Low IR Primer Green	Primer
PPG	515X410 DeSoto HS Epoxy Primer Green	Primer
PPG	519X303 High Temp Low Density Epoxy Primer	Primer
PPG	823-011 Integral Fuel Tank Coating	Primer
PPG	823-707 Integral Fuel Tank Coating	Primer
PPG	825X309 Integral Fuel Tank Coating	Primer
PPG	825X480 Koroflex Primer Green	Primer
PPG	825X537	Primer
PPG	833K086 Integral fuel tank coating	Primer
PPG	833K086G Integral fuel tank coating Green	Primer
PPG	CA7000	Primer
PPG	Desoprime HS CA7002 Green (40123600)	Primer
PPG	CA7033	Primer
PPG	CA7045 HS PU Primer	Primer
PPG	CA7055	Primer
PPG	CA7233	Primer
PPG	CA 7660TGB Chromatd Trowelable Primer	Primer
PPG	CA 7700A Urethane Compat FR HS Primer Yellow	Primer
PPG	CA 7755A Urethane Compatible F	Primer
PPG	EEAE154A Eco-Prime Green	Primer
PPG	EEAE262A Eco-Prime Sol Borne Primer Grn- Ylw	Primer
PPG	EEAY051A Eco-Prime Solventborne Yellow	Primer
PPG	EWDE072A ECO-PRIME YELLOW-GREEN	Primer
PPG	EWDE102A Eco-Prime Green	Primer
PPG	F580-2080 Epoxy Primer Green (45305467)	Primer
PPG	PP 404 Epoxy Primer Yellow	Primer
PPG	PR143 Epoxy Primer	Primer
PPG	PR205 HS Epoxy Primer	Primer
PPG	PR213 Epoxy Primer Yellow	Primer
PPG	Primer 7835 (41233600)	Primer
PPG	Primer 90 Green (41203600, 41205402)	Primer
PPG	PPG PR-1432-GP (Part B)	Basic primer
PPG	PPG 833-089	primer
Randolph Products	TT-P-1757	Primer

Annex 4: Initial list of potential alternatives to Cr(VI) containing surface treatments

ID	Alternative Substance / Alternative Process	Category
1	LTAVD (Low Temperature Arc Vapor Deposition)	This process is related to functional chrome plating replacement and not relevant for primer applications
2	5-methyl-1H-benzotriazol	Summarised under organic corrosion inhibitors (**Category 2**)
3	Silicon-based primer	This alternative is related to applications within the automotive sector and currently not relevant for primer applications within the aerospace industry
4	Acidic anodising – Nitric, boric, boric-sulfuric (BSAA), oxalic, tartaric, phosphoric, sulfuric acid anodising	This process is related to CAA replacement and as such not relevant for primer applications
5	Aluminium electrolysis	This process is related to CAA replacement and as such not relevant for primer applications
6	Case hardening: Carburising, CarboNitriding, Cyaniding, Nitriding, Boronising	This process is related to functional chrome plating replacement and not relevant for primer applications
7	Chromium-free electroplating (Cooper plating,Nickel- free electroplates and composites,Non-electrolytic zinc plating)	This process is related to functional chrome plating replacement and not relevant for primer applications
8	CVD (Chemical vapor deposition)	This process is related to functional chrome plating replacement and not relevant for primer applications
9	Detonation gun thermal spray process (D-Gun)	This process is related to functional chrome plating replacement and not relevant for primer applications
11	Epoxy-based primer systems containing Cr(VI)-free inhibitors	**Category 1**
13	Faraday Technologies' Faradaic process (Cr(III))	This process is related to functional chrome plating replacement and not relevant for primer applications
14	HVOF (High Velocity Oxy-fuel)	This process is related to functional chrome plating replacement and not relevant for primer applications
15	Iridite NCP (Al, F, Oxygen)	This alternative is related to chemical conversion coatings and not applicable for primer applications
16	Keronite (plasma electrolytic oxidation)	This alternative is related to chemical conversion coatings and not applicable for primer applications
17	Laser alloying and laser cladding	This process is related to functional chrome plating replacement and not relevant for primer applications
18	Mineral Tie-Coat (cathodic mineralisation)	This process is related to functional chrome plating replacement and not relevant for primer applications
19	Molybdates and Molybdenum-based processes	**Category 2**
20	Nanocrystalline coating (process: HVOF, Thermal spray processes)	This process is related to functional chrome plating replacement and not relevant for primer applications
21	Nickel/Tungsten/Boron electroplating	This process is related to functional chrome plating replacement and not relevant for primer applications
22	Organic corrosion inhibitors e.g. amines, N-Methyl-2- Pyrrolidone, diazocomponents, triazoles etc.	**Category 2**
23	Permanganate-based treatments	This alternative is related to chemical conversion coatings and not applicable for primer applications

24	Phosphate-based corrosion inhibiting agents	**Category 1**
25	Plasma diffusion	This process is related to functional chrome plating replacement and not relevant for primer applications
26	Plasma spraying	This process is related to functional chrome plating replacement and not relevant for primer applications
27	Polysulfide-based primer systems containing Cr(VI)- free inhibitors	This matrix-system is and not relevant for primer applications within this use
28	PU-based primer systems containing Cr(VI)-free inhibitors	Summarised in epoxy/PU-based primer systems containing Cr(VI)-free inhibitors (**Category 1)**
29	Sherardising - Non-electrolytic zinc-iron alloy coating	This process is related to functional chrome plating replacement and not relevant for primer applications
30	Silane/Siloxane	Compounds of Sol-Gel coatings, as such summarised there **(Category 1)**
31	Sol-gel coatings (e.g. Zr/Si oxide-based)	**Category 1**
32	Stainless steel	This material is not a general replacement, mass of material points against a replacement in majority of airframe components
33	Tagnite (inorganic Silica or vanadate)	This process is related to functional chrome plating/CCC replacement and not relevant for primer applications
34	TCP (Trivalent chromium plating)	This process is related to functional chrome plating replacement and not relevant for primer applications
35	PVD (Physical vapor deposition), Sputtering	This process is related to functional chrome plating replacement and not relevant for primer applications
36	Weld facing, Micro-arc welding: Electro Spark Deposition (ESD), Electro Spark Alloying (ESA)	This process is related to functional chrome plating replacement and not relevant for primer applications
37	Zinc-based materials (Zinc, Zinc-Tin, Zinc-aluminium, Zinc-Nickel-based passivation)	**Category 2**
38	Organometallics (Organic Zirconates, titanates)	This alternatives was not further assessed by the industry due to clearly insufficient performance
39	Aluminium phosphate-based corrosion inhibiting agent	Summarised under phosphate-based corrosion inhibiting agents **(Category 1)**
40	Zr or Ti fluoride (+ additives)	This alternatives was not further assessed by the industry due to clearly insufficient performance
41	Vanlube (Barium petroleum sulphonate)	This alternatives was not further assessed by the industry due to clearly insufficient performance
42	Oxide mixture of Zn,Ce,SR,W and Mo (Ecotuff)	This alternative is related to applications within the architectural sector and not relevant for primer applications within the aerospace industry
43	Tall oil fatty acid salt	This alternatives was not further assessed by the industry due to clearly insufficient performance
44	Alkylammoniumsalz of (2-benzothiazolylthio)succinic acid	This alternatives was not further assessed by the industry due to clearly insufficient performance
45	Ammoniumbenzoate	Summarised under organic corrosion inhibitors **(Category 1)**
46	Bariumsulfate	This alternatives was not further assessed by the industry due to clearly insufficient performance

47	Calcium compounds (Calcium-Borosilikate, Calciumcarbonate, Calciumhydroxide, Calciummetasilikate)	**Category 1**
48	Dinonylnaphthalindisulfonsäure	This alternatives was not further assessed by the industry due to clearly insufficient performance
49	Potassium salt	This alternatives was not further assessed by the industry due to clearly insufficient performance
50	Magnesium compounds (Mg Ferrite, Mg oxyaminophosphate)	**Category 1**
51	Manganacetat Dihydrat	This alternatives was not further assessed by the industry due to clearly insufficient performance
52	Sodium compounds (Natriumcarbonat, Natriummetasilikat, Natriumnitrit)	This alternatives was not further assessed by the industry due to clearly insufficient performance
53	Titanate	This alternatives was not further assessed by the industry due to clearly insufficient performance
54	Phosphor compounds (Phosphoroxide, phosphoric ester)	This alternatives was not further assessed by the industry due to clearly insufficient performance
55	Polycarboxylat	This alternatives was not further assessed by the industry due to clearly insufficient performance
56	RE-based applications (Rare Earth, e.g. cerium)	**Category 2**
57	Electrocoat primer technology	**Category 1**

Support document

Applicants' comments and RAC and SEAC Rapporteurs' responses to comments on the Draft Opinions on the Applications for Authorisation from the CCST consortium

Draft Opinion numbers:

ECHA/RAC/SEAC: AFA-O-0000006553-73-01/D
ECHA/RAC/SEAC: AFA-O-0000006553-73-02/D

ECHA/RAC/SEAC: AFA-O-0000006552-75-01/D
ECHA/RAC/SEAC: AFA-O-0000006552-75-02/D

ECHA/RAC/SEAC: AFA-O-0000006550-79-01/D
ECHA/RAC/SEAC: AFA-O-0000006550-79-02/D

ECHA/RAC/SEAC: AFA-O-0000006551-77-01/D
ECHA/RAC/SEAC: AFA-O-0000006551-77-02/D

ECHA/RAC/SEAC: AFA-O-0000006554-71-01/D
ECHA/RAC/SEAC: AFA-O-0000006554-71-02/D

APPLICANTS' COMMENTS AND RAC / SEAC RAPPORTEURS' RESPONSES TO COMMENTS ON THE DRAFT OPINIONS

Date		Comment number
27/10/2016		1
Comment received		

The applicants are pleased that the Committees intend to recommend authorisation for all uses applied for. However, in the view of the applicants, and due to the highly complex nature of the aerospace industry and its products, some parts of the application documents and the clarifications provided by the applicants may have not been correctly assessed / fully recognized by the Committees. This response seeks to redress these points, as follows and detailed in the respective sections below:

1. Certification and Qualification
2. Availability of Alternatives in General
3. The special issue of Upstream AfAs - General comment on upstream applications and uncertainty – Legitimate Expectations, Good Administrative Practice, Equal Treatment, Proportionality
4. Exposure Scenarios
5. Comments on Conditions
6. Additional Items

1. Certification and Qualification

The applicants believe that SEAC has misunderstood the substance and relevance of the Qualification and Certification information presented in the AoA and again in the applicants' responses to SEAC questions during the preparation of draft opinions on several fronts.

