RAC WG/R/10/2022
Final
1 February 2022

Report
of the 10th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC-AFA WG)

ECHA Conference Centre
(Telakkakatu 6, Helsinki)
via Webex

Tuesday 1 February starts at 10.00
Tuesday 1 February ends at 18.25

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 26 participants to the 10th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. He informed the participants that sections of the meeting would also be chaired by Thierry Nicot and by Johanna Peltola-Thies, Deputy Chair of RAC.

The Chair provided a short summary of the history and achievements of the working group in support of RAC in the Applications for Authorisation process.

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 WG/A/10/2022), which was adopted unchanged and is attached to this Report as Annex II.

3. Declarations of conflicts of interests to the Agenda

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

4. Authorisation applications

The recommendations by the working group on Draft opinions on 6 uses from 6 applications considered at this meeting are listed in Annex I.

5. AOB

AfA horizontal issues:

The RAC AfA WG discussed several horizontal issues presented by the Secretariat. The working group discussed but did not come to form conclusions on all the points related Section 7 (conditions), Section 8 (monitoring arrangements, including potentially human biomonitoring for Cr(VI) compounds) and Section 9 (Recommendations for the Review Report). The Secretariat will organise further discussions at the RAC 60 with the view to finalise the RAC's approach on these topics.

6. Adoption of the report of the working group

Before the Chair Johanna Peltola-Thies thanked the participants and closed the meeting, the working group adopted its report of the 10th Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I	**Working group Recommendations**
Annex II	**Agenda of the 10th meeting**
Annex III	**List of participants of the 10th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation**
Annex IV	**Declarations of potential conflicts of interest**

Annex I

Working group recommendations

Abbreviations used

4-NPnEO	4-Nonylphenol, branched and linear, ethoxylated
4-tert-OPnEO	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated
CA	chromic acid
CT	chromium (VI) trioxide
DtC	dichromium tris(chromate)
ERC	environmental release category
ES	exposure scenario
HvE	Humans via environment
LEV	local exhaust ventilation
MOCA	*2,2'-Dichloro-4,4'-methylenedianiline*
OC	operational condition
PBT	persistent, bioaccumulative and toxic
PPE	personal protective equipment
RMM	risk management measure
RPE	respiratory protective equipment
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. 236_SD_Robur (1 use)	
Use1: *Use of sodium dichromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 1.05% w/w (corresponding to 0.42% w/w as Cr(VI)) in the refrigerant solution.* 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 recommendations for the review report are	**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-60 plenary meeting via the A-listing procedure.

expected to allow RAC to evaluate the review report efficiently. The working group supported: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicant shall conduct annual monitoring programme of occupational exposure for Cr(VI) of workers directly or indirectly involved in ES 1 and ES 3, using a sufficiently sensitive analytical method. Those programmes shall be based on relevant standard methodologies or protocols, comprise both static and personal inhalation exposure sampling, include detailed contextual information on the tasks performed, the duration of monitoring, the OCs and RMMs in place and be representative of: ○ the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance/cleaning tasks; ○ the OCs and RMMs typical for each of these tasks; ○ the number of workers potentially exposed, including workers not directly using the substance. 2. The authorisation holder shall continue to conduct at least annual Cr(VI) measurements in exhaust air using a sufficiently sensitive analytical method. 3. The information gathered via the measurements referred to in paragraph 1 and 2 related contextual information shall be used by the applicant to confirm the effectiveness of OCs and RMMs as well as to review regularly the effectiveness of OCs and RMMs in place and to introduce measures to further reduce workplace exposure respectively air emissions to Cr(VI) to as low a level as technically and practically feasible. 4. The information from the monitoring programmes referred to in paragraph 1 and 2, 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 3 shall be documented, maintained and be made available by the applicant, upon request, to the competent authority, and included in any subsequent authorisation review report.	

