RAC working group/R/12/2022

Final

8 July 2022

Report
of the 12th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC AFA working group)

(Telakkakatu 6, Helsinki) via Webex

Thursday 7 July starts at 10.00 Friday 8 July ends at 13.15

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 31 participants to the 12th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. He informed them that sections of the meeting would also be chaired by Thierry Nicot and by Johanna Peltola-Thies, the Deputy Chair of RAC.

The Chair summarised the members contribution to the RAC consultations on the draft opinions prior to the working group meeting.

He informed participants about a session on the human biomonitoring of CrVI in AFA cases scheduled at the RAC-62 plenary meeting.

He reminded all that the working group will be requested to adopt its report at the end of the meeting.

2. Adoption of the Agenda

The Chair introduced the agenda for the meeting (RAC working group/A/12/2022), which was adopted unchanged and is attached to this Report as Annex II.

3. Declarations of conflicts of interests to the Agenda

The Chair requested all participants to declare any potential conflicts of interest to any of the agenda items. One participant of the meeting declared a potential conflict of interest on cases scheduled for the discussion (see also Annex IV to this Report). The Chairs all declared that they had no potential interests related to any of the agenda points of the meeting.

4. Authorisation applications

The recommendations by the working group on Draft opinions on 7 AFA cases 11 uses considered at this meeting are listed in Annex I.

5. AOB

AfA horizontal issues:

The Secretariat informed the working group about applications for authorisation and review reports, which are expected to be received in 2022 and in 2023, in particular that several hundreds of downstream users are not going to be covered by the relevant (upstream) review report that is expected to be submitted in February 2023 by Chemservice/CTAC.

The Secretariat reminded the participants about the updated technical guidance for rapporteurs (Lines-To-Take) document and the overview table.

The Secretariat informed about planned workshop on the risks of alternatives to hexavalent chrome (e.g. trivalent chrome with boric acid) (October 2022).

The Secretariat informed that the Forum is preparing its report on the REF-9 enforcement project. The Secretariat will organise a presentation of the main results to RAC at a later date.

The working group discussed the requirement to provide measured air monitoring data, the way how those data should be represented in any given application and should be supported by contextual information. The participants expressed support for a stricter approach to always require measured data.

The Commission reiterated their wish that the opinions clearly reflect the level of conservativeness of the exposure assessment and the risk assessment. The Secretariat will propose a standard text.

6. Adoption of the report of the working group

Before the Chair Johanna Peltola-Thies thanked the participants and closed the meeting, the working group adopted its report of the 12th Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I **Working group recommendations**

Annex II **Agenda of the 12th meeting**

Annex III **List of participants of the 12th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation**

Annex IV **Declarations of potential conflicts of interest**

Annex I

Working group recommendations

Abbreviations used

4-NPnEO	4-Nonylphenol, branched and linear, ethoxylated
4-tert-OPnEO	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated
CA	chromic acid
CT	chromium (VI) trioxide
DtC	dichromium tris(chromate)
ERC	environmental release category
ES	exposure scenario
HvE	Humans via environment
LEV	local exhaust ventilation
MOCA	2,2'-Dichloro-4,4'-methylenedianiline
OC	operational condition
PBT	persistent, bioaccumulative and toxic
PPE	personal protective equipment
RMM	risk management measure
RPE	respiratory protective equipment
RR	review report
SD	sodium dichromate
STP	sewage treatment plant
TCE	trichloroethylene
WWTP	wastewater treatment plant
vPvB	very persistent, very bioaccumulative

Summary of the recommendation	**Action Points**
1. 253_CT_GEA-Westfalia (1 use)	
Use1: *Chromium trioxide-based functional chrome plating of machine components for centrifugal separator and decanter centrifuges.* The working group discussed if a feasibility study on the implementation an automatic/closed system for drawing samples should be requested as standard additional conditions for the authorisation. The Working group agreed that it should be continued as a standard request regardless of a sampling frequency. The working group supported the draft opinion as proposed by the Rapporteur.	**Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group. **SECR** to schedule the draft opinion for agreement at the RAC-62 plenary meeting