- SEAC has grossly simplified and underestimated the timelines for implementation of alternatives.
- It has also criticized the applicants for a lack of commitment to develop and implement alternatives.
- And, most grievously, it indicates a misplaced lack of trust in the veracity of the applicants' supplied information.

These points are each taken in turn:

Rapporteurs' response

SEAC would like to thank the applicant for providing comments on the draft opinion. After careful consideration, SEAC is of the view that the comments do not contain new information which would require amendment of SEAC's opinion and recommendations. Where appropriate, the justification to the opinion was amended to clarify how the information provided was taken into account by SEAC. Responses to each point raised are included below.

Date		Comment number
27/10/2016		2
Comment received		

1.1. TRL Timelines

On e.g. p. 48 of the RAC/SEAC draft Opinion on potassium dichromate surface treatment, SEAC criticises the application because *"the applicant did not provide sufficient information to distinguish between type-certification by a regulatory body (e.g. of aircraft engines) and other qualification and certification steps. Consequently, SEAC is not able to conclude on the exact time needed for such*

processes although SEAC understands that the transition to alternatives takes additional time due to the need to pass such processes successfully. SEAC notes that the qualification step is not a unique characteristic for this sector and the actual time required might vary between various technical applications included in the scope of the use applied for." This critique is continued on p. 66 (draft Opinion potassium dichromate): *"SEAC notes that the brief description of the research & development activities provided as part of the analysis of alternatives is rather vague and contains few commitments and little verifiable evidence of substitution (such as concrete examples of successful replacement of chromates with alternative substance or technologies in the aerospace sector). Overall, SEAC considers the information provided too unspecific to justify a 12 year review period. Although substitution efforts in the aerospace industry are outlined in general terms, the applicant fails to clearly define steps and timelines to achieve substitution of potassium dichromate in specific applications, including those areas of use where alternatives are already implemented in parts of the sector."*

The applicants in their AfAs extensively discussed the procedure for approval of parts/supplies for the aerospace industry and further referred to the Report *"An elaboration of key aspects of the authorisation process in the context of aviation industry"* published jointly in April 2014 by ECHA and EASA which also contains such description. The ECHA/EASA document was prepared specifically to highlight the challenges facing the aerospace industry in relation to authorisation, and reflected an understanding by the authors of the timelines required to safely introduce change. Further clarification and acomprehensive description of the regulatory approval procedure was provided in response to the Trialogue questions[1] and in response to SEAC's first set of clarification questions.[2]

[1] The AoA states that 'all components of an aircraft (e.g. seats, bolts...) must be certified, qualified and industrialised'. Furthermore, in the answers to the second set of questions (8) it is stated that 'qualification is company specific and there is no general aerospace approval'. Could you elaborate more on the process of certification and qualification of individual components and companies? Is every seat, bolt etc. itself certified for every company? "The Type certificate is issued for the original design of the product in civil aviation (airframe, engine or propeller) as a whole, rather than for each part. However, every component part of the product must be designed, developed, and validated to meet the requirements of the overall product requirement and system design (how each component fits and interacts with other component parts). This approval is granted after the airworthiness certification criteria, compliance standards/requirements and methods of compliance have been successfully demonstrated to the relevant Airworthiness authority. Any change to the type certified product design must be evaluated and approved by the type certificate holder on the same basis to assure overall safety for the product to demonstrate overall airworthiness once integrated into the overall product design. If determined to be equivalent or better, the configuration is modified and documented; otherwise a supplemental type certificate (STC) is issued by the relevant Airworthiness authority. The STC certifies successful demonstration of the modified design airworthiness requirements. The above responsibilities and obligations are defined in EU regulation 748/2012 for type certificate holders in the EU. When the state of design (location of the type certificate or supplemental type certificate holder) is in the United States, the responsibility and obligations are defined in the U.S Federal Aviation Regulations (FARs) Standard parts, such as a nut or bolt, must be manufactured in compliance with a government, established industry standard, or company standard. For many standard parts, specific manufacturers have been qualified as approved sources. Once qualified, no modifications to basic 4 methods of manufacture, plant site, or quality level can be made without prior notification and approval from the OEM. There are industry standards and specifications for materials, processes and standard parts; however, in many cases, the requirements are built upon consensus negotiated in a committee. In order to reach consensus, the requirements may be less stringent than those required by individual companies. In such cases, an individual company will modify an industry standard, creating company proprietary specifications with more stringent and specific requirements to meet their product needs. These company specifications are proprietary due to the investment of significant resources and intellectual property required to develop materials and processes to meet these more stringent requirements. Qualifications required to meet these proprietary specifications are company specific. In very few cases, are the industry standards sufficient to meet all OEM requirements, thus the reliance upon company specifications. c. Could you provide example where recertification was required as a result of a change in a surface treatment/coating process? To answer this question specifically, no surface treatment/coating change has been approved that is not equivalent in engineering performance to the original material in the aircraft application. Changes that are demonstrated to be equivalent or better (usually with a margin of safety) do not require re-certification. During the Trialogue an example was described where HVOF was used as an alternative instead of hard chrome plating on some landing gear parts. In this case the surface treatment/coating was changed from one airplane model to the next, and full scale component testing of the entire landing gear was performed. This is technically part of a new certification, not a recertification."

[2] The scope of re-certification is dependent on whether the change(s) to the type certificated product as a result of implementation of a Cr(VI)-free surface treatment process or coating system have an appreciable effect on characteristics affecting the airworthiness of the product in accordance to EU Part 21 Section 21.A.91 (USA 14 CFR Part 21 Section 21.93). For any change(s) determined to have an appreciable effect on characteristics affecting the airworthiness of the product, the change(s) would be classified as major and the change(s) and relevant accumulated change to the type design would have to be evaluated according to EU 21.A.101 (USA 14 CFR 21.101) to determine the certification basis to be used for the change(s) to the type certificate. If the changes are determined to be significant according to EU

As explained, acquisition of new technology in the aerospace industry is a well-defined and closely documented process. The process explicitly ties into a gated Technology Readiness Level (TRL) procedure. The TRL concept was originally developed by NASA in the 1970s and adapted by the US Department of Defence for multiple item production cycles. It is widely used in the aerospace and defence industry. TRLs are a method of estimating technology maturity of critical technology of a program during the acquisition process. Generally, the aerospace approval procedure consists of four distinct phases including development, qualification, certification and industrialization. These phases are preceded by a lab scale validation by formulators, making 5 phases. These phases along with the timescales described in the AoA are listed in the following table, which summarises information from Section 5 of the AoA and responses to questions from SEAC.

Technology Readiness Level (TRL)	min years	max years
Validation at laboratory scale (Formulator): >1 year (up to 5 years according to previous experience)	1	5
TRL1-6 (Development phase, OEM): 3-5 years	3	5
TRL7-8 (Qualification phase, OEM): 8-15 years	8	15
TRL9 (Certification, OEM): 6 months- 3 years	0.5	3
'TRL10' (Industrialisation, OEM): 18 months to 5 years	1.5	5

The applicants here wish to emphasize that, as stated in the AoA, failure of a new technology during any of these phases results in starting again from the beginning of the development phase. R&D programs do fail regularly (particularly in the case of Cr(VI) alternatives, as demonstrated), and the use of minimum timeframes for calculating the timeframe for availability of alternatives is extremely optimistic. **The actual timeframe can be significantly longer, and adding up the shortest of the timeframes has little relevance to actual industry experience.** The timeframes were intended to reflect that there are a number of time consuming stages required after a suitable formulation is developed and qualified. In actuality, specific companies have had limited success achieving qualification of suitable replacements.

Irrespective of this, adding up the shortest of each of these phases results in a minimum time frame of 14 years before production can start. Excluding the single phase for certification still leaves 13.5 years, and this is far greater than the minimum 8 years for qualification that ECHA has cited to justify its recommendation for a 7 year review period.

The applicants request that the Committees recognize that the implementation of alternatives is not restricted to qualification or certification but that it encompasses the entire series of procedures explained in detail in the AfA and in the joint EASA/ECHA document. It therefore serves no purpose

---

21.A.101 (USA 14 CFR 21.101) [see EASA GM 21.A.101 and FAA AC 21.101-1B], the change and areas affected by the change taking into account the relevant accumulated change must comply with the latest airworthiness requirements unless one of the exceptions of EU 21.A.101(b)(3) (USA 14 CFR 21.101(b)(3)) are granted.