3. A recommendation (standard text) for the review report. The working group recommended that the draft opinion is suitable for consideration via the A-listing procedure.	
2. 237_CT_Nobili (1 use)	
Use1: *Use at industrial site electroplating of different types of substrates 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. 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 proposed additional conditions for the authorisation are expected to strengthen this conclusion. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in exposure during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently. The working group proposed: 1. additional conditions for the authorisation 1. The applicant shall carry out and document a feasibility study on (a) the implementation of an automated system to perform the manual tasks where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE (bath adjustments and bath sampling) (b) the substitution of solid CrO_3 flakes by liquid CrO_3 to further limit exposure. 2. The applicant shall use the information gathered	**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-60 plenary meeting.

via the measurements and related contextual information referred to in Section 8.1 to review the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) as low a level as technically and practically feasible. 2. monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes for Cr(VI), 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) comprise personal sampling for workers for all the WCS, including WCS 7, and static inhalation exposure sampling; (iv) be representative of: a. the range 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; (v) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to air; (ii) the applicant shall conduct air emission measurements at least yearly or more frequently if changes in the process take place; (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. 2. The applicant shall ensure that: (a) workers perform the sealing test of their respiratory protective equipment (RPE) before taking on relevant tasks (b) workers are trained to perform this test adequately	

(c) workers involved in WCS 7 use RPE even if not involved directly in the tasks being performed (supervision of the tasks external workers perform when collecting hazardous waste and cleaning the plating tanks (removal of sludge)). 3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurement as well as the outcome and conclusions of the review and any action taken in accordance with 7.1 paragraph 3, 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. 3. recommendations for the review report. [The applicant should continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). The biomonitoring should be based on validated methodologies and protocols for Cr(VI) exposure and in case of urinary sampling include pre- and post-shift sampling. This data should be considered for further exposure assessment and included in any subsequent review report. The results of the measurements referred to in sections 7 and 8 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with sections 7 and 8 paragraph 2, should be documented and included in any subsequent review report.] The working group recommended to discuss at the RAC plenary following points of the Draft opinion: 1. Section 7 2. Section 8 and 9 of the DO concerning requirements to perform human biomonitoring.	
3. 238_CT_Hueck (1 use)	
Use1: *Functional chrome plating of high-quality stainless-steel press plates for the premium wood-based materials industry.* The working group supported the Draft opinion as proposed by the Rapporteur.	**Rapporteurs** together with **SECR** to edit the Draft opinion according to the discussion of the working group.

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 proposed additional conditions for the authorisation are expected to strengthen this conclusion. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented and on associated trends in exposure during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently. The working group proposed to review following points: 1. additional conditions for the authorisation The applicant shall continue to investigate the feasibility to use liquid CrO_3 solution, for the concentration adjustment task, instead of solid CrO_3 and act on the outcome of the feasibility study. 2. monitoring arrangements for the authorisation 1. The applicant shall continue to monitor by implementing the following 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) comprise personal and / or static inhalation exposure sampling; (iv) comprise personal sampling for the workers involved in plating, sampling, concentration adjustment and maintenance activities (WCSs 2, 3, 4, 5 and 6); (v) be representative of: a. the full range of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for each of these tasks;	**SECR** to schedule the Draft opinion for agreement at the RAC-60 plenary.

c. the number of workers potentially exposed; (vi) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. 3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report The applicant should continue to conduct the annual biomonitoring programme for the workers potentially exposed to Cr(VI). The biomonitoring should be based on validated methodologies and protocols for Cr(VI) exposure, and in case of urinary sampling include pre and post-shift sampling The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1, section 9.1 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 to discuss at the RAC plenary following points of the Draft opinion: 1. Section 7 (timelines) 2. Section 8 (frequency) 3. Section 9 (HBM).	
4. 239_OPE_NPE_Prionics (1 use)	
Use1: *Use as component of buffer solutions to produce antigens (Cell extraction, cell lysis, coating of biological antigens onto articles, inactivation of microorganisms that produce targeted antigen and solvent exchange) and in-process and final Quality Control of antigens intended for use as veterinary and human health laboratory reagents in Scientific Research and Development and In Vitro Diagnostic applications.* 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 use applied for may result in approximately 0 kg per year releases of the substances to the environment. The working group supported: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. 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-60 plenary meeting via the A-listing procedure.
5. 240_OPE_Alexion (1 use)	
Use1: *Industrial use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated for virus*	**Rapporteur** together with **SECR** to edit the