The working group recommends to RAC that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The working group supported: Section 7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on the implementation an automatic/closed system for drawing samples and an automatic system for the related stirring activity. The applicant shall ensure that workers perform the sealing test, of their respiratory protective equipment (RPE) before taking on relevant tasks and workers will be trained to do this test adequately. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period. Section 8: monitoring arrangements for the authorisation 1. The applicants shall implement the following monitoring programmes: (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and/or static inhalation exposure sampling; (iv) be representative of: a. the range of tasks undertaken where exposure to Cr(IV) is possible; b. the operational conditions and risk management measures typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling; (b) Environmental releases: (i) the applicants shall continue conducting their yearly monitoring programme for Cr(VI) emission to wastewater and air; (ii) the applicants shall conduct emission measurements more frequently in the periods following any possible changes in the process;	via the A-listing procedure.

(iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicants' site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicants to confirm the effectiveness of the operational conditions and risk management measures in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicants shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicants shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the studies and monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicants, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The authorisation holder may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. 7. The applicant shall continue their existing annual biomonitoring programme for the workers potentially	

exposed to Cr(VI). Section 9: recommendation for the review report. The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent authorisation review report. The RAC AFA working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	
2. 254_CT_Ratier-Figeac (2 uses)	
Use1: *Industrial use of chromium trioxide for functional chrome plating of aircraft safety critical steel ball screws used in airplane's actuators, to decrease friction ratio, and enhance wear, corrosion, and endurance resistance, enabling targeted service life.* The working group supported the draft opinion as proposed by the Rapporteurs. The working group recommends to RAC the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The working group proposed: Section 7: additional conditions for the authorisation 1. The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 pellets by liquid CrO_3 to further limit exposure b) the implementation of a closed automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths. c) the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. d) the automation of the HCP line and coverage of the chromium baths as in the CAA line (Use 2). The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant	**Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group. **SECR** to schedule the draft opinion for agreement at the RAC-62 plenary meeting via the A-listing procedure.

actions must be implemented accordingly during the review period. Section 8: monitoring arrangements for the authorisation 1. The applicant shall continue their monitoring programmes for Cr(VI) and considering the following: a. Occupational inhalation exposure monitoring programmes, which shall: i. be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); ii. be based on relevant standard methodologies or protocols; iii. ensure a sufficiently low limit of quantification; iv. comprise personal and / or static inhalation exposure sampling; v. be representative of: 1. the full range and duration of tasks undertaken where exposure to Cr(IV) is possible, including irregular maintenance activities (WCS 1.6) 2. the OCs and RMMs typical for each of these tasks; 3. the number of workers potentially exposed; vi. include contextual information about the tasks performed during sampling; b. Environmental releases: i. the applicant shall continue conducting their yearly monitoring programme for Cr(VI) emission to air; ii. the applicant shall conduct air emission measurements more frequently following any possible changes in the process; iii. the monitoring programmes for air emissions shall: 1. be based on relevant standard methodologies or protocols; and 2. be representative of the OCs and RMMs used at the applicant's site. 3. Ensure a sufficiently low limit of quantification 2. The information gathered via the measurements referred to in paragraphs 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of	

the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The authorisation holder may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. Section 9: recommendations for the review report. The results of the feasibility studies as mentioned in Section 7 and the monitoring programmes referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent authorisation review report. The RAC AFA working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	
Use2: *Industrial use of chromium trioxide for the chromic acid anodizing of aluminum spars as critical surface preparation phase for bonding with aircraft safety critical*	**Rapporteur** together with **SECR** to edit the