In order to implement a chromate alternative for a particular process on greater than a part-by-part basis, this can only be done when the change can be considered a minor change. And it can only be considered a minor change where it can be demonstrated that the alternative process is an interchangeable solution for all parts/assemblies calling out the use of that process. This can be authorised by the internal Design Organisation Approval as delegated by EASA. The technical dossier documenting interchangeability of materials/processes has to first to demonstrate the equivalence in performance at specimen level between Cr(VI)-based and Cr(VI)-free protections. And as these processes are employed in combination with other processes (e.g., pre-treatment, main-treatment and post-treatment), the test program demonstrating interchangeability must include all combinations of treatment materials/processes employed in the process chain. Additionally, the interchangeability of materials/processes must be verified at the part/assembly level (where interchangeability relative to a specific requirement cannot be demonstrated at the specimen level). For example, where the treatment is employed on a complex part with specific complex fatigue requirements, then interchangeability must be demonstrated through fatigue tests (including fatigue tests in corrosive environments) on these parts (or test specimens of similar complexity).

In the AoA, chapter 5.4 (p43) examples are provided that illustrate the long-lasting time-frame needed until implementation of a new technology/process. The specification for the newly developed Boric-sulfuric acid (BSA) anodizing process was released in 1990. Implementation testing began in November 1994, and the specification was revised again in 2004. In 2015, industrialization of the BSA alternative for CAA was still not complete.

(and is not meaningful) to distinguish between type-certification by a regulatory body and the other parts of the approval procedure for purposes of establishing the time frame for implementation of alternatives and the review period.

Moreover, if the minimum duration however is 13.5 years before production start, then it is also not necessary to distinguish the procedure on a part by part level (25-40.000 parts) as advised by ECHA, because the minimum would be 13.5 years for the "easiest" or "least critical" part types to be treated with an alternative substance.

Finally, given the conservatism of the industry and the ramifications of shortfalls in performance, implementation would start with applications that can be inspected and monitored in a variety of actual service conditions for several years. Applications where the parts are not easily inspected and/or the formulations are expected to last the lifetime of the aircraft will require many years of validated performance before being transitioned.[3]

Moreover, the applicants specified in their response to the first set of SEAC questions that even in those cases in which Cr(VI) replacements have been implemented for single applications in single aircraft models, normally in later stages of the qualification process, so-called 'backwards compatibility' is required should the in-flight evaluation necessitate the use of Cr(VI) substances: *"Few applications where corrosion risk is low and first complete Cr(VI)-free solutions exists refers to, for example, exterior fuselage application where iron based aluminium deoxidizer (pre-treatment), plus sol-gel, plus non-Cr primer (main-treatment) and plus non-Cr topcoat (post-treatment) is used. Those applications cannot be excluded from the use applied for, as this alternative is implemented for a few aircraft models only but it is still under evaluation for the majority of aircraft models. Importantly, if the in-service evaluation turns out to be unsuccessful, backwards compatibility is required."* This backwards capability requirement to revert to Cr(VI) substances is critical given that the systems are still undergoing performance evaluation as part of the TRL assessment process, and may fail to perform in actual environmental conditions (see footnote 3). As shown in the AoA, performance in real-world conditions is far from assured even when technology has been developed over many years to this stage. However it has not been taken into account by the Committees.

Rapporteurs' response

SEAC recognises that the implementation of a new alternative encompasses several steps, yet it cannot assess the time needed to validate, develop, qualify, certify (where relevant) and industrialise a given alternative technology for a specific surface treatment or coating application based on a general description of the TRL system. The sum of the minimum timeframe for each step (14 years with or 13.5 years without certification) does not represent the time needed for substitution as that would assume that all alternatives have to be developed from scratch, thereby discounting the progress already made on some of these alternatives. SEAC acknowledges that Figure 1 provides

[3] OEMs have been working closely with paint suppliers for more than 10 years on the development of chrome free basic primers. OEM specialists and paint formulators are involved in ever deeper collaboration to probe and better understand the complex interaction between corrosion inhibiting agents and the matrix in the coating. The complex interplay must be fully understood and assessed before a 1:1 replacement for chromate basic primer can become a reality. This evaluation involves the testing and cross testing of hundreds of formulations. Potential candidates under current investigation are still in early stages of development (TRL2-3) and it can be expected to take at least 3 to 5 more years to bring a product to the required level of maturity for qualification. As discussed, standard test labs have limited capability to duplicate actual environmental conditions (i.e., vibration, temperature (freeze/thaw) and pressure cycling, ultraviolet (UV) exposure), and cannot replace other forms of testing such as outdoor exposure or testing on real aircraft parts providing valuable information on in service behaviour of the alternatives. However, this kind of testing takes years rather than weeks to complete. Confidence in an alternative's performance is critical, as some aerospace hardware is in locations that cannot be readily inspected, sometimes for the life of the aircraft. Indeed extreme caution must be exercised and risks understood before replacing a material which has proven field experience (reference: EASA document). Currently, the only way to fully assess these risks is to launch a robust in service testing programs on selected flying aircraft which is not yet agreed and would need the involvement of several stakeholders before to be authorised. In addition industrial implementation into the complete supply chain is expected to take at least 5 years based on current experience with other chrome free alternatives. In the case of primers, several products will need to be available (e.g. 15-20 for legacy aircraft of for one OEM) to cover the whole market and cope with industrial production, which will necessitate the adequate supplier capacity/capability on a timely basis. On that basis, the 12 year authorisation review period for basic primer is fully justified.

information on the overall status of development per alternative type, but notes that this does not allow SEAC to evaluate the extent of substitution that has already taken place and the time when complete substitution might be achieved on the level of specific surface treatments or coating applications. Indeed, the statement by the applicant that complete Cr(VI)-free solutions have already been implemented on *some* aircraft models is not reflected in the status of the R&D activities (Figure 1) and supports the view held by SEAC that a long review period (12 years) for the use applied for, as requested by the applicant, would not be appropriate. Taking into account all other considerations described in the opinion justification (including the advice of RAC) and the criteria laid out in document SEAC/20/2013/03, the information available to SEAC does not allow SEAC to recommend a longer than normal review period (7 years).

SEAC acknowledges and has reflected in the opinion justification the need to ensure 'backwards compatibility' for applications where alternatives are already applied (for certain aircraft models). SEAC has clarified in the justification text that this fall back option allowing to revert back to Cr(VI), according to the applicant is the reason for not excluding such uses from the scope applied for. SEAC notes that this backwards compatibility need is not an argument affecting the SEAC recommendation on the review period.

With respect to footnote 3, SEAC notes that the applicant finds a 12 year review period justified for *basic* primers, whereas the scope of the use applied for, and on which SEAC formed an opinion, covers a wider range of primers and specialty coatings. Hence, the footnote does not contain information affecting the recommendation on the review period for the use applied for (coating application).

Date		**Comment number**
27/10/2016		3
Comment received		

1.2. R&D Commitments

The applicants strongly reject the remarks that the description of R&D activities is "vague", "contains few commitments" and "little verifiable evidence". The applicants listed 13+ partially EU funded industry wide or company specific R&D programs. If the Committees require detailed reports on each of these programs over and above the summaries contained in the AfAs, the Committees could have asked for copies of those reports. In as far as SEAC asked specific R&D questions on specific R&D projects, these were responded to. A table setting out the status of the R&D time frame for the individual potential alternatives was provided in Figure 1 to the first set of RAC/SEAC questions.

Clearly in an upstream application, further guidance is needed on the information that must be delivered in order to allay concerns on such matters, or there must be greater facility to discuss and augment the information.
R&D programs have been active at industry and company level for decades. For example, the Airbus Chromate-Free (ACF) project was launched more than 15 years ago with the aim to progressively develop new environmental friendly Cr(VI)-free alternatives to qualified products and processes used in aircraft production and maintenance. The total financial investment so far of this program alone exceeds tens of millions of Euros. These programs have allowed replacement of chromates in a number of specific Airbus applications. Overall, alternatives have been qualified for approximately half of the original chromate loaded applications for Airbus structural parts.

As several layers of the protection scheme are now chrome free, it has become even more challenging to develop and qualify solutions for the remaining steps. These solutions must provide the required level of corrosion protection on metallic structures and ensure safety of the aircraft over the lifetime of the component. This is particularly true for basic primer which needs to fulfil key functions: corrosion protection, good adhesion between the metal surface and compatibility with all the other previous and subsequent layers which are currently mainly chromate free. No complete Cr(VI)-free coating system, providing all the required properties to the surfaces of all articles in the scope of this application, is available despite many years of R&D. Additionally, it has to be recognised

that individual aerospace companies have different requirements and R&D priorities, and will have a separate history of substitution of hexavalent chromium substances. In other words, the situation in each company is unique. SEAC stated that "*The applicants' claim that to date Cr(VI) must be applied either in the pre-treatment or in the coating (primer) and no full Cr(VI)-free corrosion prevention coating system exists is seemingly contradicted by information available in the public domain showing that chromate-free coating systems (chrome (VI)-free pre-treatment and coatings to be used in conjunction) are available on the market".*

During the course of the Public consultation and Trialogue, ECHA brought up a number of chromate free products qualified against AMS3095 and queried their suitability. AMS3095 is a specification for chromate-free external paint schemes used in the MRO/aftermarket. However it does not provide sufficient corrosion protection to meet the corrosion protection principles used for the design and manufacture of aircraft. Therefore it cannot be considered as a replacement for fully qualified paint systems. Despite repeated clarification provided on the differences between external and internal paint scheme, it appears that SEAC has disappointingly not taken this information into account.

Rapporteurs' response

SEAC acknowledges the listed R&D programmes. However, neither the application for authorisation itself nor previous written communications from the applicant or the comment above set out clearly defined timelines, objectives and commitments for current and future R&D activities to replace Cr(VI) in specific technical applications covered by the use applied for. See also point 1.1.

