RAC working group/R/14/2023

Final

1 February 2023

Report
of the 14th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC AFA working group)

(Telakkakatu 6, Helsinki)
via Webex

Tuesday 31 January starts at 10.00
Wednesday 1 February ends at 18.00

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 30 participants to the 14th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. He informed the group that sections of the meeting would also be chaired by Johanna Peltola-Thies, the Deputy Chair of RAC, Tim Bowmer the Chair of RAC and Thierry Nicot.

The Chair summarised and thanked the members for a high contribution to the RAC written consultations on the draft opinions prior to the working group meeting.

He reminded 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/14/2023), 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 declared potential conflicts of interest to the agenda items. The Chairs all declared that they had no potential conflicts of interest related to any of the agenda points of the meeting.

4. Authorisation applications

The recommendations by the working group on draft opinions on the 12 Applications covering 15 uses considered at this meeting are listed in Annex I.

5. AOB

AfA horizontal issues:

The Secretariat informed the working group about incoming applications for authorisation and reminded rapporteurs on ways to streamline the drafting of AfA opinions.

The Secretariat reminded the working group about the main objectives of the technical guidance for rapporteurs ("Lines-To-Take") and presented the updated standard text in section 8.2 and the standard text on feasibility study for LEV alarm/shutdown.

The working group briefly discussed on the questions to applicants. ECHA will investigate how the answers to common questions can already be provided in the AfA e.g. in the CSR. ECHA will also communicate to future applicants during a group Teleconference Information Session the latest AfA developments in terms of RAC's expectations. ECHA Secretariat clarified that if an applicant commits to implement a RMM this commitment is normally captured as a condition in section 7 unless the RMM is already clearly mentioned in the CSR.

6. Adoption of the report of the working group

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

Annex I **Working group recommendations**

Annex II **Agenda of the 14th meeting**

Annex III **List of participants of the 14th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation**

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

Annex V **Standard text for Section 8: monitoring arrangements for the authorisation and Section 9: recommendation for the review report.**

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. 273_CT_MikroMetal (1 use)	
Use1: *Electroplating of different types of substrates using Chromium Trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications.* The working group discussed: - need for feasibility study on segregation of tasks and/or covering of baths, - conditions to improve the OCs/RMMs at the manual line. 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

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 supported: Section 7: additional conditions for the authorisation • The applicant shall implement, without delay, technical improvements to the OCs/RMMs at the manual line to minimise the exposure to Cr(VI) and eliminate the overreliance on RPE. To be completed within 12 months and to be followed by a measurement campaign to validate the effectiveness of the applied technical improvements. • The applicant shall install without delay a continuous flow control device connected at the LEV of all plating lines, as indicated in the response to RAC's questions. This control will activate an alarm system in case of a decrease and/or stopping of the suction flow. • The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure. b) the implementation of an automatic and closed system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths. 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. Section 8: monitoring arrangements for the authorisation as given in Annex V. Section 9: recommendations for the review report as given in Annex V. The working group recommended to discuss at the RAC plenary following points of the draft opinion: - Section 7: Additional conditions for the authorisation.	draft opinion for agreement at the RAC-64 plenary meeting.
2. 274_CT_SD_ArcelorMittal (2 uses)	
The working group discussed: - quality and alignment of the biomonitoring data, - need for hard conditions for authorisation due inconsistency in the reported RMMs on releases to air versus to measured release, - conditions in the control rooms.	**Rapporteur** together with **SECR** to edit the draft opinion according to