propeller blades to secure reliable bonding performance and enhance spars corrosion resistance. The working group supported the draft opinion as proposed by the Rapporteurs. The working group recommends to RAC the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The working group proposed: Section 7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 pellets by liquid CrO_3 to further limit exposure b) the implementation of a closed automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths. c) the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. Section 8: monitoring arrangements for the authorisation 1. The applicant shall continue their monitoring programmes for Cr(VI) and considering the following: a. Occupational inhalation exposure monitoring programmes, which shall: i. be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); ii. be based on relevant standard methodologies or protocols; iii. ensure a sufficiently low limit of quantification; iv. comprise personal and / or static inhalation exposure sampling; v. be representative of: 1. the full range and duration of tasks undertaken where exposure to Cr(IV) is possible; 2. the OCs and RMMs typical for each of these tasks; 3. the number of workers potentially exposed; vi. include contextual information about the tasks performed during sampling; b. Environmental releases: i. the applicant shall continue conducting their yearly monitoring programme for Cr(VI) emission	draft opinion according to the discussion of the working group. **SECR** to schedule the draft opinion for agreement at the RAC-62 plenary meeting via the A-listing procedure.

to air; ii. the applicant shall conduct air emission measurements more frequently following any possible changes in the process; iii. the monitoring programmes for air emissions shall: 1. be based on relevant standard methodologies or protocols; and 2. be representative of the OCs and RMMs used at the applicant's site. 3. ensure a sufficiently low limit of quantification 2. The information gathered via the measurements referred to in paragraphs 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The authorisation holder may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation	

holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. Section 9: recommendations for the review report. The results of the feasibility studies as mentioned in Section 7 and the monitoring programmes referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent authorisation review report. The RAC AFA working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	
3. 255_CT_Chrom-Mueller (3 uses)	
Use1: *Industrial use of chromium trioxide for high ratio aspects inside hard chromium coating of firearms barrel bores subject to thermal, mechanical and chemical stresses, in order to provide wear resistance properties, as well as low friction coefficient, hardness, resistance to corrosion and gas erosion properties.* **Use2:** *Industrial use of chromium trioxide in the hard chromium coating of complex outer surfaces of firearm auxiliary parts subject to mechanical, chemical and thermal stress in order to provide optimized sliding properties as well as heat, corrosion and wear resistance properties.* **Use3:** *Industrial use of chromium trioxide in the hard chromium coating of complex outer and inner surfaces of firearms auxiliary parts requiring a customised and selective coating technique and subject to thermal, mechanical and chemical stresses, in order to provide wear resistance and barrier properties, as well as post-processing capability and resistance to hot combustion gas erosion.* The working group supported of the Draft opinions as proposed by the Rapporteur. The working group recommends to RAC that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The working group proposed:	**Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group and to prepare the DOs for uses 2 and 3. **SECR** to schedule the draft opinion for agreement at the RAC-62 plenary meeting via the A-listing procedure.

Section7: additional conditions for the authorisation 1. The applicant shall continue to carry out their plan to fully automate the plating line by 2023. 2. The applicant shall carry out and document a detailed feasibility study on: • the implementation of a closed/automated system to perform bath sampling tasks where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE; The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period. Section 8: monitoring arrangements for the authorisation 1. The applicant shall implement (or continue) the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes, which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI). (ii) be based on relevant standard methodologies or protocols; (iii) ensure a sufficiently low limit of quantification (iv) comprise personal and/or static inhalation exposure sampling; (v) be representative of: a. the full range and duration of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (vi) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; (ii) the applicant shall continue conducting air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. c. ensure a sufficiently low limit of quantification	