SEAC acknowledges that there are differences between external and internal paint schemes. As both external and internal applications as well as OEM and MRO applications are in the scope of the broad use applied for, information on potential alternatives for any one of these applications (or a combination thereof) had to be taken into account in SEAC's opinion. On a related note, the applicant's comment does not explain why chromate-free external paint schemes used in the MRO/aftermarket are not considered sufficient for the design and manufacture of aircraft.

The statement that "several layers of the protection scheme are now chrome free" appears to contradict the statement in response to a request for additional information that it is *not* possible to exclude specific layers of the coating system from the scope of the application for authorisation.

Date		**Comment number**
27/10/2016		4

Comment received

1.3. Lack of Trust in Applicants

SEAC stated that *"SEAC cannot exclude that there are indeed "coating applications" using strontium chromate, where substitution is already feasible or will become so in the short-term".*

If there was a solution free of strontium chromate available for the applications included in the AfA, dossier, and with due regard to the requirements of each company's qualification process, the authorities can rest assured that it would have been implemented. If ECHA/SEAC considers that the statements made by the applicants in the AfA are not credible or are unsubstantiated in regard to availability of alternatives for strontium chromate and therefore wish the applicants to provide an expert statement to this effect, ECHA/RAC could have asked the applicants to provide such statement. The applicants are still willing to provide such statement. Nevertheless the applicants note that SEAC has not in its opinion given any examples of applications in which the use of strontium chromate or the other substances could be replaced. Indeed, the reality today is that there are no chromate free primers available for use as part of the basic corrosion protection for current aircraft design and manufacture, and this situation is unlikely to change in the short term. Most OEMs have very high requirements, and functionality (such as compatibility with/resistance to hydraulic fluids) requires much higher performance primer than any 'chromium-free' product that may exist on the market.

The justification has been fully documented in the AoA part of the dossier. It is again disappointing to note than SEAC is giving more credence to marketing brochures of unsuitable products than the extensive technical analysis compiled by industry experts.

SEAC stated that the "*The applicants' claim that to date Cr(VI) must be applied either in the pre-treatment or in the coating (primer) and no full Cr(VI)-free corrosion prevention coating system exists is seemingly contradicted by information available in the public domain showing that chromate-free coating systems (chrome (VI)-free pre-treatment and coatings to be used in conjunction) are available on the market".*

SEAC seemingly (and alarmingly) does not trust the detailed and comprehensive justification provided in the dossier by the industry corrosion experts (see also point 2. below). There is no contradiction here; these chromate free primers which are claimed to be available on the market cannot be considered as replacement of basic primer used for the corrosion protection in the design and manufacture of aircraft. In fact, these products are supplied by the companies leading the authorisation applications: this in itself should provide a clear enough indication that these products cannot be used as alternatives for applications covered in the dossier.

The applicants therefore request that SEAC reviews its conclusions recognizing that the aerospace industry's product development and implementation cycle warrants a 12 years review period for all uses applied for.

Rapporteurs' response

SEAC, as an independent scientific body, forms an opinion based on the evidence included in the application for authorisation as well as any other available information relevant to the case (such as information from the public consultation or from publicly available sources).

As previously noted and despite the fact that this comment focuses on *basic* primer, it should be noted that the scope of the applied-for use of strontium chromate covers a wide range of primers and specialty coatings (such as bonding primer, structural primer and fuel tank primer), all of which have to be taken into account in the analysis of alternatives by the applicant and by SEAC.

As explained in detail in the justification to the opinion, SEAC concluded that it is unlikely that suitable alternatives exist for *all* technical applications covered by the broad use applied for. On that basis, SEAC supports the applicant's view that suitable alternatives are not available.

At the same time, the broad use applied for, in connection with the applicant's own statements pertaining to alternatives already implemented in *some* applications on certain aircraft models and the publicly available information to the same effect, do not allow SEAC to exclude that there will be further substitution opportunities within the normal review period. Thus, the recommendation regarding the review period is fully justified based on this argument in combination with the other arguments reflected in the SEAC opinion.

Date		**Comment number**
27/10/2016		5

Comment received

2. Availability of Alternatives in General

In the applicants' opinion, the findings of the draft opinion regarding the availability of alternatives is misjudged and does not reflect the available evidence, considering that:

- There is no robust evidence that alternatives exist (i.e. the evidence relating to availability of alternatives does not withstand scrutiny)
- There is consistent and unequivocal evidence from the aerospace industry that, despite substantial R&D efforts over many years, alternatives are not available

- Although SEAC might desire the certainty of an analysis of alternatives completed on a part by part basis, due to the multiple factors that contribute to such an analysis and the many thousands of components within the scope of the application, in practice a more pragmatic outlook is needed when evaluating and reporting the absence of alternatives. Nonetheless, there is little if any significant uncertainty associated with such an approach, and any such uncertainty is of no relevance in the overall frame of the assessment.

Rapporteurs' response

SEAC's response to each point is included below.

Date		**Comment number**
27/10/2016		6

Comment received

2.1. Absence of evidence that alternatives exist

It is noteworthy that during the public consultation not a single commentator came forward claiming that alternatives for chromates are available for the extended requirements of the aerospace sector.

Rapporteurs' response

SEAC is aware of the information submitted during the public consultation, as reflected in sections 7.1 and 7.2 of the justification to the opinion. Please also see the response to point 1.3.

Date		**Comment number**
27/10/2016		7

Comment received

2.2. Evidence that alternatives do not exist from the supply chain

The CCST applications were prepared with input from and effectively underwritten by the experts of the major OEMs (prime contractors) in the aerospace sector; these are the ultimate customers of the Downstream Users. By their involvement in CCST, these OEM companies contributed to the preparation of the application and stressed the importance of an upstream application to cover qualified contractors in the existing supply chain. Furthermore, during the public consultation, several commentators again used the opportunity to re-emphasise the necessity of qualified products for their own production, providing additional credibility and substantiation to the applicant's claims. These included corroborating statements from the AeroSpace and Defence Industries Association of Europe (ASD), which represents the aeronautics, space, defence and security industries in Europe in all matters of common interest with the objective of promoting and supporting the competitive development of the sector. ASD's membership is composed of major European aerospace and defence companies and national associations. Individual members of CCST and other aerospace companies could also have commented during the public consultation to underline the situation, though this was not identified as necessary to the success of the application given the explicit involvement in the dossier preparation itself.

Nevertheless, e.g. on p. 49 of the draft Opinion on potassium dichromate, SEAC states that it *"cannot exclude that there are indeed "surface treatment" applications or process steps using potassium dichromate, where substitution is already feasible or will become so at the short term. Furthermore, 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 on a sector wide level. SEAC should have been provided with a categorisation of surface treatment / coating applications, along with information on the specific technical requirements, to judge about the actual feasibility / infeasibility of alternatives for specific applications within the broad use applied for."* SEAC concludes that *"as a consequence of the broadly defined scope of the use applied for, covering many different surface*

treatment applications containing potassium dichromate, and the generic approach of the applicant in the analysis of alternatives, SEAC cannot exclude that there are specific surface treatment applications using potassium dichromate, where substitution is already feasible or will become so in the short-term."

Rapporteurs' response

SEAC has considered the information submitted during the public consultation, as reflected in the justification to the opinion. Please also see the response to point 1.3.

Date		**Comment number**
27/10/2016		8

Comment received

2.3. Criticism of lack of specificity of Analysis of Alternatives

Finally, this criticism translates into the conditions recommended to be imposed by the Commission for any subsequent dossier for the review period, e.g. see p. 65 of the draft Opinion on potassium dichromate: *"The applications should be defined in a meaningful and sufficiently detailed way, based on the requirements of for example, types of surface treatment processes, types of parts/components to be treated or types of end-uses (such as manufacturing or repair)."* According to SEAC (p. 66 potassium dichromate*), "SEAC considers that a more application-specific assessment (which does not summarily dismiss substances or technologies that are not a general alternative or that are not yet implemented sector-wide) is needed for the evaluation of the technical and economic feasibility of potential alternatives."*

The applicants submit that the approach suggested by the Committees in relation to the AoA cannot be implemented in practice and is disproportionate. Tens of thousands of parts/components, large and small are surface treated per airplane, by a large number of third party suppliers and the aircraft manufacturers themselves. Listing these parts even by category and aircraft type and conducting the AoA on an article by article basis would be an insurmountable task and would be subject to constant changes. For the avoidance of any doubt, an analysis of alternatives would need to be carried out per part and per aircraft type. As an example of the specificity required, even fuse pins and connector pins would need to be considered individually. Not only would this be practically impossible but also disproportionate to the aims pursued with authorisation.

The applicants have, taking a practical approach, developed their AfA on the basis of a number of critical parameters (only when these are required will chromates be used) and listed the type of surface treatment (functions of the chromates), such as Chromate Conversion Coating, Passivation of stainless steel etc. and assessed the alternatives on the basis of both these functional parameters. This is in line with applicable Guidance. Neither REACH nor the Guidance on authorisation require a listing or description of individual 'articles', only the category of article per the use descriptor system[4] is required (airplanes).[5] In addition, the Applicants provided lists of examples of typical individual articles (just as a matter of example e.g. Rotor: rear rotor shaft, rotor mast, spindles, bearing mounts; Airframe: brackets, bushes, bushings, fasteners). Substitutions have not been validated/qualified for these parts. They are exposed to severe conditions (high dynamic loads and exposure to corrosive environments), where current substitutions do not provide the required protection.

