Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Industrial use of a mixture of chromium trioxide for the hard chromium plating of military armament steels parts which are thermomechanically stressed and in contact with oxidizing gas at high temperature, so as to ensure a thermal barrier with high melting point, resistance to wear and oxidation associated with weapons as well as resistance to impact and atmospheric corrosion

ECHA/RAC/SEAC: Opinion N° AFA-O-0000006510-83-05/F

Consolidated version

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:

Industrial use of a mixture of chromium trioxide for the hard chromium plating of military armament steels parts which are thermomechanically stressed and in contact with oxidizing gas at high temperature, so as to ensure a thermal barrier with high melting point, resistance to wear and oxidation associated with weapons as well as resistance to impact and atmospheric corrosion

Intrinsic property referred to in Annex XIV:

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

Applicant:

Nexter Mechanics

Reference number:

11-2120106012-82-0000

Rapporteur, appointed by the RAC: **Lina DUNAUSKIENĖ**
Co-rapporteur, appointed by the RAC: **Susana VIEGAS**

Rapporteur, appointed by the SEAC: **Stavros GEORGIOU**
Co-rapporteur, appointed by the SEAC: **Janez FURLAN**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On **23/11/2015 Nexter Mechanics** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **01/02/2016** 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 they 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.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

The following conditions and monitoring arrangements are recommended in case the authorisation is granted:

Additional conditions and monitoring arrangements for the authorisation:

The applicant must implement regular measurement campaigns for occupational exposure assessment (sampling at least annually) relating to the use of Cr(VI) as described in the application. They shall comprise both personal and stationary inhalation exposure measurements 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. Measurement campaigns shall be undertaken according to standard sampling and analytical methods, where appropriate. The results of the monitoring must be included in any subsequent authorisation review report submitted.

The information gathered in the monitoring campaigns shall be used by the applicant to review the risk management measures (RMMs) and operational conditions in order to further reduce workers' exposure to Cr(VI), including a review of the feasibility of implementing general mechanical ventilation in the plating shop and exploring alternative ways of working (including improved access control) that would not require armament parts to be assembled and dismantled in the plating shop. 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 retained, be made available to national enforcement authorities on request and included in any subsequent review report submitted.

The effectiveness of the current LEV equipment should be ensured by implementing appropriate preventative maintenance programmes.

Emissions of Cr(VI) to air shall be subject to regular measurements 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.

REVIEW

Taking into account the information provided in the application for authorisation prepared by the applicant and the comments received on the broad information on use(s) the duration of the review period for the use is recommended to be **12 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):

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 Final).

3. Hazard assessment. Are appropriate reference values used?

Justification:

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

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.

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.

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.

In the socio-economic analysis (SEA) the remaining human health risks are evaluated

based on the dose-response relationship for carcinogenicity of hexavalent chromium (RAC27/2013/06 Rev.1 agreed at RAC-27).

Are all appropriate and relevant endpoints addressed in the application?

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

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

Description:

Short description of the use

Nexter Mechanics is a downstream user of Cr(VI).

This application for authorisation relates to the use of chromic acids for the hard chromium plating of military armament steels parts. Hard chromium plating is needed to protect military armament steel parts which, while in use, are thermo-mechanically stressed and in contact with oxidizing gas at high temperature. Chromium coating provides a barrier with high melting point, resistance to wear and oxidation as well as resistance to impact and atmospheric corrosion.

The tasks are conducted at the Nexter Mechanics' site in Tulle, France. The applicant estimated the maximum annual tonnage that could be required over the requested review period based on use during previous years (2012, 2013 and 2014) and considerations of the production capacity in the plating shop. The maximum tonnage of chromium trioxide for this use is estimated to be 0.25 tonnes per year (0.5 tonne for the hard chromium plating described in use 1 and 2, with 50% assigned to each use). A maximum of 0.3 tonnes per year is estimated for use 3.

Cr(VI) application is by immersion/ dipping of the part in a series of tanks containing solutions; the systems are open. It is a "wet-in-wet" process, without intermediate storage of products at any time in the process chain. The assembling and dismantling of parts takes place nearby the main daily tasks performed in the plating shop, i.e. addition of hexavalent chromium into the baths and the dipping and flushing of armament parts. The sampling of chromium baths, in order to control the Cr(VI) concentration, is also performed in the same area.

It is important to recognise that the final chromium coating does not contain chromium trioxide or any other Cr(VI) substance. During the electroplating process the Cr(VI) is transformed into Cr(0) and any Cr(VI) remaining on the surface of the article is removed by rinsing. Therefore, no Cr(VI) is present in the finished articles, which are further assembled into military equipment and not used by consumers.

According to the applicant, the exposure scenario describes 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 nine Worker Contributing Scenarios (WCSs) and one Environmental Contributing Scenario (ECS).

Worker exposure

Table 1: Summary of Worker Contributing Scenarios

Contributing ES	Brief Description	RMMs
WCS 2 Sampling of bath (PROC 8a)	*Sampling is performed with a flask attached to a rod, which is dipped into the bath.* *1 operator involved in sampling.* *Primary emission source is at arm's length.* *The weight fraction of Cr(VI) can vary but it does not exceed 40%.* *Sample size: less than 100ml per operation.* *Flow of transfer <0.1 l/min.* *Size of the work area is ~ 800 m^3* *Exposure duration: frequency: 4 per week; duration: 2 min*	-Technical: Good natural ventilation; Fixed capturing hood; -Organisational: General housekeeping practices in place; Manipulation performed by a dedicated, trained operator; -PPE: Half mask with P3 filter (EN 143 – APF 10); Nitrile protective gloves with breakthrough time >480 min (EN 374); Protective clothes (EN 13034 Type 6).
WCS 3 Titration of the hexavalent chromium (PROC 15) (*analysis*)	*Titration is performed in a laboratory vessel with open surface of approximately 15 cm^2 (0.0015 m^2) maximum.* *1 operator involved in titration.* *Primary emission source proximity is at arm's length.* *The weight fraction of hexavalent chromium compound can vary but does not exceed 40%, and it is dissolved in lab reagents.* *Sample size: Less than 100ml per operation.* *Open surface <0.1 m^2.* *Size of the work area is ~ 224 m^3 (8×7×4m).* *Exposure duration: frequency: weekly period, 12 per week + 8 per month; duration: 3 min per titration*	-Technical: fume cupboard; -Organisational: General housekeeping practices in place; Manipulation performed by a dedicated operator; - PPE: Half mask with P3 filter (EN 143 – APF 10); Nitrile protective gloves with breakthrough time >480 min (EN 374); Protective clothes (EN 13034 Type 6).
WCS 5 Addition of solid hexavalent chromium in bath (PROC 8a)	*1 worker per operation (maximum of 5 workers involved).* *Primary emission source proximity is at arm's length.* *Activity variable, performed in order to adjust the concentration of the bath which does not exceed 40% (w/w) and the total use does not exceed 0.5 ton per year. Open process.* *Drop height < 0.5 m.* *Size of the work area is ~ 800 m^3.* *Exposure duration: frequency: - addition after drain of tank: once a year; - addition to supplement the routine use: monthly; duration: - addition after drain of tank: 60 min; - addition to supplement the*	-Technical: Good natural ventilation; Local exhaust ventilation fixed on the lip of the bath; -Organisational: General housekeeping practices in place; trained workers; - PPE: Half mask with P3 filter (EN 143 – APF 10); Nitrile protective gloves with breakthrough time >480 min (EN 374); Protective clothes (EN 13034 Type 6).

	routine use: 30min.	
WCS 6 Dipping armament parts in baths treatment (PROC 13)	*Maximum of 5 workers involved.* *Primary emission source proximity is at arm's length.* *The concentration of baths is maintained at a substantial level (10-50%).* *Open surface ~ 0.7 to 1.5 m².* *Size of the work area is ~ 800 m³.* *Exposure duration: frequency: every day; duration : 40 min.*	-Technical: Good natural ventilation; Local exhaust ventilation fixed on the lip of the bath; -Organisational: General housekeeping practices in place; trained workers; -PPE: PPE: Half mask with P3 filter (EN 143 – APF 10); Nitrile protective gloves with breakthrough time >480 min (EN 374); Protective clothes (EN 13034 Type 6).
WCS 7 Flushing of the armament part (PROC 8a)	*Water is used for rinsing contaminated surfaces of armament parts. Rinsing water flows along the armament part and then falls in the bath. Open process. The concentration in the rinsed liquid very low (0.5-1%).* *Maximum of 5 workers involved.* *Primary emission source is at arm's length.* *Open surface ~ 0.7 to 1.5 m².* *Size of the work area is ~ 800 m³.* *Exposure duration: frequency: - daily; duration: 2 min.*	-Technical: Good natural ventilation; -Organisational: General housekeeping practices in place; trained workers; Flow of liquid: 1 – 10 l/min; - PPE: Half mask with P3 filter (EN 143 – APF 10); Nitrile protective gloves with breakthrough time >480 min (EN 374); Protective clothes (EN 13034 Type 6).
WCS 8 Dipping armament parts in rinsing baths (PROC 13)	*The concentration in the rinsing bath is very low (0.5-1%).* *Maximum of 5 workers involved.* *Open surface ~ 0.7 to 1.5 m².* *Size of the work area is ~ 800 m³.* *Exposure duration: frequency: every day; duration : 30 min.*	-Technical: Good natural ventilation. -Organisational: General housekeeping practices in place; trained workers; - PPE: Half mask with P3 filter (EN 143 – APF 10); Nitrile protective gloves with breakthrough time >480 min (EN 374); Protective clothes (EN 13034 Type 6).
WCS 9 Dipping armament parts in baths treatment, in the workers' far field (PROC 13)	*Maximum of 5 workers involved.* *The weight fraction of Cr(VI) in the bath can vary but it cannot exceed 40%.* *Open surface ~ 0.7 to 1.5 m².* *Size of the work area is ~ 800 m³.* *Exposure duration: frequency: - daily; duration: 420 min.*	-Technical: Good natural ventilation; Local exhaust ventilation fixed on the bath. -Organisational: General housekeeping practices in place; trained workers; - PPE: Half mask with P3 filter (EN 143 – APF 10); Nitrile protective gloves with breakthrough time >480 min (EN 374); Protective clothes (EN 13034 Type 6).
WCS 10 Cleaning of the waste collector pit (PROC 10)	*Cr(VI) concentration extremely small (representing 0.1-0.5% of the water spread).* *1 worker per operation (maximum of 5 workers involved).* *Activity in a small workroom with air exchange with the plating shop through the duckboard.* *Exposure duration: frequency: 2 per year; duration: 120 min.*	-Technical: No restriction on natural ventilation. -Organisational: General housekeeping practices in place; trained workers; - PPE: Half mask with P3 filter (EN 143 – APF 10); Nitrile protective gloves with breakthrough time >480 min (EN 374); Protective clothes (EN 13034 Type 6).