Use1: *Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP)* 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 implement technical measures to stop addition of solid CT pellets at Basse-Indre and Etxebarri by the end of 2024. 2. In the event that T8 (Dissolution of solid CT/SD) is undertaken at any site during the review period, the applicant shall implement appropriate OC/RMMs to reduce workplace exposure to Cr(VI) in addition to those proposed in the CSR. As a minimum, the following RMMs shall be implemented: - Install a local exhaust ventilation system or an air extraction system to reduce dust generation during dissolution of solid CT/SD. - Restrict access to the area where the dissolution will take place. - Ensure operators that carry out the activity are trained in how to minimise exposure. - Monitor exposure of the operators by air monitoring and biomonitoring. The potential for exposure shall be brought to as low a level as technically and practically feasible prior to commencement of the activity. 3. The applicant shall carry out and document a detailed feasibility study at all sites 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. • vacuum removal of sludge at all sites and the use of LEV in the interim. 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. Section 8: monitoring arrangements for the authorisation as given in Annex V. Section 9: recommendations for the review report as given in Annex V. **Use2:** *Use of Chromium (VI) Trioxide for Electrolytic Chromium Coating of Steel (ECCS); also known as Tin Free Steel (TFS)*	the discussion of the working group. **SECR** to schedule the draft opinion for agreement at the RAC-64 plenary meeting.

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. In the event that T8 (Dissolution of solid CT) is undertaken in Basse-Indre, during the review period, the applicant shall implement appropriate OC/RMMs to reduce workplace exposure to Cr(VI) in addition to those proposed in the CSR. As a minimum, the following RMMs shall be implemented:
   - Install a local exhaust ventilation system or an air extraction system to reduce dust generation.
   - Restrict access to the area where the dissolution will take place.
   - Ensure operators that carry out the activity are trained in how to minimise exposure.
   - Monitor exposure of the operators by air monitoring and biomonitoring.

   The potential for exposure shall be brought to as low a level as technically and practically feasible prior to commencement of the activity.
2. The applicant shall carry out and document a detailed feasibility study on:
   a. 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, in both sites.
   b. the substitution of solid CrO_3 flakes by liquid solutions of CrO_3, or if not feasible, pellets, to further limit exposure in Etxebarri.

   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.

Section 8: monitoring arrangements for the authorisation as given in Annex V.
Section 9: recommendations for the review report as given in Annex V.

The working group recommended to discuss at the RAC plenary following points of the draft opinion:

- similarities and differences of the Basse-Indre site versus the KYB site in the RMMs to control release to air and measured releases and consider whether for this site for MvE overall conclusion is correct and whether a condition is needed.

3. 275_CT_Sicrom (1 use)	
Use1: *Functional chrome plating of hydraulic cylinders and swivel joints using chromium trioxide* 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 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 1. The applicant shall ensure that workers perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before taking on relevant tasks and workers shall be trained to do this test adequately. 2. The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 flakes with liquid CrO_3 to further limit the exposure; b) the implementation of a closed automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths and the implementation of an automated or closed 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. 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. Section 8: monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programmes: (a) Occupational inhalation exposure monitoring programmes for Cr(VI) at both sites, 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) ensure a sufficiently low limit of quantification (iv) comprise personal and/or static inhalation exposure	**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-64 plenary meeting via the A-listing procedure.

sampling;

(v) 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;

(vi) 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 air at the Visano site and implement the same monitoring programme at the Acquafredda site;

(ii) the applicants shall conduct emission measurements more frequently in the periods following any possible changes in the process;

(iii) the monitoring programmes for 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 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 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 annual biomonitoring programme for the workers potentially exposed to Cr(VI) at the Visano site and implement the same monitoring programme at the Acquafredda site. Section 9: recommendations for the review report as given in Annex V. The working group recommended that the draft opinion is suitable for consideration via the A-listing procedure.	
4. 276_CT_Osmaplast (2 uses)	
Use1: *Industrial use of hexavalent chromium for a pre-treatment step (etching) in the electroplating process for various applications.* **Use1:** *Industrial use of hexavalent chromium to create a long-lasting and high durability chromium decorative surface on plastic substrates in the electroplating process for various applications.* The working group discussed: - correctness and outcome of air monitoring and biomonitoring. 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 draft opinion are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The working group supported: Section 7: additional conditions for the authorisation 1. The applicant shall ensure that workers perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before	**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-64 plenary meeting via the A-listing procedure.