Rapporteurs' response

Since the broad use applied for covers many types of surface treatment and coating applications and since a *general* alternative for the use as a whole is unlikely to emerge, the condition for the review report recommended by SEAC foresees that the analysis of alternatives should assess the suitability

[4] https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

[5] Guidance on Authorisation p. 32: "Where the substance is used in production of articles, the use descriptor system will include the category of article into which the substance is incorporated". https://www.echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf

of potential alternatives with a view to the possible substitution of Cr(VI) in the relevant types of technical applications. As stated in the opinion justification, the technical applications could be categorised, for example, based on types of surface treatment or coating processes, types of parts/components to be treated or types of end-uses (such as manufacturing or repair). SEAC does not suggest to conduct a separate analysis of alternatives for each and every part or component, but rather recommends as a condition for the review report to conduct a more application-specific assessment. The phrasing of this condition allows for the flexibility to develop an appropriate and implementable approach other than a single article-based approach.

With respect to the individual parts listed by the applicant for which substitutions have not been validated/qualified (e.g. Rotor: rear rotor shaft, rotor mast, spindles, bearing mounts; Airframe: brackets, bushes, bushings, fasteners), SEAC recalls that it was stated in previous communications and in the analysis of alternatives that the scope of the application for authorisation is not limited to any particularly corrosion prone areas or parts of aircraft. Accordingly, SEAC was not provided with information about specific performance requirements for such parts. Should the applicant have information which indicates that substitution of Cr(VI) is possible for some parts but not for others because of certain distinct performance requirements, SEAC would consider such information relevant for inclusion in the review report.

With further categorisation in the analysis of alternatives, the applicant may end-up refining the use applied for into more specific uses to allow SEAC to recommend use-specific review periods.

Date		**Comment number**
27/10/2016		9

Comment received

3. The special issue of Upstream AfAs - General comment on upstream applications and uncertainty – Legitimate Expectations, Good Administrative Practice, Equal Treatment, Proportionality

Upstream applications present unique challenges for applicants, policy makers and enforcement authorities alike. However, they are critical and fundamental to the authorisation process for myriad reasons. The applicants argue that certain pillars have to be established to ensure upstream applications can function as intended, to the benefit of all, and taking account of due market and safety considerations:

- In the absence of specific guidance for upstream applications, available guidance must prevail
- How to manage uncertainty in Exposure Scenarios in upstream applications
- Market considerations
- Safety considerations
- Implications for setting review period and conditions

Rapporteurs' response

The Rapporteurs' response to each point is included below.

Date		**Comment number**
27/10/2016		10

Comment received

3.1. Lack of guidance for upstream applications (including uncertainty)

The AfA was finalised and submitted prior to the development of any substantial opinions by RAC and SEAC in relation to other authorisations, let alone so-called upstream applications. In this context, it should also be acknowledged that there is no specific guidance published relating to the approach for an upstream application. Also, no FAQs have been published to address the specific

issues that have arisen in the upstream applications submitted to date (e.g. how to submit confidential data in case of a joint application). The applicants therefore suggest that this and any application should be assessed with clear respect to the guidance available and applicable at the time of preparation and submission. While thinking in the Committees regarding data requirements and the methods appropriate for both upstream applications and applications in general appears to have evolved in recent months, as evidenced in opinions published in recent months, this is not captured in the current guidance and was not available to CCST at the time the AfA was prepared and submitted.

Accepting this, the applicants submit that technical approaches or methodologies meeting the requirements of the published guidance should be treated with equivalent merit.

For example, as noted above RAC deplores that *"the applicant should have provided more detail for the OCs & RMMs …, i.e.: on the type of surface treatment undertaken, scale and frequency of operation, size and geometry of the parts to be treated, in order to justify that the sample covers the broad spectrum of surface treatment operations to be covered by this application...."* and also 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".* However, the applicants point to the absence of guidance (formal or otherwise) on the collection and provision of such representative information, such that it could not reasonably have anticipated (or been expected to anticipate) such a requirement. Since providing the information requested by RAC would require mapping and investigating the entire supply chain, such an expectation for information not only removes any efficiency of an upstream application but renders it wholly impractical in cases such as this when the supply chain is very complex. Furthermore, when such perceived shortcomings in data gathered and submitted with respect to available guidelines lead to a significantly shortened review period (or 'license to operate') beyond an imminent sunset date, the risks associated with an upstream application approach become untenable for industry.

Rapporteurs' response

The role of the applicant is to ensure sufficient information is provided to allow the Committees to draft their opinions. This need is particularly important for applications covering a wide variation of operational controls and risk management measures across a large number of EU sites.

In relation to the guidance available to the applicant, ECHA notes that there were several guidance documents available at the time of preparing the application, including Guidance on the preparation of an application for authorisation, Guidance on how to develop the description of uses in the context of authorisation, Guidance on the preparation of socio-economic analysis as part of an application for authorisation, Guidance on information requirements and chemical safety assessment, and Guidance on occupational exposure estimation (https://echa.europa.eu/guidance-documents/guidance-on-reach). Moreover, during the Pre-Submission Information Session (PSIS) the applicant received the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process. Lastly, during the opinion making the applicant also has received three sets of questions from RAC and SEAC (including the recommendation to submit confidential information to ECHA via a third party, thus preventing co-applicants from having access to the information) as well as a Trialogue, which gave the applicant several opportunities to provide further data and detailed contextual information on the variations in exposure related the different processes, operational controls and risk management measures.

Regarding the use of measurements from 9 sites to cover the broad spectrum of surface treatment operations in hundreds of sites, RAC reminds that the version of the Guidance on occupational exposure estimation that was available to the applicants before submission stressed that information on key exposure determinants needs to be available in order for measurement data to be of good quality. Generally, it is the applicants' role to ensure the necessary information is provided to allow the Committees to evaluate the representativeness of measurement data. This need is particularly important for applications covering a wide variation of operational controls and risk management measures across a large number of EU sites.
A single ES is used by the applicant to define the OCs and RMMs to limit the risks to workers in a myriad of surface treatment operations in hundreds of sites, covering open and closed processes, manual or automatic processes, the treatment of small parts and large parts, using high or low

chromium bath concentrations, high or low bath temperature, with and without electric current. This made it difficult for RAC to determine how variations in controls impacted exposure, for it to confirm that the operational controls and risk management measures were appropriate to manage the risk from this non threshold substance.
While RAC does not consider mapping of each company in the supply chain would have been needed to develop more specific ESs and characterise exposure determinants in more detail, the applicant could for instance have chosen to define more specific exposure scenarios, WCSs and tasks in greater detail (e.g. providing details on whether the process is open or closed, manual or automated, the size of parts coated, the sampling methods used, the locations of sampling, the exposure estimates and measurement data at each of the chosen representative sites) to justify that the chosen sample of sites represents the variety and type of processes and associated exposure estimates.

Date		**Comment number**
27/10/2016		11

Comment received

3.2. Managing uncertainty in upstream applications

Uncertainties cannot be avoided in any application for authorisation. This is why the guidance explicitly requires an uncertainty analysis. In upstream applications there is increased potential for uncertainty. The uncertainty is 'systemic'. SEAC itself acknowledges the problems of uncertainty such as broad use and inevitable variations in operating conditions between facilities in the draft opinions. At the same time there is no explicit guidance to applicants on how to deal with uncertainty and to which level uncertainty is acceptable because it would be upstream systemic. How specific should scenarios be? Is it possible to work with representative data from facilities and articles? This was suggested during the Trialogue but is not reflected in existing Guidance. How is representativeness and reliability established? Can applicants exclude older or unreliable data in order to better represent the use applied for?

Leaving aside the unavailability of detailed guidance on upstream applications, from a practical point of view, however, it is evident that for the upstream application to work as a concept, it must be possible not only to tolerate but to deal pragmatically with uncertainty. The corollary of not doing so is that the terms of an upstream application will always be less favourable than that which can be achieved by a downstream application, conferring commercial disadvantage to those reliant on upstream authorisation.

A pragmatic approach to addressing uncertainty might involve various qualitative and/or quantitative approaches (e.g. contextual information, sensitivity analysis) or the Committees could engage independent experts or hear expert witnesses to corroborate the facts in the AfA. In the case of this application, failing explicit guidance and instruments, the applicants' approach was to err on the side of caution by making conservative assumptions that would avoid criticism that the assessment under-represented risks or over-represented health impacts and was therefore not robust[6]. At the same time, the applicants provided available contextual information and sensitivity analysis to demonstrate that the conclusions were highly conservative. However, in spite of this very conservative approach, the RAC and SEAC nevertheless consider the uncertainty as that significant as to propose both conditions and shorter than applied for review periods for all uses, which we perceive as an excessive "double penalty".

Rapporteurs' response

RAC and SEAC acknowledge that uncertainties cannot be avoided in applications for authorisation, however, applicants should reduce uncertainties in their application to the extent possible and reasonable. It is not the task of the committees to engage independent experts or witnesses in support of the application. The uncertainties raised by RAC and SEAC are considered to be due to

[6] The RAC acknowledges this cautious approach, for example at pg71 of the draft opinion for Strontium Chromate use in paints "The applicant's assessment of the exposure, risk and impacts for humans via the environment is based on a series of default assumptions that are likely to result in a significant overestimate of health impacts".

the way the applicants approached the assessment, and do not relate to the nature of upstream applications themselves (e.g. the broad scope, the limited measurement data, the approach for assessing economic impacts, etc.). The committees informed the applicant about the weaknesses of the application during the opinion-development stage, and the applicant had the opportunity to provide further information in response to three sets of questions from RAC and SEAC. Furthermore, guidance on how to deal with uncertainty in an application for authorisation is available on ECHA's website, e.g. within the "Guidance on the preparation of socio-economic analysis as part of an application for authorisation" (http://www.echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf).

