Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

sodium dichromate use: Formulation of mixtures

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

Consolidated version

Date: 9 December 2016

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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): sodium dichromate
EC No.: 234-190-3
CAS No.: 10588-01-9, 7789-12-0

for the following use:

Formulation of mixtures

Intrinsic property referred to in Annex XIV:

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

Applicant:

Brenntag UK Ltd
Henkel AG & Co. KGaA
AD International BV

Reference number:

11-2120105291-73-0000
11-2120105291-73-0001
11-2120105291-73-0002

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 04 December 2015 Brenntag UK Ltd, Henkel AG & Co. KGaA; AD International BV submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **22 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 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 socio-economic 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:

Sodium dichromate has a harmonised classification as Carcinogen Cat. 1B, Mutagen Cat. 1B, Toxic to reproduction 1B with H350, H340 and H360FD according to CLP.

Based on studies which show its genotoxic potential, the Risk Assessment Committee (RAC) has concluded that sodium dichromate should be considered as non-threshold substance with respect to risk characterisation for carcinogenic effects of hexavalent chromium (reference to the studies examined are included in the RAC document RAC/27/2013/06 Rev. 1 Final).

Based on studies which show reprotoxic effects of potassium and sodium dichromate, RAC has concluded that sodium dichromate should be considered as a threshold reprotoxicant (RAC/35/2015/09).

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 sodium dichromate is the Cr(VI) ion, which is released when sodium dichromate 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).

The applicant has derived DNELs for the reprotoxic properties of sodium dichromate. RAC has proposed higher reference DNELs for the reprotoxic properties of some Cr(VI) compounds, including potassium dichromate and sodium dichromate (RAC/35/2015/09).

Are all appropriate and relevant endpoints addressed in the application?

All endpoints identified in the Annex XIV entry are addressed in the application with dermal exposure (relevant for assessing reproductive toxicity) only being assessed in a qualitative way.

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

Description:

Short description of the use

This application for authorisation relates to the stand alone[1] formulation of sodium dichromate containing mixtures.

Sodium dichromate is used in the aerospace industry in Europe for its corrosion inhibiting properties for metallic structures. It is mainly used for surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, as well as composites and sealing of anodic films.

The applicant has indicated that formulation is in most cases a batch process that is predominately carried out under closed conditions.

Use 1 generally involves storage, decanting, weighing (for solid form), transfer and charging of chemicals to a blend tank, mixing and/or reaction, transfer from the mixing tank to packaging, maintenance and cleaning of equipment, transfer of waste for waste disposal and laboratory activities.

The tonnage of sodium dichromate used is 1 300 tons/year equating to **520 tons/year of Cr(VI)**. According to the applicant's Chemical Safety Report (CSR) the number of sites conducting the use may be **up to 10 sites** in the EU. The applicants' Socio-Economic Analysis (SEA) clarifies that there are currently 3 sites covered by this application.

One exposure scenario (ES) with 11 worker contributing scenarios (WCS) is presented in the CSR with one environmental contributing scenario (ECS). Although formulation is generally a non-continuous batch process, the applicant has treated it as a continuous process in the exposure assessment in the sense that WCSs are assumed to be conducted each day and exposure is based on a 8 h TWA.

[1] Stand alone formulation is a term used here to distinguish between sites covered by Use 1 where only formulation takes place and sites covered by Use 2 where surface treatment activities and limited on-site formulation activities are carried out.

Table 1: Contributing Scenarios of the Exposure Scenario "Formulation of Mixtures"

Contributing scenario	ERC / PROC	Name of the scenario
ECS1	ERC 2	Formulation of Mixtures
WCS 1	PROC 1	Delivery and storage of raw material
WCS 2	PROC 8b	Decanting and weighting of solids
WCS 3	PROC 8a/8b	Transfer to mixing vessel- aqueous solution
WCS 4	PROC 8b	Transfer to mixing vessel- solid
WCS 5	PROC 2-5	Mixing by dilution, dispersion, wet-grinding (closed or op process)
WCS 6	PROC 9	Transfer to small containers (including filtering
WCS 7	PROC 8b	Cleaning of equipment
WCS 8	PROC 8a	Maintenance of equipment
WCS 9	PROC 1	Storage of formulation
WCS 10	PROC 15	Laboratory analysis (sampling, laboratory analysis, t spraying)
WCS 11	PROC 8b	Waste management

Worker contributing scenarios

The ESs presented by the Applicant were built based on the resuts from consultations with the CCST consortium[2] members (see below).

The place of use of the substance is indoors for all WCSs except WCS 9 (Storage of formulation), which may occur indoors or outdoors.

The contributing scenarios are presented in Table 1 and described in more detail below in Table 2.

WCS 1

Sodium dichromate is either produced in the formulation plant or delivered as wet paste or dry powder in railway-containers or by qualified ADR truck drivers and removed from vehicles by trained staff via fork lifts. The substance can be delivered immediately before use or can be stocked in designated warehouses. It is delivered either as dry powder in sealed 25 to 1 000 kg bags or as aqueous solutions 0.5 to 1 000 L containers, 20 tons ISO containers or within 23 tons tank trucks. No additional information is given about task content (for example transport of bags within the chemical storage room).

WCS 2

Solid sodium dichromate may be decanted and weighted before it is transferred to the mixing vessel. The applicant stated that manual weighing and decanting of solid chromates

[2] The CCST (Chromium VI Compounds for Surface Treatment) Consortium applied for five chromium VI containing substances for uses 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.

is only relevant if small amounts are used in formulation and exposure can be clearly controlled.

WCS 3

The sodium dichromate aqueous solution is transferred to and filled into the mixing vessel. This might be an open, manual process or an automatic, closed process. The connection of the receiving vessel to the source vessel is done manually.

WCS 4

Solid sodium dichromate is transferred to and filled into the mixing vessel. Typically 25 kg bags are directly decanted into mixing vessels by operators using respiratory protection. This is normally a manual process. The open empty bags are then disposed of (see WCS 11).