Note 1: The applicant states that workers are skilled operators receiving regular training with regard to chemical risk management and proper use of personal protective equipment.
Note 2: Monitoring measurement will be performed yearly to validate the exposure estimated in this CSR.
Note 3: Table compiled by RAC with information from the application.

According to the information provided by the applicant in the CSR, the overall number of workers that could be directly exposed to Cr(VI) at the workplace via the inhalation route and/or via the dermal route is 6 (1 laboratory worker and 5 workers in the plating shop).

Methodology used by the applicant

Worker exposure

Inhalation exposure:

For inhalation exposure assessment the applicant uses a combination of modelling data (ART model, version 1.5) and air monitoring data (stationary measurements). Input parameters were provided for the ART modelling of each of the WCS. In response to a query from RAC, the applicant confirmed that estimated exposure concentrations derived from ART were reported directly, without any further amendment to express exposures on the basis of Cr(VI). Measured exposure data are expressed as Cr(VI) concentration.

The approach used by the applicant to determine the inhalation exposure levels is as follows: for each of the activities, the exposure levels were modelled (90^{th} percentile for inhalation exposure), all exposure levels of the different activities per specific worker were aggregated to arrive at a total exposure for each worker, including all their activities of the day.

The applicant claims that the inputs used for the modelling cannot be strictly representative of the actual situation performed on site. They state that the inputs for each contributing scenario were chosen in order not to underestimate exposure. Furthermore, the duration and frequency of tasks were considered by taking into account the maximum possible increase of activity, in accordance with the tonnage estimations. The applicant suggests that the chosen task frequencies most probably do not reflect the exact frequency and duration of tasks. However, they consider that the frequency and duration of tasks presented represent realistic maximum estimates, in order to cover for potential future activities.

The applicant presented stationary measurement data that was obtained during the most recent measurement campaign undertaken in 2015. During this campaign the ambient air concentration in the plating shop was measured in four different places and one measurement was performed directly above a chromium bath (measurement reports were provided by the applicant). The applicant states that measurements taken before 2015 were performed using a methodology that was not sufficiently sensitive to measure ambient concentration in the range of $\mu g/m^3$. Therefore, the applicant considered that these earlier measurements were not suitable for risk assessment (due to the high detection limits) and did not use them in their application.

The applicant considered that the measurement from above the chromium plating bath could be taken as the maximum exposure (0.25 $\mu g/m^3$) that a worker could be subject to when they are located next to the chromium bath, such as when performing WCS 2 and 6. The applicant notes that this exposure concentration is lower than any of

modelled exposure values for the tasks performed near to chromium baths.

The applicant then compared measured ambient air concentrations with modelled data for WCS 9 (far field exposure). The modelled results (90th percentile for inhalation exposure) indicate an exposure level of 0.18 µg/m^3 (without RPE) assuming that a worker would perform far-field activity for a maximum of 420 minutes per day. The four available stationary measurements range from 0.09 to 0.12 µg/m^3 Cr(VI) and result in an average exposure concentration of 0.103 µg/m^3 Cr(VI).

The applicant notes that measured exposures for both far-field tasks and tasks occurring adjacent to plating baths were lower than the corresponding modelled exposure estimates and therefore consider that modelled exposure estimates would result in a more conservative assessment of workplace exposure. Therefore the applicant based their exposure and risk characterisation solely on modelled data, corroborated by the available measurement data. RAC considers that the modelled and measured estimates of exposure appear reliable and are in good agreement, but would have preferred that the applicant's exposure assessment for all WCS had been based on representative measured exposure data, as this would have resulted in fewer uncertainties.

Exposure and risks were estimated per individual WCS and also after considering combined exposure of workers across different WCS. It should be noted that the applicant chose to use an APF of 10 for the RPE (based on the recommendation of INRS, Institut National de Recherche at de Sécurité). RAC notes that an APF of 10 used in France is less than the APF values applied in some other EU Member States (e.g. APF 20-30, observed in UK, Germany and Italy).

Table 2 provides a summary of the duration and frequency of all tasks taking part in the plating shop, irrespective of if they occur for Use 1, Use 2 or Use 3. The adjusted exposure estimates provided are specific to Use 1 and are per individual worker and have corrected based on the relative tonnage of Cr(VI) used across uses 1, 2 and 3, unless otherwise stated in the table.

Table 2: Duration and frequency of tasks and estimated exposure concentrations

Contributing scenario	**Duration and frequency of exposure**	**ART modelling (90th percentile), 8 hr TWA** ***[Stationary measurements]*** **(all µg/m^3)**	**Exposure adjusted for frequency of task (per year without RPE)** **(µg/m^3)**	**Exposure adjusted for frequency of task (per year with RPE APF = 10)** **(µg/m^3)**
WCS 2* Sampling of bath (PROC 8a)	2 min/day 4/week	0.87	1.09×10^{-3}	1.09×10^{-4}
WCS 3* Titration of the hexavalent chromium (PROC 15)	3 min/day 12/week + 8/month = 56 per	0.11	7.31×10^{-4}	7.31×10^{-5}

	month			
WCS 5 Addition of solid hexavalent chromium in bath (PROC 8a)	*After drain:* 60 min/day 3 baths per year *Routine supplement* 30 min/ day 1/month/ bath (3 hard chromium baths) = 12 x 3/year)	19	2.02×10^{-2}	2.02×10^{-3}
WCS 6 Dipping armament parts in baths treatment (PROC 13)	40 min/ day 5 workers, daily 44 weeks/year	0.86	2.24×10^{-2}	2.24×10^{-3}
WCS 7 Flushing of the armament part (PROC 8a)	2 min/ day 5 workers, daily 44 weeks/year	20	2.60×10^{-2}	2.60×10^{-3}
WCS 8 Dipping armament parts in rinsing baths (PROC 13)	30 min/ day 5 workers, daily 44 weeks/year	0.4	7.81×10^{-3}	7.81×10^{-4}
WCS 9 Dipping armament parts in baths treatment, in the workers' far field (PROC 13)	420 min/day 5 workers, daily 44 weeks/year	0.18 *[0.11, 0.12, 0.09, 0.09]*	4.92×10^{-2}	4.92×10^{-3}
WCS 10 Cleaning of the waste collector pit (PROC 10)	120 min/day 2 times /year	23	3.27×10^{-3}	3.27×10^{-4}

* 3 out of 4 baths in the plating shop are dedicated to use 1 and use 2, which means that the frequencies are adjusted to 3/4. The remaining frequencies are evenly distributed between both uses (50% for Use 1 and 50% for Use 2). The frequencies noted above are thus adjusted by a factor of 3/8 for Use 1.

After the Trialogue the applicant informed RAC that biomonitoring had not been carried out at the of Tulle site since 2012 but provided reassurance that biomonitoring will be reinstated by the occupational doctor. The applicant was not able to obtain the historical biomonitoring data requested by RAC due to medical confidentiality reasons. However, the applicant assured RAC that Nexter Mechanics has never received any occupational doctors' alert or information on particularly high exposures or any alarming trends.

RAC acknowledges that the interpretation of biomonitoring data for chromium can be complex, but considers that biomonitoring data remains an important source of information for a risk assessment, particularly in terms of monitoring trends over time. As such, RAC would welcome suitably anonymised biomonitoring data in a review report for this use.

Dermal exposure:

The applicant has not assessed dermal exposure, in accordance with 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).

Combined exposure

The applicant reports combined exposure for the different types of workers. This is done by adding up the time weighted exposure levels of the different tasks for a specific type of worker. It is reported in the CSR which tasks (WCS) a specific type of worker has to perform. The laboratory worker performs tasks associated with WCS 2 and 3. The main worker performs tasks associated with WCS 5, 6, 7, 8, 9 and 10.