RAC considers that it would have been possible to make use of representative data to describe the exposure in the applicants' supply chain, thereby limiting uncertainties as indicated in response to comment 10 (point 3.1). It is up to the applicant to justify that the sample of sites chosen are representative of appropriate risk management measures and operational controls relevant to the broad range of processes applied for.

For each of the chosen representative sites older data could have also been used to show how changes to new OCs & RMMs reduced exposure (which aids characterising exposure determinants and effectiveness of implemented OCs & RMMs) and to document progressive reduction of exposure.

It is important to highlight that RAC not only has to assess the exposure estimates, but also has to form a view on the appropriateness of the OCs & RMMs. The applicant should have defined sufficiently specific ESs, provided robust exposure estimates to WCSs of such specific ESs, and justified why the OCs & RMMs in the WCSs are appropriate and effective in limiting the risk (e.g., what are the impediments to implementing automated, closed processes).

In the absence of sufficiently detailed information, RAC has recommended conditions and monitoring arrangements to limit exposure to this non-threshold substance for all users in the supply chain. RAC does not agree to the applicant's view that the conditions imposed are a double penalty as REACH Article 60 provides that authorisations "shall normally be subject to conditions, including monitoring". Regardless of the length of the review period, RAC considers the conditions and monitoring agreements necessary and justified.

SEAC does not share the applicant's view that the conditions imposed are a double penalty. In addition to the point made by RAC, SEAC notes that the criteria for the review period as laid down in the document "Setting the review period when RAC and SEAC give opinions on an application for authorisation"[7] were followed when formulating the opinion. The latter document clearly points out that 7 years is regarded as the *normal* review period and thus a review period of 7 years should not be seen as a penalty –on the contrary.

Date		**Comment number**
27/10/2016		12
Comment received		

3.3. Market Considerations

As noted at 3.2, it is necessary to deal pragmatically with uncertainty in an upstream application in order to avoid conferring commercial disadvantage to those reliant on upstream authorisation. These organisations of course contain a high proportion of SMEs who cannot financially afford or handle the complexities of a downstream application. These SMEs and companies with complex supply chains are at a clear disadvantage to large companies that do not require coverage of their supply chain with authorisations and have the resources to submit individual, bespoke applications with specific technical and financial data and can therefore apparently realise longer review periods with,

[7] Available at https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf

consequently, an improved commercial position in terms of, for example, securing long term contracts for supplying their products or external investment.

Nevertheless, under the REACH authorisation regime, there is no option other than upstream AfAs for OEM companies in the aerospace sector who have to ensure continued use across their whole supply chain, from the qualified formulators to the thousands of qualified subcontractors and suppliers using the substances to comply with the aerospace specifications. As explained in the SEA, failure of the supply chain at any one point could result in major consequences.

In addition to the market implications and the question of equal treatment of same or similar situations, it should also be emphasized again that the upstream application approach from a policy perspective provides many advantages and should therefore be the favoured approach to REACH authorisation rather than to become a last resort vehicle for those who cannot afford or manage to file their DU AfA or lack the technical skills or know-how of their customers or competitors to do so. Upstream AfAs reduce administrative and financial burden for the authorities and industry; they inherently are better designed and adequately flexible to ensure fair competition and a level playing field (all companies in the same situation obtain the same review periods, new DUs can easily come onto the market ensuring flexibility of supply). Through the setting of appropriate conditions, certainty can be achieved without compromising safety. Equally, such conditions are necessary to maintain a level playing field and avoid market distortion that will follow when companies carrying out the same or similar activities are granted 'licenses to operate' of differing duration.

Rapporteurs' response

SEAC re-iterates that 7 years is regarded as the normal review period (see point 3.2). If the authorisation holder wishes to continue placing the substance on the market and/or using it beyond the expiry date of the review period, he will need to submit a review report[8]. The possibility to re-apply should be clearly communicated within the industry to reduce possible concerns on continued supply.

Under the principle of equal treatment, comparable situations must not be treated differently and different situations must not be treated in the same way unless such treatment is objectively justified. Breach of the principle of equal treatment as a result of different treatment presumes that the situations concerned are comparable, having regard to all the elements which characterise them. If downstream users of CCST would have submitted an individual application for authorisation, there may be objective reasons to treat such applications differently such as differences in the scope of the use applied for and differences in the assessment. Therefore, it is not clear on what basis the draft opinions would violate the principle of equal treatment.

Date		**Comment number**
27/10/2016		13

Comment received

3.4. Safety Considerations

The RAC finds that the lack of clear information on the relationship between OCs and RMMs and exposure levels is a significant source of uncertainty and indicates that reliance on RPE to control elevated exposure levels results in risk-control concerns. However, variation in OC and RMM is inevitable within an upstream application where prevailing circumstances (including regulation) do not already ensure consistent and tightly defined exposure conditions. As noted above, uncertainty regarding representativeness cannot be removed without mapping and investigating the entire supply chain and there is a lack of clarity regarding how to address this. However, while such uncertainty relates to the extent to which the current situation is described or characterised, it does not relate to the ability of downstream users to minimise exposure through implementation of a

[8] ECHA's document on the review report is available at https://echa.europa.eu/documents/10162/13637/authorisation_review_report_en.pdf/cbc94819-bdb8-4d98-8687-7372df779bcf

combination of OC and RMM selected to optimally (according to existing regulatory requirements) reflect its own individual circumstances. Indeed, it is recognised that OC and RMM can effectively control exposure.

Given the uncertainty analysis conducted by the applicants themselves and their conservative approach, the applicants suggest that any remaining perceived uncertainty should be tackled with the least restrictive measure achieving the same aim, which is the imposition of suitable conditions rather than also a reduction of review periods.

Finally on this point, the applicants note that the European Commission circulated at the CARACAL meeting of June 29-July 1, 2016 a Doc. CA/51/2016 concerning 'setting the review period in authorisation decisions." In this document which comments on and generally acknowledges the RAC/SEAC document on the same subject the Commission adds that "*an additional consideration that could be taken into account for setting a longer review period could be where it is shown that the risks to human health or the environment resulting from the non-use of the substance significantly outweigh the risks to human health or the environment resulting from continued use*."

The applicants are of the view that the applications that are the subject of this draft opinion are a prime case for consideration in this respect. As set out in the application, air safety is paramount in civil aviation and it is for this reason, effective corrosion protection, that chromates are used in this industry and still cannot be substituted despite long standing R&D efforts to replace them. Passenger and crew safety concerns clearly cannot be side-lined or taken for granted. It is perhaps too easy to overlook this issue precisely because high standards in and expectations for air safety have reduced in-service incidents related to corrosion. Nevertheless a review published in 2002[9] looked at metallurgical failure investigations from an unbroken sequence of records exists from the Second World War, containing approximately 6000 case histories, of which approximately half relate to structural failure on aircraft. 29% of failures of engineering components related to corrosion, greater than that for any other failure mechanism. Further case studies specifically relate corrosion to aircraft incidents. The risks to passenger safety cannot be readily weighed against the continued use of Cr(VI) substances (hence these issues have been discussed qualitatively in the AfA), but Cr(VI) has been employed specifically and continues to be used in the absence of an alternative with similarly high performance to minimise such concerns, as discussed in the application. **Not recognising or taking into account inherent safety issues in the aerospace sector would be a manifest error of assessment.**

Rapporteurs' response

RAC does not dispute that variation in OCs & RMMs are inevitable for upstream applications. It is the role of the applicant to define sufficiently specific ESs, provide robust exposure estimates to WCSs of such specific ESs, and to justify why the OCs & RMMs in the WCSs are appropriate and effective in limiting the risk. See also section 3.2 above.

In response to the second part of the applicant's comment, the committees are fully cognisant of the importance of corrosion protection for aerospace safety. SEAC took this qualitative aspect into account when forming a supportive opinion on the applicant's conclusion that the socio-economic benefits outweigh the risk and when deciding to recommend a normal review period, despite the uncertainties described in the opinion justification which arise from the applicant's approach to the analysis of alternatives and the socio-economic analysis. The opinion justification was updated to clarify this point.

Date		**Comment number**
27/10/2016		14

Comment received

[9] S. Findlay, N. Harrison, "Why Aircraft Fail" Materials Today, Vol. Volume 5, Issue 11, pp. 18-25, Nov. 2002 (http://www.ae.utexas.edu/courses/ase324_huang/MT2002.pdf)

3.5. Implications for setting review period and conditions

Therefore workable conditions rather than the shortening of the review period are the proportionate (least restrictive and suitable) instrument to deal with systemic uncertainty. Such conditions are equally suitable to achieving the same aim (protection of workers and phase out of uses in cases alternatives are deemed available) whilst maintaining business and work places in the EU. Interim reporting can be provided (as a further condition) to provide enforcement authorities (ECHA, MSCA) with confidence that due progress is being made in relation to the implementation of conditions.

An adequate review period is critical for companies in order to provide the legal certainty necessary to justify investment, particularly considering the long investment cycles in the aerospace industry. An inadequate review period is not merely inefficient, but can have substantial negative repercussions for industry, such as failure to secure necessary orders or investment. Thus, consistent setting of review periods is important to avoid market distortion. In any case, shortening review periods due to e.g. a perceived lack of exposure data will not in itself improve risk management. Rather it will drive re-location of activities to locations outside the EU, which is, if anything, rather likely to result in a net increase in occupational and environmental exposure; aerospace dependence upon these chemicals is not going to change because of a short review period. As noted above, a more effective and proportionate tool is to install appropriate conditions and consistent review periods, while the review period would be set according to prevailing guidance[10].

Rapporteurs' response

See points 3.2 and 3.3.