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The authorisation holders may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible 7. The applicant shall continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9: recommendations for the review report The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1 and 7, as well as the outcome and conclusions	

of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report. The RAC AFA working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	
4. 256_CT_KaVo-Dental (1 use)	
Use1: *Chromium trioxide based functional chrome plating of dental instruments applied by professionals for dental treatment.* The working group discussed if requirements are proportionate taking into account the low exposure levels and the small dimensions of the baths and on the other hand the fully manual process. The working group recommends to RAC that the operational conditions and risk management measures described in the application are **not** appropriate and effective in limiting the risk. The working group proposed: Section7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 flakes by liquid CrO_3; (b) the implementation of an automated system to replace the manual bath adjustments and the implementation of a closed/automatic system to replace the manual bath sampling tasks (c) the implementation of a closed/automatic system to replace the manual operation of the baths (d) the implementation of further RMMs to reduce exposure from the baths (e.g., coverage of the baths). The feasibility studies must be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period. Section 8: monitoring arrangements for the authorisation The applicant shall implement the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure: the applicant shall implement a monitoring programmes for Cr(VI)	**Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group. **SECR** to launch RAC consultations on the DO. **Rapporteur** together with **SECR** to revise the draft opinion according to RAC comments. **SECR** to schedule the draft opinion for agreement at the RAC-62 plenary meeting.

exposure, which shall: (i) be conducted at least annually for the workers exposed to Cr(VI) within WCS 2, 3, 4 and 5.2. Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of: a. the range of tasks undertaken where exposure to Cr(IV) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue their monitoring programme for Cr(VI) emission of wastewater; (ii) the applicant shall conduct air emission measurements at least annually at emission point or more frequently in the periods following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraphs 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and made available	

by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. Section 9: recommendations for the review report The information gathered via the measurements referred to in section 8 and 9 as well as the outcome and conclusions of the review and any other action taken should be documented and included in any subsequent authorisation review report. The RAC AFA working group recommended that the Draft opinion is suitable for general agreement at the RAC plenary.	
5. 257_CT_Qualipac (1 use)	
Use1: *Industrial use of chromium trioxide for the etching of polypropylene (PP) substrates, as a pretreatment step of the electroplating process, for the luxury sector and other applications.* The working group discussed: - use of model data instead of measured data while the measured data are not representative - the applicant's statement that there is no exposure in the loading/unloading area - 20% split factor between workers exposure related to the use of CrVI in the application and other uses of CrVI performed in the same place but covered by other authorisation application - clear explanation of the conservativeness of the exposure assessment when the excess risk is in the range 10^{-3} or higher (horizontal request applicable to all DOs). The working group supported the Draft opinion as proposed by the Rapporteur. The working group recommends to RAC that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The working group supported: Section 7: additional conditions for the authorisation 1. The applicant shall carry out and document feasibility studies on: a. the substitution of solid CrO_3 flakes by liquid CrO_3 to further limit worker exposure both at	**Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group. **SECR** to schedule the draft opinion for agreement at the RAC-62 plenary meeting via the A-listing procedure.

Graindorge and Qualipac. The automation of manual tasks at the treatment lines including the concentration adjustment of the chromium baths and the bath sampling at both sites, and the weighing of chromium trioxide at QualipacThe feasibility studies shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. 2. The applicant shall implement a regular maintenance program of the LEV systems (at least annual). 3. The applicant shall ensure that where RPEs are needed to control exposure to chromium trioxide, they used in accordance with standard procedures for use and maintenance. Those procedures shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards. The existing training, supervision of the wearer and maintenance of the RPE shall be continued. Medical fitness of the wearer shall be ensured. Section 8: monitoring arrangements for the authorisation 1. The applicant shall continue their monitoring programme for Cr(VI) based on relevant methodologies at the Graindorge and the Qualipac sites: a) Occupational inhalation exposure which shall: i. be conducted at least annually for the workers exposed to Cr(VI). The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); ii. be based on relevant standard methodologies or protocols; iii. ensure a sufficiently low limit of quantification; iv. comprise personal and static inhalation exposure sampling. In addition to the current personal measurements performed, static measurements at the vicinity of the bath from the baths are requested at both sites and at far field from the bath; v. be representative of: a. the full range and duration of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed;	

vi. include contextual information about the tasks performed during sampling;

b) Environmental releases:

i. the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater, i.e daily internal monitoring and 4 times a year monitoring by an external company;

ii. the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process;

a. be based on relevant standard methodologies or protocols;

b. be representative of the OCs and RMMs use at the applicant's sites.