taking on relevant tasks and workers shall be trained to do this test adequately. 2. The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 flakes with 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 an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. d) the installation of a system that controls continuously the local exhaust ventilation and triggers and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s), in case the local exhaust ventilation is not functioning properly. 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. Section 8: monitoring arrangements for the authorisation as given in Annex V. Section 9: recommendations for the review report as given in Annex V. The working group recommended that the draft opinion is suitable for consideration via the A-listing procedure.	
5. 277_CT_Ritmonio (1 use)	
Use1: *Chromium trioxide-based functional chrome plating of machine components for centrifugal separator and decanter centrifuges.* The working group discussed: - need for feasibility study on segregation. 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:	**Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group. **SECR** to schedule the

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 with 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 an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen d) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s), in case the local exhaust ventilation is not functioning properly e) the physical separation between the loading/unloading working area and the plating line. 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. Section 8: monitoring arrangements for the authorisation as given in Annex V. Section 9: recommendations for the review report as given in Annex V. The working group recommended to discuss at the RAC plenary following points of the draft opinion: - Section 7: Additional conditions for the authorisation.	draft opinion for agreement at the RAC-64 plenary meeting.
6. 278_RR1_Diglyme_Isochem (1 use)	
Use1: *Use of diglyme as a process solvent in one step of the manufacturing of an Active Pharmaceutical Ingredient used in an anti-protozoal drug* The working group supported the draft opinion as proposed by the Rapporteur. The working group recommends to RAC that the risk assessment presented in the review report demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the review	**SECR** to schedule the draft opinion for agreement at the RAC-64 plenary meeting via the A-listing procedure.

report are implemented and adhered to.

The working group proposed:
Section 7: additional conditions for the authorisation
none
Section 8: monitoring arrangements for the authorisation

1. The authorisation holder shall continue the following occupational inhalation exposure monitoring programmes for Diglyme, 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 Diglyme
   (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 Diglyme 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.
2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the authorisation holder to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Diglyme 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 and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the authorisation holder, 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 measurements referred to in section 8.1 paragraph 1 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 working group recommended that the draft opinion is suitable for consideration via the A-listing procedure.	
7. 279_CT_GalvanoPlus (1 use)	
Use1: *Industrial use of chromium trioxide for functional chrome plating with decorative character of sanitary equipment.* The working group discussed: - authorisation conditions for applicant to perform a feasibility study on segregation. The working group supported the draft opinion as proposed by the Rapporteur with agreed changes. 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 ensure that workers perform a 'fit check' of the seal, of their respiratory protective equipment (RPE) before taking on relevant tasks and workers shall be trained to do this test adequately The applicant shall install without delay, as indicated in the response to RAC's questions: • an automated system at Briga Novarese site for the	**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-64 plenary meeting via the A-listing procedure.

transfer of jigs over the activation step to ensure that also this step, is automated. This is currently performed manually by workers who rely mostly on RPE as a protective measure against exposure. An automatic system for the transfer of the jigs from the activation bath to the chrome plating bath is already installed in San Maurizio's site; • a closed/automated supply system to transfer the CrO_3 solution directly in to the baths in both sites (San Maurizio and Briga Novarese). This operation is currently performed manually by workers which rely mostly on the use of RPE as safety measure. The applicant shall carry out and document a detailed feasibility study on: a) the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of RPE; b) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and/or the shutdown of the plating operation in case the local exhaust ventilation is not functioning properly; c) the physical separation between the loading/unloading working area and the plating line. 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. Section 8: monitoring arrangements for the authorisation as given in Annex V. Section 9: recommendations for the review report as given in Annex V. The working group recommended that the draft opinion is suitable for consideration via the A-listing procedure.	
8. 280_CT_Tecnocrom_Industrial (2 uses)	
Use1: *Functional chrome plating of parts with at least one axis of symmetry and simple surface geometry.* **Use2:** *Functional chrome plating of parts with complex surface geometry and requiring the use of an auxiliary anode* The working group discussed: - hard conditions in section 7 - monitoring arrangements in section 8.	**Rapporteurs** together with **SECR** to edit the draft opinion according to the discussion of