RAC expressed concerns that there are uncertainties in the exposure assessment and that the RMMs and OCs are not appropriate and effective in limiting the risk to workers. Therefore, RAC considers that a review period of no longer than seven years appears to be appropriate, which will allow RAC to evaluate the progress made in reducing these uncertainties and whether the operational controls and risk management measures are appropriate.

Date		**Comment number**
27/10/2016		15

Comment received

4. Exposure Scenarios

In the applicants' opinion, uncertainty regarding exposure (and risk) is inevitable in an upstream application of this nature, as explained previously, but is most fairly and effectively dealt with through the setting of appropriate conditions. The following sections set out applicants' concerns regarding the draft opinion, addressing:

- Setting appropriate conditions to address uncertainty
- RMMs already required by EU Legislation
- Complex supply chain – no legal recourse for obtaining measurement data
- Enforcement officials have access to data that CCST does not

Rapporteurs' response

The Rapporteurs' response to each point is included below.

Date		**Comment number**
27/10/2016		16

Comment received

[10] https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf

4.1. Setting appropriate conditions to address uncertainty

The draft opinion finds (e.g. pg 72 draft opinion for strontium chromate use in paint) there are "uncertainties in exposure assessment, which may result in underestimation of the risk to workers" and 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".

RAC considers (e.g. draft Opinion potassium dichromate p. 24) that *"in order to demonstrate that the ES is indeed representative, the applicant should have provided more detail for the OCs & RMMs at the very least at each of the 9 facilities providing measured data, i.e.: on the type of surface treatment undertaken, scale and frequency of operation, size and geometry of the parts to be treated, in order to justify that the sample covers the broad spectrum of surface treatment operations to be covered by this application....RAC questions the representativity of the correction for RPE for bath applications since according to the ES in the SCR, RPE is in fact not required for any of the tasks in WCS 8-15."* RAC considers (p. 29 draft Opinion potassium dichromate) that the *"lack of detailed descriptions of the type of surface treatment and onsite OCs and RMMs linked to the presented exposure measurement data is a weakness of the AfA."*

As noted in Section 3, the applicants defend the submission as appropriate and in line with available guidance and emphasise that they had no means of anticipating such a requirement during the application. **In any case, as noted above, the absence of such information does not limit the possibility to control risks through setting of appropriate conditions.** Furthermore, this specific information was not requested by RAC during the evaluation of the application and, as also discussed in Section 3, even if this information was available, it could not have increased certainty for representativeness of the measured data as the distribution of these variables in the supply chain is unknown (and uncertainty could only be resolved by mapping the entire supply chain).

RPE is not specified in WCS8-15 but, as explained in the CSR, exposure monitoring data has been corrected for some facilities where RPE was confirmed to be used and adequate information was available to conservatively evaluate the exposure protection it provided. The use of RPE in WCS8-15 provides an example of the variation in OC and RMM that might currently occur between different operations. Indeed company specific exposure controls might include or might not include the use of RPE of some description depending on other OC and RMM in place (e.g. partial/total segregation or automation of process) and with due reference to existing obligations (including the hierarchy of control) under health and safety legislation including Directive 2004/37/EC. The final set of OC and RMM in place at any facility is determined based on a complex set of circumstances that cannot be easily reduced to a simple set of rules or tick boxes; in practice there would be many 'grey areas' that did not readily fit the rules. Therefore, the handling of exposure data by the applicants is appropriate and reflects reality in the supply chain to the extent possible. Moreover, the applicants' approach avoids the problems for downstream users attached to interpretation of 'grey areas'. The applicants submit that the measured data for the 9 facilities was provided in support of the modelled emission scenarios and the data was sufficiently set in context.

Rapporteurs' response

As stated previously it is the role of the applicant to define sufficiently specific ESs, provide robust exposure estimates to WCSs of such specific ESs, and to justify why the OCs & RMMs in the WCSs are appropriate and effective in limiting the risk. RAC is of the view that more detailed and specific ESs will in fact help to avoid interpretation issues for downstream users, and importantly may be more appropriate and effective in limiting the risk.

RAC would like to emphasise that, contrary to the applicant's claim in the comment, this type of information was requested repeatedly (three times) in the questions and remarks from RAC during the evaluation of the application, requesting more detailed ESs, justifications regarding the OCs & RMMs in the ES, more measurement data, and more details regarding the measurement data. Amongst those questions, RAC requested and remarked for instance:

- *The application provides only limited measurement data for a limited number of WCSs and the variation in measured values is high. Please provide any additional measured*

data.

- *Where WCSs cover both open or closed operations, it needs to be clarified what the related OCs and RMMs for each of the situations are and how the OCs and RMMs are reflected in the exposure estimates. The same is needed for WCSs that cover both manual or automated processes.*
- *[…] Please clarify why you consider that these worst-case conditions reflect good industrial hygiene practice and how they are appropriate and effective in limiting the risks. For example, how do the ESs ensure that a semi-closed and automatic process is implemented whenever that is possible when this is not required in the ES and requires an investment?*

Regarding the measurement data for WCS 8-15, RAC remarks (as in the justification to the opinion) that RPE is not specified in the ES as defined by the applicant and thus there are no clear reasons for exposure data that is corrected for RPE to be representative of the estimated exposure for this ES.

Date		**Comment number**
27/10/2016		17
Comment received		

4.2. RMMs already required by EU Legislation

The same draft opinion concludes that "*several WCSs have a high potential for elevated air concentration in the workplace environment and rely heavily on well-functioning and correct use of RPE to control elevated exposure levels; therefore, 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*".

The application for authorisation is clear that RPE may be used to reduce exposure to aerosols for critical tasks where alternative OCC and RMM are not available. OC and RMM allow risks relating to elevated air concentration in the workplace to be adequately controlled. As for any physical RMM such as RPE, the equipment must function-well and be correctly used. EU legislation also requires employers to provide the systems, procedures and training necessary to ensure this is the case. However, the detail of such systems vary between companies. It is not realistic to describe these in detail in an application for authorisation, but this RMM is stipulated in the Exposure Scenarios (i.e. Advanced Occupational Health and Safety Management System). **Furthermore, describing such processes which are in any event required under EU legislation would not improve confidence in risk management. This can only be a matter of enforcement.** Enforcement authorities can inspect facilities to ensure adequate processes and risk management measures are in place. Risk limitation in any system depends on the extent to which implementation of such measures is effectively delivered, and assurance in this regard can only be delivered through inspection by the enforcement authorities.

The RAC also notes for example that "*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 of the RPE is very much dependent on the individual wearer. 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 if RPE is used for longer time-periods*". The applicants note that such a statement is true of any activity that involves the use of RPE. Furthermore, the applicants are not responsible for a lack of harmony between Member States regarding allocation of APF for RPE. The CSR shows that risk management measures, effectively implemented, control exposure. **Concerns around correct implementation of OC and RMM are a matter for enforcement and should not in themselves lead to a reduced review period.**

Rapporteurs' response

The exposure estimates presented by the applicant are for certain tasks heavily reliant on the use of RPE. PPE (RPE) is considered as a last resort under the hierarchy of control measures to eliminate or minimise exposure. RAC are concerned that exposure control to an SVHC is dependent on RPE (particularly negative pressure RPE) as RAC notes the protection afforded by RPE is dependent on the correct use of the RPE by the worker. Where possible, OCs & RMMs further up the hierarchy should be used to control worker exposure so as not to be dependent on PPE (RPE) to protect workers.

Under REACH (Title VII) it is the applicant's responsibility, not the enforcement authorities, to ensure that the OCs & RMMs proposed are appropriate and effective in limiting the risk. It is the role of RAC to give its opinion on the appropriateness and effectiveness of these OCs & RMMs. Therefore a thorough justification for the chosen RPE in each WCS, with a high reliance on RPE, should have been provided by the applicant.

Regarding the remark on the APF factors used, RAC merely pointed out that the exposure estimates may not be conservative when using the factors provided by the German BG rule "BGR/GUV-R190".

Date		**Comment number**
27/10/2016		18

Comment received

4.3. Complex supply chain – no legal recourse for obtaining measurement data

The applicants have explained at length (in the dossier content, in the answers to RAC and SEAC questions and during the Trialogue) the complexity and breadth of the aerospace supply-chain and, as noted above, that an upstream application is necessary to cover the whole supply chain (several hundreds of sites in Europe). Therefore, formulators and OEMs / prime contractors (who specify the use of the substances in their process to their suppliers and subcontractors) joined forces in a consortium in order to secure supply-chain coverage. **However, as also explained during answers to RAC and SEAC questions and during the Trialogue, at the time of preparation of the AfA there was and still is no mandate or legal recourse for the applicants to obtain comprehensive individualized exposure and emissions data for submission to ECHA.** The OEMs were dependent on the good will of their (part) suppliers to submit the data to the independent consultants who in turn were obliged to consolidate and aggregate the data for submission to ECHA to avoid identification. The available neutralized measurement data was provided to ECHA after the Trialogue and no further questions from RAC ensued thereafter.

Rapporteurs' response

RAC has amended the justification to the opinion to clarify that one of the reasons the applicant provided for the limited availability of measurement data is that the applicant has no legal recourse to obtain exposure and emission data from downstream users. It is important that the applicant makes downstream users aware of the requirements and conditions of the authorisation should it be granted, as only those downstream users who comply with the granted authorisation will be covered by this authorisation.

Date		**Comment number**
27/10/2016		19

Comment received

4.4. Enforcement officials have access to data that CCST does not

RAC has asked why data for only a small fraction of sites represented in the application is provided. We have explained (also in the Trialogue) that data is not being withheld, but there is no mechanism for industry to access this data in the supply chain. This is not reflected in the draft opinion. **On the other hand enforcement authorities can access such information but may not do so systematically and/or make such data publicly available.**

Rapporteurs' response

See response to 4.3.