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.

3. The authorisation holder shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.

4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review described under paragraph 2 above including any action taken in accordance with Section 7.1, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.

Section 9: recommendations for the review report

The results of the feasibility studies and of the implementation of OCs and RMMs requested in section 7 and of the monitoring arrangements referred to in section 8.1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1, should be documented and included in any subsequent review report.

The RAC AFA working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	
6. 258_CT_Schulte (2 uses)	
Use1: *Chromium trioxide-based functional chrome plating of large components and small components with complex geometries and/or requiring special approval procedures for their application in demanding sectors such as medical, aerospace, defence and mining industry.* **Use2:** *Chromium trioxide-based functional chrome plating of small components with simple geometries not requiring special approval procedures for their application in demanding sectors such as hydraulic systems, food, paper and chemical industry.* The working group discussed: - lack of verification of the LEV efficacy versus proper functioning of the LEV - need to expand justification why the OCs and RMMs are not appropriate - additional questions to the applicant - additional conditions for the authorisation. The working group recommends to RAC that the operational conditions and risk management measures described in the application are **not** appropriate and effective in limiting the risk. The working group proposed: Section 7: additional conditions for the authorisation RAC stresses the importance of the plating process automation for the protection of workers at both sites and proposes the following conditions for the authorisation: 1. The applicant shall carry out and document a detailed feasibility study on: i) the substitution of solid CrO_3 flakes by liquid CrO_3 to further limit exposure. ii) the implementation of an closed system to perform the bath adjustment and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the	**Rapporteur** together with **SECR** to submit additional questions to the applicant. **Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group and additional information provided by the applicant. **SECR** to schedule the draft opinion for agreement at the RAC-62 plenary meeting.

review period.

2. Without prejudice to point 1 above, the applicant shall:
   (i) introduce other OC/RMMs (at minimum **bath coverage**) to reduce the exposures of workers taking place in the vicinity of baths to comply with the principles of hierarchy of controls.
   (ii) implement the necessary OCs and RMMs (at minimum **physical segregation**) to ensure that the exposure to Cr(VI) at the loading/unloading working area is as low a level as technically and practically feasible.
3. The applicant shall ensure that:
   i) Where RPE is needed to control exposure to chromium trioxide, it shall be used in accordance with standard procedures for use and maintenance. Those procedures shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards, and shall ensure training and medical fitness checking and supervision of the wearer and maintenance of the RPE.
   ii) LEV and emission control systems are tested regularly to ensure the efficacy needed.

Section 8: monitoring arrangements for the authorisation

1. The applicant shall continue to perform the following monitoring programmes for Cr(VI) at both sites:
   (a) Occupational inhalation exposure monitoring programmes, which shall:
      (i) be conducted at least annually; The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI).
      (ii) be based on relevant standard methodologies or protocols;
      (iii) ensure a sufficiently low limit of quantification;
      (iv) comprise personal and/or static inhalation exposure sampling
      (v) be representative of:
         a. the full range and duration of tasks undertaken where exposure to Cr(VI) is possible;
         b. the OCs and RMMs typical for each of these tasks;
         c. the number of workers potentially exposed;
      (vi) include contextual information about the tasks performed during sampling.
   (b) Environmental releases:
      (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to air and wastewater;
      (ii) the applicant shall conduct air emission

measurements at least annually or more frequently following any possible changes in the process;

(iii) the monitoring programmes for wastewater and air emissions shall:

a) be based on relevant standard methodologies or protocols; and

b) be representative of the OCs and RMMs used at the applicant's sites.

