RAC working group/R/13/2022

Final

12 October 2022

Report
of the 13th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC AFA working group)

(Telakkakatu 6, Helsinki) via Webex

Tuesday 11 October starts at 10.00
Wednesday 12 October ends at 18.40

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 30 participants to the 13th 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 and Tim Bowmer the Chair of RAC.

The Chair summarised the members written contribution to the RAC consultations on the draft opinions prior to the working group 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/13/2022), 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. None of the participants declared any potential conflicts of interest to any of 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 13 Applications covering 16 uses considered at this meeting are listed in Annex I.

5. AOB

AfA horizontal issues:

The Secretariat presented the updated sections of the technical guidance for rapporteurs (Lines-To-Take) document following the seminar on human biomonitoring of Cr(VI) at RAC-62 in September 2022. The working group supported the changes proposed by the secretariat in the document. Participants provided several editorial proposals particularly about situation 3 (i.e. high concern workplaces) regarding, for instance when workers manually remove sludges from plating baths. In addition, the group as well considered when the recommending of human biomonitoring could enhance the control of exposure in workplaces. The participants also provided clarification on how the human biomonitoring should be performed (e.g. pre and post shift urine samples).

The Secretariat informed the working group about incoming applications for authorisation and review reports, which are expected to be received in 2023 and in 2024 and added that updated RAC and SEAC overview tables have been uploaded to the S-CIRCABC.

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, requesting the Secretariat to make any necessary editorial changes.

Annex I	**Working group recommendations**
Annex II	**Agenda of the 13th meeting**
Annex III	**List of participants of the 13th 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. 260_CT_Sarrel (1 use)	
Use1: *Industrial use of chromium trioxide for the etching of plastics materials, as a pre-treatment step of the electroplating process, for automotive applications mostly.* The working group discussed: - Potential conditions for the authorisation that the applicant shall install a system that continuously controls the adequate functioning of the local extraction ventilations at the Cr(VI) containing baths and that is connected with an alarm system that will be set off when a failure is detected. The working group supported the draft opinion as proposed by the Rapporteur.	**SECR** to check the previous applications regarding LEV failure. **Rapporteur** together with **SECR** to edit the draft opinion according to

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: 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 in all lines; c) the implementation of an closed/automatic 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 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 the following points of the draft opinion: - Potential conditions for the authorisation that the applicant shall install a system that continuously controls the adequate functioning of the local extraction ventilations at the Cr(VI) containing baths.	the discussion of the working group. **SECR** to schedule the draft opinion for agreement at the RAC-63 plenary meeting.
2. 261_CT_Metalbrass (1 use)	
Use1: *Electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector.* 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 generally appropriate and effective in limiting the risk, provided that they are implemented and adhered to.	**Rapporteurs** together with **SECR** to edit the draft opinion according to the discussion of the working group.

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 by liquid solutions of CrO_3 to further limit exposure, (b) the implementation of an automated system to perform the bath concentration 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. 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.	**SECR** to schedule the draft opinion for agreement at the RAC-63 plenary meeting via the A-listing procedure.
3. 262_CT_Cromoplastica (2 uses)	
Use1: *Use of chromium trioxide for etching of plastic substrates as a key pre-treatment step for creating an electrically conductive surface to enable electroplating.* **Use2:** *Use of chromium trioxide for electroplating of plastic substrates to achieve a protective and durable surface with a silvery finish.* 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: Section 7: additional conditions for the authorisation The applicant shall carry out and document detailed feasibility studies on:	**Rapporteur** together with **SECR** to edit the draft opinions according to the discussion of the working group. **SECR** to schedule the draft opinions for agreement at the RAC-63 plenary meeting via