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 not 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 1. The applicant shall implement additional OCs and RMMs at all sites, to ensure segregation of the chrome plating areas (e.g. reconfiguration/redesign to remove loading and unloading from the plating area, removal of the workers from the plating area through remote operations of hoists, baths coverage when in use), to comply with the hierarchy of control principles. The additional OCs and RMMs shall be implemented within 12 months of the granting of an authorisation for this use. 2. Until the implementation of the additional OCs and RMMs, the applicant shall ensure that workers involved in chrome plating activities (WCS 2) use appropriate and properly fit-tested RPE, with due consideration for the duration of the tasks and the comfort of the workers during their use. 3. Without prejudice to points 1 and 2 above, the applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 by liquid solutions of CrO_3 (at 11 sites) to further limit exposure, (b) the implementation of an automated system to perform the bath concentration adjustment (at 11 sites), (c) the implementation of a closed/automated system to perform bath sampling tasks (at all sites), 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 all across the sites and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex V Section 9: recommendations for the review report as given in Annex V. The working group recommended to discuss at the RAC plenary following points of the draft opinion: - Section 7: Additional conditions for the authorisation.	the working group. **SECR** to schedule the draft opinion for agreement at the RAC-64 plenary meeting.

- Section 8: Proposed monitoring arrangements for the authorisation.	
9. 281_CT_Electro_Durocrom (1 use)	
Use1: *Industrial use of chromium trioxide for the hard chromium plating of moulds, dies and custom-made finished parts on any metal base, in order to provide hardness, wear resistance, corrosion resistance, demoulding properties, low friction ratio, for the manufacture of high-quality metal parts in several sectors as automotive, pharmaceutical, food and packaging industries.* The working group discussed: - different options of additional conditions for the authorisation, - needs for biomonitoring requirements. 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 to workers. The working group recommends to RAC that the OCs and RMMs related to environmental release minimisation are appropriate and effective in limiting the risk to the general population via the environment. The working group proposed: Section 7: additional conditions for the authorisation 1. The applicant shall implement additional OCs and RMMs, such as segregation (e.g. reconfiguration/redesign) of the chrome plating area from other work areas to avoid that loading and unloading activities are performed in the vicinity of the plating baths and remote operations of hoists to reduce presence of workers in proximity of plating baths. The implementation of these additional measures complies with the hierarchy of control principles. The additional OCs and RMMs shall be implemented within 12 months of the granting of an authorisation for this use. 2. Until the implementation of the additional OCs and RMMs, the applicant shall ensure that workers involved in chrome plating activities (WCS 2) use appropriate and properly fit-tested RPE, with due consideration for the duration of the tasks and the comfort of the workers during their use. 3. Without prejudice to points 1 and 2 above, the applicant shall carry out and document a detailed feasibility study on: (a) the implementation of a closed/automated system to	**Rapporteurs** 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-64 plenary meeting.

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.

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 all across the sites and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation

1. The applicant shall implement the following monitoring programmes for Cr(VI):

a) Occupational inhalation exposure monitoring programme, which shall:

i. be conducted *within 6 months of the granting of an authorisation on this use, and at least annually afterwards,* 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 with which to assess minimisation of emissions.

iv. comprise personal and 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 conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process.

ii. the monitoring programmes for wastewater and air emissions shall:

a. be based on relevant standard methodologies or protocols.

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

c. ensure a sufficiently low level of quantification.