WCS 5

Mixing/blending of the preparation is performed within a mixing tank, often a closed or semi-closed system with automated mixing.

WCS 6

Once the formulation is mixed it is then either manually or automatically filled into specified containers or tanks.

WCS 7

The cleaning of equipment is conducted by those employees working in the mixing area as part of their normal working procedure.

WCS 8

Regular maintenance of formulation equipment, it is assumed that it will be carried out for 30 minutes every day during the formulation process. Infrequent maintenance activities (outside of the formulation process), with longer duration are usually conducted by other workers.

WCS 9

The final formulation is stored in sealed containers.

WCS 10

Samples are taken and brought to the laboratory where they are diluted and analysed.

WCS 11

Before disposal as hazardous waste, the workers remove the empty bags that previously contained solid chromate to a storage area for collection. Further information on the preparation of empty bags (WCS 11) before being sealed for disposal was provided by the applicant in response to RAC's requests. The empty bags are first placed into a large bag before being sealed and marked as hazardous waste for certified disposal. Alternatively empty bags may be pressed in a bag-press and collected in a hazardous waste container. These containers are cleaned, re-used if possible, or alternatively sealed for disposal as hazardous waste and stored in closed hazardous waste containers which are collected by licensed waste management companies for treatment, incineration and disposal of incineration residues to contaminated landfill.

Exposure estimation methodology

The main route of exposure is via inhalation and the applicant has assumed that all particles are in the respirable size range and thus oral exposure was not assessed.

Exposure has been assessed qualitatively and quantitatively using measured exposure data and modelled exposure.

According to the applicants, the exposure estimates are conservative. The applicants stated that 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 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.

WCS 1 & 9

For WCSs 1 and 9, the applicant has used a qualitative assessment. The applicant claims that there is no potential for exposure because the raw sodium dichromate material is delivered in sealed bags (as a dry powder) or in sealed containers (aqueous solution). The final formulation is again also stored in closed containers.

WCS 2-8

For WCS 2-8 the applicant used aggregated measurement data from 2005-2011 from 2 companies who formulate strontium chromate and one company formulating sodium dichromate to estimate the exposure. Out of around 30 personal and static measurements from 2005-2011 from 3 EU countries, 19 personal samples from 3 companies were selected. The applicant used the 90^{th} percentile following adjustment for RPE from these measurements in their further analyses.

The applicant indicated they only used measurement data that corresponded to good practice, as the applicant considered that this data represented the RMMs & OCs outlined in the exposure scenario which downstream users will be required to comply with. Any measurement data that was not proven to meet these RMMs and OCs or any data that was outdated, inadequately reported, or with inadequate sampling or analytical methods was not used. Personal measurement data was selected by the applicant because they were considered most representative of actual worker exposure. The applicant did not use static measurement data because they did not consider such measurements as representative of worker exposure, arguing that a high or low static measurement is irrelevant if a worker is not exposed or only exposed for a fraction of the time. The applicant stated that biomonitoring data was not used because it does not provide a reliable metric for exposure to Cr(VI).

Measurements below the limit detection were used and accounted for by using 50% of the LoD, as common practice in occupational exposure assessment.

WCS 9, 10 & 11

For WCSs 9, 10 and 11, inhalation exposure has been estimated using the ART 1.5 model. Input parameters for the model including operational conditions (OCs) and risk management measures (RMMs) have been provided in the CSR. According to the applicant the input parameters of the exposure modelling are conservative and represent the reasonable worst case. The 90th percentile full shift exposure estimate is used for the exposure and risk assessment

For WCS 10, twelve personal air sampling measurements are available. However the applicants consider that the small sample size does not allow for using them as the basis for exposure estimation.

Exposure via dermal route

Although requested by RAC, the applicant has not undertaken a quantitative assessment for dermal exposure but a qualitative dermal exposure assessment based on the premise that the substance is classified as Skin Corr 1B (causes severe skin burns and eye damage) and as Skin Sens. 1 (may cause an allergic skin reaction) such that due to the severe local effects any dermal contact with the substance at the workplace has to be avoided by organizational measures and adequate dermal protection, and, exposure is only expected to occur incidentally.

RMM applied

An overview on WCSs and related OCs and RMMs applied in each contributing scenario are presented below.

Table 2: Operational Conditions and Risk Management Measures for the use of sodium dichromate in the formulation of mixtures

Contributing scenario (PROC) and type of process scenario	**Duration and frequency of exposure**	**Physical state & Conc. of (CRVI)**	**LEV [1]**	**RPE**	**PPE used**	**Other additional RMMs**
WCS 1 (PROC 1) Delivery and storage of raw material	< 8 h, daily	Solid/liquid Cr(VI) < 40%	No	No	No	Closed system: bags & containers sealed, basic general ventilation (1-3 air changes per hour)
WCS 2 (PROC 8b) Decanting and weighing of solids	< 1h, daily	Solid Cr(VI) < 40%	Yes	Yes [2,3]	Yes [4) & 5)]	Basic general ventilation (1-3 air changes per hour).
WCS 3 (PROC 8a/8b) open, manual or automatic, closed Transfer to mixing vessel – aqueous solution	< 8h, daily	Liquid Cr(VI) < 40%	Yes	No	Yes [4) & 5)]	Basic general ventilation (1-3 air changes per hour) and RPE if no LEV is in place.
WCS 4 (PROC 8b) normally manual Transfer to mixing vessel – solids	< 4h, daily	Solid Cr(VI) < 40%	Yes	Yes [2,3]	Yes [4) & 5)]	Generally a manual process where RPE Is worn, basic general ventilation (1-3 air changes per hour).
WCS 5 (PROC 2 to 5) closed or semi-closed with automatic mixing Mixing by dilution, dispersion (closed or open process)	< 8h, daily	Liquid Cr(VI) < 20%	Yes	No	Yes [4) & 5)]	Basic general ventilation (1-3 air changes per hour).
WCS 6 (PROC 9) manual or automatic Transfer to small container (including filtering)	< 8h, daily	Liquid Cr(VI) < 20%	Yes	No	Yes [4) & 5)]	Basic general ventilation (1-3 air changes per hour)and RPE if no LEV is in place
WCS 7 (PROC 8b) Cleaning of equipment	< 1h	Liquid Cr(VI) < 20%	Yes	Yes	Yes [4) & 5)]	Basic general ventilation (1-3 air changes per hour) and RPE in cases where exposure to the substance in solid form may occur [4)]
WCS 8 (PROC 8a) Maintenance of equipment	< 30 min, daily	Solid/liquid Cr(VI) < 20%	Yes	Yes [2,3] And air fed masks for higher	Yes [4) & 5)]	Basic general ventilation (1-3 air changes per hour). General maintenance is performed by same workers who undertake formulation activities. Only performed by trained personnel