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. The feasibility studies shall be concluded within 12 months of granting an authorisation for this use. In accordance with the conclusion of the feasibility studies, 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 opinions are suitable for consideration via the A-listing procedure.	the A-listing procedure.
4. 263_CT_Orelec (1 use)	
Use1: *Industrial use of chromium trioxide for the hard chrome plating of injection moulds in order to provide hardness, wear resistance and good demoulding properties, critical for the manufacture of high-quality plastic parts.* The working group discussed: - that hierarchy of control has not been followed by the applicant, - unrealistic requirement to workers to wear RPE 8h per shift, - the need for conditions for the authorisation to segregate the workspace and to enclosure the bath. 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 recommended that the draft opinion is suitable for general agreement at the RAC plenary.	**Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group. **SECR** to launch RAC consultations on the draft opinion. **Rapporteur** together with **SECR** to revise the draft opinion

	according to RAC comments. **SECR** to schedule the draft opinion for agreement at the RAC-63 plenary meeting.
5. 264_CT_Cristina (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 Rapporteur with proposed changes in the Section 7 of the daft pinion. 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. The working group supported: 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/automatic system to perform manual 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 as given in Annex V. Section 9: recommendations for the review report as given in	**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-63 plenary meeting via the A-listing procedure.

Annex V. The working group recommended that the draft opinion is suitable for consideration via the A-listing procedure.	
6. 265_TXP_EDF (2 uses)	
Use1: *Industrial use as a hydraulic fluid in closed systems to drive and control the steam inlet valves of turbines.* **Use2:** *Industrial use as a hydraulic fluid in closed systems to drive and control main steam isolation valves.* The working group supported the draft opinions as proposed by the Rapporteur. The working group recommends to RAC that the risk assessment presented in the application demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the application 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 applicant shall continue the following occupational inhalation exposure monitoring programmes for Trixylyl phosphate (TXP), 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 TXP (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 TXP 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 applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures	**Rapporteur** together with **SECR** to edit the draft opinions according to the discussion of the working group. **SECR** to schedule the draft opinions for agreement at the RAC-63 plenary meeting via the A-listing procedure.

to further reduce workplace exposure to TXP 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 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. 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 opinions are suitable for consideration via the A-listing procedure.	
7. 266_CT_Olivari (1 use)	
Use1: *Electroplating of brass substrates using chromium trioxide to achieve functional surfaces for architectural fittings.*	**Rapporteur** together with

The working group discussed additional conditions for the authorisation for the applicant to carry out and document feasibility studies to use liquid Cr(VI), to reduce exposure during the sampling procedure and to separate electroplating line from other activities performed in the same place. Generally, 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 1. The applicant shall carry out and document feasibility studies on: a. *Measures to eliminate or minimise the potential for exposure to solid CrO_3 flakes during addition to the electroplating bath** b. *Measures to reduce the potential for exposure during sampling** ** to be edited following the working group discussion to be align with the LTT document* c. *Physical separation of the physical vapour deposition line from the electroplating line.* The 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 ensure that workers use the RPE in accordance with standard procedures for use and maintenance. Those procedures shall include: (a) procedures for fit testing of RPE masks, applied in accordance with relevant standards (b) training and medical fitness checking and supervision of the wearer and (c) maintenance of the RPE 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.	**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-63 plenary meeting via the A-listing procedure.

8. 267_CT_SPGPrints (1 use)	
Use1: *Use of Cr(VI) in an integrated process to create a hard surface with selective adhesion properties on mandrels used to manufacture screens for Rotary Screen Printing (RSP) for textile and other (printing) applications.* 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 application 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 None 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.	**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-63 plenary meeting via the A-listing procedure.
9. 268_CT_Paffoni (1 use)	
Use1: *Functional chrome plating with decorative character of metal substrates for sanitary applications.* The working group discussed: - functioning of the LEV systems. 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 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	**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

1. The applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 flakes 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 in both lines (c) the coverage of the baths. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented 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.	the RAC-63 plenary meeting via the A-listing procedure.
10. 269_CT_Rubinetterie3M (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: - additional conditions to improve the way rare maintenance tasks are performed, - segregations of tasks performed under the WCS2. 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 carry out and document feasibility studies on: a. The substitution of solid CrO_3 flakes by liquid CrO_3 to further limit worker exposure. b. The implementation of an automated system to perform the bath adjustment, and the implementation of a	**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-63 plenary meeting via the A-listing procedure.