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 OCs and RMMs 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 (i.e. workers and general population) has been reduced to as low a level as technically and practically possible and that the OCs and RMMs 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 OCs or RMMs that may affect the exposure of workers and humans via environment at the site 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 and humans via environment continues to be reduced to as low a level as technically and practically possible. 7. The applicant shall adapt and continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI). This programme must consist, as a minimum, of pre and post shift urine samples (beginning of the week --> end of the week), valid existing standard methodologies are e.g. HSE, HBM4EU, etc. This annual biomonitoring program must be synchronised with the annual occupational air monitoring campaign specified in 1.a above. Section 9: recommendations for the review report The results of the actions/ feasibility study as mentioned in section 7 and the measurements referred to in section 8.1, the conclusions from the investigation on the source of measured concentration of Cr(VI) in wastewater referred in section 2.5, 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 authorisation review report. The applicant should consider splitting WCS 2 - functional plating - into further contributing scenarios to cover specific tasks such as loading/unloading, manual plating and semi-automated plating, separately.	

The applicant shall report the results of their monitoring programme for Cr(VI) emission to wastewater. The working group recommended that the draft opinion is suitable for general agreement at the RAC plenary.	
10. 282_CT_Hazet_Werk (1 use)	
Use1: *Chromium trioxide-based functional chrome plating of hand tools to achieve a high level of abrasion resistance as well as corrosion and chemical resistance.* The working group discussed: - segregation of tasks and information related to the exposure dataset, - additional conditions for the authorisation to workers taking manual tasks to wear proper RPE. 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 proposed: Section 7: additional conditions for the authorisation 1. The applicant shall ensure that workers perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before taking on relevant tasks, and workers shall be trained to do this test adequately. 2. The applicant shall ensure that appropriate RPE is worn during baths sampling (WCS 4) due to the increased potential for exposure to CrO_3. The use of RPE could stop if the task starts being performed with an automated system or closed sampling system. 3. The applicant shall carry out and document a detailed feasibility study on: a) the segregation between the loading/unloading areas and the plating area, either by the introduction of a physical barrier or by the removal of loading/unloading from the plating area; b) the implementation of a closed/ automated system for sampling to perform bath sampling tasks, where exposure to Cr(VI) is foreseen. The feasibility study shall be concluded within 12 months of the	**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-64 plenary meeting via the A-listing procedure.

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. Section 8: monitoring arrangements for the authorisation as given in Annex V. Section 9: recommendations for the review report as given in Annex V. The working group recommended that the draft opinion is suitable for consideration via the A-listing procedure.	
11. 283_CT_KYB (1 use)	
Use1: *Functional chrome plating of piston rods for shock absorbers for automotive applications.* The working group discussed: - impact of use different RPEs for the exposure values presented by the applicant for the both sites, - additional conditions for the authorisation related to the Rapporteurs concern on the HvE exposure level at the KYBSE Ororbia site. 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 to the workers but not appropriate and effective in limiting the risk to the general population at the Ororbia site. The working group proposed: Section 7: additional conditions for the authorisation The applicant shall continue to carry out and document a detailed feasibility study on the implementation of a closed/automated system to perform bath sampling tasks (at KYBSE Ororbia site), 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. The applicant shall take further action related to the air emissions of the KYSBE site: • At the latest within three months of the granting of an	**Rapporteurs** 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-64 plenary meeting with short presentation on selected points of the draft mopinion.

authorisation for this use, the applicant shall conduct a measurement campaign on all emission points for emissions of Cr(VI) to air at the KYBSE site. This campaign shall be conducted in accordance to section 8.1, paragraph 1.b)iii. • The applicant shall carefully analyse the results of the measurement campaign and recalculate the release factor for the air of the KYBSE site. o A release factor of a same level of magnitude or lower than the one derived for the KMCZ site shall be achieved; o If the release factor is not of the same order of magnitude or lower than for KMCZ, the applicant shall conduct a root cause analysis for the difference and implement immediately appropriate actions to improve the situation in terms of achieving a higher level of efficiency of the applied OCs and RMMs at the site for air release control. If necessary, additional RMMs shall be implemented to further reduce these releases to as low a level as technically and practically feasible. o Control measurements shall be conducted to confirm the impact of any action. The "control measurement – analysis – action" cycle shall be continued until a release factor of the same level of magnitude or lower than KMCZ is achieved. All of the actions taken shall be reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex V. Section 9: recommendations for the review report as given in Annex V. The working group recommended to discuss at the RAC plenary following points of the draft opinion: - exposure calculations, - concerns related to the Rapporteurs concern on the HvE exposure level at the KYBSE Ororbia site, - Section 7: Additional conditions for the authorisation.	
12. 284_CT_CGS (1 use)	
Use1: *Electroplating of different types of substrates using Chromium Trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications.* The working group supported the draft opinion as proposed by the Rapporteurs.	**SECR** to verify the coverage of the EUSES output for the MvE routes for the

