# Committee for Risk Assessment (RAC)

# Committee for Socio-economic Analysis (SEAC)

## Opinion

## on an Application for Authorisation for

## use of chromium trioxide as an oxidising and hardening agent in the manufacture of coloured stainless steel

**ECHA/RAC/SEAC: AFA-O-0000006485-68-02/F**

**Date: 06/09/2016**

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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): Chromium trioxide**
**EC No.: 215-607-8**
**CAS No.: 1333-82-0**

for the following use:

**Use of chromium trioxide as an oxidising and hardening agent in the manufacture of coloured stainless steel**

Intrinsic property referred to in Annex XIV:

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

Applicant:

**Rimex Metals (UK) Ltd**

Reference number:

**11-2120105116-73-0000**

Rapporteur, appointed by the RAC: **Elodie Pasquier**
Co-rapporteur, appointed by the RAC: **João Carvalho**

Rapporteur, appointed by the SEAC: **Åsa Thors**
Co-rapporteur, appointed by the SEAC: **João Alexandre**

This document compiles the opinions adopted by RAC and SEAC.

## PROCESS FOR ADOPTION OF THE OPINIONS

On **10/12/2015 Rimex Metals (UK) Ltd** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **21/01/2016** 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 **10/02/2016**. Interested parties were invited to submit comments and contributions by **06/04/2016**.

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 as well as third parties to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

The draft opinions of RAC and SEAC were sent to the applicant on **29/07/2016**.

The Applicant informed ECHA that they did not wish to comment on the opinions. The draft opinions of RAC and SEAC were therefore considered as final on **06/09/2016**.

### ADOPTION OF THE OPINION OF RAC

#### The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **03/06/2016**.

The draft opinion of RAC was agreed by consensus.

#### The opinion of RAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of RAC was adopted as final on **06/09/2016**.

### 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 **09/06/2016**.

The draft opinion of SEAC was agreed by consensus.

#### The opinion of SEAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of SEAC was adopted as final on **06/09/2016**.

THE OPINION OF RAC

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

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

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

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

RAC confirmed that the operational conditions and risk management measures described in the application limit the risk, provided that these are adhered to as described in the application along with the suggested conditions and monitoring arrangements.

THE OPINION OF SEAC

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

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

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

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

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

THE FOLLOWING CONDITIONS AND MONITORING ARRANGEMENTS ARE RECOMMENDED IN CASE THE AUTHORISATION IS GRANTED:

Based on exposure control concerns, the Applicant must implement regular campaigns of occupational exposure measurements relating to the use of Cr(VI) described in this application. These monitoring campaigns must be based on relevant standard methodologies or protocols and ensure a sufficiently low detection limit. They shall comprise both personal and static inhalation exposure sampling and be representative of the range of tasks with possible exposure to Cr(VI) and of the total number of workers that are potentially exposed. The results of the monitoring must be included in any subsequent authorisation review report submitted.

Emissions of Cr(VI) to ambient air shall be subject to regular measurement with the results of monitoring made available to enforcement bodies on request. Measurement campaigns shall be undertaken according to standard sampling and analytical methods, where appropriate. Emissions data shall be presented in any subsequent review report.

RMMs to reduce exposure of workers and emissions to the environment from the local exhaust ventilation and roof fans need to be assessed and the most appropriate RMM applied.

The information gathered in the monitoring campaigns shall be used by the applicant to review the risk management measures (RMMs) and operational conditions to further reduce workers' exposure to Cr(VI) as well to as Cr(VI) emissions to ambient air.

The outcomes and conclusions of this review including those related to the implementation of any additional RMMs must be documented.

The results of the monitoring and of the review of the OCs and RMMs must be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted.

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 **10 (ten) years**.

## JUSTIFICATIONS

The justifications for the opinion are as follows:

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

☒ Carcinogenic (Article 57(a))

☒ Mutagenic (Article 57(b))

☐ Toxic to reproduction (Article 57(c))

☐ Persistent, bioaccumulative and toxic (Article 57(d))

☐ Very persistent and very bioaccumulative (Article 57(e))

☐ Other properties in accordance with Article 57(f) [please specify]:

**2. Is the substance a threshold substance?**

☐ YES

☒ NO

Justification:

Chromium trioxide has a harmonised classification as Carcinogen Cat. 1A and Mutagen Cat. 1B with H350 and H340 according to CLP.

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

| |
|---|
| **3. Hazard assessment. Are appropriate reference values used?**<br><br>Justification:<br><br>Chromium trioxide is included in Annex XIV based on two intrinsic properties: Carcinogenic (category 1A) and Mutagenic (category 1B).<br><br>RAC has established a reference dose response relationship for carcinogenicity of hexavalent chromium (RAC/27/2013/06 Rev.1) which was used by the applicant.<br><br>The molecular entity that drives the carcinogenicity of chromium trioxide (Cr(VI)) is the Cr(VI) ion, which is released when the substances solubilise and dissociate.<br><br>Cr(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. There are no data to indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans.<br><br>Dose-response relationships 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 an overestimate.<br><br>In the socio-economic analysis (SEA) the remaining human health risks are evaluated based on the dose-response relationship for carcinogenicity of hexavalent chromium (RAC/27/2013/06 Rev.1).<br><br>Are all appropriate and relevant endpoints addressed in the application?<br><br>All endpoints identified in the Annex XIV entry are addressed in the application. |
| **4. Exposure assessment. To what extent is the exposure from the use described?**<br><br>Description:<br><br>**Short description of the use**<br><br>Rimex Metals is a downstream user of chromium trioxide.<br><br>This application for authorisation relates to use of chromium trioxide as an oxidising and hardening agent in the manufacture of coloured stainless steel (CSS) under the INCO[1] process. CSS is used in the architectural, engineering, machinery, refrigeration, elevator (lifts) and transportation sectors for aesthetic and durability reasons.<br><br>Colouring of stainless steel takes place through immersion in a solution of chromic acid and sulphuric acid at elevated temperatures. Chromium (VI) trioxide forms a thin film of chromium (III) oxide ($Cr_2O_3$) on the surface of the stainless steel. Colouring takes place through thin film interference that occurs when light waves pass through the transparent |

[1] INCO process is called the electrochemical process used by Rimex to produce CSS. It consists of a chemical colouring stage with CrO3 and sulphuric acid and a mild electrochemical stage with CrO3. It was patented by International Nickel Co Ltd (INCO).

passive layer. The immersion time of the stainless steel in the chromium trioxide containing acid solution determines the thickness of the colourless surface film, the light wave interference and the intense reflected colour effect. To make the soft and porous chromium (III) oxide layer (thickness below 1 µm) more durable an additional hardening step is necessary. Hardening takes place through cathodic treatment in a chromium trioxide containing acidic solution at ambient temperature.

Colouring of stainless steel by the Applicant takes place in three colouring lines which are installed in parallel in the production hall of the Applicant. Each colouring line is built up of several open tanks (e.g. for alkaline degreasing, colouring, hardening, rinsing). Stainless steel components are manually fixed on jigs located in front of the colouring line and then moved semi-automatically via a pendant controller along a transport bar to the single open tanks, immersed and after final washing removed back to the loading area. There, the stainless steel components are rinsed with water after finalisation of the colouring and moved on drying racks before they are transported to the packaging area where they are wrapped for transport.

Chromium trioxide is purchased and transported to the production plant as a flaked solid, in clip-top steel drums. To control the ventilation in the production hall roof fans are in place. Additionally, the colouring tanks and the black colouring tanks containing $CrO_3$ are equipped with lip extractions, except one using pump to mix the liquid around (according to the Applicant as a best available technique, indicating that other tanks will be equipped with this in the future)  to reduce emission of chromium (VI) into the production hall. Emission of spray or mist to the workplace atmosphere from the hardener tanks which are run without lip extraction or other local exhaust ventilation is reduced by addition of PFOS-free mist suppressing chemicals. Workers are separated from the colouring/hardening tanks by Plexiglas shields. According to the Applicant this is done to prevent exposure to splashes as well as to reduce exposure to aerosols and mist generated during immersion of stainless steel or cathodic hardening.

All waste water is collected at an effluent treatment plant, where it is chemically treated to reduce chromium (VI) to chromium (III). Chromium (III) is subsequently precipitated and disposed as hazardous waste. The remaining waste water with chromium (VI) concentrations usually below the limit of quantification (10 µg/L) is led into the municipal sewage drain from where it enters the municipal sewage treatment plant.

It is important to note that there is no Cr(VI) present in the finished coloured stainless steel.

The average consumption of chromium trioxide during 2007-2014 by the Applicant was near the low end of the 10-100 tonnes per year range. Since 2012 there has been an increase in the consumption of chromium trioxide due to an increase in CSS production and sales. Chromium trioxide consumption is still expected to marginally increase in the coming years due to an envisaged increase in sales of INCO-made CSS reaching a maximum production capacity by the Sunset Date in 2017 (consumption of chromium trioxide still being in the low end of the 10-100 tonnes per year range).

According to the Applicant, the exposure scenario (table 1) include all relevant processes and tasks associated with the use of Cr(VI) that could result in either environmental or worker exposure. The exposure scenario is comprised of eighteen Worker Contributing Scenarios (WCS) and one Environmental Contributions scenarios (ECS).

All tasks are conducted in the applicant's manufacture site, in the UK.

**Table 1: Contributing Scenarios presented in the Use**

| Contributing scenario | ERC / PROC | Name of the scenario |
|---|---|---|
| ECS1 | ERC 5 | Industrial use resulting in inclusion into or onto a matrix |
| WCS 1 | PROC 8b | Decanting of a solid |
| WCS 2 | PROC 8b | Dissolution of solid CrO3 in tanks |
| WCS 3 | PROC 8b | Re-filling of bath-liquids |
| WCS 4 | PROC 8b | Cleaning of solid CrO3 with a hose |
| WCS 5 | PROC 8b | Cleaning of equipment |
| WCS 6 | PROC 8b | Tank sampling |
| WCS 7 | PROC 15 | Laboratory analyses |
| WCS 8 | PROC 8b | Addition of mist suppressant |
| WCS 9 | PROC 4 | Operating effluent treatment plant |
| WCS 10 | PROC 4 | Tank fill up |
| WCS 11 | PROC 8a | Maintenance |
| WCS 12 | PROC 8b | Waste handling (filter press) |
| WCS 13 | PROC 4 | Operating colouring line – controller |
| WCS 14 | PROC 4 | Operating colouring line – loading |
| WCS 15 | PROC 4 | Operating colouring line – rinsing |
| WCS 16 | PROC 4 | Operating colouring line – off loading |
| WCS 17 | PROC 4 | Operating colouring line – colour control |
| WCS 18 | - | Activities in packaging area |

The ERC and PROCs listed above, primarily serve for orientation but are not key in the exposure assessment performed here, since the monitoring data used in the exposure assessment as well as ART (Advanced Reach Tool) modelling performed in addition for some WCS are completely independent of PROCs.

**Workers exposure**

According to the Applicant, operators involved in CSS production can be divided in several groups:

- Colouring line: 15 workers operating the colouring line (WCS 13 -17)
- Maintenance: 3 workers performing general maintenance tasks (WCS 10 -12) and special tasks similar to maintenance workers (WCS 1-6)
- Chemist: 1 worker performing general chemist tasks (WCS 7-9) and special tasks similar to maintenance workers(WCS 1-6 )
- Packaging unit: 6 workers performing activities in the packaging area (WCS 18)
- Supervisor: 1 worker with no direct exposure which can be described by a WCS
- Plant manager: 1 worker with no direct exposure which can be described by a WCS.

A total of 27 workers are involved in the CSS production.

The exposure of individual workers is mainly driven by the location of their workplaces in the production hall as well as the tasks performed by the different groups of workers and the exposure is therefore estimated for each different group of workers.

Operators of the colouring line handle the pendant controller by which the immersion time of the objects is controlled and are responsible for loading and off-loading of the components from the jigs, of rinsing the coloured components with a water hose and of controlling the colour (WCS 13, 14, 16, 15 and 17 respectively).

Maintenance workers and chemists are responsible for regular refilling of the tanks with $CrO_3$ by manually decanting drums of chromium trioxide flakes into mesh baskets in the loading area (WCS 1) and by performing dissolution of $CrO_3$ filled into the mesh baskets in the tanks using a semi-automatic transporter (WCS 2). Addition of concentrated sulfuric acid from a drum to the tanks is also performed when needed using a hand pump (WCS3). Work area and drums are cleaned from solid $CrO_3$ with a hose after tank make up (WCS4). Samples of the different tanks are regularly taken for laboratory analysis using glass pipettes and transferred into glass flasks. Sampling is performed either through windows in the Plexiglas shields or between the line where no Plexiglas shield is installed (WCS 6). The hand pump and pipettes are cleaned with water behind a water barrier in the effluent treatment plant that is located in the production hall (WCS 5).