Table 3: Calculated combined exposure levels for each of the different types of workers

	Calculated combined exposures (µg / m³) per year	
Function	**Without RPE**	**With RPE (APF = 10)**
Main worker WCS 5, 6, 7, 8, 9 and 10	1.29×10^{-1}	1.29×10^{-2}
Laboratory worker WCS 2 and 3	1.82×10^{-3}	1.82×10^{-4}

The highest exposure is observed for *Main worker* and is 0.129 µg/m³ and 0.0129 µg/m³ without and with RPE respectively.

It should be noted that the laboratory worker who performs the sampling and titration of the chromium baths in Use 1 is the same laboratory worker who performs the same tasks for the Uses 2, 3 and 4 at the site of Tulle. Consequently, this laboratory worker is subject to combined exposure for all these tasks.

Table 4: Calculated combined exposure levels for laboratory worker for Uses 1, 2, 3 and 4 at the site of Tulle.

	Calculated combined exposure (µg/m³) per one year	
Laboratory worker (at the site of Tulle)	**Without RPE**	**With RPE (APF = 10)**
Use 1: hard chromium plating of military armament steels parts which are thermomechanically stressed and in contact with oxidizing gas at high temperature, so as to ensure a thermal barrier with high melting point, resistance to wear and oxidation associated with weapons as well as resistance to impact and atmospheric corrosion	1.82×10^{-3}	1.82×10^{-4}
Use 2: hard chromium plating of military armament parts in order to ensure surface hardness, resistance to atmospheric corrosion, abrasive wear resistance and friction coefficient for parts in relative movement	1.82×10^{-3}	1.82×10^{-4}
Use 3: use of a mixture of chromium trioxide for the black colour hard chromium plating of exterior surface of steel weapon barrel designed for military use, to ensure, during the whole gun barrel service life, stealth, erosion, corrosion and high temperature resistances in the condition of uses	1.21×10^{-3}	1.21×10^{-4}
Use 4: use, of a qualified mixture of chromium trioxide by immersion for the chromate conversion coating of welded mechanical structures of armoured vehicles and associated parts made of high mechanical properties aluminium alloys for military use, and requiring a maintained electrical conductivity after severe climatic environments, atmospheric corrosion resistance and paint adhesion.	1.86×10^{-4}	1.86×10^{-4}
Total	$\boldsymbol{5.04 \times 10^{-3}}$	$\boldsymbol{6.71 \times 10^{-4}}$

RAC notes that laboratory analysis, for the purposes of quality control, are exempted from authorisation However, sampling is still an authorised activity.

Uncertainties related to the exposure assessment:

RAC notes that a total of five stationary measurements were available from five separate locations in the plating shop. RAC considers that the representativeness of the stationary measurements provided by the applicant is limited as they are from a single sampling campaign. Further measurements are needed to verify the modelled exposure estimates and justify the use of a model-based assessment. Due to high worker mobility in the plating shop, personal measurements should also be performed. RAC notes that personal measurements are preferred to stationary measurements in this case and a suitable limit of detection should be used as the criterion for deciding how sampling is performed.

Finally, suitably anonymised biomonitoring data (historical and current) would have supported the applicant's exposure assessment and could be included in any subsequent authorisation review report submitted.

Environmental releases / Indirect exposure to humans via the environment

Releases to the environment

The applicant considered that "industrial use resulting in inclusion onto a matrix" (ERC 5)" is the most appropriate Environmental Contributing Scenario. The applicant states that strict emission control measures to avoid Cr(VI) emissions towards all compartments are in place.

As discussed in the EU RAR for chromate substances (EU 2005), Cr(VI) is expected reduce to Cr(III) under most environmental conditions after release. As a result, the impacts of Cr(VI) are generally considered to be limited to the area around the source of release. Based on this, the applicant considered only local emissions from the site.

According to the applicant, Cr(VI) emissions to air are considered to be very low but relevant. Air emissions from local extraction of the baths in the plating shop are collected through a specific system and treated via a mist eliminator/scrubber. The air is then evacuated through a chimney on the roof of the plating shop. No further technical details of the risk management measure for preventing release from the Tulle site were provided by the applicant, despite a request from RAC.

In the absence of measured data, the applicant used release factors from the NONS/ESR Technical Guidance Document on risk assessment (TGD, 2003). The associated release factor was determined using the following parameters: IC 16 (Industrial category: engineering industry), MC=3 (Main category: Non-dispersive use), Intrinsic properties of the substance (solubility > 1 g/l and vapour pressure < 10 Pa). Using methodology described above, the release factor to air for the site of Tulle was set as 0.00001 (0.001%). In response to a query from RAC, the applicant confirmed that estimated releases to the atmosphere are based on the tonnage of chromium trioxide used, without correcting for the Cr(VI) content of chromium trioxide.

The applicant based release estimates on the total volume of chromium trioxide used at the Tulle site for uses 1, 2 and 3 (0.8 tonnes/y). Exposure from the separate uses was subsequently apportioned based on the relative tonnage used for use 1 and 2 (0.5 tonnes) and use 3 (0.3 tonnes). As a result, the exposure (and corresponding risks / impacts) estimated for Use 2 includes exposure as a result of Use 1. According to the applicant this leads to an overestimation of the risk.

The applicant states that releases of Cr(VI) to wastewater do not occur as aqueous wastes are either recycled within the plating line, or disposed of as hazardous waste. (for details, see Table 8). The applicant considers that releases to wastewater from the Tulle site are zero.

The applicant claims that at the end of the process all wastes are managed by a specialised waste management company.

Table 5: Releases to the environment (total for uses 1, 2 and 3)

Release	Release rate	Release estimation method and details
Water	Final release factor: 0%	All wastewater recycled within plating process or disposed as hazardous waste
Air	Final release factor: 0.001% Local release rate: 36.36 mg/day	Release factor from NONS/ESR TGD (2003) - IC 16 (Industrial category: engineering industry), MC=3 (Main category: Non-dispersive use), Intrinsic properties of the substance (solubility > 1 g/l and vapour pressure < 10 Pa)
Soil	Final release factor: 0%	Expert judgment

Indirect exposure to humans via the environment

For the assessment of indirect exposure of the general population the applicant considered two exposure routes - inhalation and oral intake (ingestion of drinking water via air deposition). The size of the general population was conservatively assumed to consist of 10,000 residents within a 4 km radius around the source of emission.

The applicant chose not to use the EUSES software to estimate environmental exposure on the basis that EUSES input parameters are not completely adapted for inorganic substances like hexavalent chromium (some inputs such as boiling point, vapour pressure, octanol/water partition coefficient are not relevant). RAC notes that EUSES can be used to assess inorganic substances by adapting the input parameters used (ECHA R16 Guidance).

In order to calculate the dispersion of Cr(VI) in the atmosphere around the Tulle site the applicant used the “Doury Abacus” (Doury et al, 1980), a non-standard model. The applicant notes that the use of Doury Abacus is recommended in the compendium of the methodologies for the calculation of atmospheric dispersion made by the French National Institute for Industrial Environment and Risks (INERIS, Ω-12 Dispersion atmosphérique (Mécanismes et outils de calcul), 2012).

Using the Doury abacus, the applicant calculated the exposure concentration that would occur 100 m from the Tulle site (which was consistent with the actual distance from the site to the nearest residence).

To calculate exposure via the oral route the applicant used the equations for deposition

from the TGD and assumed that all Cr(VI) deposited within the 4 km radius from the site would be transferred to drinking water (after accounting for dilution using default factors).

The applicant states that there are no actual release measurements available for the Tulle site and commits to perform such measurements regularly in the future in order to confirm the correctness of the estimated exposures.

Table 6: Summary of indirect exposure to humans via the environment (inhalation route)

Exposure estimate, local scale (100 m from point source)			
Protection target	**Site**	**Amount used, tonnes / year**	**Exposure**
Man via Environment – Inhalation (USES 1 and 2), (µg/m^3)	Tulle:	0.5 (chromium trioxide)	2.96×10^{-4}
Man via Environment – Inhalation (USE 3), (µg/m^3)	Tulle:	0.3 (chromium trioxide)	1.78×10^{-4}

Table 7: Summary of indirect exposure to humans via the environment (oral route)

Exposure estimate, local scale			
Protection target	**Site**	**Amount used, tonnes / year**	**Exposure**
Man via Environment – Oral (Uses 1 and 2), (µg/kg bw/day)	Tulle:	0.5 (chromium trioxide)	2.94×10^{-6}
Man via Environment – Oral (Use 3), (µg/kg bw/day)	Tulle:	0.3 (chromium trioxide)	1.77×10^{-6}

Note: Cr(VI) was not considered to be eliminated or reduced during the transfers from the atmospheric emission to drinking water, despite the fact that it is very reactive in the environment.