Contributing scenario (PROC) and type of process scenario	Duration and frequency of exposure	Physical state & Conc. of (CRVI)	LEV [1]	RPE	PPE used	Other additional RMMs
				risk operations		according to standard procedures and risk assessments. For higher risk operations Air-fed masks, hooded disposable overalls, disposable vinyl work gloves, anti-static protective boots and barrier cream are worn.
WCS 9 (PROC 1) Storage of formulation	< 8 h, daily	Liquid Cr(VI) < 20%	No	No	No	Basic general ventilation (1-3 air changes per hour) and containment: closed system (sealed steel drums or sealed containers)
WCS 10 (PROC 15) Sub-activity: Drawing of sample and transfer to laboratory Laboratory analysis (sampling)	< 30 min, daily	Liquid Cr(VI) in mixture: <20% Substantial (5-10%)	Yes	No	Yes [4) & 5)]	Good natural ventilation(ART1.5) 1-3 air changes per hour
WCS 10 (PROC 15) Sub-activity: Laboratory analysis Laboratory analysis	< 60 min, daily	Liquid Cr(VI) in mixture: minor (5 - 10%)	No	No	Yes [4) & 5)]	Good natural ventilation (ART1.5) 1-3 air changes per hour
WCS 11 (PROC 8b) Waste management (dry product, fine dust)	< 30 min, daily	Solid: powder wt. fraction (Cr (VI): substantial (10-50%)	No	Yes [2]	Yes [4) & 5)]	Good natural ventilation (ART1.5) 1-3 air changes per hour and low level containment (90% reduction) in hazardous waste containers.

[1)] LEV effectiveness is available only for modelled exposure

[2)] According to German BG rule 190[3] at least half-mask with P3 filter is worn during handling of solid chromates (APF 30).

[3)] Where Local Exhaust Ventilation (LEV) is not sufficient to minimize Cr(VI) exposure, respiratory protection is worn.

[4)] Goggles & protective clothing are mandatory for those tasks involving handling of the liquid and solid formulation.

[5)] Chemical resistant nitrile rubber gloves with a minimum layer thickness of 0.11 mm and a break through time of at least 480 min

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

Other Risk management measures used to control exposure:

According to the applicant, the Occupational Health and Safety Management System supporting all the WCS is advanced (Standard Operating Procedures, training, prohibition on eating/drinking in risk areas etc.) and the use of RPE is specifically required in cases where exposure to sodium dichromate in solid form may occur.

Discussion of the exposure information

Exposure estimates are presented in Table 3.

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

Contributing scenario	**Method of assessment**	**Exposure TWA 8h (µg Cr(VI)/m³)**	**Exposure TWA 8hr following correction for RPE (µg Cr(VI)/m³)**
WCS 1	Qualitative	**0**	-
WCS 2 to 8	Measured data	arithmetic mean: 3.97 geometric mean: NA 90th percentile: NA	arithmetic mean: 0.11 geometric mean: 0.03 90th percentile: **0.26**
WCS 9	Qualitative	**0**	-
WCS 10 Sub-activity: Drawing of sample and transfer to laboratory. Sub-activity: Laboratory analysis	ART 1.5	90th percentile for both sub-activities: **0.65**	Personal sampling (n = 12) yielded a 90th percentile of 0.64 When excluding two high LODs, the 90th percentile is 0.12
WCS 11	ART 1.5	6.6	90th percentile: **0.22**

NA = not available (Table 4 presents uncorrected values for the individual sites, however the aggregated value across sites was not presented by the applicant)

Table 4: Measurements based on aggregated company/site measurement data based on personal sampling -strontium chromate and sodium dichromate (solid and liquid) covering WCSs 2-8

Company & Period & substance	Total no. of measurements	Duration of sampling period	90th Percentile (µg Cr(VI)/m³) (without RPE)	90th Percentile (µg Cr(VI)/m³) (with RPE)	Arithmetic Mean (µg Cr(VI)/m³) (no RPE)	Arithmetic Mean (µg Cr(VI)/m³) (with RPE)	Geometric Mean (µg Cr(VI)/m³) (with RPE)	Process type	Where there changes to RMM & OC during monitoring period?	Large facility*	LOD of the measurements	What is the Frequency of formulation activity using chromates
A 2005-2009 strontium chromate	10	30-390	1.22	0.02[1]	0.47	0.02	0.01	Manual. Semi-open. (Open while the raw materials are loaded.)	No	YES	No value below LoD	Around 50d/year
B 2009-2011 sodium dichromate	1	≥ 120	9.5	0.32	9.5	0.32	0.32	Manual. Non-continuous semi open during charging of the solids (with PPE), closed during the rest of the process.	Yes, improvement of LEV	YES	No value below LoD	Around 50d/year
C 2007 strontium chromate	8	15-30	2.75	0.01	1.94	0.01	0.00	manual/ automatic. Semi open non-continuous batch process	No	YES	50% of values below LOD. The LOD was between 23 and 43 µg/m3	Around 40d/year

*"Large facility" in the sense of "no SME" on the background that company size may give some indication to the level of organization, training and process controls.

Following RAC's request, the applicant confirmed that the data in Table 5 (Company A in Table 4) corresponded to the same company as in Table 6.