In addition, maintenance workers are involved in daily semi-automatic tank fill-up with water using pumps and equalisation of the temperature of the tanks (WCS 10). The maintenance operator performs various maintenance activities in all areas of the production hall, including activities in the packaging area as well as in the area around the colouring lines, between the colouring lines (where no Plexiglas shield is installed) or in the effluent treatment plant (WCS 11). He also removes twice a day the sludge from the filter press (outside) used to filter waste water twice a day by scraping-off the filter cake with a tool (WCS12).

Additional tasks for the chemist consist of analysis of the samples taken from the tanks starting by a rapid 1:1000 dilution of the sample. Most of the analyses are then performed on the diluted sample. Other laboratory activities that do not involve direct handling of $CrO_3$ are also performed (WCS 7). Addition of mist suppressant to the hardener tanks is performed by filling the jar into the tank and it is performed either through windows in the Plexiglas shields or between the line where no Plexiglas shield is installed (WCS 8). The chemist is also responsible for operating the effluent treatment plant in the production hall by controlling the liquid flows, the addition of reducing and precipitating agents, controlling the automated process, and taking samples of the waste water (WCS 9).

Packaging operators are not in contact with any chromium (VI) containing liquids or objects. But, as packaging area is located in the production hall the workers of the packaging unit may also be exposed to chromium (VI) in the workplace air.

The office of the supervisor is located within the production hall and can be indirectly exposed through workplace air.

The plant manager can be exposed through the workplace air as his office is located close to the production hall. In addition, he is the deputy of the chemist during his absence.

*Exposure estimation methodology:*

*Inhalation:*

For inhalation exposure assessment the applicant presents air monitoring data (annex 2 of CSR) of chromium VI from a 2015 monitoring campaign (static measurements, 17 monitoring points, 36 samples) and some modelling data.

Modelling data were produced using ART model (version 1.5) for some WCS (WCS 1, 6, 7, and 12) for comparison purpose in support of monitoring data. The printouts provided from ART were attached in the annex 5 of the CSR with input parameters and upper interquartile confidence intervals of the predicted 75$^{th}$ percentile were used. The applicant considered that modelling was not possible for other WCS as operators do not directly handle chromium trioxide. RAC however notes that modelling of exposure to chromium trioxide through the tasks performed around the tanks can be performed with ART and further to RAC's request the applicant provided an additional modelling representative for activities performed around the tanks such as control of the line, loading and off-loading.

The Applicant stated that chromium exposure was previously monitored to show compliance with national legislation. However, neither biological monitoring values (urine) nor air monitoring values performed in the past seemed to be sufficiently sensitive to be used for exposure assessment in the context of this application for authorisation. Further to RAC's request, the applicant provided these previous monitoring and biomonitoring data in support to the assessment of worker exposure. Biological monitoring (assessment of total chromium in urine) does not allow a differentiation between Cr(III) and Cr(VI). Results (91 measures performed in 2012, 2014 and 2015) are however generally consistent with the expected level of exposure. Chemists (mean of 1.933 Cr µmol/mol creatinine based on 3 measures) and operators of the colouring line (mean of 1.908 Cr µmol/mol creatinine based on 13 measures) seems to be more exposed than maintenance workers (mean of 1.311 Cr µmol/mol creatinine based on 9 measurements. It is noted that some isolated variations are difficult to interpret and to link with a level of exposure as other factors (smoking, diet) may impact the result.

Air monitoring results from personal and stationary monitoring in the years 2011, 2013, and 2014 document that the exposure is well below the 8-h TWA and mainly below 2-3 µg/m$^3$ (= LoQ) but these methods are not sensitive enough to refine the exposure in the low nanogram range. All the 25 static measures were below the LOQ and only 1 out of 17 personal samplings resulted in a value above the LOQ. For this sampling a concentration of 7 000 ng/m$^3$ was measured over a 355 min period for a task entitled "colouring tanks chemical top ups". According to the applicant, this measure was performed on a chemist that has performed activities involving use and cleaning further to the use of solid $CrO_3$ (WCS 1, 2, 4 and 5), operating the effluent treatment plant (WCS9), tank fill up (WCS10) and waste handling at the filter press (T12). It is unclear whether this high exposure was cumulative or based on a singular high exposure from one task. No other personal sampling result is available for a similar task so that the representativeness of this measure is not known.

New air monitoring data was collected in August 2015 for this authorisation application. In order to achieve a sufficiently low limit of quantification of chromium VI, the applicant decided not to include personal monitoring, but to perform stationary sampling. Each monitoring point was selected to reflect exposure during specific tasks or exposure at certain places of the production hall and was located as close to a potential source of worker exposure or to the worker as possible. Each monitoring point was performed on two days.

Measured exposure levels were therefore not available for each WCS. The exposure levels were calculated for some specific WCS and for each group of workers on the basis of the aggregation of a selection of static measurements that were considered representative based on his daily activities, his working location in the hall and the share of time spent in the main activities/locations. Air monitoring results from samples of the production hall were all above the LoQ (=1.8 ng/m$^3$).

*Dermal:*

Taking into consideration the RAC reference document which states that there are no data to indicate that dermal exposure to Cr(VI) compounds presents a potential cancer risk to humans (RAC27/2013/06 Rev. 1), the Applicant has not assessed dermal exposure.

*RMMs applied*

The RMMs used and taken into consideration in this assessment are listed in Table 2.

**Table 2: Operational Conditions and Risk Management Measures**

| **Contributing scenario** | **Duration and frequency of exposure** | **Effectiveness of waste water and waste air treatment** | **RMM used** | **PPE** |
|---|---|---|---|---|
| EC1 | - | Waste water is treated with sodium metabisulphite ($Na_2S_2O_5$) to reduce Cr(VI) to Cr(III) which is precipitated with lime; no waste air treatment | | |
| WCS 1 | Duration: 16 min Frequency: 72 days/year | | Basic general ventilation, 1-3 ACH | Chemical resistant overall, apron, chemically resistant gloves[2], RPE[1] |
| WCS 2 | Duration: 20 min Frequency: 72 days/year | | Basic general ventilation, 1-3 ACH | Chemical resistant overall, apron, chemically resistant gloves[2], RPE[1] |
| WCS 3 | Duration: 15 min Frequency: 72 days/year | | Basic general ventilation, 1-3 ACH | Chemical resistant overall, apron, chemically resistant gloves[2], RPE[1] |

| | | | | |
|---|---|---|---|---|
| WCS 4 | Duration: 30 min Frequency: 48 days/year | | Basic general ventilation, 1-3 ACH | Chemical resistant overall, apron, rubber boots, chemically resistant gloves[2], RPE[1] |
| WCS 5 | Duration: 30 min Frequency: 48 days/year | | Basic general ventilation, 1-3 ACH | Depends on the equipment cleaned and the task performed in combination with this one: cleaning of glas pipettes: same PPE as in WCS 6; cleaning of hand pump: same PPE as in WCS 3 |
| WCS 6 | Duration: 15 min Frequency: 48 days/year | | Basic general ventilation, 1-3 ACH | Overall, apron, chemically resistant gloves[2], face shield |
| WCS 7 | Dilution of concentrated solution: Duration: 15 min Frequency: 48 days/year Total activities in laboratory: Duration: 240 min Frequency: 240 days/year | | Fume hood (at least 50% reduction; only for dilution of concentrated solutions) | overall, gloves[3], goggles |
| WCS 8 | Duration: 2 min Frequency: 96 days/year or more (ad hoc additions) | | Basic general ventilation, 1-3 ACH | overall, gloves[3], goggles |
| WCS 9 | Duration: max. 240 min Frequency: max. 240 days/year | | Basic general ventilation, 1-3 ACH | overall, gloves[3], goggles |
| WCS 10 | Duration: 45 min Frequency: 240 days/year | | Basic general ventilation, 1-3 ACH | overall, gloves[3], goggles |
| WCS 11 | Duration: up to 480 min Frequency: 240 days/year | | Basic general ventilation, 1-3 ACH | At least overall, gloves[3], goggles (adaption due to situation but no further |

| | | | | |
|---|---|---|---|---|
| | | | | information provided) |
| WCS 12 | Duration: 60 min Frequency: 240 days/year | | (outside) | overall, gloves[3] |
| WCS 13 | Duration: up to 480 min (overall work at colouring line) Frequency: 240 days/year | | Basic general ventilation, 1-3 ACH; LEV on some colouring and black colouring tank | overall, gloves[3] |
| WCS 14 | Duration: up to 480 min (overall work at colouring line) Frequency: 240 days/year | | Basic general ventilation, 1-3 ACH; LEV on some colouring and black colouring tank | overall, gloves[4] |
| WCS 15 | Duration: up to 480 min (overall work at colouring line; rinsing up to 180 min) Frequency: 240 days/year | | Basic general ventilation, 1-3 ACH; LEV on some colouring and black colouring tank | overall, goggles, gloves[3] |
| WCS 16 | Duration: up to 480 min (overall work at colouring line) Frequency: 240 days/year | | Basic general ventilation, 1-3 ACH; LEV on some colouring and black colouring tank | overall, gloves[4] |
| WCS 17 | Duration: up to 480 min (overall work at colouring line) Frequency: 240 days/year | | Basic general ventilation, 1-3 ACH; LEV on some colouring and black colouring tank | overall, goggles, gloves[3] |
| WCS 18 | Duration: 480 min Frequency: 240 days/year | | Basic general ventilation, 1-3 ACH | Overall, gloves |

*1) Powered respirator with hoods equipped with 3M A2BEK1P3 Jupiter filter and with assigned protection factor (APF) of 20*

*2) Chemically resistant gloves= Honeywell (KCL) Butoject 897 (butyl rubber gloves, 0.3 mm);*

*3) Gloves= natural rubber/natural latex (0.5 mm) gloves;*

*4) Rubberized gloves= RGA X5LE Palm Latex. Abrasion 4, Blade cut 5, Tear 4, Puncture 4.*

*Other Risk management measures used to control exposure:*

The three colouring lines are operated as semi-automated open tanks. Containment consists of Plexiglas shields installed on one side of colouring lines 1 and 2 and both sides of colouring line 3. The Plexiglas shields aim to protect workers from corrosive splashes and to reduce exposure to mists. They are equipped with openings generally used to access tanks e.g. to perform sampling. The height of the Plexiglas shield is variable across the three lines. There is no Plexiglas shield at the end and the beginning of the line but the first and last tanks do not contain chromium trioxide and it allows (off)-loading. Presence of workers is also needed in the area between colouring lines 1 and 2 where no Plexiglas shields are installed for some specific tasks of short duration: tank sampling (WCS 6), addition of mist suppressant (WCS 8) and maintenance (WCS 11).

The general ventilation of the hall consists of roof fans providing a minimal air change (1-3 ACH). Doors of the hall are widely open during production. Whether this is the case all year round is not known.

Lip extractions are installed on (black)-colouring tanks except on the colouring tank on line 1 as a pump is used in this tank instead of air agitation on the other (black)-colouring tanks.

As no LEV are installed above hardener tanks where cathodic hardening occur mist suppressants are added to the hardening tanks to prevent mist generation. Addition of mist suppressant is performed on a regular basis (twice weekly) as well as on an ad hoc basis if the laboratory analysis shows that the surface tension in the tank is above 0.035 $N.m^{-1}$ or if the air monitoring over the hardener tanks exceeds 20 $\mu g/m^3$ (measurement done 20 cm above the tanks using personal pump fixed at the edge of the tank) analysis and monitoring conducted fortnightly). It is not known by RAC how frequently these ad hoc additions are needed, however the duration of this task is only 2 min per additions to all three tanks.

In addition, the applicant mentions the use of chromium trioxide flakes instead of powdered material as a source for refilling of tanks as a principal risk management measure to reduce dust exposure.

An annual training session is provided to all colouring plant personnel on chemical hazard awareness, PPE usage and control, occupational health testing and waste management and environmental management system. Only a small number of highly trained personnel are permitted to decant chemical. All unusual maintenance tasks are subjected to a risk assessment prior to the start of the work.

*Discussion of the exposure information:*

The assessment by the applicant of exposure to chromium trioxide by inhalation for each WCS as well as for each type of worker is summarised in the Table 3 below and is expressed as 8-hour time-weight average (TWA). In addition, monitoring data relevant for each WCS based on the corresponding locations are also presented in the Table. All results are expressed as chromium VI.