Table 8: Measures for environmental exposure reduction

Compartment	**Risk management measure**
Water	All the liquid effluents containing chromic acids on the site of Tulle (including baths treatment described in the Uses 1, 2 & 3) are collected in specific wastewater pipes and treated with a specific treatment in the waste treatment plant (WTP) of the site. *Uses 1, 2 & 3:* Water used in the two rinsing baths is recycled by using a treatment with active carbon. This treatment produces demineralised water. Chromium is

	consequently eliminated from water. Mixture drained from the used baths treatment is collected. Hexavalent chromium is reduced with soda. Then a flocculation, followed by a filtration on filter is performed. The water produced during this process is then recycled to produce demineralised water through the process with active carbon described above. There is no liquid effluent from the immersion process. The integrity of the process and efficiency of the sewage treatment plant in Tulle is regularly monitored.
Air	*Uses 1, 2 & 3:* Air from local extraction of the baths is directed through a specific process for air treatment. This process is composed of a fan specifically designed to treat air with dusts or damp air. The air is then directed to an acido-basic scrubber specifically designed to treat air containing acid components.

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

RAC notes the efforts made by the applicant to calculate the indirect exposure of humans via the environment. However, RAC is of the opinion that the environmental exposure assessment is uncertain, and could be an underestimate, because of the use of a generic release factor (0.00001) from the superseded ESR/NONS TGD that was not specifically linked to operating conditions and risk management measures (i.e. the type and efficiency of air abatement equipment). RAC was specifically concerned as the generic release factor was for a substance with a low vapour pressure which, whilst true for inorganic solutions of Cr(VI), is not a relevant consideration for electroplating where a fine mist of particulates that contain Cr(VI) is generated from the surface of plating baths. These mists are removed from the workplace and potentially released to the environment by an LEV. Although requested by RAC the applicants were not able to provide more than a very general description of the RMM in place at the Tulle site to prevent emissions of Cr(VI) to the atmosphere (Table 8). No specific details of the efficiency of the atmospheric RMM were available.

Whilst RAC recognises that the applicant's assessment is conservative on the basis that releases were estimated without first correcting for the Cr(VI) content of chromium trioxide, RAC considers that the applicant should address the uncertainty in their release estimate by obtaining representative measurements for releases to the air compartment from Tulle.

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 (EU RAR 2005). This will reduce the potential for indirect exposure to humans via the environment after release. Therefore, regional assessment is not required.

Regarding air emissions and exposure of general population, the assessment is based on a non-standard approach. According to the applicant, highly effective systems to control air emissions are in use. In addition, reduction of Cr(VI) to Cr(III) in the air is also likely

to further reduce the general population exposure. However, RAC notes that the reliability of the exposure assessment would be increased by providing measurements of local emissions to air.

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

Conclusion

RAC considers that:

- the description of use provided allows conclusions to be drawn related to exposure situations.

- the methodology used to derive exposure levels is suitable. However, RAC notes that the exposure assessment provided by the applicant is principally based only on the results of modelling. While performing modelling the applicant took a conservative approach thus exposures at the workplace could be overestimated.

- the number of stationary measurements provided by the applicant is rather low.

- no personal measurements are available.

- the information provided, related to exposure resulting from the use applied for, is considered to be sufficient to use in the risk assessment and in the risk characterisation.

- the indirect exposure calculated by the applicant is acceptable for risk characterisation and impact assessment, but contains uncertainties related to the lack of measurements of emissions to the air.

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

The applicant has estimated cancer risk according to the RAC reference dose-response relationship for carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1, agreed at RAC 27). The applicant has conservatively assumed that all inhaled chromium trioxide particles are in respirable range and contribute to the lung cancer risk. Thus, the excess life-time lung cancer risk is 4×10^{-3} per µg Cr(VI)/m^3 for 40 years of exposure (8 h/day, 5 d/week).

Evaluation of the Risk Management Measures

The applicant states that risk management measures (RMMs) that minimise exposure to chromium trioxide are already implemented. The applicant explains that except for the titration of hexavalent chromium, all the operations relating to the chromium plating take place in the same, dedicated room. The laboratory where the samples are analysed is separate to from the plating shop.

The applicant has outlined that the following RMMs are used on site to reduce exposure to Cr(VI): semi-automated process, lip extraction at the edges of the Cr(VI) baths, general housekeeping and the use of PPE (such as RPE, special clothing and gloves).

The applicant also considers that specific organisational measures (such as supervision of each operator involved, regular workplace measurements performed by external and independent experts and periodic control of effectiveness of equipment) are implemented to ensure RMM efficiency, compliance with national OELs and achieve the levels of exposure described in their application.

The applicant also notes that the site in Tulle is ISO 14001, ISO 9001, AS9100C/JIS Q 9100 / EN9100 certified and these certifications involve regular control of all implemented risk management measures.

Furthermore, the applicant states that in the future, should an authorisation be granted, compliance with the ES submitted as part of their application will be periodically checked and that the effectiveness of RMM (mainly LEV and RPE) will be regularly verified. All workers involved in the use applied for will be made aware of the best practices at the workplace in order to ensure that exposure to Cr(VI) is as low as possible. The applicant is also planning to perform further measurements in order to verify the exposures estimated using ART. The applicant states that measurements of atmospheric emissions will also be performed annually.

RAC acknowledges the RMMs used by the applicant but considers that the current practice of assembling and dismantling armament parts within the plating shop, in close proximity to operating plating baths, is not consistent with hierarchy of control principles. Therefore, RAC recommends that the applicant considers alternative ways of organising their workplace to avoid that assembling and dismantling of armament parts takes place in the plating shop (i.e. explore the potential for these tasks to take place in a separate room). This would also reduce the requirement for RPE be worn for long periods of time to reduce far-field exposure. RAC also notes that the effectiveness of implemented RMM could be improved by replacing natural ventilation in the plating shop with general mechanical ventilation and potentially by the introduction of more automation (if possible) into the process.

Risk characterisation

The risk characterisation was performed by the applicant by calculating the average inhalation exposure levels of specific types of workers over a year and, based on these calculations, by deriving the average excess risk levels for each of the types of workers (see table 9).

Table 9: Excess risk estimates for 40 years exposure per type of operator with and without RPE

	Lung cancer risks per individual worker	
Function	**Without RPE**	**With RPE (APF = 10)**
Main worker	5.16×10^{-4}	5.16×10^{-5}
Laboratory worker	7.28×10^{-6}	7.28×10^{-7}
Total per Use	5.23×10^{-4}	5.23×10^{-5}

Note: values calculated by RAC

It should be noted that the laboratory worker who performs the sampling and titration of hexavalent chromium is the same operator who performs the operation of sampling and titration of the chromium bath described for the Uses 1, 2, 3 and 4 at the site of Tulle. Consequently, this operator is subject to combined exposure and exposure risk estimation for these tasks.

Table 10: Excess risk estimates for 40 years exposure for laboratory worker with and without RPE for all 4 Uses performed in Tulle.

	Lung cancer risks per individual worker	
Laboratory worker (at the site of Tulle)	**Without RPE**	**With RPE (APF = 10)**
Use 1: hard chromium plating of military armament steels parts which are thermomechanically stressed and in contact with oxidizing gas at high temperature, so as to ensure a thermal barrier with high melting point, resistance to wear and oxidation associated with weapons as well as resistance to impact and atmospheric corrosion	7.28×10^{-6}	7.28×10^{-7}
Use 2: hard chromium plating of military armament parts in order to ensure surface hardness, resistance to atmospheric corrosion, abrasive wear resistance and friction coefficient for parts in relative movement	7.28×10^{-6}	7.28×10^{-7}
Use 3: use of a mixture of chromium trioxide for the black colour hard chromium plating of exterior surface of steel weapon barrel designed for military use, to ensure, during the whole gun barrel service life, stealth, erosion, corrosion	4.85×10^{-6}	4.85×10^{-7}

and high temperature resistances in the condition of uses		
Use 4: use, of a qualified mixture of chromium trioxide by immersion for the chromate conversion coating of welded mechanical structures of armoured vehicles and associated parts made of high mechanical properties aluminium alloys for military use, and requiring a maintained electrical conductivity after severe climatic environments, atmospheric corrosion resistance and paint adhesion	7.43×10^{-7}	7.43×10^{-7}
Total	***2.01×10^{-5}***	***2.68×10^{-6}***

Note: values calculated by RAC

Indirect exposure

Exposure to humans via the environment was based on modelled data.

The risk characterisation was performed by taking into account the risk for the general population (10,000 residents and workers) in the vicinity of Cr(VI) industrial settings. For the general population the sum of the risk due to inhalation and water consumption was taken into account by the applicant.

Indirect exposure / local and regional

The applicant has estimated excess cancer risk for general population on the basis of the inhalation exposure and also on the basis of water consumption. The risk characterisation has been performed using 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, an excess life-time lung cancer risk is 2.9×10^{-2} per µg Cr(VI)/m^3 for 70 years of exposure (24 h/day, 7 d/week).

Table 11: Excess risk estimates for 70 years exposure for the inhalation route

Excess risk level	**Location**
Inhalation	**Tulle**
Uses 1 and 2	8.6×10^{-6}
Use 3	5.16×10^{-6}

Note: values calculated by RAC

Table 12: Excess risk estimates for 70 years exposure for oral intake

Excess risk level	**Location**
Oral intake	**Tulle**
Uses 1 and 2	2.35×10^{-9}
Use 3	1.41×10^{-9}

Note: values calculated by RAC

Table 13: Excess risk estimates for 70 years combined routes

Excess risk level	**Location**
Total excess risk all routes per site	**Tulle**
Uses 1 and 2	8.6×10^{-6}
Use 3	5.16×10^{-6}

Note: values calculated by RAC

The applicant has not calculated the risk related to regional exposure. However, Cr(VI) is effectively reduced to Cr(III) in the environment, which is why EU RAR concluded that the regional exposure may not be relevant. RAC considers this conclusion as reliable.