[1] Previously the applicant reported a value of 0.04 µg/m³

Table 5: Aggregated company/site measured data - <u>personal sampling</u> strontium chromate (solid and liquid) (2nd Response to RAC questions)

Period	Total no. of measurements	Arithmetic Mean (µg Cr(VI)/m³) (no RPE)	Arithmetic Mean (µg Cr(VI)/m³) (with RPE)	Geometric Mean (µg Cr(VI)/m³) (with RPE)	90th Percentile (µg Cr(VI)/m³) (no RPE)	90th Percentile (µg Cr(VI)/m³) (with RPE)	LEV	Process type	RPE	Duration (min)	LOD of the measurements
2005-2009	10	0.47	0.02	0.04	1.22	0.02	Yes	manual	yes	30-390	No value below measurement specific LOD

Table 6: Aggregated company/site data - <u>static sampling</u> strontium chromate (solid and liquid) (2nd Response to RAC questions)

Period	Total no. of measurements		Arithmetic Mean (µg Cr(VI)/m³)	Geometric Mean (µg Cr(VI)/m³)	90th Percentile (µg Cr(VI)/m³)	LEV	Process type	Duration (min)	LOD of the measurements
2007	7		0.78	0.58	1.74	Yes	manual/ automatic	15-46	No value below measurement specific LOD

The applicant was asked by RAC why only a limited amount of data was available and presented in the application. 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[1] data based on current good practice. The applicants state that the industry is receptive to collection of new measurement data, recognising this will take months to collect.

The exposure levels presented in the application are based on an 8 h TWA. The applicant has indicated they represent the upper bound of exposure levels that can be achieved using best available technology. Downstream users would be required to implement at least the RMMs & OCs indicated, using best available technology.

Data from 3 companies who formulate strontium chromate/sodium dichromate was used to estimate the exposure. Disaggregated exposure data from the 3 individual companies (average exposure concentrations in air measured from personal sampling) were provided at RAC's request. The applicant used aggregated measurement data from these 3 companies[2]. The applicants indicated that the three companies where the measurements were taken are using LEV & RPE and the process can be described as a semi-open non-continuous batch process (open during charging raw solid material and closed during the rest of the process).

The applicant corrected the 90th percentile of the personal air measurements for the use of respiratory protection (APF 30) to derive a 90th percentile exposure estimate of 0.26 µg/m^3. The range of the arithmetic averages (with RPE adjustment) is between 0.00 to 0.32 µg/m^3 and the range of result values without RPE adjustment is between 0.47 to 9.5 µg/m^3 (noting 9.5 µg/m^3 is based on 1 measurement over >2hr period for sodium dichromate). RPE with APF 30 is only specified for tasks involving the handling or decanting of solid chromates WCS 2 & 4. There is therefore uncertainty with respect to correct exposure for work tasks that do not require use of RPE. Furthermore, the exposure is dependent on the functioning and proper use of RPE. 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. It is noted that other countries allocate lower APFs than Germany. Therefore the exposure estimates may not be sufficiently conservative.

Differences in the OCs, RMMs and the scale of operations at each of the three sites was not detailed in the application nor was information on the monitoring methodology and detection limits from the measurements provided. However, during the application process additional information was provided to RAC.

[1] Monitoring data used in the application was based on the use of strotium chromate and sodium dichromate but not potassium dichromate or dichromium tris(chromate).

[2] The applicant was asked to clarify why the CSR referred to the use of 24 personal sampling measurements but the table of measured data references only 19 personal samples. The applicant clarified that one measurement for Company B from 2009 (19 µg/m^3 before consideration of RPE) was not used because the LEV system was subsequently improved and therefore the 2011 measurement data reflected the exposure situation with respect to the relevant RMMs & OCs. Four measurements from Company A in 2005 and 2007 were not used (AM 1.81 µg/m^3, GM 0.82 µg/m^3, 90th percentile 3.18 µg/m^3; before consideration of RPE) because the 10 measurements from 2008 and 2009 were considered by the applicant to provide a more stable and recent basis for exposure estimation.

The most significant potential for exposure occurs during the weighing and transfer of the solid chromate substance to the mixing vessel (WCS 2-6) where the formulation takes place. The mixing vessel is typically closed, apart from when the dry formulation constituents are added when RPE is worn. While all WCS 2-8 indicate the use of LEV it is not clear where this LEV is located, as the applicant stated that the mixing vessel does not have LEV.

Exposure during cleaning (WCS 7) and maintenance (WCS 8) activities are considered by the applicant to be included in the measured data. General maintenance is based on an exposure time of <30mins every day. The exposure during infrequent maintenance activities outside the formulation process was not estimated separately and no OCs and RMMs were specified in the CSR. In response to questions, the applicant has indicated that infrequent specialist maintenance is performed by trained personnel according to standard procedures and risk assessments.

For WCS 11, ART 1.5 was used to estimate the exposure levels. Only the value of 0.22µg/m^3 which corrected for the use of RPE was provided.

Regarding the static monitoring contextual information such as the WCSs covered and location of measurements are lacking, which makes it difficult to interpret the results.

In the SEA, the applicant divided workers into different exposure groups according to their average exposure duration per day. According to this data, 90% of workers are exposed for 6-8 h/day, 0% are exposed for 3-6 h/day, 1% are exposed for 1-3 h/day and 1% are exposed for less than 1 h/day. In addition, 8% of workers are exposed only infrequently (e.g. once a week, month, year). It is unclear if the extrapolation of the questionnaire data is based on formulators (Use 1) or companies carrying out Use 2 or both. On request by RAC, the applicant provided the number of workers exposed. The number was given as full-time equivalent workers. This appears to suggest that a correction for exposure duration was applied.

According to the SEA, currently 3 sites perform formulation in the EU.