**Table 3: Exposure by inhalation to chromium trioxide (expressed as Cr(VI)) according to the Applicant (with addition of relevant monitoring data for each WCS)**

| | | WCS | | | Estimation for each group of workers |
|---|---|---|---|---|---|
| | | ART modelling | Monitoring | | |
| | | | Applicant analysis | Additional analysis | |
| CHEMIST | WCS 1 - Decanting of a solid | 7972 ng/m3 (400 ng/m3 with RPE) | 39 - 422 ng/m3 (6 measurements in the loading areas on 2 different days - WCS1 performed on 1 of the days only: differences according to the lines but not to the day of monitoring). | - | **229.14 ng/m3** considering 50:50 time share between laboratory (60.5 ng/m3) and production hall (397,77 ng/m3, 90th percentile of 25 measurements indoor except packaging unit and including between the lines) |
| | WCS 2 - Dissolution of solid CrO3 in tanks | Not possible | Not specifically calculated | Corresponding locations: 39 - 422 ng/m3 (6 measurements in the loading areas on 2 different days - WCS1 performed on 1 of the days only: differences according to the lines but not to the day of monitoring). | |
| | WCS 3 - Re-filling of bath-liquids | Not possible | Not specifically calculated | Corresponding locations: 8 measurements presented from 4 monitoring points around the tanks with Plexiglas shield. Range: 19 - 177 ng/m3. | |
| | WCS 4 - Cleaning of solid CrO3 with a hose | Not possible | Not specifically calculated | Corresponding locations: 39 - 422 ng/m3 (6 measurements in the loading areas on 2 different days - WCS1 performed on 1 of the days only: differences according to the lines but not to the day of monitoring). | |
| | WCS 5 - Cleaning of equipment | Not possible | Not specifically calculated | Corresponding locations: 34 - 144 ng/m3 (2 measurements in the effluent treatment plant). | |

| | | | | | |
|---|---|---|---|---|---|
| | WCS 6 - Tank sampling | ART: 52 ng/m3 | Not specifically calculated. 12 measurements presented from 6 monitoring points around the tanks (with and without Plexiglas shield) Range: 19 - 430 ng/m3 | The task can be performed between the lines without Plexiglas shields. Corresponding locations: 4 measurements from 2 monitoring points between the lines (without Plexiglas shield) Range: 245 - 430 ng/m3. | |
| | WCS 7 - Laboratory analysis | ART:17.9 ng/m3 | 60.50 ng/m3 (Highest from 3 measurements performed in the laboratory. Range 5-60 ng/m3). | | |
| | WCS 8 - Addition of mist suppressant | Not possible | Not specifically calculated | The task can be performed between the lines without Plexiglas shields. Corresponding locations: 4 measurements from 2 monitoring points between the lines (without Plexiglas shield) Range: 245 - 430 ng/m3. | |
| | WCS 9 - Operating effluent treatment plant | Not possible | Not specifically calculated | Corresponding locations: 2 measurements from the effluent treatment plant: 34 and 144 ng/m3 | |
| MAINTENANCE | WCS 1 - Decanting of a solid | ART: 7972 ng/m3 (400 ng/m3 with RPE) | Not specifically calculated. 39 - 422 ng/m3 (6 measurements in the loading areas on 2 different days - WCS1 performed on 1 of the days only: differences according to the lines but not to the day of monitoring). | - | **373.02 ng/m3** (90th percentile from 32 measurements including all indoor measures and outdoor monitoring at the press filter. Range: <LOQ - 430 ng/m3) |
| | WCS 2 - Dissolution of solid CrO3 in tanks | Not possible | Not specifically calculated | Corresponding locations: 39 - 422 ng/m3 (6 measurements in the loading areas on 2 different days - WCS1 performed on 1 of the days only: differences according to the lines but not to | |

| | | | | | |
|---|---|---|---|---|---|
| | | | | the day of monitoring). | |
| | WCS 3 - Re-filling of bath-liquids | Not possible | Not specifically calculated | Corresponding locations: 8 measurements presented from 4 monitoring points around the tanks with Plexiglas shield. Range: 19 - 177 ng/m3 | |
| | WCS 4 - Cleaning of solid CrO3 with a hose | Not possible | Not specifically calculated | Corresponding locations: 39 - 422 ng/m3 (6 measurements in the loading areas on 2 different days - WCS1 performed on 1 of the days only: differences according to the lines but not to the day of monitoring). | |
| | WCS 5 - Cleaning of equipment | Not possible | Not specifically calculated | Corresponding locations: 34 - 144 ng/m3 (2 measures in the effluent treatment plant). | |
| | WCS 6 - Tank sampling | ART: 52 ng/m3 | Not specifically calculated. 12 measurements presented from 6 monitoring points around the tanks (with and without Plexiglas shield) Range: 19 - 430 ng/m3 | The task can be performed between the lines without Plexiglas shields. Corresponding locations: 4 measurements from 2 monitoring points between the lines (without Plexiglas shield) Range: 245 - 430 ng/m3. | |
| | WCS 10 - Tank fill-up | Not possible | Not specifically calculated | Corresponding locations: 8 measurements presented from 4 monitoring points around the tanks with Plexiglas shield. Range: 19 - 177 ng/m3 | |

| | | | | | |
|---|---|---|---|---|---|
| | WCS 11 - Maintenance | Not possible | Not specifically calculated | Corresponding locations 25 measurements indoor except packaging unit: 90th percentile of 397.77 ng/m3 (with and without Plexiglas shield) Range: up to 430 ng/m3. | |
| | WCS 12 - Waste handling (filter press) | ART: 0 ng/m3 | 5.53 ng/m3 (Highest of 3 measurements at the filter press).. Range: < LoQ (1,8 ng/m3) - 5.53 ng/m3. | - | |
| OPERATORS OF COLOURING LINES | WCS 13 - Operating colour line - controler | ART: 120 ng/m3 | Not specifically calculated | - | **387.04 ng/m3** (90th percentile of 14 measurements from 7 monitoring points in the loading area and around the colouring/rinse/hardening tanks but excluding measures between the lines where no Plexiglas shield is installed - no activities there). Range: 19 - 421 ng/m3 |
| | WCS 14 - Operating colour line - loading | Not possible | Not specifically calculated | - | |
| | WCS 15 - Operating colour line - rinsing | ART: 120 ng/m3 | Not specifically calculated | - | |
| | WCS 16 - Operating colour line - off-loading | ART: 120 ng/m3 | Not specifically calculated | - | |
| | WCS 17 - Operating colour line - colour control | Not possible | Not specifically calculated | - | |
| PACKAGING | WCS 18 - Activities in packaging area | Not possible | 36.66 ng/m3 (Highest of 4 measurements from 2 monitoring points in the packaging area). | - | **36.66 ng/m3** |
| SUPERVISOR | No specific WCS | - | - | - | **217.22 ng/m3** considering 50:50 time share between packaging area (see WCS 18) and production hall (397,77 ng/m3, 90th percentile of 25 measurements indoor except packaging unit and including between the lines) |
| PLANT MANAGER (CHEMIST DEPUTY) | No specific WCS | - | - | - | **147.47 ng/m3** considering indoor air (126 ng/m3, 90th percentile of all indoor values) combined with chemist exposure 50 days/year. |

In summary, the values presented in Table 4 below were proposed by the applicant.

**Table 4: Summary of combined exposure by inhalation**

| Function | Exposure value corrected for PPE and frequency |
|---|---|
| Operators of colouring line | 387.04 $ng/m^3$ |
| Operators of packaging Unit | 36.66 $ng/m^3$ |
| Maintenance workers | 373.02 $ng/m^3$ |
| Chemist | 229.14 $ng/m^3$ |
| Supervisor | 217.22 $ng/m^3$ |
| Plant Manager | 147.47 $ng/m^3$ |

*Uncertainties related to the exposure assessment:*

Tasks were generally well described by the applicant and activities performed by each type of workers are generally clearly explained.

The analysis of monitoring data however raises some questions. Decanting of solid chromium trioxide flakes (WCS 1) is expected to generate dust and to be a significant source of exposure. This task was performed only on one of the two days of monitoring in the corresponding loading areas and has apparently no impact on the levels of exposure. Although it is recognised that the duration of the task is limited compared to the 8 hr monitoring time, it raises uncertainties on the ability of the corresponding static monitoring to reflect this source of exposure that is expected to be significant. The potential for exposure of this task and the concern regarding its appropriate estimation by monitoring is confirmed by ART modelling. Although ART is expected to provide a conservative estimate it predicts for WCS1 an exposure level 2 orders of magnitude higher than monitoring data.

It is also noted that the level of exposure monitored around the different lines differs in particular with a lesser exposure on line 3. The applicant considers that these differences are linked to differences in efficiency in LEV (line 3 is more modern) as well as in a reduced (50%) activity in line 3 that is consistent with the typical level of activity in the plant.

The exposure assessment provided by the Applicant is principally based on the results of static air measurements performed during the campaign of August 2015. The monitoring campaign has been carefully designed to provide a sensitive estimation of exposure and to characterise exposure in the most relevant locations of workers' activity. However, the measurements provided don't allow estimating the exposure during the different specific tasks but only a mean daily exposure related to a specific location. Due to technical constraints, static measurements cannot be as close as workers to the sources of exposure e.g. for tank sampling and may underestimate workers exposure. There are also uncertainties because of the limited measurements that are restricted to a single time period (August 2015). It is noted that the level of production during the monitoring campaign was representative for the typical production level of the plant. Overall, RAC considers that baseline exposure estimates should be based on a larger dataset to ensure their representativeness, as well as during different months.

It is noted that the modelled results (upper interquartile confidence interval of the predicted 75$^{th}$ percentile used for inhalation exposure) for WCS 6, 7 and 12 as well as for representative tasks around the colouring line (WCS 13/14/16) are generally consistent with the measured levels of exposure although slightly lower and support the use of the modelling data as a rather conservative assessment. However, for WCS 1, the monitoring results suggest levels of exposure that are not reflected in the monitoring dataset available and raise some uncertainties on these results as discussed above.

An increase in production is foreseen in the next years. The applicant considers that it is not expected to impact the worker exposure. RAC notes that the increase is moderate (20% approximately) and agrees that it would probably not result in higher worker exposure if it occurs concurrently with the further application of foreseen additional RMM.

Despite these uncertainties, RAC considers:

- The level of exposure for operators of the colouring lines, operators of the packaging unit, the supervisor and the plant manager depends highly on the respective location of their various activities rather than to performance of specific tasks involving direct handling of chromium trioxide. RAC therefore agrees that estimation of their exposure can be based on an appropriate selection and aggregation of monitoring data in relation to the location of their activities as proposed by the applicant, which is considered to adequately reflect their general exposure to chromium trioxide.
- Chemists and maintenance workers performs a range of tasks expected to result in specific exposure including WCS involving solid chromium trioxide (WCS 1, 2 and 4) and tasks involving access to the area between colouring lines 1 and 2 that is not equipped with Plexiglas shield (WCS 6, 8 and 11). Monitoring data shows that exposure in this area (4 measures, range 245-430 ng/m3) is significantly higher than exposure around tanks equipped with Plexiglas shields (8 measures, range 19-177 ng/m3).
- For chemists these activities are however only activities of short duration and frequency (up to 30 minute weekly) whereas a significant amount of time is spent in the laboratory (half of the worktime) or operating the effluent treatment plant (40 to 50% of worktime) where exposure is lower and considered to be adequately reflected by static monitoring data. In addition, RPE are used during handling of solid flakes and have not been considered in the proposed estimation, which provides additional conservatism. RAC therefore agrees with the estimation of exposure proposed by the applicant for chemists.
- For maintenance workers, same comments apply to specific activities of short duration and frequency and to the use of RPE for handling of solid flakes. In addition, WCS 11 (maintenance) is performed daily and for up to 8 hours. This task involves operations in different locations of the production hall including the area between the colouring lines 1 and 2 that are not protected by Plexiglas shield and are shown to involve higher exposures. It is however not known which proportion of maintenance time is spent in this area and its impact on the overall level of exposure of maintenance workers. RAC however notes that a very worst case (mots probably unrealistic) would be to consider that maintenance workers spend their entire work shit between the line 1 and 2. In this specific area the highest of the 4 monitoring data available is 430 ng/m$^3$. This value is in the same range than the value of 373.02 ng/m$^3$ proposed by the applicant and considering the very (unrealistic) worst case is not expected to significantly impact the excess of cancer risk estimated for these workers (1.72 x 10-$^3$ instead of 1.49 x 10-$^3$). RAC therefore agrees that the exposure estimated by the applicant for maintenance workers is representative and acceptable.