According to the applicant, releases to the wastewater are minimal/ non-existent and no exposure assessment or risk assessment on the basis of this source of exposure was performed.

Conclusion

RAC considers that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. However, RAC notes that the applicant's strategy for monitoring of exposure for workers and releases to the atmosphere is not yet sufficiently developed. In addition, the applicant should consider alternative ways of working that would avoid the need to assemble and dismantle armament parts in the plating shop. Equally, the on-going effectiveness of the current LEV equipment should be ensured by implementing appropriate preventative maintenance programmes.

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:

In this application, chromium trioxide is used within an electroplating bath to obtain a hard chromium surface for the manufacture of thermo-mechanically stressed steel armament parts in contact with oxidising gas at high temperature (for example bore of the gun barrel). Specifically, coatings produced must be characterised by the following properties:

- Present a thermal barrier with high melting point thus preventing the barrel steel exceeding its tempering temperature which would severely reduce its mechanical properties.
- Present a high level of wear resistance associated with the firing of projectiles so as to prevent excessive degradation of the internal surface of the gun barrel during firing of the ammunition, thus ensuring its durability and accuracy. Hard chromium plating provides a well-balanced surface hardness between the ammunition and the inner surface of the gun barrel.
- Present a high level of corrosion resistance against conditions generated by the combustion of the propellant charge, which generates highly oxidising gases.
- The treated surface must allow high impact resistance generated by the shooting of various small, medium and large calibres with high rates of fire.
- Sufficient corrosion resistance is also needed during non-shooting periods to prevent damage due to atmospheric corrosion across the lifetime of the gun barrel.

The levels of performance with regard to the above mentioned characteristics are required by the customers, specifically DGA in the case of French armed forces (French Armament Procurement Agency of the French Ministry of Defence).

Given the importance of Use-1 (hard chromium for thermo-mechanically stressed armament parts) for Nexter and its customers' activities, a significant amount of research, testing and benchmarking of potential alternatives was carried out over the last two decades. Between 1988 and 2006 two research programmes on alternatives were conducted by Nexter Systems. These programmes did not lead to the identification of appropriate alternatives for the specific requirements of this use. Due to confidentiality agreements, further description cannot be provided about these research programmes.

Four potential alternative treatments have been evaluated and two of them are currently undergoing in-depth testing, but only in view of their potential as substitutes for Use-2 of this same AfA. However, none of them is deemed appropriate to substitute in Use-1 and were consequently abandoned for possible substitution in this use:

- *Nickel electroless plating:* Melting point too low; insufficient efficiency as a thermal barrier to protect the gun steel of metallurgical changes due to the temperature induced by the firing; possible diffusion of Nickel in steel at high temperature and formation of

compounds leading to a weakening of the steel; volatile oxides formation at high temperature.

- *Nickel electroless plating with Poly Tetra Fluoro Ethylene (PTFE):* Same reasons as Nickel electroless plating with lower allowable temperature before degradation.

- *Atmospheric Plasma Spraying - MCrAlY // Refractory oxides:* Evaluated in past years and failed as gun barrel bores protection surface treatment; failure of the adhesion at firing was observed; no impact resistance due to the weakness of refractory oxides.

- *Nitro carburation with post oxidation:*
Limited to nitridable steels, which are not qualified for use on gun barrels; no thermal barrier; no protection against oxidizing gas; too thin layer to provide wear resistance for the lifetime of the gun barrel.

Some publications describe works based on Physical Vapour Deposition (PVD) processes. This alternative had earlier been considered in a study conducted by DGA between 1998 and 2006 but further research work was abandoned due to identified insurmountable shortcomings:
- PVD process needs to be carried out under high vacuum (10^{-6} mbar), and the vacuum chamber has to be compliant with the length of the gun barrel. Given the size of the parts to be treated by Nexter, this would make the overall treatment extremely complex, if feasible at all;

- Plasma assisted technologies need a cathode inside the gun barrel and a distance between the cathode and the gun compliant with plasma creation. This does not comply with the gun barrel bores internal dimensions;

- The deposition speed is very low and the coatings are currently around 2 to 10 µm, which is not sufficient for this use.

In 2014 Nexter Systems entered a consortium (HCTC) dedicated to develop a hard chromium plating process not involving Cr(VI) compounds. This consortium aims to develop a Cr(VI) free and boric acid free hard chromium coating process based on a Cr(III) electrolyte, which is now the only short listed alternative which looks promising after the sunset date.

Technical feasibility of Cr(III) alternative

The exact composition of the Cr(III) electrolyte is confidential, but as stated above, it is Cr(VI) free and boric acid free and is being developed having human health and environment safety as the main (non-technical function) criterion.

Preliminary results of the study, in terms of comparison between Cr(III) and Cr(VI) processes are the following:
- Cr(VI) deposits are denser than Cr(III) deposits;

- Cr(III) appear smoother than Cr(VI) deposits;

- Cr(VI) deposits exhibit more cracks than Cr(III) deposits but Cr(III) deposits appear to be subject to through-cracking and cracking networks appear totally different between the two processes;

- Cr(III) use carbonaceous substances which induce an increase of hardness with temperature, probably by the creation of chromium carbides. This behaviour is not seen with the Cr(VI) process;

- Overall deposit rate and size of nodules appear similar for both Cr(III) and Cr(VI) deposits.

Those preliminary results demonstrate the possible feasibility of Cr(III) deposits and therefore appear encouraging. Technical issues have nevertheless emerged, notably concerning cracking and hardness mechanisms that have to be resolved in order to be, at the very least, nearly compliant with Nexter specific requirements associated with Use 1.
It should be noted that Nexter's requirements in terms of performance far exceed the requirements of other members of the HCTC consortium (due to the nature of the respective uses). Compliance of the final process developed by the consortium with Nexter requirements cannot therefore be guaranteed. Moreover, if the level of performance obtained in 2018 in respect of the consortiums requirements, offers a first level of compliance with the requirements of Use-1, it has to be taken into account that this process will also have to be adapted for a full compliance with Nexter requirements as well as to be industrialised in Nexter Mechanics plant and qualified by the DGA on each set of equipment.

Economic feasibility of Cr(III) alternative

If the alternative is deemed feasible, the applicant estimates that the costs of industrialisation of the new process and the costs of internal and external qualifications will amount to 5 to 7 million €. Compared to the global turnover of Nexter Systems, Nexter Mechanics and CTA International, the applicant considers that the estimated costs for research & development are not substantial. The infeasibility of an alternative for this use is more of a technical feasibility issue than an economic feasibility one.

Conclusion

SEAC notes that over the last 28 years, long before the phasing out of Cr(VI) was imposed by REACH, the applicant has tested and evaluated the technical feasibility of four alternative processes which would make the use of Cr(VI) redundant, not only in use 1 but also in other uses needed in their production (Use-2). While 2 assessed alternatives seem to be feasible in use 2, none of them can replace hard chromium for thermo-mechanically stressed armament parts (Use-1) and were consequently abandoned for this use. SEAC cannot assess if the performance requirements (required by their clients) described at the beginning of this point are absolutely necessary, however, in view of the very specific conditions (high thermo-mechanical stress, highly corrosive and oxidising atmosphere at high temperatures) in which the coating has to perform, these performance requirements seem very much plausible. The shortcomings of the abandoned alternatives are transparently described and the reasons for their rejection are deemed relevant by SEAC.

Finally, the applicant joined a consortium whose goal is to develop a boric acid free Cr(III) process whose preliminary results demonstrate its possible feasibility and appear encouraging. However, SEAC concurs with the applicant's statement (quote p. 50) "*that Nexter's requirements in terms of performances far exceed the requirements of other*

members of the consortium" and that the compliance of the final process developed by the consortium with Nexter requirements cannot therefore be guaranteed. SEAC also concurs, that if the process developed by the consortium offers a first level of compliance with the requirements of Use-1, it has to be taken in account that this process will also have to be adapted for a full compliance with Nexter requirements as well as to be industrialised in Nexter Mechanics plant and qualified by the DGA on all the types of armaments produced. The applicant did not present an elaborated plan for substitution activities. Their explanation, why internal and external qualifications (including necessary R&D, military testing and industrialisation) would take up to 12 years includes the fact that their customer, DGA, will consider this switch to a new process (even if it would still be hard chromium plating) a major change requiring an in-depth qualification (functional and military testing approval) to ensure the proper functioning and required military capability of the gun itself and auxiliary parts. SEAC understands that military use does not necessarily require formal 'type approval' qualification (akin to airworthiness certification) in all cases, but cannot ascertain or evaluate if the proposed length of 12 years is always required, especially since the customers military approval requirements are confidential for reasons of national security.

The applicant mentioned that the costs of transition to this new process would amount to between € 5 and 7 million. SEAC cannot assess how accurate this estimate is, however since the applicant confirmed that (quote p.51) "*compared to the global turnover of Nexter Systems, Nexter Mechanics and CTA International, the estimated costs for research development are not substantial. The unfeasibility of an alternative for this use is more of a technical feasibility issue than an economic feasibility one*". SEAC agrees and accepts this approach.