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment (air and wastewater) to as low a level as technically and practically feasible. While doing so, the authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.
3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.
4. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.
5. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible.
6. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially

exposed to Cr(VI). Section 9: recommendations for the review report The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1 and paragraph 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report. The RAC AFA working group recommended that the Draft opinion is suitable for general agreement at the RAC plenary.	
7. 259_CT_ST-SRL (1 use)	
Use1: *Use for electroplating of different types of substrates with the purpose to create a long-lasting high durability surface with bright (shiny) or matte look (functional electroplating with decorative character).* The working group supported the Draft opinion as proposed by the Rapporteur. The working group recommends to RAC the operational conditions and risk management measures described in the review report **are** appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The working group proposed: Section 7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 flakes by liquid solutions of CrO_3 to further limit exposure (b) the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath testing/sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.	**Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group. **SECR** to schedule the draft opinion for agreement at the RAC-62 plenary meeting via the A-listing procedure.

Section 8: monitoring arrangements for the authorisation 1. The applicant shall continue the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes, which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI). (ii) be based on relevant standard methodologies or protocols; (iii) ensure a sufficiently low limit of quantification (iv) comprise personal and/or static inhalation exposure sampling; (v) be representative of: a. the full range and duration of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (vi) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. c. ensure a sufficiently low limit of quantification. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further	

ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.

4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.
5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.
6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible
7. The applicant shall continue their existing biomonitoring programme for the workers potentially exposed to Cr(VI).

Section 9: recommendations for the review report

The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1, and paragraph 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report.

The RAC AFA working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.

Annex II

7 July 2022
RAC working group /A/12/2022
Final

Agenda

Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group (RAC AFA working group) reporting to RAC-62

7-8 July 2022

WebEx meeting

Thursday 7 July starts at 10.00
Friday 8 July ends at 13.15

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/12/2022
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

1. 253_CT_GEA-Westfalia centrifugal separator and decanter centrifuges
2. 254_CT_Ratier-Figeac (2 uses) aircraft safety
3. 255_CT_Chrom-Mueller (3 uses) firearms
4. 256_CT_KaVo-Dental dental instruments
5. 257_CT_Qualipac luxury sector and other applications
6. 258_CT_Schulte (2 uses) medical, aerospace, defence, and mining industry, hydraulic systems, food, paper and chemical industry
7. 259_CT_ST-SRL (decorative "HansGrohe")

For discussion

Item 5 – AOB

1. AfA horizontal issues

For discussion

Item 6 – Adoption of the Report from the working group

For discussion and adoption

Annex III

List of participants of the 12th Meeting of the RAC AFA working group

RAC Members
Baranski Boguslaw
Brovkina Julija
Chiurtu Elena (co-opted)
Deviller Geneviève (co-opted)
Doak Malcolm
Docea Anca
Ginnity Bridget (co-opted)
Kadiķis Normunds
Leinonen Riitta
Moldov Raili
Pribu Mihaela
Printemps Nathalie
Schlüter Urs
Tobiassen Lea Stine
Užomeckas Žilvinas
Van der Haar Rudolf (co-opted)
Viegas Susana

European Commission
Roebben Gert

RAC Regular Stakeholders
Janosi Amaya

Members' advisers
Beetstra Renske (adviser to Gerlienke Schuur)
Catone Tiziana (adviser to Gabriele Aquilina)
De Kort Thijs (adviser to Betty Hakkert)
Jankowska Agnieszka (adviser to Beata Peczkowska)
Panieri Emiliano (adviser to Pietro Paris)
Seba Julie (adviser to Wendy Rodriguez)
Silvestri Federico (adviser to Pietro Paris)

ECHA
Bowmer Tim
Di Bastiano Augusto
Gmeinder Michael
Klausbruckner Carmen
Lazic Nina
Loukou Christina
Marquez-Camacho Mercedes
Nicot Thierry
Peltola-Thies Johanna
Regil Pablo
Schakir Yasmin
Sosnowski Piotr
Vazquez-Rodriguez Jesus
Väänänen Virpi

Annex IV

Declaration of potential conflicts of interest

The following participants, including those for whom the Chair declared the interest on their behalf, declared potential conflicts of interest with the Agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC AFA WORKING GROUP MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chair.