- In the previous monitoring campaign a significantly higher exposure of 7 000 ng/m$^3$ has been measured in the single personal sampling available that involves tasks related to the use of solid $CrO_3$, operating the effluent treatment plant, tank fill up and waste handling at the filter press and are relevant for chemists and maintenance workers. This result raises concern on a potential for higher exposures and introduce some degree of uncertainty to the assessment. As no other personal sampling result is available for a similar task, the representativeness of this single personal sampling measure is not known.

Overall, RAC therefore considers that the data presented allow an appropriate assessment of worker exposure and that uncertainties related to estimation of worker exposure are generally rather low.

**Environmental releases / Indirect exposure to humans via the environment**

Environmental Contributing Scenarios

The applicant considered that "Industrial use resulting in inclusion into or onto a matrix" (ERC 5) is the most appropriate Environmental Contributing Scenario.

The applicant states that colouring of stainless steel is performed under conditions which show a high degree of closures from an environmental perspective (e.g. usage of barriers and sumps to collect all waste water, waste water treatment before discharge).

No releases to **soil** were considered from the use covered by the CSR. Sludge from the sewage treatment plant (STP) to which the plant discharges is either incinerated (when nickel levels are elevated) or deposited as hazardous waste at landfill. (Therefore, the EUSES default dry sludge application rate was set to zero in the local assessment.)

The releases to **water** were based on monitoring data (85 measurements of Cr (VI) from 06/01/2014 to 01/09/2015) in the effluent of the plant that is sent to the (STP). These data show that the vast majority of samples (85 %) are below the limit of detection of 10 µg/L. The arithmetic mean concentration of 8.6 µg Cr(VI)/L was taken as the basis for calculating the release factor.

The releases to **air** were calculated both from:

1) Emission measurements performed on stack emissions (line 1 black colouring tank, line 2 colouring tank, and line 3 blank and colouring tanks) at the site. This resulted in a release factor of 4.43 x $10^{-4}$ based on total chromium measurements (PECair = 2.28 ng Cr/m3).
   However, this value was not considered representative because no quantitative differentiation could be made since the measurement of stack emissions only determined total chromium levels. On request from RAC, the Applicant confirmed that, emissions from colouring tanks in line 1, hardening tanks and roof fans were not measured.
2) Monitoring of Cr(VI) in the immediate vicinity of the source
   Four outside samples were taken on the plant premises approximately 25 m from the production hal. (1 sample/day downwind and upwind, respectively during 2 days). Cr(VI) concentrations at all 4 monitoring points were below the limit of quantification (LOQ) of 1.8 ng/m$^3$. If one half of the limit of quantification is used, a local PEC air of 0.9 ng Cr(VI)/m$^3$ can be derived on the basis of direct Cr(VI) measurements. The applicant explained that, despite the limitations of the data

basis (n=4), all samples (up and downwind) were below the LOQ, and considering the process-based argument, the Cr(VI) measurements were more relevant than modelled data for total chromium.

Thus, in the risk assessment a local PECair of 0.9 ng Cr(VI)/$m^3$ was used.

**Table 5: Summary of environmental emissions**

| Release route | Release factors | Release estimation method and details |
|---|---|---|
| Water (before municipal waste water treatment plant) | $2.98 \times 10^{-6}$ | Based on measured release data (Site-specific data) |
| Air | $1.75 \times 10^{-4}$ | Estimated release (Based on site-specific monitoring) |
| Soil | 0 | - |

*Methodology used by the Applicant - Indirect exposure humans via the environment*

The Applicant considered two exposure routes - **inhalation and oral intake** (through ingestion of drinking water and consumption of fish) for the exposure of the general population.

Inhalation exposure of humans via the environment was assessed using monitoring data (explained above “monitoring of Cr(VI) in the immediate vicinity of the source”), from which release factors were derived and used in EUSES modelling. This resulted in a Regional Cr(VI) PEC in air of $5.77 \times 10^{-9}$ ng/$m^3$ and a Local Cr(VI) PEC in air of 0.90 ng/$m^3$.

In relation with indirect **oral** exposure of humans via the environment, the applicant only considered exposure via **(drinking) water** and consumption of **fish**, following the conclusion of the CONTAM Panel, that states “*that all the chromium ingested via food is in the trivalent form in contrast to drinking water where chromium may easily be present in the hexavalent state”*, and the approach chosen in the EU Risk Assessment Report for hexavalent chromium (ECB, 2005).

Since there are only three sites in different countries of Europe which use chromium (VI) trioxide for colouring of stainless steel and as there is no wide dispersive use of chromium (VI) trioxide, the Applicant considered a Regional assessment not relevant, but nevertheless, these Regional (Cr(VI) PEC in water were estimated for completeness. As previously explained, monitoring data of Cr (VI) levels in the effluent of the plant that is sent to the sewage treatment plant (STP) was used to determine the release factors used for modelling the oral exposure for humans via the environment. Exposure modelling results (table 6) show that oral exposure of Cr(VI) is dominated by the drinking water pathway (>98 % of combined oral exposure from drinking water and fish) both at the regional and the local scale.

*RMMs applied*

The Applicant considers that measures to prevent/limit the release of Cr(VI) to the work environment during its operations to be of best practice.

Releases of Cr(VI) to wastewater is controlled at various points. According to the Applicant, all waste water is collected at an effluent treatment plant, where it is chemically treated to reduce chromium (VI) to chromium (III). Chromium (III) is subsequently precipitated. The suspension with the precipitated chromium (III) is then directed to a filter press where the sludge is removed and transferred to a waste deposit to be disposed as hazardous waste. The remaining waste water with chromium (VI) concentrations usually below the limit of quantification (10 µg/L) is led into the municipal sewage drain from where it enters the municipal sewage treatment plant.

Engineering RMMs to control emissions in the production hall include ventilation roof fans, lip extractions, PFOS-free mist supressing chemicals. On request from RAC, the Applicant confirmed that filters/scrubbers are not present in any of these fans/extractors to control Cr(VI) releases to ambient air.

**Table 6: 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: 0.90 ng/m$^3$<br>Regional: 5.77 x $10^{-9}$ ng/m$^3$ |
| Man via Environment - Oral | *Drinking water*<br>Local: 0.0229 ng/(kg x d)<br>Regional: 0.00240 ng/(kg x d)<br><br>*Fish*<br>Local: 0.000214 ng/(kg x d)<br>Regional: 0.0000312 ng/(kg x d)<br><br>*Sum of drinking water and fish*<br>Local: 0.0231 ng/(kg x d)<br>Regional: 0.00243 ng/(kg x d) |
| Man via Environment - Combined | Not relevant |

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

- related to RMMs

Emissions from roof fans were not measured, hence Cr(VI) amounts released to ambient air via this route is not known, and consequently not taken into account in the EUSES model. There are also no filters/scrubbers on the local exhaust ventilation and lip extractions which could reduce the amount of Cr(VI) released to the environment.

- related to exposure estimation methodology

In relation to oral exposure of humans via the environment, RAC acknowledges that Cr(VI) will transform in the environment to Cr(III), which has been previously described in the EU RAR for chromate substances (ECB, 2005). This will reduce the potential for indirect exposure to humans via the environment after release, particularly via the oral route of exposure. On this basis, the EU RAR only included oral exposure from drinking water and the consumption of fish. RAC thus supports the Applicant´s approach of oral exposure.

The Applicant highlights that the modelled drinking water (oral) exposure is overestimated taking into account that worst-case assumptions inherit in EUSES. For example, the estimate is based on a modelled Cr(VI) concentrations in groundwater, which neglects transformation and dilution in deeper soil layers. It also equates the concentration in groundwater with the concentration in drinking water assuming no mixing with other water.

RAC notes that the Applicant provides site-specific outside air monitoring data based on measured Cr(VI), in order to reduce uncertainties. However, the number of samples taken on the plant premises was very limited (n=4), as well as the time scale (only 2 days), limiting the representativeness of this dataset. Furthermore peak concentrations may occur further away from point sources (measurements done 25 m away, EUSES default is 100 m from point source).

The sampling and analytical procedures were identical to the ones for the occupational monitoring campaign with a LoQ of 1.8 ng/$m^3$, however, this method was still not sufficiently sensitive for the ambient levels. Consequently, all 4 monitoring points were below the LoQ. Taking into consideration the current REACH guidance where it states that when measurements are below the LoQ, then one half of the LoQ is acceptable for use in risk assessment the Applicant used a local PEC value of 0.9 ng Cr(VI)/$m^3$. RAC assessed the impact associated with use of a local PEC air of 0.9 ng Cr(VI)/$m^3$ vs the actual LoQ value of 1.8 ng Cr(VI)/$m^3$, and concludes that the impact is minimal as the cancer risk associated with a local PEC of 0.9 ng Cr(VI)/$m^3$ is estimated to be 2.61 x $10^{-5}$, while with a local PEC of 1.8 ng Cr(VI)/$m^3$ is 5.22 x $10^{-5}$.

Taking the uncertainties mentioned above into account, RAC still considers that the indirect exposure calculated by the applicant is acceptable for risk characterisation and impact assessment.

**Conclusion**

RAC considers that:

- The description of the use provided allows to draw conclusions related to exposure situations
- The methodology used to derive exposure levels is suitable. However, RAC considers that baseline exposure estimates should be based on a more comprehensive dataset and improved measurement methodology to ensure their representativeness of task based exposure.
- The information provided related to exposure resulting from the use applied is considered to be acceptable overall to use in risk characterisation and impact assessment.

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

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification: RAC has concluded that chromium trioxide (Cr(VI)) 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**

*Evaluation of the Risk Management Measures*

A series of RMM are in place to limit exposure to Cr(VI) through dust exposure as well as mist exposure from the tanks as described above under section 4. RAC notes that the level of exposure to Cr(VI) that has been monitored is generally low, which is in support of the general effectiveness of RMM in place, although higher exposures are identified for some tasks and/or locations.

In particular, RAC notes the following points:

- Handling of solid chromium trioxide flakes and protection from dust exposure rely heavily on RPE, in particular during the initial phase of decanting (WCS1). Flakes are handled manually in an open area without specific ventilation and RMM of higher priority than PPE in the hierarchy of control measures are not applied. In this respect, RAC also notes that alternative solutions such as use of concentrated solutions instead of handling of solid flakes may reduce exposure to dust and should be further considered.
- Use of a fume hood for laboratory analysis (WCS 11) was assumed in ART modelling. However, dilution of concentrated liquid was not performed in the fume hood during the monitoring campaign and higher exposure was measured on the day this task was performed in the laboratory. This task is therefore a significant source of Cr(VI) exposure and RMMs need to be in place. In this regard, RAC acknowledges that the activity is now performed in a fume hood as modelled and included in the summary of conditions of use for this WCS in the application.
- Concerning the control of mist exposure from the tanks:
    - o Some containment of open tanks is provided by Plexiglas shields. Monitoring data available indicates that exposure around tanks at locations equipped with Plexiglas shields (8 measures from 4 monitoring points ranging from 19 to 177 ng/m3) are significantly lower than at locations without Plexiglas

shields (4 measures from 2 monitoring points ranging from 245 to 430 ng/m3). Plexiglas shields therefore may provide a reduction of exposure to Cr(VI). It is however noted that the Plexiglas shields may rearrange the exposure. Mists might diffuse in the air from above the Plexiglas shields, in particular in tanks that do not have a LEV. It is also noted that some activities (WCS 6, 8 and 11 involving chemists and maintenance operators) can be performed between the line that are not equipped with the shields and no additional specific RMM are described for these activities.

- LEV is not included in the summary of conditions of use for WCS around the colouring lines (WCS 13 to 17). Indeed, lip extractors are installed on most (black)-colouring tanks but not on colouring tank 1 due to the use of a centrifugal pumps with a submerged sparger system to mix the liquid around rather than using air agitation. This is considered by the applicant as the best available technique to be installed in future at the other tanks too. And there is no LEV on hardening tanks that are expected to generate significant mists due to cathodic reaction and control of exposure relies on the use of mist suppressant. RAC therefore notes an uneven application of RMM for the different tanks.

The applicant is considering additional measures for improvement of RMM already in place that includes improvement of general ventilation and of a dividing curtain between packaging and production areas (planned for 2016), installing pumps on the rest of the tanks of lines 2 and 3 which are currently air-agitated, consideration of a wider implementation of LEV and improved use of mist suppressants.

*Risk characterisation*

Occupational exposure was based mainly on static measured data from the 2015 monitoring campaign for risk characterisation as discussed above under section 6 and risk characterisation was calculated for each worker group. As there is no information on the fraction of inhalable but non-respirable particles, the applicant has conservatively assumed that all inhaled chromium trioxide particles are in respirable range and contribute to the lung cancer risk as recommended by RAC (RAC 27/2013/06 Rev. 1).