Combined exposure

According to the applicant, there is no potential for combined exposure, other than that shown in the respective sub-scenarios. WCSs 2 to 8 are carried out by the same worker(s) and the measured data presented is said to represent exposure during these activities. It is expected that the laboratory tasks (WCS 10) are performed by workers other than those working in the formulation process[3]. Even in the case where the same worker(s) would conduct all activities (WCS 1-9 and WCS 11) except laboratory work (WCS 10), the applicants estimated combined potential exposure is considered by the applicant to remain below 0.5 µg Cr(VI)/m^3.

[3] Use in scientific research and development is exempted from authorisation where these activities are carried out under controlled conditions and in a volume not exceeding one tonne per year and per legal entity. Where these conditions are met, there is no need to apply for an authorisation for this use or to include this task as a working contributing scenario (i.e. PROC 15) in an application for authorisation. This exemption applies irrespective of where the analysis is performed i.e. on-site or off-site facilities. Laboratory tasks in WCS 10 may therefore partly fall under the exemption, however, the exemption does not cover the sampling activities that are also part of WCS 10.

Uncertainties related to the worker exposure assessment

The exposure assessment for WCSs 2-8 is based on measured data (19 measurements from 2 companies using strontium chromate and 1 company using sodium chromate), the variation between the measurements is high (the range of three arithmetic means following RPE adjustment is 0.00-0.32 µg/m^3) but all three 90th percentiles are below 0.5 µg/m^3.

Only three WCSs in WCS 2-8 require RPE (WCS 2, 4 and 8), however the measurement data for WCS 2-8 was corrected for the use of RPE. The details of the corrections were not provided by the applicant. It is therefore not clear if some workers are therefore exposed to higher levels than 0.5 µg/m^3.

Detailed information of how the tasks are performed and the RMMs/OCs in place at the three individual sites is lacking which weakens the data's representativeness with regards to exposure of workers in WCSs 2-8.

The use of exposure data from other chromates creates some uncertainty especially where solid chromates are used since granulometry and hygroscopic properties vary among the different chromates and therefore the capacity to become airborne and being inhaled might be different (WCSs 2-8).

In addition, estimates of exposure have not taken the frequency of activities into account which also creates uncertainty. RAC considers that the resulting uncertainty regarding combined eposure may have a significant effect but it is difficult to quantify. This could have been reduced by more detailed information on the tasks and duration undertaken by the workers for which measurement data were provided and by providing more measured data. Modelled data could have supported WCS 2-8, but was not provided by the applicant even though it was requested by RAC.

No WCS and corresponding exposure estimate was provided by the applicant for external maintenance workers who undertake maintenance for longer periods (>30 min/day). RAC is of the opinion that if specific maintenance is undertaken by dedicated specialised staff for longer duration (not involved in formulation work activities) using different RMMs / OCs, then an exposure scenario prepared should have been prepared for this group of workers.

It is not clear to which extent fugitive emissions of chromates caused by the performing of formulation tasks and waste management can lead to exposure of other workers not involved in these tasks but working in or nearby the same workplace and who are not wearing RPE.

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 considers that measures to prevent or limit the release of Cr(VI) to the environment during the formulation of sodium dichromate containing mixtures are a matter of best practice (as described by BREFs). Whilst emissions to air (via fine dust and particulates) are considered to occur at all sites, the applicant states that not all sites will have releases of Cr(VI) to wastewater as both liquid and solid wastes containing Cr(VI) can rather be collected from sites by an external waste management company instead of being discharged in wastewater to the municipal sewer or directly to the environment. The applicant did not provide exposure assessment for waste disposal contracted out to

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

Release to air

Loss of sodium dichromate by gas or vapour is not expected during formulation due to the physiochemical properties of the substance. Losses as particulate matter[4] are estimated however these are considered by the applicant to be minimal for sodium dichromate as it is a non-dusty substance with a granulometry of 5.2%<100um.

For the formulation of sodium dichromate no air emission data is available. Air emissions from LEV or extraction systems are treated prior to release to the environment through filters or wet scrubbers according to best available technology.

Emissions to the air compartment are therefore modelled. An initial release factor of 2.5% was used (default release factor for ERC 2). According to the applicant, a removal efficiency of at least 99% is typical for the risk management measures applied, and this gives a final release factor of 0.025%. Wastes from scrubber systems can be collected by an external waste management company or disposed in wastewater after appropriate on-site treatment. 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 3.808×10^{-5} mg/m^3.

Release to water

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. The applicant provided limited data in support, following RAC questions, for 4 sites that were stated to "coincide predominantly with activities in the scope of CCST". The variation in the data ranges 0.03 µg/l to 25 µg/l.

Release to soil

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

Table 7: Summary of environmental emissions

Release route	**Release factor / rate**	**Release estimation method and details**
Water	0	Considered by applicant to be negligible
Air	Initial: 2.5% Final:0.025%	based on release factors of 2.5% from ERC 2 – Formulation of mixtures
Soil	0	Considered by applicant to be negligible

[4] This term covers aerosols and dust in air.

Table 8: 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: 3.808×10^{-5} mg/m^3 Regional: 4.93×10^{-14} mg/m^3
Man via Environment - Oral	Not considered relevant by the applicant
Man via Environment - Combined	Not considered relevant by the applicant

In summary, the applicant's assessment of regional exposure via air is based on EUSES modelling. Exposure via air is the only element included in the assessment of indirect exposure to humans via the environment. Exposure via food and drinking water (oral route of exposure) has been waived 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.

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

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.

Regarding emission to air, 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, RAC considers that 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 meaning emissions to air are a relevant source of indirect exposure of Cr(VI) to humans via the environment at the local scale. RAC therefore considers that the indirect exposure calculated by the applicant using a release factor of 2.5% is acceptable for risk characterisation and impact assessment, but contains some uncertainties as it is not supported by any measurement data.

Regarding the limited data on releases to the wastewater it is not clear if the data has come from sites undertaking stand alone[1] formulation of mixtures or from sites undertaking surface treatment activities or other activities. The LOD reported for wastewater 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 (to be compared with the variation in the data that ranges 0.03 µg/l to 25 µg/l).