Date		**Comment number**
27/10/2016		20

Comment received

5. Comments on Conditions

The applicants acknowledge that the Committees require representative exposure scenarios for the different types of processes and individual tasks for 'typical surface treatment operations describing the OCs and RMMs together with resulting exposure levels and that these shall be provided to downstream users'. However, considering the activities involved, it is unrealistic to expect that the applicants would have validated monitoring and measurement campaigns from their downstream users to assess the resulting exposure by the sunset date or within three months after the date on which authorisation will have been granted.

Indeed:

- There is no legal vehicle to facilitate the gathering and exchange of data and/or which can guarantee the safe exchange of often sensitive, confidential and personal (e.g. biomonitoring) data. The possible use of the data by applicants and the rights of the users with regard to data shared also needs to be established;
- In most cases there is no direct contractual relationship between downstream-users and the applicants, and even if there was, the reporting of data upstream would make the market transparent and could be viewed by governmental authorities as contrary to competition law.
- Requirements related to exchange of data necessitate very complicated and burdensome (and probably costly) processes; it is unclear who will implement them and how costs could be shared or whether the burden would deter the involvement of key actors;
- It is unclear how the applicants could (a) ensure the data is of sufficient detail, quality and consistency and (b) be assured that any data provided is representative of the overall user base;
- Checking of downstream-user compliance is the duty of enforcement authorities, not the applicants.

The applicants therefore require clarification of the concept of validation of exposure scenarios by an analysis of tasks as well as through representative occupational and environmental release measurement campaigns. Moreover, for practical reasons it should be specified that this validation is due only for eventual review or, as appropriate, interim reports with realistic timeframes reflecting the complexity of the tasks involved. The applicants emphasise it will not be logistically possible to submit this information by the sunset date without substantially sacrificing quality.

The applicants therefore require clarification of the concept of validation of exposure scenarios by an analysis of tasks as well as through representative occupational and environmental release measurement campaigns. Moreover, for practical reasons it should be specified that this validation is due only for eventual review or, as appropriate, interim reports with realistic timeframes reflecting the complexity of the tasks involved. The applicants emphasise it will not be logistically possible to submit this information by the sunset date without substantially sacrificing quality.

The applicants understand that, so far as the revised Exposure Scenarios are concerned, they can identify and group tasks when it makes sense to do so (for example when tasks are performed sequentially by a single operator), and request confirmation of this understanding.

Nonetheless, in many cases, it will still make little sense to gather measurement data and particularly biomonitoring data (e.g. for very short duration, well controlled tasks that are unconnected to other chromate related processes or for tasks that have been demonstrated to reliably result in no appreciable/measureable exposure (e.g. use of touch-up pens, for which there are no standard monitoring programs). The applicants request confirmation that professional discretion is acceptable in terms of identifying such scenarios and evaluating them appropriately, or whether measurement is expected in each instance.

ECHA requires "*programmes of inhalation exposure monitoring through personal sampling shall be undertaken in combination with post-shift biomonitoring*" for workers undertaking tasks relating to e.g. spray painting and machining. This is a broad overly burdensome requirement that does not take into account concentration of substance and duration of exposure. Biomonitoring of incidental maintenance and repair activities that occur under WCS 3-5 or WCS 15-21 place an undue cost burden on DUs with no benefit to worker health and safety. Furthermore, the frequency of such biomonitoring is not specified (does RAC expect the frequency is similar to the other workers exposure monitoring (at least annually)?).

Rapporteurs' response

A distinction should be made between the conditions under the title "Exposure scenarios" and "Validation of Exposure Scenarios". The former condition requires more specific ESs including detailed OCs & RMMs to be developed without delay and not later than 3 months after the applicant has been informed that an authorisation is granted for this use.

The latter condition is the second step and requires the applicant to validate and verify these specific ESs on the basis of exposure monitoring relevant to the specific OCs & RMMs at the Downstream Users' sites. The monitoring programmes shall be at least annually, and thus measurement data shall be available at least 1 year after the date on which authorisation will have been granted. This means that the validation and verification of the ESs occurs after the results of the first monitoring programme associated with the specific OCs & RMMs are made available to the applicant. RAC has not provided a deadline in the condition, but 24 months after the date on which authorisation will have been granted might be a reasonable point in time to expect the validation to be finalised. In any event, such information will also need to be provided in any review report.

Once it has been clearly demonstrated that exposure has been reduced to as low a level as technically and practically possible and that the OCs and RMMs are function appropriately, the monitoring[11] requested for this authorisation may be discontinued. The condition also clarifies when subsequent changes in OCs or RMMs are made that affects the exposure consideration needs to be given to further monitoring in order to demonstrate that exposure is still as low a level as technically relevant.

The condition states that "… *where relevant* the applicant shall implement at least annual programmes of occupational exposure measurements relating to the use of the substance described in this application" (emphasis added). Thus, it is acknowledged that no measurements may be necessary for tasks for which it can demonstrate that no relevant exposure occurs. Such instances should be well justified and clearly documented.

The monitoring programme should be relevant and representative to the tasks to be undertaken. The condition does not specify the type of occupational monitoring that needs to be undertaken. The exception to this is for Use 2 of strontium chromate and potassium hydroxyoctaoxodizincatedichromate, where biomonitoring is specifically required for workers undertaking tasks covered by WCSs 3-5 and WCS 15-21. The condition has been amended to

[11] Monitoring covers all workplace monitoring (i.e., personal, static measurements, biomonitoring) and environmental monitoring.

specify that the biomonitoring is required on an annual basis. Where results of the biomonitoring indicate that exposure has not been reduced to as low a level as technically and practically possible, the frequency of biomonitoring shall be increased. The duration of the WCSs 3-5 and WCSs 15-21 as defined in the ES are between 30 min/day and 240 min/day depending on the WCS. The ES clarifies that cleaning after machining is included in the WCSs 15-21. In any case, all tasks would be covered by post-shift biomonitoring (even if the applicant would choose to split the WCS to separate out such cleaning activities). RAC therefore considers there should not be a concern with "incidental maintenance and repair activities" or with tasks of short duration. RAC does not see a concern regarding the concentration either, since the concentration in chromium paints and coatings used for spraying is always high (liquid 5-10% Cr(VI)), and the machining activities concern surfaces with Cr(VI) paints.

The Commission may decide that downstream users shall make the exposure monitoring information, as well as information regarding the review of OCs and RMMs, available to ECHA for transmission to the authorisation holders. This solution may alleviate some of the concerns regarding data exchange (e.g. lack of direct contractual relationship between downstream-users and the authorisation holders, complexity of the supply chains).

As part of the implementation of monitoring programmes, the applicant may prepare recommendations/guidelines for downstream users (e.g., regarding the use of relevant standards and practices, how to record relevant exposure determinants corresponding to the measurements). Moreover, the applicant may develop, or be involved in the development of, a format for submission of exposure data by downstream users. In this manner, the applicant may contribute to the good quality, consistency and detail of exposure monitoring data provided by downstream users.

RAC confirms that several tasks may be grouped into one WCS when it make sense to do so, bearing in mind that the WCSs need to be sufficiently specific and that OCs & RMMs in the WCSs should be appropriate and effective in limiting the risk.

Date		**Comment number**
27/10/2016		21
Comment received		

6. Additional Items

Please also take into account the following comments:

- Correct spelling of Mankiewicz
- In the strontium chromate and potassium hydroxyoctaoxodizincatedichromate draft opinions, ECHA states in section 9. Specific Condition C "At least a full mask with at the minimum APF 400 is required for WCS 4 and WCS 5." This is inconsistent with Table 2.
- In the strontium chromate and potassium hydroxyoctaoxodizincatedichromate draft opinions, in the section "Alternative 3: Silane-based processes including sol-gel coatings" (pg 59 – strontium chromate, pg 56 – potassium hydroxyoctaoxodizincatedichromate) it is stated that "Sol–gel protective coatings have shown excellent chemical stability, oxidation control and enhanced corrosion resistance for metal substrates". This is not an adequate description of the alternative. The applicants acknowledge that this sentence is in the AoA, but it was only in reference to an independent research article referenced in the AoA (Wang and Bierwagon, 2009). The actual conclusion for the corrosion resistance of sol-gel coatings in the AoA is as follows: "Corrosion resistance: Sol-gel chemistries by themselves do not provide significant stand-alone corrosion resistance, therefore rely on additives or subsequent coatings to provide the corrosion resistance to meet part requirements. Currently there are no known additives to the silane matrix that have shown stand-alone corrosion resistance that meets aerospace requirements. First generation Sol-gel coatings (aiming at adhesion promotion) generally prevent corrosion by their function as a physical barrier, rather than through active corrosion protection. Furthermore, coatings like e.g. ZrO2-based sol-gels do not provide active corrosion inhibition (Paussa, 2011), thus not providing corrosion protection of

scratched surfaces. Therefore, sol-gel coatings require a suitable anti-corrosion coating on top.”
Rapporteurs’ response
Rapporteurs would like to reply as follows: • The spelling of Mankiewicz in Annex 3 to the justification to the opinion for strontium chromate has been corrected. • Table 2 refers to the data presented in the CSR by the applicant. In section 9, RAC recommends that for WCS 4 and WCS 5 RPE with APF 400 is a condition to the authorisation of Use 2 of strontium chromate and potassium hydroxyoctaoxodizincatedichromate, if granted. • The text has been deleted considering that the focus of section 7.3 is on comparison of risks of alternatives with Cr(VI).