The weighted average inhalation exposure estimates were compared with the RAC reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1). The latter being that occupational exposure to 10 ng/m$^3$ of Cr(VI) is associated with an excess lung cancer risk of 4 x $10^{-5}$. The risks resulting from the application of this dose-response relationship to the worker inhalation exposure estimates presented above are shown in Table 7 and are in the range of 1.47 x $10^{-4}$ to 1.55 x $10^{-3}$ under the described use conditions.

**Table 7: Excess risk estimates for 40 years exposure for workers**

| Worker Group | Inhalation route | |
|---|---|---|
| | Adjusted exposure (ng/m³) | Excess risk |
| Colouring line operator | 387.04 | $1.55 \times 10^{-3}$ |
| Packaging unit operator | 36.66 | $1.47 \times 10^{-4}$ |
| Maintenance | 373.02 | $1.49 \times 10^{-3}$ |
| Chemist | 229.14 | $9.17 \times 10^{-4}$ |
| Supervisor | 217.22 | $8.69 \times 10^{-4}$ |
| Plant Manager | 147.47 | $5.90 \times 10^{-4}$ |

**Indirect exposure**

The risk estimates above already incorporate groups of workers with indirect exposures.

The different types of workers perform different tasks which are associated with a possible exposure to Cr(VI). Some of these activities like working in the packaging unit (WCS 18) or performing maintenance work somewhere in the production hall (WCS 11) are only indirectly associated with exposure to Cr(VI) due to its presence in the workplace air, but not due to the direct handling of Cr(VI) containing liquids or solids.

Other workers in the plants are expected to be exposed to local air levels and included in the risk estimates for man via environment.

**MvE exposure / local and regional**

The applicant has estimated cancer risk for inhalation and oral exposures of general population.

Exposure estimation used in the risk assessment was based on the ambient air monitoring data.

Risk assessment has been made 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 chromium trioxide particles are in respirable range and contribute to the lung cancer risk. Thus, the following excess life-time cancer risks were used:

- General population inhalation exposure: An excess lifetime lung cancer mortality risk = $2.9 \times 10^{-2}$ per µg Cr(VI)/m³
- General population oral exposure: An excess lifetime intestinal cancer risk = $8 \times 10^{-4}$ per µg Cr(VI)/kg bw/day

For general population living in the vicinity of the site, an excess life-time lung cancer risk of $2.61 \times 10^{-5}$ was calculated. Also, an excess life-time intestinal cancer risk of $1.83 \times 10^{-8}$. The risk from inhalation exposure dominates the local assessment.

The applicant has also calculated the risk related to regional exposure, with excess life-time lung cancer risk of $1.67 \times 10^{-13}$ from inhalation exposure and an excess life-time intestinal cancer risk of $1.92 \times 10^{-9}$ from drinking water. The regional assessment was regarded as not relevant because there are only three sites in different countries of Europe which use chromium (VI) trioxide for colouring of stainless steel and there is no wide dispersive use of chromium (VI) trioxide. RAC acknowledges and agrees that Cr(VI) will transform in the environment to Cr(III), which has been previously described in the EU RAR for chromate substances (ECB, 2005).

The risk at the regional scale is almost entirely due to the modelled Cr(VI) intake via drinking water. The Cr(VI) concentration calculated for regional drinking water is 0.084 ng/L. This value is about three orders of magnitude lower than the Cr(VI) concentration in drinking water (270 ng/L) corresponding to a risk of 1 x $10^{-6}$

Overall, the risks at the regional scale and for oral intake at the local scale are very low given the conservative nature of the exposure assessment via drinking water. For the local risk from inhalation exposure, it must be stressed that the risk calculated applies only to the immediate vicinity of the site.

Local:

| **Inhalation route** | | **Oral route** | | | |
|---|---|---|---|---|---|
| | | **Drinking water** | | **Fish** | |
| **Adjusted exposure (ng/m³)** | **Excess risk** | **Adjusted exposure (ng/kg bw/d)** | **Excess risk** | **Adjusted exposure (ng/kg bw/d)** | **Excess risk** |
| 0.90 | 2.61 x $10^{-05}$ | 0.0229 | 1.83 x $10^{-08}$ | 0.000214 | 1.71 x $10^{-10}$ |
| **Combined route excess risk** | | 2.61 x $10^{-05}$ | | | |

Regional:

| **Inhalation route** | | **Oral route** | | | |
|---|---|---|---|---|---|
| | | **Drinking water** | | **Fish** | |
| **Adjusted exposure (ng/m³)** | **Excess risk** | **Adjusted exposure (ng/kg bw/d)** | **Excess risk** | **Adjusted exposure (ng/kg bw/d)** | **Excess risk** |
| 5.77 x $10^{-9}$ | 1.67x $10^{-13}$ | 0.00240 | 1.92 x $10^{-09}$ | 0.0000312 | 2.50 x $10^{-11}$ |
| **Combined route excess risk** | | 1.94 x $10^{-09}$ | | | |

**Conclusion**

RAC considers that RMMs and OCs described in the application are generally appropriate and effective in limiting the risk to workers and the general population, however some improvements are needed:

- For workers, RAC has identified some shortcomings with regard to exposure control that require consideration in the context of continuous reduction of exposure to Cr(VI). They are related to the application of appropriate RMM according to the hierarchy of control, in particular:
    a) the reduction of exposure to dust by handling of solid chromium trioxide,
    b) the harmonisation of RMM in place for control of mist exposure from tanks according to the best available practice, including improved LEV.

- For releases to the air, RAC considers that RMMs are required to control emissions to the environment from the LEV/roof fans.

In addition, it is noted that the strategy of monitoring of exposure and emissions is not yet sufficiently developed, thus the exposure and emission assessment should be improved to increase its reliability.

**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:

Chromium trioxide is used as an oxidiser and hardening agent in the so called INCO process for the manufacture of coloured stainless steel that can be used in several different applications such as in architecture, lifts and escalators, transport, refrigeration and food service and other engineering applications. Chromium trioxide is used along with sulfuric acid to apply a thin film on the surface of stainless steel, colouring it through the interference with the visible spectrum of light. In a second step the film is subject to a cathodic deposition in an aqueous bath of chromium trioxide to harden it to achieve an aesthetic, decorative surface with high durability when exposed to demanding conditions.

Coatings produced by the INCO process aims to achieve the following properties: increased resistance to scratching and marking; a wide palette of uniform stable and bright colours; good wear and UV resistance and a combination of colours and patterns on stainless steel that permits an increased range of produced products. The INCO process offers according to the applicant versatility, aesthetical quality and durability at a relatively low production cost.

For the identification of alternatives, the applicant consulted one expert in the INCO process, manufacturers of PVD CSS (Physical Vapour Deposition also known as titanium sputtering) in China and Taiwan, manufacturers of PVD equipment and other experts in PVD CSS technology. Also RIMEX (UK) carried out a literature review, developed an internal R&D program focused on the assessment of PVD, collected information from the Chromium Trioxide REACH Authorization Consortium (CTAC) and commissioned a research project in order to benchmark the INCO production method and identify suitable alternatives. Based on these efforts, the applicant identified and screened a number of alternatives that perform the same or that have similar functions within the existing production process and therefore theoretically could replace Cr (VI) in the INCO CSS process. When assessing the potential alternatives for the manufacturing of CSS the applicant focused on substances that would substitute $CrO_3$ in the colouring and hardening process of manufacturing CSS (that could use the same equipment) and on technologies for colouring stainless steel (without the use of hexavalent chromium). A master list of 15 potential alternatives for the colouring and some for the hardening process stages was the result of this work. Alternatives that would involve a complete change of substrate were not evaluated by the applicant as they were considered unrealistic due to required radical changes to the nature and focus of the business.

All the identified alternatives, except the ones that involve a change of substrate, were taken forward by the applicant for a screening in three steps. These include a screening for commercialisation to exclude those potential alternatives that are not proven on an industrial scale and/or are not available on the market. The screening also includes an assessment of technical feasibility and finally a screening to exclude the ones that could not guarantee a reduction in hazards.

Based on the assessment the applicant grouped the possible alternatives into three groups:

- Realistic alternatives in the medium and long-term - as the most promising on which further R&D is taking place; as are commercially proven and technically acceptable although with limitations (only one alternative, PVD).
- Promising alternatives but unrealistic in the short-to medium-term – showing some promising qualities in the open literature but have not been proven on an industrial scale. Therefore, they require additional research before their true potential can be established. At least one of them it is the focus of further commissioned R&D efforts (thermal hardening, sulphuric acid and another two substances).
- Unrealistic alternatives – are those alternatives which are technically poor and commercially unproven. Therefore, RIMEX (UK) would not consider them as possible alternatives for the INCO CSS process.

The applicant then concluded that none of the alternatives meet all the demands of the company and its subsidiaries. Based on the screening of the availability and the suitability of alternatives in relation to the hazard profile and the technical feasibility, one realistic potential alternative was identified as possible replacement of $CrO_3$. Other possible alternatives were excluded due to feasibility constraints and/or inadequate demonstration on an industrial scale and/or complexity of implementation and their required operating conditions. The applicant concludes that PVD CSS is an available technology that could reduce carcinogenicity risks to workers but that it is currently neither technically nor economically ("unviable") feasible due to the extent of performance improvement and plant modifications that would be required.

**Technical feasibility**

According to the applicant the INCO process requires the use of chromium trioxide as an oxidising and hardening agent that ensures that the applicant is able to manufacture coloured stainless steel with high quality and durability in a wide range of colours. The technical feasibility criteria identified by the application are therefore; colour quality, product range (at least the current 10 INCO colours), durability (resistance to UV radiation and salt spray testing - cladding on buildings could last for at least 10-40 years and elevators and escalators for 15 years), process temperature (process temperatures below 100 ºC), process duration), use of existing equipment and energy consumption These are relevant due to product specifications and process requirements/criteria.

<u>PVD CSS</u>

The applicant considers the PVD CSS process to be the only realistic alternative that could be used for colouring stainless steel avoiding the use of $CrO_3$. However the company is unfamiliar with that process and the PVD technology is a totally different process than the INCO process. Therefore, it implies an investment in new equipment and a thorough transformation of the plant that includes the installation of three PVD lines, the decommissioning of the current three INCO lines, the installation of additional power supply and a new effluent treatment plant. Since 2013, after the inclusion of $CrO_3$ in REACH Annex XIV, the applicant has commissioned R&D activities to identify alternatives to the substance or to the whole process. The company itself focused the R&D efforts on PVD which can be seen as the main competitor in the CSS market. However, with the current state of the art, PVD CSS process cannot yield products corresponding to the applicant's performance standards concerning colour range, UV/wear resistance, aesthetics, life time behaviour and process parameters such as the restriction to the size of the sheets due to requirement of use a vacuum chamber. The applicant describes the advantages and deficiencies of CSS products coloured with the PVD process with regard to their performance standards and the lack of testing data in some uses. He also describes technical issues that are directly bound to the economic factors of production such as the longer process duration, the possible higher energy consumption and the non-use of existing equipment. Nevertheless, the applicant presents a detailed plan of R&D activities and investment aiming for the eventual overcoming of these deficiencies, for the implementation of three PVD colouring lines and for the removing of the current INCO CSS lines (this conversion was carefully thought in terms of duration and timelines for each planned action). The applicant concludes that PVD process will not be technically or economically feasible before the sunset date due to the technical deficiencies and the investment costs for the implementation of the PVD CSS process. The applicant expects that after overcoming the identified deficiencies, customers would be willing to accept PVD CSS products although they would have somewhat different aesthetic properties when compared to the INCO CSS products.

<u>The applicant considers the following alternatives as promising but unrealistic in the short- to medium-term:</u>

- Sulphuric Acid – Could be used in an electrochemical colouring process alternative to INCO process. From the vast literature the applicant concludes that much more investigation work should be done in terms of film properties and more given proof on an industrial scale. As advantages this process needs lower solution concentration, lower temperature and various different colours could be produced however with poor quality in the opinion of the applicant. It requires long colouring times when compared with INCO process. Sulphuric acid has a suitable hazard profile as it is classified as Skin Corrosive 1A. However a RMOA analysis is under preparation.
- Thermal hardening – This technology cannot produce coloured films by itself, so there is always a need for a colouring step, but it could be used to harden coloured films obtained through an electrochemical process. Other disadvantages are no given proof on an industrial scale and existing restriction on sheets size because the process requires a furnace. Nevertheless, it can produce films with improved properties but with high energy costs. There is also a lack of control regarding the colour quality over large areas such as the steel sheet. And as no chemicals are required there is no chemical hazard profile for this alternative.
- KOH – The patent and the literature point out some potential, but it is not proven at industrial scale. Process temperatures and colour range are promising, process parameters seem to be similar to INCO process. However it has never been tested in the coating of stainless steel substrates and the films produced have poor durability from the view of the applicant. This substance has a suitable hazard profile as it is classified as oxidising solid 3 or not classified.