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 at local scale.

RAC notes that these emissions to water, irrespective of their magnitude, were not incorporated into the applicant's estimates of excess risk for the general population and corresponding impact, upon which a conclusion on negligibility could have been presented more transparently i.e. the relative risks from air and oral exposure 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.

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

Estimated emissions to air are based on modelling only, using an initial release factor of 2.5% (default release factor for ERC 2) which could lead to an overestimate of exposure to man via environment.

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, 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 reduce its usefulness within the context of impact assessment (for non-threshold carcinogens)[6]. Alternative 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.

[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."*

Conclusions

RAC concludes that:

- There are uncertainties in the worker exposure assessment due to the lack of contextual information on the tasks and the limited monitoring data set. This could have been reduced by more specific detailed information on RMMs & OCs at each of the three individual companies and more measured data. Modelled data could have also supported the measured data but it was not provided even though it was requested by RAC.
- RAC underlines that mechanical ventilation is more efficient than natural ventilation to minimise exposure levels and is more in agreement with the general principles of the hierarchy of control.
- It is acknowledged that release to air of Cr(VI) during formulation activites are likely to be low due to the low volatility of sodium dichromate and modern abatement technology with high efficiency.
- Because of the limited data provided, there are some uncertainties related to the applicant's claim that wastewater releases are "negligible". It is not clear if the limited data from 4 sites relates to facilities who only formulate the mixtures.
- With respect to emissions to air and exposure of the general population through inhalation, the assessment is based on modelled data. Since no measurement data is available, the representativeness of these estimates is uncertain but, according to the applicant, highly effective systems to control air emissions are typical for the industry. The default release factor could lead to an overestimate of exposure to man via environment. Furthermore, 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 may overestimate exposure.
- Weighing the evidence as a whole, RAC considers that the exposure estimates made by the applicant are sufficient for risk characterisation and impact assessment. However, RAC notes that the applicant's approach for assessing general population inhalation exposure is likely to overestimate exposures for the majority of the general population and 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 sodium dichromate 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 inhaled sodium dichromate 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

RAC questioned why it was not possible for the applicant to describe the specific OCs & RMMs at the three sites where measurements were taken, and compare it to the monitoring data in order to justify why the OCs & RMMs and monitoring data are representative for formulation of sodium dichromate.

According to the SEA, 3 sites currently perform formulation in the EU. The applicant has stated that it is not possible to develop a description of OCs & RMMs applicable to every individual situation at different formulators in the ES and that formulators must have in place an equivalent or better level of protection than those set out in the ESs. 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. Moreover, RAC is of the view that more detailed generic descriptions, supported by examples and audio visual material could have been provided.

Risk management for activities related to formulation are based on the use of SOPs, LEV and RPE for the formulation, cleaning, maintenance and waste management activities. However, no specific WCS with the corresponding RMMs/OCs was undertaken for specific maintenance activities (WCS8) that might last more than 30 mins. RAC is of the opinion that if specific maintenance is undertaken by dedicated specialised staff for longer duration (not involved in formulation work activities) using different RMMs / OCs, then an exposure scenario prepared should have been prepared for this group of workers.

According to the applicant, the operations and use of LEV varies between the sites and therefore no single description of the RMMs applicable to all sites was provided. While WCS 2-8 indicate the use of LEV, it is not clear where this LEV is located, as the applicant stated that the mixing vessel does not have LEV.

The main concern with the RMM relates to the handling of solid chromates where there is a heavy reliance on the use of RPE, at least a half-mask respirator with P3 filter (APF 30 according to German BG rule 190) is to be worn. 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.

LEV is one of the key measures to control exposure however no data was available to demonstrate the efficiency of existing LEV at the three sites where measurements were undertaken.

For WCS2-8 general ventilation with an ACS1-3 is specified, however without specifying whether it is natural or mechanical ventilation. For WCS 10 and WCS11 it is stated in the CSR that natural ventilation is in place. RAC considers that relying on natural ventilation for reducing exposure is questionable considering that openings like doors and windows responsible for natural ventilation maybe closed during some periods of the year due to prevailing weather conditions.

Risk characterisation

Occupational exposure in formulating mixtures has been assessed by measured data from three companies involved in formulating chromates (strontium chromate and sodium chromate). A generalised estimation of maximum combined individual exposure level of 0.5 µg/m^3 was made by the applicant and used for the human health impact assessment in the SEA on the basis of the measurement data (with 90th percentile of 0.26 µg/m^3 after the use of RPE has been taken into account) and ART modelling (with 90th percentile of 0.22 µg/m^3; WCS11).

However, there is uncertainty in the measurement data and how the OCs & RMMs in place corresponded to the exposure measurement data in terms of closed and automated processes or semi-closed and manual. The personal measured data has not been supported by modelling but the static monitoring data provided at RAC request combined with the uncertainties described above might support the use of a higher exposure value. However, it should also be noted that the exposure estimate above is based on the assumption that formulation tasks are conducted each day. This is not usually the case since formulation is generally a non-continuous batch process and the measured data has not been corrected for other chromate substances used on site.

In the SEA, the applicant presents data collected showing that the majority of the workers (90%) are exposed frequently 6-8 hours per day whereas 8% are exposed less frequently (once per week or once per month or even less often). It is assumed that the applicant already corrected the number of exposed workers for exposure durations. Therefore, the frequency of these tasks does not add any margin of safety to the applicant's exposure assessment and there are questions regarding the methodology used to obtain these estimates. RAC proposes to use the applicant's maximum combined exposure level of 0.5 µg/m^3 as an 8 h average, resulting in an excess risk of 2×10^{-3} as the basis of further analyses by SEAC, but these uncertainties should be considered.

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.

RAC acknowledged that excess risk inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an overestimate. RAC also notes that the applicant has conservatively assumed that any sodium dichromate particles present in air are in the respirable range and contribute to the lung cancer risk.