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 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 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 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. 270_CT_Maier (2 uses)	
Use1: *Functional chrome plating with decorative character for automotive applications.* **Use2:** *Etching of plastics with chromium trioxide as pre-treatment step for electroplating of plastics for automotive applications.* The working group discussed: - a need for separation of the workspace at the Gernika site, - concerns related to the lack of general mechanical ventilation at the Verdellino site, - conditions to install a system that continuously controls the adequate functioning of the local extraction ventilations at the Cr(VI) containing baths. The working group supported 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.	**SECR** to check the previous applications regarding LEV failures. **Rapporteur** together with **SECR** to edit the draft opinions according to the discussion of the working group. **SECR** to schedule the

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 full substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure. b) the implementation of an automated system for sampling or sampling in a closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen. 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. Additionally following recommendations: External workers potentially exposed to Cr(VI) at the sites where the use applied for takes place shall be included in the risk assessment of any subsequent authorisation review report. The working group recommended to discuss at the RAC plenary the following points of the draft opinions: - Potential conditions for the authorisation that the applicant shall install a system that continuously controls the adequate functioning of the local extraction ventilations at the Cr(VI) containing baths.	draft opinions for agreement at the RAC-63 plenary meeting.
12. 271_CT_Villeroy (1 use)	
Use1: *The use of chromium trioxide for electroplating of metal substrates with the purpose to create a long-lasting high durability surface with bright look for kitchen and bathroom sanitary ware.* The working group supported the draft opinion as proposed by the Rapporteurs. The working group recommends to RAC that the operational conditions and risk management measures described in the	**Rapporteurs** together with **SECR** to edit the draft opinion according to the discussion of the working

application are generally 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 applicants shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 by liquid solutions of CrO_3 to further limit exposure (at the FMMMG site); (b) the implementation of an automated system to perform the bath concentration adjustment at the FMMMG site, 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 (at both sites). 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.	group. **SECR** to schedule the draft opinion for agreement at the RAC-63 plenary meeting via the A-listing procedure.
13. 272_CT_RIGHI (1 use)	
Use1: *Electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector.* The working group supported the draft opinion as proposed by the Rapporteurs. The working group recommends to RAC that the operational conditions and risk management measures described in the application are generally 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 by liquid solutions of CrO_3 to further limit exposure.	**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-63

(b) the implementation of an automated system to perform the bath concentration 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. 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.	plenary meeting via the A-listing procedure.

Annex II

11 October 2022
RAC WG/A/13/2022
Final

Agenda

Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group (RAC AFA WG) reporting to RAC-63

11-12 October 2022

WebEx meeting

Tuesday 11 October starts at 10.00
Wednesday 12 October ends at 18.40

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/13/2022
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

1. 260_CT_Sarrel (1 use)
2. 261_CT_Metalbrass (1 use)
3. 262_CT_Cromoplastica (2 uses)
4. 263_CT_Orelec (1 use)
5. 264_CT_Cristina (1 use)
6. 265_TXP_EDF (2 uses)
7. 266_CT_Olivari (1 use)
8. 267_CT_SPGPrints (1 use)
9. 268_CT_Paffoni (1 use)
10. 269_CT_Rubinetterie3M (1 use)
11. 270_CT_Maier (2 uses)

12. 271_CT_Villeroy (1 use)
13. 272_CT_RIGHI (1 use)

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 13th 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
Geoffroy Laure
Ginnity Bridget (co-opted)
Kadiķis Normunds
Leinonen Riitta
Moldov Raili
Peczkowska Beata
Pribu Mihaela
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 Pietro Paris)
Jankowska Agnieszka (adviser to Beata Peczkowska)
Panieri Emiliano (adviser to Pietro Paris)
Seba Julie (adviser to Wendy Rodriguez)
Silvestri Federico (adviser to Pietro Paris)

European Commission
Dunauskiene Lina
Fabbri Marco
Roebben Gert

RAC Regular Stakeholders
Barry Frank
Janosi Amaya

ECHA
Bowmer Tim
Gmeinder Michael
Klausbruckner Carmen
Lefevre Sandrine
Logtmeijer Christiaan
Loukou Christina
Ludborzs Arnis
Nurmi Väinö
Peltola Jukka
Peltola-Thies Johanna
Pillet Monique
Regil Pablo
Richarz Andrea
Roberts Julian
Schakir Yasmin
Sosnowski Piotr
Thierry-Mieg Morgane
Vazquez-Rodriguez Jesus
Wilk Mateusz

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		
None		

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