- Transition Metal Compounds – This substance is a very promising candidate to substitute the $CrO_3$ in the INCO CSS process. It has potential to produce interference colours like $CrO_3$ films, and so it is expected that the same range of colours can be achieved, but any given proof on an industrial scale is unknown. It is also not known if it could be used to coat the type of stainless steel used by RIMEX (UK) as substrate, because there is a lack of experimental data to characterize the film properties. The applicant has some expectations about the findings of the current R&D efforts, which could lead him to hold back the decision to change to PVD CSS technology.

The applicant considers the following alternatives as unrealistic:

- Permanganate salts and Pentavalent vanadium salts – These alternatives substances are considered infeasible by the applicant because they produce a poor colour range and do not avoid the use of $CrO_3$ to produce coloured films in stainless steel surfaces.
- $H_3PO_4$ – This alternative substance is considered infeasible by the applicant because in addition to the need for high temperatures, the use of phosphoric acid also implies a long process to achieve some colours. Therefore this alternative would be unsuitable to implement on an industrial scale.
- NaOH & $NaNO_3$ and Ionic liquids - These alternatives substances are considered infeasible by the applicant. Because in addition to the need for high temperatures, the use of sodium compounds and ionic liquids they would also demand a change of the current density or the solution temperature to achieve different colours. Therefore these alternatives would be unsuitable to implement on an industrial scale.
- Heat colouring – This technology is considered infeasible because it produces poor colours at high temperature, and in order to achieve different colours the user needs to change the furnace temperature. This alternative also requires new equipment. This alternative is therefore found to be impractical to implement on an industrial scale.
- Laser induced colour making and Colouring with titanium complex fluorides and zirconium complex fluorides– These technologies only produce yellow colours and have not been tested on stainless steel thus being considered infeasible by the applicant.
- Zirconisation - This technology only produces grey, light-blue and light-gold colours which are not compatible with the standards of the applicant. This process in intended to be used as a surface pre-treatment for posterior coating by paint rather than an actual coating for stainless steel.
- Metallic coatings - This technology only produces grey colours films with poor properties which do not satisfy the applicant's requirements.

**Economic feasibility**

Economic feasibility was only assessed by the applicant for the PVD which is the only potential alternative that was found to have no critical technical weaknesses. According to the applicant the economic feasibility of PVD is poor but could be acceptable to the applicant if a gradual introduction of the technology would be possible.

The applicant estimates that cost of plant adaptation to the PVD process would be between €1 million and €10 million. A qualitative assessment of changes to operating costs is presented that shows an expected increase due to higher energy consumption, increased water consumption, increased production testing and loan payments. This expected increase is not substantially higher than those of the INCO process. Alltough some uncertainty around the precise magnitude still exists. The adaptation plan foresees stopping the INCO CSS production only after the installation and optimization of the second PVD line. The time estimate to phase-out of the INCO process is approximately one and a half year (planned to end at 31 January 2027), and only after that the installation of the third PVD line would be started. This difficult equilibrium has the goal of never stopping the production of the plant because the applicant could neither commit too many resources to a one-off switch nor could he absorb the impact of loss of production capacity, as the company makes a large part of its profit from this CSS market. This is the main reason for the applicant to ask for a 10 years review period. Finally, RIMEX (UK) will continue to fund research on alternatives substances for $CrO_3$ to the INCO process and if any positive results are achieved, RIMEX will consider the possibility to abandon their plans to convert to PVD CSS process in favour of an alternative substance that could be employed within the INCO process.

**SEAC evaluation and conclusion**

SEAC notes that the applicant's assessment of alternatives is detailed and transparent and includes not only alternative substances but also alternative technologies. The basis of the selection of the alternatives by the applicant keeps the aim to achieve a set of characteristics which allows relatively high added value to sustain the company's profitability. The assessment regarding technical feasibility is sufficiently detailed. For the available alternative, the PVD CSS technology, both technical and economic feasibility are assessed in detail. A large number of potential alternatives were identified, screened and classified, but it should be pointed out that no consultation has been carried out with actors in the supply chain or with other manufacturers in Europe. SEAC wishes to point out that such a consultation could have been helpful in order to gain further knowledge on the possibility to substitute to the PVD CSS technology.

The assessment of alternatives, substances and technologies gives a clear picture about the viability of the substitution of Cr (VI) on an industrial scale, according to market availability and technical feasibility as well as hazard profile. The assessment gives a good overview of why all alternatives except PVD CSS, are considered to be unrealistic alternatives. The alternatives are neither technically feasible nor commercially available. According to SEAC, adequate reasons are provided by the applicant that some of the alternative substances and alternative technique could be promising from a technical point of view. But they can only be considered suitable in the long term since they have not been proven on an industrial scale.

For the only alternative considered realistic in the medium long-term, the PVD CSS, a description of the technology and a discussion on how the PVD technology performs against each technical feasibility criterion, was provided. An evaluation of the state of the art of PVD CSS products and the required actions for making the alternative technically feasible was provided for concluding on technical feasibility. A sufficiently detailed assessment of economic feasibility was provided that SEAC found to be in line with ECHA guidance. This assessment provides a justification to the proposed conversion plan for INCO CSS to PVD CSS. SEAC is thus able to concur with the conclusions reached by the applicant in terms of the suitability of alternatives. It is difficult for SEAC to assess the time that would be necessary for the installation of the PVD lines and to industrialise any new developments, while still maintaining the INCO CSS production active for economic reasons. The information provided by the applicant is however sufficiently indicative that realistic prospects for substitution will be possible and at least needs the timelines of a normal review period. SEAC would like to highlight that as the applicant's consultation does not include companies in the supply chain or other European manufacturers, this brings uncertainty to the committee's evaluation. SEAC takes note that the applicant's consultation was focused on companies and experts that in their view are likely to have the most advanced knowledge on the PVD CSS technology.

However the assessment of the applicant points out that there are three substances that could be potential substitutes to Cr (VI) in similar INCO CSS processes. For one of them, further research is undertaken and the results seem to be important for the decision taken by the applicant to implement the PVD technology to produce CSS.

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

☐ YES

☒ NO

Justification:

**The applicant's conclusion on technical feasibility of the shortlisted alternatives**

The applicant concludes that according to the comparison against the technical feasibility criteria the PVD does not fully comply with any of them. The technical feasibility criteria for the applicant are colour quality, product range, durability, process temperature, process duration/throughput, use of existing equipment and energy consumption. The PVD does not meet three of the criteria, for the other four criteria the performance decline or technical shortcomings could be tolerated. PVD cannot for instance generate all the colours achieved by the INCO method and additional PVD colouring lines that would be needed. Furthermore there are important issues about the characteristics of the film that needs to be resolved to improve exterior applications of PVD CSS.

**The applicant's conclusion on economic feasibility of the shortlisted alternatives**

Although the applicant has not assessed the economic feasibility of all alternatives, it should be noted that the achievement of the necessary performance standards is a requirement derived ultimately from the demands and expectations of the market of such products, and from this view, related to economic considerations. Nonetheless, it is clear that the inability to fulfil these standards would result in customers switching to other materials as solution for their requirements and demands with subsequent total loss of RIMEX CSS sales.

The applicant concludes that the PVD technology will not be an economically feasible alternative on the $CrO_3$'s sunset date (due to a number of significant uncertainties that might not be possible to resolve by the sunset date). It also concludes that PVD technology might be economically feasible in the future if a number of conditions are met, such as: planned R&D results are positive, post-conversion (increased operating costs not to diminish profit), price of the PVD CSS products retain a profit margin that compares to INCO CSS.

For the implementation of PVD technology to be economically feasible and for the PVD CSS products to achieve the applicant’s required standards, the applicant proposes a detailed conversion plan which allows the establishment of a number of PVD lines alongside with the INCO lines. The goal of this conversion design is to maintain the applicant´s INCO CSS production and its turnover until the installation of the last PVD line. SEAC finds this plan to be based on a comprehensive technical and economic assessment and justifications.

**SEAC evaluation and conclusion**

SEAC notes that the AoA is sufficiently detailed and transparent and includes not only alternative substances but also alternative technologies. The current technical infeasibility of all the identified alternatives is well supported by technical explanations of their limitations and stages of development. Though SEAC cannot asses in detail the technical feasibility of all the alternatives, the technical and economical infeasibility of the most promising alternative – PVD CSS technology - is underpinned by the fact that it requires relevant investment costs which include a thorough transformation of the plant and R&D efforts to bring this technology to conform to the applicant’s standards. Even though the extent of the remaining R&D efforts needed is not clear, SEAC concludes that it is justified that the alternatives are technically and economically infeasible before the sunset date. The economic viability of the transformation and the lack of knowhow of the applicant in PVD CSS process, is sufficient too. SEAC also recognises the applicant’s efforts to identify alternatives in research projects and to acquire knowhow and review of the state of art of PVD CSS process.

However SEAC would like to point out that in this case a consultation with the European competitors would have been important in order to clarify the extension of R&D work needed to meet the applicant’s demands, as there are at least two other European companies that produce PVD CSS. Furthermore one of them also produces INCO CSS and the other appears to produce PVD CSS sheets for exterior uses in a colour range relevant, even for the standards of the applicant. Notwithstanding SEAC’s acknowledgment of the R&D efforts made by the applicant to update the state of art of the PVD CSS products, for SEAC there is still uncertainty in the assessment for products of European companies that produce PVD CSS sheets for exterior applications. The applicant’s answers to the rapporteurs’ questions however showed that it has a good knowledge of the CSS products and of the companies that are established on the European market.

SEAC concurs with the applicant that from the applicant’s point of view there is no economical;y feasible alternative before the sunset date. About technical feasibility, SEAC also concurs that from the applicant’s point of view there is no alternative available by the sunset date. The justifications for this are the following:

- The implementation of a new technology is expected to take some years and in this case the applicant needs to make a thorough transformation of the plant, to acquire knowhow and to schedule training for the staff.

- The PVD CSS technology is not a mature technology regarding exterior applications, which represents a major part of RIMEX's CSS sales. There is therefore a need to develop the technology further and this is likely to take some time before PVD CSS sheets for exterior applications reach an equivalent performance to the INCO CSS products.
- Even if there is a company using a more advanced PVD CSS technology, that technology would not be commercially available to the applicant.

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

Description:

The Applicant has identified a list of 15 different possible alternatives for the purpose of replacing the use of chromium trioxide as a process additive in the manufacture of coloured stainless steel (CSS).

These 15 alternatives were screened for a minimum guarantee of technical feasibility and suitability. The screening steps involved screening for commercialisation, screening for technical feasibility as well as screening for suitability/hazard profile to exclude those potential alternatives that could not guarantee a reduction in hazards/risks in comparison to $CrO_3$. The intrinsic properties of the substances used in each of the alternatives were investigated to identify those critical properties that would make them unsuitable for substituting $CrO_3$ on the basis of their harmonised or if any of their registered classification. Such properties are primarily Carcinogenic, Mutagen or Toxic for Reproduction (CMR) and Persistent, Bioaccumulative and Toxic (PBT) status (where applicable) and, secondarily, environmental classification (mainly for inorganics which cannot be PBT substances). The results of this analysis are summarized in table 8 below.