Table 9: Excess risk estimates for 40 years exposure for workers

WCS	Inhalation route	
	Adjusted exposure (µg/m³)	**Excess risk**
Total	0.5	2×10^{-3}

Regarding risks from reproductive toxicity from worker exposure, the applicant considered that the derived inhalation DNEL for workers is much higher than the highest estimated potential combined exposure to Cr(VI) resulting in an RCR < 0.1. The applicant derived an inhalation DNEL of 30 µg/m³. RAC agrees that no risks of reproductive effects from exposure via inhalation are to be expected.

Although requested by RAC, the applicant did not provide a quantitative assessment of dermal exposure. The applicant stated that sodium dichromate is classified as Skin Corr 1B and as Skin Sens. 1 under the CLP Regulation and that therefore any dermal contact with the substance at the workplace has to be avoided by organisational measures and adequate dermal protection. The Applicant claims that dermal exposure is effectively eliminated through the use of appropriate PPE (e.g. chemical resistant gloves) and implementation of good hygiene practices and management systems. RAC notes that dermal exposure is not eliminated by the use of PPE. However, RAC considers that dermal exposure is likely to be low in comparison to the DNELs derived by RAC (43 and 93 µg/kg bw/day for fertility and developmental toxicity respectively) and therefore RAC concludes that no risks of reproductive effects from dermal exposure are likely to be expected. RAC would have had greater confidence in this conclusion if a quantitative assessment would have been provided to substantiate the assessment of the potential for dermal exposure.

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 sodium dichromate 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 1.1×10^{-3}.

The applicant also calculated the excess risk related to regional 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 10: Excess risk estimates for 70 years exposure for man exposed via the environment

ECS	Inhalation route	
	Exposure level (mg/m³)	**Excess risk**
ECS 1, local exposure	3.808×10^{-5} mg/m³	1.1×10^{-3}
ECS 1, regional exposure	Not considered relevant by RAC	

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. Risks from oral exposure via food or water were not considered relevant by the applicant. RAC considers these risks from oral exposure may be low in comparison to inhalation exposure, 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.

Regarding risks from exposure of the general population to reproductive toxicity, the applicant considered that the inhalation DNEL for the general population is much greater than the estimated potential local and regional exposure, resulting in RCRs < 0.01. The applicant derived an inhalation DNEL of 7 µg/m³.

The applicant did not consider a quantitative assessment of dermal exposure. The applicant stated that "*dermal exposure potential is not expected for the general population"*.

RAC agrees to the conclusion that no risks for humans exposed via the environment for reproductive effects due to inhalation or dermal exposure are to be expected.

Conclusion

RAC concludes that:

- There are uncertainties related to the description and use of OCs and RMMs and their ability to adequately limit the risk to workers.
- RAC proposes to use the applicant's estimated maximum combined exposure level of 0.5 µg/m³ as an 8 h average, resulting in an excess cancer risk of 2×10^{-3} , as the basis of further analyses by SEAC. It should be noted that this value is proposed by the applicant in their CSR and its use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC of this as a safe or acceptable exposure level for this non-threshold substance.
- There is an uncertainty related to the oral exposure of the general population via drinking water due to the applicant's assessment that releases to the wastewater are negligible, which is not supported by RAC.
- For exposure of the general population by inhalation, the estimate is based on modelled releases based on ERC default values and default assumptions of dispersion in the environment that are considered likely to over rather than underestimate exposure. The applicant indicates that, highly effective RMMs to control air emissions are typical for the industry.
- RAC proposes to use the applicant's estimate of general population exposure at local scale for further analysis by SEAC. Regional exposure is not considered to be relevant by RAC.

- RAC considers that no risks for workers or humans exposed via the environment for reproductive effects are to be expected.
- Considering these uncertainties in relation to the risks, RAC proposes to apply conditions and monitoring arrangements (see Section 9).

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

Sodium dichromate is used in the surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic film (use 2) and the electrolytic passivation of tin plated steel for the packaging industry (use 3). Use 1 covers the formulation of the mixtures that are used in a large variety of surface treatment applications, both in the construction of aerospace and aeronautical parts as well as the maintenance of such parts. For this use, 1300 tonnes per annum of sodium dichromate are currently used in at least 10 different product formulations. Sodium dichromate functions as corrosion prevention and inhibiting agent in a number of surface treatment processes and steps that may be applied to a number of different metal substrates. According to the applicant, surface treatment based on sodium dichromate provides 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.

At the formulation stage, strontium chromate has no (separate) function. Hence, no analysis of alternatives was performed by the applicant for use 1. An analysis of alternatives has been submitted for the subsequent use 2 and 3 of this application for authorisation covering surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic film (use 2) and the electrolytic passivation of tin plated steel for the packaging industry (use 3). For use 1 no alternatives have been identified.

Technical feasibility

Not applicable.

Economic feasibility

Not applicable.

Conclusion

See summary above.

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

☐ YES

☒ NO

Justification:

Not applicable.

Conclusion

At the formulation stage, sodium dichromate has no (separate) function. Hence no analysis of alternatives was performed by the applicant for use 1. An analysis of alternatives has been submitted for the subsequent use 2 and 3 of this application for authorisation covering the surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic film (use 2) and the electrolytic passivation of tin plated steel for the packaging industry (use 3).

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

Description:

This application covers the Use 1 of sodium dichromate: Formulation of mixtures. At the formulation stage sodium dichromate has no (separate) function, hence no alternatives have been identified.

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 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 risk value presented in section 6 and the estimation of the number of exposed workers provided by the applicant as full-time equivalent numbers. It is assumed that the applicant already corrected these numbers for exposure duration according to the fractions presented in section 4.

RAC notes that these calculations are based on the estimation of exposed populations as provided by the applicant. Furthermore, RAC notes that the applicant 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.