The applicant has not assessed the technical and economic feasibility of outsourcing of Cr(VI) plating services or relocating outside the EU considering that this would not be acceptable for their main client, the French armed forces, since this would compromise the integrity of French sovereignty and the field operation capacity of the armed forces through the release of critical military know-how. SEAC cannot assess these statements, since they are not scientific arguments but rather socio-political (see also section 8 for further discussion on this). During the Trialogue meeting, the applicant also stressed that even in the case of outsourcing of the chrome plating process, their customer, DGA, would consider the switch to an outsourced sub-contractor a sufficient change in manufacturing provenance so as to require requalification, such that authorisation for continued use of Cr(VI) in the hard chromium plating process would still be needed during the period required for requalification, and expected to require a long review period.

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

☐ YES

☒ NO

Justification:

The aim of the above mentioned consortium developing a boric acid free Cr(III)

electrolyte is to obtain a “standard” hard chromium coating in 2018, which is after the sunset date of Cr(VI). However the applicant stated that Nexter’s requirements in terms of performances far exceed the requirements of other members of the consortium and that the compliance of the final process developed by the consortium with Nexter requirements cannot therefore be guaranteed. Regarding economic feasibility, the applicant considers that the costs of transition to Cr(III) process (between € 5 and 7 million) are not substantial compared to the turnover of the group, but the infeasibility of the alternative for this use before the sunset date is a technical feasibility issue and not an economic feasibility issue.

Conclusion

SEAC concurs with the conclusion by the applicant, that technically the substitution of Cr(VI) before the sunset date is not feasible for this use. SEAC accepts the applicant’s conclusion regarding economic feasibility, in which the costs of transition to Cr(III) of between 5 and 7 million € are not substantial compared to the turnover of the group, but are nevertheless irrelevant in this case, because the transition is not feasible anyway as a result of technical issues.

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

Description:

The applicant has considered six different alternatives for the purpose of replacing the use of chromium trioxide in hard chromium plating. According to the applicant a significant R&D work was and is carried out by the applicant in order to develop alternatives. Several potential alternatives are subject to ongoing R&D, but do not currently support the necessary combination of key functionalities to be considered as technically feasible alternatives to the use of Cr(VI) in hard chromium plating. All of the identified potential alternatives are assessed by the applicant in terms of their technical feasibility, economic feasibility, and availability. A detailed risk assessment of the alternatives to facilitate a comparison with chromium trioxide has not been conducted. The alternative assessments do not provide an overview of general information on the substances used within the alternatives and alternative processes as well as the risk to human health and environment.

The applicant states that the following alternatives were assessed and found not appropriate to substitute Cr(VI) in hard chromium plating for thermomechanically stressed armament parts: Nickel electroless plating, Nickel electroless plating with Poly Tetra Fluoro Ethylene (PTFE), Atmospheric Plasma Spraying - MCrAlY // Refractory oxides, Nitrocarburation with post oxidation, Physical Vapour Deposition (PVD) processes. According to the applicants further R&D on those alternatives was abandoned due to their costs, technical limitations and the lack of necessary thickness of the coating to insure a thermal barrier for the gun steel.

One of the possible alternatives is shortlisted and considered in more detail as it is judged to be more promising for future development: hard chromium plating based on trivalent chrome solution.

- **Alternative 1: Hard chromium plating based on trivalent chrome solution**

According to the applicant the most promising potential alternative, based on a Cr(III)

electrolyte, is being developed at the moment. The applicant states that there are still uncertainties about the technical and economic feasibility of this alternative. These uncertainties are directly related to the applicant's specific requirement to withstand thermomechanical stresses induced by the firing of ammunition. The applicant mentions that if this alternative will be considered appropriate in 2018, delays for industrialisation as well as very stringent internal and external qualification processes would prevent its implementation in armament systems before 2029.

In general, the trivalent electroplating processes are less toxic than chromium trioxide plating due to the oxidation state of the chromium. Cr(III) solutions do not pose serious air emission issues, but still pose the problems of disposal of stripping solutions (depending on the type of stripping solution) and exposure of workers to chrome dust during grinding. The bath chemistry typically also comprises a high concentration of boric acid, which is a SVHC substance (Repr. 1B) included on the candidate list and possibly subject to further regulatory action. However the applicant stated that currently research is carried out on finding alternative solutions that do not involve the use of substances included in the candidate list (i.e. Cr(VI) substances, boric acid).

In conclusion, the transition from chromium trioxide to trivalent chromium might eventually constitute a shift to less hazardous substances but further consideration is required.

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:

With respect to the 6 alternatives for chromium trioxide included in the applicant's analysis of alternatives the applicant stated that the most promising alternative is hard chromium plating based on trivalent chrome solution. Transition from chromium trioxide – which is a non-threshold carcinogen – to this alternative might constitute a shift to less hazardous substances.

Conclusion

The most promising alternative is hard chromium plating based on a trivalent chrome solution. Transition from chromium trioxide to this alternative might constitute a shift to less hazardous substances.

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

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

No alternative feasible before the sunset date was identified.

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

☒ YES

☐ NO

☐ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:

Additional statistical cancer cases estimated by RAC

The estimated number of additional statistical cancer cases has been calculated using the excess risk values 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 cases 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 in the CSR.

Table 14: Estimated additional statistical cancer cases. 40 years exposure

	Excess lung cancer risk		**Number of exposed people**	**Estimated statistical lung cancer cases**	
	Without RPE	With RPE (APF = 10)		Without RPE	With RPE (APF = 10)
Main worker	5.16×10^{-4}	5.16×10^{-5}	5	2.58×10^{-3}	2.58×10^{-4}
Laboratory worker	7.28×10^{-6}	7.28×10^{-7}	1	7.28×10^{-6}	7.28×10^{-7}
Total	***5.23×10^{-4}***	***5.23×10^{-5}***	***6***	***2.59×10^{-3}***	***2.59×10^{-4}***

Table 15: Estimated additional statistical cancer cases for the requested review period (12 years)

	Excess lung cancer risk per individual worker (12 years)		**Number of exposed people**	**Estimated statistical lung cancer cases per worker population (12 years)**	
	Without RPE	With RPE (APF = 10)		Without RPE	With RPE (APF = 10)
Main worker	1.55×10^{-4}	1.55×10^{-5}	5	7.74×10^{-4}	7.74×10^{-5}
Laboratory worker	2.18×10^{-6}	2.18×10^{-7}	1	2.18×10^{-6}	2.18×10^{-7}
Total	***1.57×10^{-4}***	***1.57×10^{-5}***	***6***	***7.76×10^{-4}***	***7.76×10^{-5}***

Table 16: Estimated additional, fatal and non-fatal, statistical cancer cases for the requested review period (12 years)

	Estimated statistical lung cancer cases per worker population (12 years)
Fatal cases	*7.76×10^{-5}*
Non-fatal cases*	*2.50×10^{-5}*

** The non-fatal cases are calculated by applying the ratio of survival (24%) to mortality (74%) rate for lung cancer in France (Institut National du Cancer, Incidence nationale du cancer du poumon, 2015).*

Table 17: Estimated additional statistical cancer cases due to man via environment inhalation and oral exposure for the requested review period (12 years)

Excess risk level	**Site**
Inhalation (lung cancer cases) General population (10,000 residents and workers)	**Tulle** (Use 1)
Fatal cases	1.47×10^{-2}
Non-fatal cases	4.69×10^{-3}
Oral (small intestine cancer cases) General population (10,000 residents and workers)	**Tulle** (Use 1)
Fatal cases	1.87×10^{-6}

Non-fatal cases	2.17×10^{-6}
Total number of fatal cases (inhalation and oral)	1.47×10^{-2}
Total number of non-fatal cases (inhalation and oral)	4.69×10^{-3}

Assessment of Impacts

The Assessment of impacts associated with this authorisation application and which has been undertaken by the applicant includes a comparative quantitative assessment between the monetised impacts associated with the "applied for use" and the "non-use" of Chromium Trioxide. The perspective of the analysis is such that it can be used to show that the benefits to society of continuing to use Chromium Trioxide exceed the risks of continued use over the analytical timeframe considered in the applicant's analysis. Although the assessment does not provide an overall "net benefit" ("net loss") estimate for the *applied for use* (*non-use*) scenario, a comparison of the benefits and costs estimated by the applicant makes this straightforward. It should also be noted that the analytical timeframe (temporal boundary) considered in the applicant's analysis is based on a period of 12 years (post sunset date: 2018-2019), which is the period of authorisation being sought by the applicant. There is no explicit justification of the 12 year analytical boundary beyond the fact that it coincides with the review period being sought. As such, whilst it covers the decision-making time horizon, it is unclear the extent to which all major impacts are appropriately covered. In this respect the applicant does not convincingly explain the rationale for using an "impact period" of 12 years, given that in the application they appear to suggest a more realistic timeframe of 20-30 years for the "applied for use" impacts. Specifically, the inclusion of latent cancer burden risk estimates (see benefits section below) is based on an exposure period of 40/70 years, whereas the health impacts associated with this latent cancer burden are all assumed to occur within the 12 year analytical boundary. As such, whilst the arguments for the 12 year analytical time horizon are not well founded, the approach is acceptable since any bias introduced will tend to induce conservatism (overestimation) in the economic burden of health impact estimates derived. The discounting period used is consistent with assessing the present value of all impacts at the date of drafting the analysis. Overall, given the decision making time frame, the approach provides a consistent comparison of benefits and costs over the time period of analysis selected.