**Table 8: Hazard profile of substances associated with the 15 identified alternatives**

| Alternative | Chemical | | Classification | Conclusion |
|---|---|---|---|---|
| | Formula | EC number | | |
| Permanganate salts | $KMnO_4$ | 231-760-3 | Ox. Solid<br>Acute Tox. 4 (oral)<br>Aquatic Acute 1<br>Aquatic Chronic 1<br><br>Proposal by France to classify as Repr. 1B, H360Df | Acute hazards but also proposal for classification as CMR 1B<br>Environmental hazards<br><br>Not eligible to replace $CrO_3$ (due to hazard profile of $KMnO_4$) |
| | $H_2SO_4$ | 231-639-5 | Skin Corrosive 1A | |
| | $MnO_2$ | 215-202-6 | Acute Tox. 4 (oral)<br>Acute Tox. 4 (inhalation) | |
| | NaOH | 215-185-5 | Skin Corrosive 1A | |
| Pentavalent vanadium compounds | $Na_3VO_4$ | 237-287-9 | Acute Tox. 4 (oral)<br>Acute Tox. 4 (inhalation)<br>Acute Tox. 4 (dermal) | Only acute hazards<br><br>Suitable |
| | $H_2SO_4$ | 231-639-5 | Skin Corrosive 1A | |

| | | | | |
|---|---|---|---|---|
| $H_2SO_4$ continuous electrochemical colouring | $H_2SO_4$ | 231-639-5 | Skin Corrosive 1A | Only acute hazards<br><br>Suitable |
| $H_3PO_4$ | $H_3PO_4$ | 231-633-2 | Skin Corrosive 1B | Only acute hazards<br><br>Suitable |
| KOH | KOH | 215-181-3 | Acute Tox. 4 (oral)<br>Skin Corrosive 1A | Only acute hazards<br><br>Suitable |
| NaOH & $NaNO_3$ | NaOH | 215-185-5 | Skin Corrosive 1A | Only acute hazards<br><br>Suitable |
| | $NaNO_3$ | 231-554-3 | Ox. Solid 3<br>Eye irritant 2 | |
| Ionic liquids ($KNO_3$ & $NaNO_3$) | $KNO_3$ | 231-818-8 | Ox. Solid 3 | Only acute hazards<br><br>Suitable |
| | $NaNO_3$ | 231-554-3 | Ox. Solid 3<br>Eye irritant 2 | |
| Transitional metal compounds | | | Not classified | No identified hazards<br><br>Suitable |
| | | | Not classified | |
| Physical vapour deposition (titanium sputtering) | Ti | 231-142-3 | Not classified | No identified hazards<br><br>Suitable |
| Heat colouring (heat tint/thermal colouring) | Not applicable | | | |
| Laser induced colour marking | Not applicable | | | |
| Colouring with titanium complex fluorides and zirconium complex fluorides | $H_2TiF_6$ | 241-460-4 | Metal Corrosive 1<br>Acute tox. 3 (oral)<br>Acute tox. 3 (dermal)<br>Skin Corrosive 1B<br>Acute tox. 3 (inhalation) | Only acute hazards<br><br>Suitable |
| | $H_2ZrF_6$ | 234-666-0 | Metal Corrosive 1<br>Acute tox. 3 (oral)<br>Acute tox. 3 (dermal)<br>Skin Corrosive 1B<br>Acute tox. 3 (inhalation) | |
| Zirconisation™ | $HNO_3$ | 231-714-2 | Ox. Liquid 3<br>Skin Corrosive 1A | Only acute hazards<br><br>Suitable |
| | $CH_3SO_3H$ | 200-898-6 | Skin Corrosive 1B | |
| | $H_2TiF_6$ | 241-460-4 | Metal Corrosive 1<br>Acute tox. 3 (oral)<br>Acute tox. 3 (dermal)<br>Skin Corrosive 1B<br>Acute tox. 3 (inhalation) | |
| | $H_2ZrF_6$ | 234-666-0 | Metal Corrosive 1<br>Acute tox. 3 (oral)<br>Acute tox. 3 (dermal)<br>Skin Corrosive 1B<br>Acute tox. 3 (inhalation) | |
| Metallic coatings | Cu | 231-159-6 | Not Classified<br>Or | Acute hazards |

| | | | | |
|---|---|---|---|---|
| | | | Acute Tox. 4<br>Aquatic Acute 1<br>Aquatic Chronic 2<br>Or<br>Aquatic Acute 1<br>Aquatic Chronic 3 | Some environmental hazards<br><br>Suitable |
| | Sn | 231-141-8 | Not classified | |
| Thermal hardening | Not applicable | | | |

The assessment results summarized in the table above indicate that the chemical substances that would need to be used as alternatives to replace the INCO process are generally eligible as replacements for $CrO_3$ due to more benign hazard profiles, with the exception of potassium permanganate which has been proposed for harmonised classification as Repr 1B. A small number of the identified alternatives may pose some environmental risk, but generally no CMR Cat 1A or 1B are present.

Taking into consideration commercial availability and technical feasibility the applicant concluded that the only realistic alternative is Physical Vapour Deposition (titanium sputtering) and a more detailed assessment of risk reduction for this technology was conducted by the applicant including substances used and auxiliary processes. It is based on a more thorough analysis of chemicals and chemical processing aids involved in this alternative, on a description of their hazards based on classification and a short discussion of other possible risk factors.

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

☒ YES

☐ NO

☐ NOT APPLICABLE

Justification:

Focusing on the most realistic PVD alternative, the Applicant concluded that risks to human health and the environment would be lower with PVD compared to the INCO process. A SVHC is substituted by a range of materials with no repeated dose or systemic toxicity. Furthermore, acute health effects, such as corrosiveness and acute toxicity are limited. However, physico-chemical risks would become much higher, mainly due to the emission of flammable titanium dust, acetylene and the presence of oxygen gas. Other risks, such as asphyxiation and those associated with noise are also relevant to PVD and special attention to these by Rimex would be necessary.

**Conclusion**

Overall, RAC agrees that it appears that worker risks are lower with PVD, provided that sufficient measures are taken to prevent fires and explosions.

**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:

The applicant considered and assessed 8 alternative substances and 7 alternative technologies. The applicant concluded that neither of the considered alternatives were found to be suitable nor available before the sunset date. The main obstacle identified by the applicant is that none of the identified alternatives could replace Cr (VI) or the INCO CSS process or produce products that would meet the performance characteristics corresponding to the applicant's standards.

Although there are some uncertainties already pointed out in section 7.1 and 7.2, SEAC concurs with the applicant's conclusion that promising alternatives are in a very early stage of development and that the implementation of the best alternative identified requires further investment.

**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 cancer cases has been calculated using the excess risk value presented in section 6 and the estimation of the number of exposed people provided by the applicant. It reflects the expected statistical number of cancer case for an exposure over the working life of workers and entire life for general population.

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

**Table 9: Estimated additional statistical cancer cases**

| | Excess lung cancer risk | Number of exposed people | Estimated statistical cancer cases |
|---|---|---|---|
| **Workers, 40y exposure** | | | |
| Colouring line operator | $1.55 \times 10^{-3}$ | 15 | 0.023 |
| Packaging unit operator | $1.47 \times 10^{-4}$ | 6 | 0.001 |
| Maintenance | $1.49 \times 10^{-3}$ | 3 | 0.004 |
| Chemist | $9.17 \times 10^{-4}$ | 1 | 0.001 |
| Supervisor | $8.69 \times 10^{-4}$ | 1 | 0.001 |
| Plant Manager | $5.90 \times 10^{-4}$ | 1 | 0.001 |
| TOTAL - Workers | | | 0.031 |
| **General population exposed via environnement, 70y exposure** | | | |
| Local | $2.61 \times 10^{-05}$ | $1.15 \times 10^{6}$ | $2.61 \times 10^{-03}$ |
| Regional | $1.94 \times 10^{-09}$ | $2.00 \times 10^{7}$ | $3.88 \times 10^{-06}$ |
| TOTAL – General population | | | $2.61 \times 10^{-03}$ |

### Assessment of Impacts

When assessing the impacts the applicant has not considered impacts on human health due to exposure via the environment. The applicant presented the following arguments for this:

-all measured air samples in the vicinity of the plant are below the limit of quantification,
- the calculated Cr6+ concentration in regional drinking water is very low
-the Cr6+ reduction to Cr3+ is expected to occur the vast majority of environmental conditions
-people don't consume 100% of their food products from the immediate vicinity of a point source, the local assessment represents an unrealistic situation

| **Human health impact area** | **Parameter** | **Impacts under the applied for use scenario** |
|---|---|---|
| Workers health | Statistical excess number of cancer cases | $8.8 \times 10^{-3}$ |
| | Monetised human health costs (PV) | €33,071 (PV) |
| Exposure via the environment | Statistical excess number of cancer cases | Not considered |
| | Monetised human health costs (PV) | Not considered |

PV=present value

The impacts on environment and human health via the environment are projected by the applicant to be small. The applicant points out that the colouring of stainless steel is performed under closed systems from an environmental perspective as different waste water systems are applied to treat the waste water before discharge. The assessment of impacts is focused on the EU-based stakeholders, but as 50% of the company's CCS related turnover occurs outside of the EU this cannot be disregarded according to the applicant.

The assessment of impacts that has been undertaken by the applicant is based on the impacts occurring within the EU, both with concern to the plant in the UK as well as for Rimex's subsidiaries. It should be noted that the analytical timeframe considered in the applicant's analysis is based on a period of 10 years (10 years after the sunset date of 2017).

The economic impacts of the non-use scenario includes the profit from CSS sales, profit from non-CSS sales, R&D and exposure improvement expenditures, sunk investments, plant decommissioning and ground rehabilitation. According to the calculations of the applicant the difference between the applied for use and the non-use scenarios would according to the present value be within the range of €1-10 million (the total capital investment costs).

Under the non-use scenario the applicant would avoid costs for exposure improvement and the investment costs that a transition to PVD would involve. These include the capital investment costs for installation of the new PVD lines including the R&D costs, the costs for new effluent treatment plants, the costs for one year of downtime as well as the overall costs of loan interest. The sunk investments calculated by the applicant are <€1 million.

**Costs of continued use (HH)**

In the applied for use scenario the assessment period applied is 10 years. A discount factor of 4% has been used with the start of FY 2017-2018 as the starting point for discounting. In the SEA the applicant has monetised the costs to human health based on health impacts for workers from the continued use of chromium trioxide. According to the applicants calculations, over the 10 year period during which chromium trioxide would continue to be used in the manufacture of CSS, $7.74 \times 10^{-3}$ statistical excess fatal cancer cases and $1.04 \times 10^{-3}$ non-fatal cases might arise. The monetised health costs from a continued use would according to the applicant be about €33,000 over 10 years (Present Value, discounted at 4%) or about €3,900 per year.

As the human exposure to Cr6+ is currently very well controlled a refused authorisation would according to the applicant only bring small benefits to EU workers' health. The applicant therefore concludes that the cost to human health within the EU from a continued use of chromium trioxide is predicted to be small.

Some of the uncertainties of importance for the impacts on human health identified by the applicant are the actual production volumes and the Enfield plant capacity as well as the employment levels and employment information and exposure concentrations.

The applicant has monitored workers' exposure to chromates. The result has been described in detail in the provided CSR. The monitoring includes air (static monitoring), inhalation exposure monitoring, biomonitoring of workers and monitoring using a new method for the preparation of the CSR. The CSR provides risk estimates for each type of worker and are based on the exposure mortality risk relationship (ERR) derived by ECHA (2013).

In its assessment the applicant has included the costs for cancer treatment.

The quantitative analysis of the costs of continued use is based on a human health impact assessment that use an approach that is based on linking quantitative relationships between exposure and the health impact of interest. This general procedure is considered to be an appropriate methodological approach. In this respect, the applicant makes use of the linear exposure-response relation for lung and intestinal cancer as a result of exposure to Cr(VI) compounds, as estimated by and in accordance with the related ECHA paper (ECHA 2013). The quantitative health impact assessment thus estimates the number of excess cases of lung cancer and intestinal cancer as a result of the continued exposure to Cr (VI) under the continued use scenario. Since the ECHA exposure-response relationships are defined in terms of fatal risks only, the applicant also develops estimates of the number of cases of non-fatal cancer, based on the fatality and survival rate derived for the UK from the GLOBOCAN 2012 database.

It should be noted that the exposure response relationships are based on an exposure time period of 40 years, and hence the applicant treats exposures as linear over time in order to derive annual cases to take into account only the time frame of 10 years. SEAC considers such an approach appropriate and consistent with existing practice in authorisation applications.

For exposures related to 'Man via Environment', the number of cases of excess lung cancer has been estimated but were considered by the applicant as overly conservative and thus it would be inappropriate to consider it as a cost but it was taken into account in the sensitivity analysis.

Concerning the estimation of economic welfare losses associated with this number of excess lung and intestinal cancer cases, the applicant assess the 'human' welfare losses associated with morbidity and mortality. The valuation of morbidity and mortality effects follows the ECHA guidance on SEA. SEAC finds the specific approach and assumptions used to derive the health costs transparent and based on standard assessment practices, such that the estimates derived are robust and valid.

In the worst case estimates also calculated by the applicant the costs to human health including both workers and human via the environment is estimated at about €122,000 (PV over 10 years). SEAC recognises that the benefits of continued use of chromium trioxide would outweigh the costs to human health and would be within the range of 100-1,000 also with the worst-case estimates.