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: 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 with liquid CrO_3 to further limit exposure; b) the implementation of an automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium bath and the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE; c) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s), in case the local exhaust ventilation is not functioning properly; d) the physical separation between the loading/unloading working area and the plating line. 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. Section 8: monitoring arrangements for the authorisation as given in Annex V, only points 1-6. Section 9: recommendations for the review report as given in Annex V. The working group recommended that the draft opinion is suitable for consideration via the A-listing procedure.	oral exposure. **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-64 plenary meeting via the A-listing procedure.

Annex II

1 December 2022
RAC WG/A/14/2023
Draft

Agenda

Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group (RAC AFA WG) reporting to RAC-64

31 January - 1 February 2023

WebEx meeting

Tuesday 31 January starts at 10.00
Wednesday 1 February ends at 18.10

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/14/2022
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

1. 273_CT_MikroMetal
2. 274_CT_SD_ArcelorMittal
3. 275_CT_Sicrom
4. 276_CT_Osmaplast
5. 277_CT_Ritmonio
6. 278_RR1_Diglyme_Isochem
7. 279_CT_GalvanoPlus
8. 280_CT_Tecnocrom_Industrial
9. 281_CT_Electro_Durocrom
10. 282_CT_Hazet_Werk
11. 283_CT_KYB
12. 284_CT_CGS

For discussion

Item 5 – AOB

1. AfA horizontal issues

For discussion

Item 6 – Adoption of the Report from the WG

For discussion and adoption

Annex III

List of participants of the 14th Meeting of the RAC AFA working group

RAC Members
Angeli Karine
Barański Boguslaw
Brovkina Julija
Chiurtu Elena (co-opted)
Deviller Geneviève (co-opted)
Doak Malcolm
Docea Anca
Esposito Dania
Geoffroy Laure
Ginnity Bridget (co-opted)
Kadiķis Normunds
Leinonen Riitta
Menard Anja
Moldov Raili
Peczkowska Beata
Rakkestad Kirsten Eline
Schlüter Urs
Tekpli Nina Landvik
Tobiassen Lea Stine
Užomeckas Žilvinas
Van der Haar Rudolf (co-opted)
Viegas Susana

Members' advisers
Beetstra Renske (adviser to Gerlienke Schuur)
Catone Tiziana (adviser to Gabriele Aquilina)
Granato Giuseppe (adviser to Dania Esposito)
Jankowska Agnieszka (adviser to Beata Peczkowska)
Seba Julie (adviser to Wendy Rodriguez)

European Commission
Fabbri Marco
Roebben Gert

RAC Regular Stakeholders
Janosi Amaya

ECHA
Ahtiainen Heini
Bowmer Tim
Di Bastiano Augusto
Gmeinder Michael
Klausbruckner Carmen
Logtmeijer Christiaan
Loukou Christina
Ludborzs Arnis
Mäkelä Petteri
Nicot Thierry
Peltola Jukka
Peltola-Thies Johanna
Pillet Monique
Regil Pablo
Schakir Yasmin
Sosnowski Piotr
Thierry-Mieg Morgane
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.

Annex V

Standard text for Section 8: monitoring arrangements for the authorisation and Section 9: recommendation for the review report.

Section 8: monitoring arrangements for the authorisation

1. The applicant shall implement 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 (or "implement a") 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 (i.e. workers and general 0population) 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 and humans via the environment 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 and humans via the environment 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 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 authorisation review report.