The assessment of impacts is based on impacts occurring mainly in France and which are incremental to the respective baselines under the "applied for use" and "non-use" scenarios considered by the applicant. Although the applicant does not therefore use a single analytical baseline (i.e. define the baseline in terms of either one of the scenarios), the comparison of benefits and risks of granting authorisation is such that whilst it is somewhat analytically circuitous, it nevertheless compares in a consistent way the positive and negative impacts across the 'applied for use" and "non-use" scenarios. With respect to the "non-use" scenario, the applicant, in line with their analysis of alternatives (see earlier sections), posits that they will have to cease the manufacture and maintenance of the armament systems covered by Use 1, with a consequence that Nexter Mechanics' activity would cease and Nexter Systems (the parent company) would be severely endangered. Moreover, France's armed forces would thus be unable to secure the supply of armament systems that constitute the

backbone of their operational capability, such as to "jeopardise France's national sovereignty". SEAC considers this "non-use" scenario to be based on justifications outside the realm of its competence, given that it is largely related to socio-political considerations (see later). SEAC's assessment of this authorisation application is thus based on a tacit acceptance that these socio-political arguments have political legitimacy and standing. Given this, the applicant's socioeconomic assessment of the "non-use" scenario considers the direct financial costs to their operations (in terms of loss of profits) in the event of not being granted an authorisation, as well as impacts on loss of orders, investment, unemployment, and distributional impacts related to France's national sovereignty being compromised. Whilst the analysis of economic impacts related to the loss of profits to the applicant is based on a well-established methodological approach to societal costs assessment, the estimation and inclusion of some of the other socioeconomic impacts is questionable in a number of respects as far as generating a methodologically robust measure of the total net economic cost to society of the non-use scenario (see cost section for details). As a result, the exact magnitude of the net economic costs is considered by SEAC to be somewhat uncertain. The analysis of the economic burden of human health impacts is based on established procedures for the calculation of economic welfare changes as a result of human health risk reductions, albeit with the proviso noted above about the time period regarding latent effects associated with cancer exposures.

Overall, whilst an acceptable economic valuation methodology underpins the assessment of health impacts, the overall methodological approach underpinning the assessment of economic and other impacts has some deficiencies but is nevertheless still sufficient to indicate that benefits do exceed risks, in particular with respect to some key parameters considered in the applicant's sensitivity analysis. Whilst SEAC thus identify some uncertainty relating to the exact magnitude by which benefits exceed risks, the analysis is proportionate given the likely magnitude of risks assessed by RAC.

Costs of continued use (HH)

The quantitative analysis of the costs of continued use is based on a human health impact assessment using a methodology following the SEA guidance. The applicant estimates the physical health impacts (disease burden) associated with the exposures as described in the CSR as a result of the "applied for use" scenario. The approach is based on linking quantitative relationships between exposure and the health impact of interest. This general procedure is widely used for the assessment of benefits related to pollutants and is considered to be an appropriate methodological approach. In this respect, the applicant makes use of the linear exposure-response relationships for lung cancer as a result of exposure to Cr(VI) compounds, as estimated by and in accordance with the related ECHA paper (ECHA 2013). Using this general approach to quantitative health impact assessment, the applicant then estimates the disease burden associated with lung cancer as a result of the exposure to Cr(VI) under the "applied for use" scenario using two separate, but complementary approaches. Under the first (considered as the primary) approach, the applicant calculates disease burden in terms of disability adjusted life years (DALYs) associated with the cancer mortality and morbidity from exposures to Cr(VI) under the "applied for use" scenario. Under the secondary complementary assessment, the applicant calculates disease burden in terms of the expected count of fatal and non-fatal cancer cases (i.e. people with disease) arising from exposures to Cr(VI) under the "applied for use" scenario. Whilst the general

approach is in both cases appropriate and complementary, the applicant in their original estimation appears to have made some minor errors and been inconsistent in their execution of the approaches. Specifically, in the case of the assessment based on DALYs, the applicant used the linear exposure-response relationship for lung cancer mortality given in ECHA (2013) to assess the combined mortality and morbidity impacts related to the excess lung cancer mortality cases. However, since the exposure response functions in ECHA (2013) are defined in terms of cancer mortality only, the excess risk of lung cancer is higher than the excess risk of lung cancer mortality estimated via the exposure response functions, such that for every fatal case of lung cancer, there are additional non-fatal cases of lung cancer, with associated morbidity impacts. Whilst these were not included in the applicant's original analysis using this DALY approach (and hence the health impacts will have been underestimated), the applicant provided a revised analysis in which these additional impacts were included. Likewise, in the assessment based on the number of fatal and non-fatal lung cancer cases, the applicant originally assumed that the exposure response functions relate to the excess risk of lung cancer *per se* rather than lung cancer mortality, and hence divides the associated incidence between fatal and non-fatal cases rather than estimating the additional non-fatal cases. Again whilst this led to health impacts being underestimated in the original analysis, the applicant provided a revised analysis taking account of the additional non-fatal cases. Whilst SEAC thus have some concerns regarding the applicant's original execution of both methodological approaches, the subsequent analytical revisions render these concerns no longer relevant. Furthermore, it should be remembered that the estimates presented by the applicant are likely to be a conservative (overestimate) assessment of the cancer burden since they do not apply any discounting in order to account for latency effects related to the exposures.

The number of cases of excess lung cancer has thus been estimated by the applicant at 7.76×10^{-5} fatal and 2.50×10^{-5} non-fatal cases for workers for the requested review period (12 years). 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 'separable' over time in order to derive annual cases. SEAC considers such an approach appropriate and consistent with existing practice in authorisation applications.

For exposures related to 'Man via Environment', these are considered by the applicant to be negligible. However in accordance with RAC's evaluation of the CSR and subsequent recommendation, the applicant provided an updated assessment of impacts related to man via environment. The associated number of cases of excess lung and intestinal cancer has been estimated at $1.47 \times 10^{-.2}$ fatal and 4.69×10^{-3} non-fatal cases for the requested review period (12 years). Once again, it has been necessary to treat the exposures as 'separable', given that the exposure response function is based on an exposure time period of 70 years for residents. SEAC thus considers the estimates to be appropriately calculated and in accordance with ECHA guidance.

Although there are uncertainties then with the disease burden analysis, SEAC in its assessment considers the estimates are likely to provide an adequate order of magnitude estimate of the expected level of cancer impacts relevant to the length of review period sought by the applicant.

Concerning the estimation of economic welfare losses associated with the disease burden estimated using the two approaches described above, the applicant assesses both the medical treatment and the 'human' welfare losses associated with morbidity and mortality. The specific assumptions, methodology and studies used to derive the

medical costs of cancer treatment are clear, appropriate and proportionate. The valuation of the human welfare related morbidity and mortality effects estimated using the two disease burden approaches (mentioned earlier) follows the ECHA guidance on SEA and uses a value of life year lost of € 66,000 (and which is used to value a DALY[1]), alongside a Willingness To Pay (WTP) value of € 1.25 million to avoid a fatality and € 0.43 million for a non-fatal cancer case (based on uprating for the current price level of the recommended values contained in ECHA guidance on SEA). Whilst the applicant's derivation of some of these values is not entirely clear (and in some cases relate to fatalities generally and not cancer fatalities), they are broadly in line with the relevant literature. Irrespective, the applicant applies an upper and lower bound sensitivity value for the value of a life year. This does not result in any change in the conclusions reached. It should also be noted that the applicant applies a discount rate of 3% to the assessment of health impacts. Whilst it is standard practice to use the same discount rate for both cost and benefits, the rationale for using a different discount rate for health impacts to that used for the economic impacts in this instance is only rather vaguely described by the applicant. Nevertheless, the approach is in line with practice and guidelines found elsewhere (e.g. WHO), though the practice of manipulating the discount rate in this way has been called into question by some commentators. Irrespective, and for the sake of consistency, the applicant undertakes a sensitivity check using a 4% discount rate, which again indicates no substantive change in the conclusions reached.

Based on applying the value of life year lost and the WTP values for fatal and non-fatal cancer to the disease burden estimates described above, the applicant estimates that the central value estimate of the human health costs of the "applied for use" scenario are € 19,924 for workers and man via the environment combined. SEAC finds that the specific approaches and assumptions used to derive the health costs of the "applied for use" are on the whole clear, transparent and based on standard assessment practices, such that the estimates derived are robust and valid in terms of their order of magnitude.

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

The applicant's analysis of the benefits of continued use is based on a "non-use" scenario in which Nexter ceases the manufacture and maintenance of the armament systems concerned by use 1. In its assessment of this scenario, the applicant estimates the economic impacts in terms of the economic costs associated with loss of revenues, profits and orders. Social impacts of the non-use scenario are estimated in terms of the costs of unemployment arising from the ceasing of Nexter's operations. The applicant also discusses what are termed "distributional impacts", but which are essentially the impact of the loss of supply of the military equipment manufactured under Use 1 on the French States military capability and sovereignty, as well as some losses of "investments" for the French State and wider impacts to Nexter's industrial partners. These "distributional impacts" are not quantified but only discussed in qualitative terms. SEAC considers the applicants approach to assessing the economic and social impacts to be only partly based on a sound methodological foundation, as discussed further below.