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

The applicant has considered three different non-use scenarios:

1) A closure of the CSS production lines in the UK and exit from the CSS market:
(1a) A closure of the CSS lines and simultaneous closure of the other UK based production lines or
(1b) a closure of the CSS lines and continuation of the other UK based lines
2) A relocation of the CSS production lines to a country outside the EU and continuation of the use of chromium trioxide
3) A switch of the CSS business to importing and trading third-party-made PVD CSS from

Asia while gradually converting the production in the UK to a PVD technology.

In the assessment of non-use scenario, the applicant also takes into account the possibility of its EU-based competitors obtaining or not obtaining an authorisation. As the CSS lines are the most profitable in the Rimex Metals (UK´s) operations, the non-use scenario 1a - a closure of the CSS lines and simultaneously a closure of the other UK based production lines - is concluded by the applicant to be the most realistic non-use scenario. Resulting in a closure of all manufacturing operations at the UK site.

The most likely non-use scenario would be to close the entire UK manufacturing plant as its operations would be unprofitable. This would also bring negative impacts on the profitability of the Rimex's subsidiaries due to their dependency on supply from the Rimex Metal Enfield plant in the UK.

SEAC likes to point out that scenario 3 is an unrealistic scenario for Rimex Metals because the sale of PVD products is not as profitable as the sale of the INCO CSS products. The economic impact of these lost profits will be expressed as net losses for all operations. This situation would become unsustainable in the medium term and the result would be the shutdown of the company like in scenario 1.

In the continued use scenario the application would continue manufacturing to the same extent the whole range of CSS products that would be sold both to the EU market and outside of the EU. This would bring a €1-10 million in annual net profit for Rimex Metals UK.

The social impacts of the non-use scenario are estimated in terms of employment impacts indicating that the 90-94 employees would lose their jobs. Other impacts assessed are the redundancy costs, an average service length of 7.8 years, a higher proportion of the workers having lower or middle level education (secondary or vocational education) whilst a smaller number of the workers having higher education (tertiary or university education).

When assessing the social impacts the applicant both include an assessment of the employment under the applied for use scenario and the employment impacts under the non-use scenario. It is assumed that the number of employees would be the same over the review period in the applied for use scenario. In the non-use scenario a total of 90- 94 employees are assumed to lose their jobs. The applicant also presents confidential information on the unemployment impact on Rimex subsidiaries and companies outside the EU. The expected total redundancy costs for all current employees is confidential but would be <€1 million. The redundancy costs for subsidiaries have not been calculated.

The wider economic impacts considered by the applicant are impacts with regard to trade and competition both within and outside of the EU. The applicant also considers the distributional impacts among stakeholders.

The applicant's assessment of the different non-use scenarios is very thorough and plausible. SEAC finds the arguments to justify that the closure of the Rimex's CSS production lines simultaneously as a closure of the other production lines is the most credible option for the application if an authorisation would not be granted. No technically or economically feasible alternatives would be available to the company by the sunset date. Furthermore the confidential calculations presented by the applicant shows that the net profit of the entire operation is dependent on the profit made from the sales of the INCO CSS. SEAC considers the non-use scenario, which assumes a permanent closure of

Rimex (UK) plant to be justified and most appropriate for assessing the socioeconomic impacts.

The applicant's estimates of economic costs are reasonable although the non-confidential ranges presented are quite broad. The applicant has used correct procedures for discounting. The confidential calculations presented by the applicant are furthermore transparent and clear.

In the calculations of social impacts the applicant presents somewhat different numbers for the employees (90 people working at the UK plant of which 5 are temporary workers, and in another part of the application the number for employees mentioned is 94. The employment levels and employment information is also identified by the application as one of the uncertainties. ) These differences do however still result in a high number of unemployment locally. The assessment of possibilities for re-employment for redundant employees has also been assessed by the applicant.  SEAC recognises that some of these employees would be able to find other jobs within the London region and consider that the assumed unemployment impacts could have been somewhat overestimated by the applicant. The applicant has not identified and does not expect any impact on employment levels on other stakeholders. SEAC however finds the assessment to show that a non-use scenario would bring important negative social impacts in terms of unemployment locally.

When comparing the benefits and costs for a granted authorisation or a continued use the applicant used 2014 as the year that present values (discounted at 4 %) for the period 2017-2026 are calculated. The economic benefits from a granted authorisation include the avoided loss of net profit for Rimex Metals (UK) as well as for the remaining Rimex group companies. Benefits to suppliers exist but are small and have not been taken into account. Over a period of 10 years from the sunset date the benefits to Rimex Metals (UK) would be within the range of €0-1 million per year (discounted at 4%) and for Rimex's subsidiaries within a range of €10-100 million per year (discounted at 4%). The ratio of benefits over costs is according to the applicants calculations between the ranges of 100-1,000.

**SEAC conclusion**

The confidential information and answers provided by the applicant to the questions from SEAC are clear and transparent. The assumptions and calculations made to arrive at the B/C ratio are furthermore clearly stated and plausible.

The applicant has conservatively  assumed that if the total cost to human health would rise to €122,000 over 10 years or €14,400 per year, reducing the ratio of benefits over costs, the range would still be somewhere between 100-1,000.  SEAC also finds it plausible that the B/C ratio would persist throughout the entire review period of 10 years applied for.

SEAC finds the uncertainties identified by the applicant to be clearly described.

SEAC considers the conclusion of the applicant that the benefits outweigh the costs of continued use to be justified.

**9. Do you propose additional conditions or monitoring arrangements**

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation:

Based on exposure control considerations, the Applicant must implement regular campaigns of occupational exposure relating to the use of Cr(VI) described in this application. These monitoring campaigns must be based on relevant standard methodologies or protocols and ensure a sufficiently low detection limit. They shall comprise both personal and static inhalation exposure sampling and be representative of the range of tasks with possible exposure to Cr(VI) and of the total number of workers that are potentially exposed. The results of the monitoring must be included in any subsequent authorisation review report submitted.

Emissions of Cr(VI) to ambient air shall be subject to regular measurement with the results of monitoring made available to enforcement bodies on request. Measurement campaigns shall be undertaken according to standard sampling and analytical methods, where appropriate. Emissions data shall be presented in any subsequent review report.

Risk management measures (RMMs) to reduce exposure of workers and emissions to the environment from the local exhaust ventilation and roof fans must be assessed and the most appropriate RMM applied.

The information gathered in the monitoring campaigns shall be used by the applicant to review the RMMs and operational conditions to further reduce workers' exposure to Cr(VI) as well to as Cr(VI) emissions to ambient air.

The outcomes and conclusions of this review including those related to the implementation of any additional RMMs must be documented.

The results of the monitoring and of the review of the OCs and RMMs must be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted.

Justification:

The available monitoring dataset is considered by RAC to be relatively small and limited in time, which introduces some degree of uncertainty to the exposure and emission assessment. In addition, a significantly higher exposure has been measured in the single personal sample that has been performed on a chemist (involving many tasks also performed by maintenance workers), which adds to the uncertainty and supports the need for additional personal sampling. The proposed conditions and monitoring arrangements should address these uncertainties with a view to reducing exposures.

RAC notes that RMMs are not applied evenly across the colouring lines and tanks and further reduction of exposure and emissions is possible. Handling of solid chromium trioxide flakes and protection from dust exposure rely heavily on RPE, in particular during the initial phase of decanting (WCS1) and RAC considers that additional ways to control exposure for this specific operation must be considered. In addition, RAC considers that RMMs are required to control emissions to the air from the LEV/roof fans.

RAC recognises that additional measures for improvement of RMMs are already being considered by the applicant (the improvement of general ventilation and a dividing curtain between packaging and production areas (planned for 2016 and including, the installation of internal pumps on the remaining tanks of line 2 and 3 which are currently air-agitated, the wider implementation of LEV, improved use of mist suppressants). Implementation of the additional RMMs considering also reduction of exposure due to handling of solid chromium trioxide and control of emissions to the air is considered essential by RAC. Implementation shall be documented.

**10. Proposed review period:**

☐ Normal (7 years)

☐ Long (12 years)

☐ Short (... _years)

☒ Other: 10 years

<u>Justification</u>:

The applicant has applied for a 10 year long review period in order to change from INCO CSS process to a PVD CSS process. The applicants main arguments for a longer review period (10 years, i.e. to 21 September 2027) are the following:

- $CrO_3$ is used as a process chemical in relatively small quantities under well controlled conditions. The current consumption at the lower end of the 10-100 t/y tonnage range will remain during the 10 year review period.
- $Cr^{6+}$ is not present in the final INCO CSS product
- Residual risks to workers and EU citizens are very low by virtue of low exposures, the low number of exposed workers, and well-controlled releases to the environment.
- Feasible alternatives are not available at present and the most promising technology (PVD) faces significant technical challenges (the range of available colours is smaller than INCO CSS. The cost of conversion is high, but the company is willing to invest. Should the planned R&D resolve the known technical issues and demonstrates that PVD CSS can be sold at a price that allows the continued profitability of Rimex Metals (UK)'s operations
- In 2011 the Enfield plant acquired and installed a new INCO manufacturing line. The line has a minimum lifetime of 20 years and the plant itself is capable of operating under the current CrO3- dependent process for several decades.
- A longer than normal review period would allow Rimex to recoup the cost of that investment. In addition, in 2015, Rimex upgraded Line 1.

**RAC's advice:**

RAC has not provided any specific advice on the length of the review period as the uncertainties in the exposure assessment identified by RAC are low and there is no major concern on OC/RMM applied (some improvement of RMM in place is needed, some residual uncertainties on exposure assessment mainly because of the small number of measurements available). The uncertainties identified by RAC resulted in a proposal to request continued monitoring and for implementation of additional RMM by applicant with a specific focus on points of concern as can be read in section 9.

**Other socio economic considerations**

When assessing the requested review period SEAC took note of the following considerations presented by the applicant:

- The level of risk associated with the continued use are relatively low, alongside the corresponding negligible costs for the applicant of continued use of chromium trioxide.
- There are no alternatives that are technically and economically feasible to be implement by the sunset date.
- The applicant has been proactive in undertaking research to develop an alternative. There is no indication that success is expected or will be achieved within a short timeline, though the applicant is committed to continuing the R&D efforts to search for alternative substances while developing the PVD technology.
- The applicant's investment cycle is very long. In 2011 the Enfield plant acquired and installed a new INCO manufacturing line and in 2015, Rimex upgraded Line 1. The lines have a minimum lifetime of 20 years and the plant itself is capable of operating under the current $CrO_3$- dependent process for several decades. A longer than normal review period would allow Rimex to recoup the cost of this investment.
- The development and implementation of a new technology could be expected to take some years. Even if an alternative substance of equivalent performance was to become available, it would probably take time to industrialise the production process for large scale manufacturing of final products.
- The applicant presents a detailed plan of R&D activities and investment aiming for the eventual overcoming of PVD CSS products deficiencies; for the implementation of three PVD colouring lines; and for the removing of the current INCO CSS lines. This significant investment is currently on hold pending a decision on authorization because it needs to be supported by maintaining the INCO CSS, and so the use of Cr (VI), until the installation of the last PVD line. Whilst this does not necessarily indicate a long investment cycle the applicant states that a reduced review period would lead to a questioning of the feasibility of that investment.
- The remaining risks are relatively low and the socio-economic benefits are high, and there is clear evidence that this situation in not likely to change during the review period.

When assessing the review period SEAC found that none of the criteria for a short review period were fulfilled.

A normal review period is considered normally sufficient for the authorisation holder to[2]:

- Take benefit from technical progress and carry out Scientific Research and Development activities in order to find and deploy technically and economically feasible alternatives, taking into account the interlinks and complexities in the supply chain,

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

- Continue actively looking for alternatives but not too long.

SEAC found the considerations listed above to be met for this application. The applicant has showed that the company would benefit from technical progress and further research and development. SEAC therefore finds justifications to allow the applicant to continue searching for substitutes.

**SEAC conclusion**

The applicant has provided confidential information on the progress in research since November 2015. This information shows that one alternative substance has distinct possibilities but that the coatings are not robust enough, neither durable nor permanent and that this substance will not be a simple drop in substitute. There is therefore a further need to develop the process. The time required for plant conversion to the PVD technology, including time to undertake science development and research, setting up and conduction tests in a pilot plant, seems credible.

Although it is difficult to assess the longer time perspective for developing suitable alternatives SEAC considers that realistic prospects for substitution will not be possible within the timelines for a short or normal review period. The applicant is not the owner of the relevant technologies and therefore dependent on their development and the cooperation with the suppliers of the technology and chemicals. Based on this assessment SEAC finds a 10 year review period to be justified.

**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**

**<u>Justification</u>:**

Applicant did not provide comments to the draft final opinion.