Table 11: Estimated additional statistical fatal cancer cases for 12 years of exposure (12 is the review period applied for)

Workers – Combination of WCS	**Exposure 8 h (µg/m³)**	**Excess lung cancer risk**	**Number of full-time equivalent exposed workers**	**Estimated statistical fatal cancer cases (12 years of exposure)**
	0.5 µg/m3	0.0020	17	1.02×10^{-2}
	Exposure 24h (mg/m³)		**Numer of exposed people**	
Man via environment - Local	3.81×10^{-5}	1.10×10^{-3}	10,000 per site)x 6 sites = 60,000	5.68
Man via environment - Regional	Not relevant			
Total				**5.69**

The estimated additional statistical fatal cancer cases reported in Table 11 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 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.

Conclusions

The application for authorisation covers 3 inter-related uses of sodium dichromate: formulation of mixtures (use 1) and surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic film (use 2) and the electrolytic passivation of tin plated steel for the packaging industry (use 3).

Use 1 serves no other purpose than to allow for the formulation of the mixtures required for use 2 and 3 and the substance does not have any (separate) functionality at the formulation stage. Therefore, the assessment conducted by the applicant in the analysis of alternatives and socio-economic analysis covers both uses simultaneously and no distinction between the formulation and actual uses is made. Consequently, SEAC's considerations and conclusions on the benefits and risks of continued use as described in the opinion document for uses 2 and 3 are valid also for use 1.

In conclusion, SEAC concurs with the applicant that the benefits of continued use of dichromium tris(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 formulation processes and their individual tasks, including e.g. automatic versus manual, open versus closed systems. 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. These ESs shall be developed and made available to formulators 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. Progressive reduction of exposure and releases shall be documented and such reports made available for enforcement authorities.

Where possible the work process should be enclosed from the worker to eliminate the potential for exposure and in particular to reduce excessive reliance on RPE. LEV systems should be regularly checked to guarantee adequate functioning and extraction efficiency.

Where workers are required to wear RPE, the respiratory protective devices, the standard procedures of adequate use and maintenance must be applied accordance to national and European legislation.

Validation of Exposure Scenarios

Such ESs shall be validated and verified by the applicant through an analysis of tasks 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

Appropriate Standard Operating Procedures (SOPs) shall be developed and implemented to minimise release of dust into the air during the preparation, transfer and storage of empty bags, filters and other process waste in accordance with the hierarchy of control. Whenever technically and practically possible, activities under WCS 11 shall be conducted under appropriately designed and installed LEV.

Monitoring

Workers

With immediate effect, the formulators covered by this application shall implement at least annual programmes of occupational exposure measurements relating to the use of the substance described in this application in order to validate their exposure estimates as quickly as possible. 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 (i.e. the programme shall include both process and maintenance workers).

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

LEV and RPE efficiency are key control measures. Therefore, LEV and RPE shall be checked and tested periodically (including fit testing of RPE). Records of these periodical checks and tests shall 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. The results of monitoring shall be made available to enforcement bodies on request. Measurement programmes should be undertaken according to standard sampling and analytical methods, where appropriate. The results of monitoring programmes shall be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted.

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 formulator 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 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 working conditions.

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 formulation plant, listing OCs and RMMs 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 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 is not as defined 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.

The possible lack of containment described by the applicant at some sites, possible high reliance on the use of RPE and the small sample or lack of exposure monitoring data raises concerns on containment and the appropriateness of OCs and RMMs in limiting the risk, hence the need for conditions and monitoring arrangements.

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 and monitoring arrangements for the authorisation by SEAC:

Sodium dichromate may only be used for the formulation of mixtures within the scope of uses 2 and 3 of this application.

Justification for the additional conditions and monitoring arrangements by SEAC:

The application for authorisation covers inter-related uses of sodium dichromate: formulation of mixtures (use 1) and surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic film (use 2) and the electrolytic passivation of tin plated steel for the packaging industry (use 3). Use 1 serves no other purpose than to allow for the formulation of the mixtures required for uses 2 and 3 and the substance does not have any (separate) functionality at the formulation stage. Therefore, the assessment conducted by the applicant in the analysis of alternatives and socio-economic analysis covers both uses simultaneously and no distinction between the formulation and actual uses is made. Consequently, SEAC recommends that authorisation for formulation should be limited to the mixtures that are in the scope of uses 2 and 3.

10. Proposed review period:

☒ Normal (7 years)

☐ Long (12 years)

☐ Short (…. _years)

☐ Other:

Justification:

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

RAC's advice:

The possible lack of containment described by the applicant at some sites, possible high reliance on the use of RPE and lack of exposure monitoring raises concerns on containment and the appropriateness of OCs and RMMs in limiting the risk, hence the need for conditions and monitoring arrangements. Although there are significant uncertainties, the conservative approach, assuming that formulation tasks are conducted each day suggests that the risks of these tasks may compensate for this in the worker exposure assessment.

Therefore, RAC considers that the risk at most formulation sites is not likely to be substantially higher than the risk estimated on the basis of the data presented by the applicant. RAC gave no advice to SEAC on the length of the review period.

Other socio economic considerations

The application for authorisation covers inter-related uses of sodium dichromate: formulation of mixtures (use 1) and surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic film (use 2) and the electrolytic passivation of tin plated steel for the packaging industry (use 3). Use 1 serves no other purpose than to allow for the formulation of the mixtures required for use 2 and 3 and the substance does not have any (separate) functionality at the formulation stage. Therefore, the assessment conducted by the applicant in the analysis of alternatives and socio-economic analysis covers the formulation use simultaneously with use 2 or use 3. As the recommended review period for use 2 is longer (7 years) than for use 3 (4 years), 7 years is recommended for use 1.

In summary, SEAC has established its recommendation on the review period based on the following considerations for use 2:

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

2. For use 2, RAC has given advice to not recommend more than 7 years.

3. Some criteria for a short review period, but also some of the criteria for a long review period, could be regarded as fulfilled.

For the reasons outlined in detail in section 10 of the justification to the opinion of use 2, SEAC recommends a normal (7 years) review period.

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:

The comments provided by the Applicant concentrated on Use 2 (surface treatment), only minor edits were made in the justification to the opinion for this use (Use 1).

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

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

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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).