[1] SEAC is aware that valuation of DALYs is not without criticism in the valuation of life and health literature. Nevertheless, valuations of disease burden conducted on this basis are routinely undertaken by regulatory agencies and others (e.g. WHO).

SEAC consider that the arguments put forward by the applicant to justify their 'non-use' scenario are largely outside of the realm of socioeconomic analysis *per se*, relying instead on political imperatives related to national security and defence. Essentially the credibility of the scenario rests on the fact that France's strategic autonomy is based on national ownership of key capabilities for defence and security. Whilst such argument may be questioned, especially given the acquisition strategy of other member states, as well as internal market considerations, the applicant describes the political, legal and administrative constraints that apply in this case. As such, SEAC has to accept at face value the credibility of the "non-use" scenario in so far as it describes the *de facto* situation faced by the applicant and the French State in the event of no authorisation being granted and there being no suitable alternatives (see section on analysis of alternatives). Further questioning and challenge on this issue during the Trialogue did not reveal any further insights in this regard.

Regarding the applicant's calculation of economic costs, SEAC considers these to represent an acceptable order of magnitude estimate of the situation faced by the applicant. The applicant has included a mixture of net economic welfare relevant measures alongside some measures that are not relevant (i.e. transfers) in order to arrive at an aggregate measure of impact. Discounting in order to derive present values has been undertaken correctly where relevant using a 4% discount rate.

The specific cost items are set out and included in a spreadsheet, though the rationale for their inclusion is not always clear, for example the value of capital assets made redundant (given that these are sunk costs). The loss of profits is estimated on the basis of lost revenues along with the average operating margin for Nexter Group. However, whilst it was not originally possible for SEAC to scrutinise the precise derivation of these calculations, further evidence provided by the applicant was sufficient to establish the credibility of their estimation. The applicant uses the 3 year average of annual revenues over the period 2015-17 to estimate annual lost revenues over the review period, along with an assumption of a zero growth rate over the period. Although the 3 year average is greatly influenced by an almost 500% increase in revenues between the last two years of the 3 year period (indicating considerable variability in sales in this sector), the applicant also uses the maximum and minimum revenues observed during the period in order to perform a sensitivity check. SEAC is thus content that the loss of profits thus calculated is thus not influenced by an "outlier" observation. In addition to the loss of profits, the applicant also assesses "losses of orders", i.e., future sales orders. Although these are estimated quantitatively, the applicant does not include them in their aggregate measure of economic impacts. SEAC consider this appropriate since their relevance in the face of the existing inclusion of future profit streams is questionable. As already mentioned the applicant also assesses the value of lost investments (capital assets) in the period prior to the sunset date, which are then included in the aggregate measure of economic impact. However, no rationale for their inclusion is specified by the applicant, such that SEAC have no grounds to deviate from the view that these are sunk costs and any losses associated with them are already reflected within the lost future profits of the applicant. As such SEAC do not include these investments as relevant to the comparison of benefits and risks.

In addition to economic impacts, the applicant also assesses the expected social impacts of the "non-use" scenario. The primary impact assessed here is the loss of employment associated with redundancies resulting from the applicant ceasing to manufacture and

maintain the armament systems concerned by use 1. Whilst costs related to unemployment can in principle be included in a net economic welfare analysis (CBA), this is not a straightforward matter and requires appropriate qualification and justification. So for example, only those costs related to the period of temporary unemployment and associated loss of economic output (usually represented by salary costs) can typically be included. In this respect, it is not clear that the applicant has appropriately considered the duration of temporary unemployment for the workers affected, and moreover has assessed the costs in terms of social welfare payments alongside other social contribution payments and taxation losses. Given that these are usually considered to be transfers in net economic welfare (CBA) analysis, SEAC considers their inclusion in the present analysis to be inappropriately undertaken, and hence does not include them within the comparison of benefits and risks. Other indirect impacts on employment related to Nexter's value chain are also noted by the applicant, but are not quantified. In any case, their relevance is again not appropriately demonstrated by the applicant

The final set of impacts considered relate to what the applicant terms "distributional impacts". The impacts appear to be related to the implications of a disruption of supply of Nexter's equipment to the French armed forces and consequent endangerment of France's national sovereignty. SEAC find that the characterisation of these impacts as "distributional" does not conform with accepted norms or guidance on such matters. Whilst endangerment of national sovereignty may well have societal welfare effects (and hence could in principle be included in a net welfare analysis), such impacts are hardly distributional in nature, and hence would more appropriately be considered as wider social impacts. Irrespective, these impacts are not quantified, but clearly have a qualitative importance to the overall argumentation provided by the applicant in support of authorisation (bearing in mind the proviso that the arguments accepting the politically based "non-use scenario" are accepted). Such qualitative argument can be considered, if necessary, alongside the quantitative estimates of benefits and risks of authorisation.

Conclusion

Overall, given the very small negative human health impacts associated with the applicants use of chromium trioxide, the benefits of the "non-use" scenario are negligible, whilst the additional costs associated with the loss in profits from the ceasing of manufacture of relevant armaments at the applicant's facility are relatively substantial, such that the benefits of the "applied for use" of chromium trioxide exceed the corresponding risks. Any uncertainties are relatively inconsequential and would in any case tend to magnify the magnitude by which the benefits exceed the risks. The total net cost of the "non-use" scenario (and hence the net benefits from granting the authorisation) are estimated at around € 10 – 100 million for a period of 12 years (the authorisation period being sought). The applicant has included a sensitivity analysis for some of the parameters used in the analysis. This indicates that for the range of values for the parameters used to assess the economic burden of health impacts, the conclusion that benefits outweigh the risks of continued use is robust.

SEAC consider the conclusion that benefits outweigh the risks of continued use to be robust.

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation:

The applicant must implement regular measurement campaigns for occupational exposure assessment (sampling at least annually) relating to the use of Cr(VI) as described in the application. They shall comprise both personal and stationary inhalation exposure measurements 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. Measurement campaigns shall be undertaken according to standard sampling and analytical methods, where appropriate. The results of the monitoring must be included in any subsequent authorisation review report submitted.

The information gathered in the monitoring campaigns shall be used by the applicant to review the risk management measures (RMMs) and operational conditions in order to further reduce workers' exposure to Cr(VI), including a review of the feasibility of implementing general mechanical ventilation in the plating shop and exploring alternative ways of working (including improved access control) that would not require armament parts to be assembled and dismantled in the plating shop. 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 retained, be made available to national enforcement authorities on request and included in any subsequent review report submitted.

The effectiveness of the current LEV equipment should be ensured by implementing appropriate preventative maintenance programmes.

Emissions of Cr(VI) to air shall be subject to regular measurements 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.

AND / OR

Description of conditions and monitoring arrangements for review reports:

None

Justification:

The available monitoring dataset for this use is considered by RAC to be relatively small, introducing an uncertainty to the exposure assessment. The proposed conditions and monitoring arrangements should address these uncertainties with a view to reducing exposures.

10. Proposed review period:

☐ Normal (7 years)

☒ Long (12 years)

☐ Short (…. _years)

☐ Other:

Justification:

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

RAC's advice:

RAC gave no advice to reduce the proposed review period.

Other socio economic considerations

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

- The level of risk associated with the "applied for use" are low, alongside the corresponding negligible costs of the "applied for use" of chromium trioxide by the applicant;
- There is no technically and economically feasible alternative to implement by the sunset date.
- The conditions in which the plating of the gun barrel bore has to perform are very specific (thermomechanical stress, in contact with oxidizing gas at high temperature) and the performance requirements in those conditions by far exceeds the requirements of any other member of the consortium in which they are trying to develop the Cr(III)-free alternative.
- The applicant has been proactive in undertaking research to develop an alternative. These attempts have been unsuccessful in achieving a technically feasible so far. There are indications that success and eventual substitution may be achieved in the longer terms, though not within the normal review period time horizon. The applicant is committed to continuing the development and eventual substitution of an alternative.
- Even once a technically feasible alternative does become available, the necessary internal and external qualification processes (including necessary R&D, military testing and industrialisation) will prevent its implementation in armament systems before 2029. The applicant states that such qualification will require a minimum of 12 years. It was not possible for SEAC to fully scrutinise the validity of this claim since it relies on knowledge of, amongst other things, customers military approval requirements, which SEAC understands are confidential for reasons of national security.
- The applicant also stressed that even in the case of outsourcing of the chrome plating process, the switch to an outsourced sub-contractor would constitute a change in manufacturing provenance so as to require technical and military requalification, again necessitating the need for authorisation for a period of greater than the normal review period.
- The benefits of continued use outweigh the risks by a considerable degree (in the range between 1,000-10,000 times).

Although it is difficult to assess the technical prospects for developing a suitable

alternative, SEAC, having taken into account the above points, considers that realistic prospects for substitution will not be possible within the timelines of a short or normal review period, in particular keeping in mind that the internal and external qualification processes (in accordance with the applicants claims) will prevent its implementation in armament systems before 2029.

As such, SEAC recommends a 12 year review period.

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

☐ YES

☒ NO

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

☐ **YES**

☐ **NO**

☒ **NOT APPLICABLE**

<u>Justification</u>:

Applicant did not provide comments to the draft final opinion.