inactivation in the manufacture of Andexanet alfa for treatment of adult patients treated with a direct factor Xa (FXa) inhibitor when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. 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 not expected to be appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in releases during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently. The use applied for may result in up to 31.62 kg per year releases of the substance to the environment. The working group supported: 1. additional conditions for the authorisation As soon as the new process becomes operational, the applicant shall carry out a mass balance analysis based on measurements as indicated in section 8 below. Based on the results, the applicant shall assess if and how the operational conditions and risk management measures can be optimised in such a way that the releases of 4-tert-OPnEO to the environment can be effectively minimised taking into account the outcomes of the measurement programme. 2. monitoring arrangements for the authorisation As soon as the new process becomes operational, the applicant shall undertake a monitoring programme, measuring the concentration of 4-tert-OPnEO in individual waste streams prior to release to the municipal STP. The initial sampling frequency	Draft opinion according to the discussion of the working group. **SECR** to schedule the Draft opinion for agreement at the RAC-60 plenary meeting via the A-listing procedure.

should be sufficient to account for daily fluctuations. Once established, RAC recommends that the applicant should monitor at least quarterly / 4 times per year (during the time of operation) 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the municipal STP, using an analytical method capable of adequately characterising the substance and its degradation products in water and at an appropriately low level of detection. The results of the monitoring programme 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. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report The information gathered via the measurements referred to in Section 8 as well as the outcome and conclusions of the review and any action taken should be included in any subsequent authorisation review report. The working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	
6. 241_CT_Gessi (1 use)	
Use1: *Use of chromium trioxide for electroplating of metal substrates with the purpose of creating a long-lasting high durability surface with bright look for kitchen and bathroom sanitaryware (functional plating with decorative character).* 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 <u>are</u> appropriate and effective in limiting the risk at the Gessi site, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. RAC concluded that the operational conditions and risk	**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-60 plenary meeting.

management measures described in the application are not appropriate and effective in limiting the risk at the San Marco site for the workers. [The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in exposure and releases during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently.] The working group proposed: 1. additional conditions for the authorisation 1. The applicant shall carry out and document a feasibility study on (a) the implementation of an automated system to perform the manual tasks where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE (bath adjustments and bath sampling for both sites, manual electroplating at the San Marco plant). This of particular relevance for the San Marco site due to the foreseen increase of the volume used. (b) the substitution of solid CrO_3 flakes by liquid CrO_3 to further limit exposure at the Gessi plant. 2. The applicant shall ensure that the RPE provided to the workers in San Marco site guarantee a protection of at least APF 20 while ensuring workers' comfort during the use of the RPE. This is of particular relevance in tasks that, although of short duration, might imply higher exposure (e.g. dipping of jigs or presence near the line in WCS 5). 3. The applicant shall use the information gathered via the measurements and related contextual information referred to in Section 8.1 to review the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) as low a level as technically and practically feasible.	

2. monitoring arrangements for the authorisation 1. The applicant shall continue to perform the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: (vii) 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) (e.g. due to the increase of the substance use expected for San Marco site); (viii) be based on relevant standard methodologies or protocols; (ix) comprise personal sampling for workers for WCS that might imply exposure, including WCS 7, and static inhalation exposure sampling; (x) be representative of: a. the range of tasks undertaken where exposure to Cr(VI) is possible, particularly the short duration tasks that might imply higher exposure moments (e.g. baths sampling, dipping of jigs); b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (xi) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to air and water. (ii) the applicant shall conduct air emission measurements more frequently (at least yearly), particularly if changes in the process justifies such as the expected increase of volume; (iii) the monitoring programmes for air and water emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant´s site. 2. The information 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. 3. recommendations for the review report The applicant should continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). The biomonitoring should be based on validated methodologies and protocols for Cr(VI) exposure and in case of urinary sampling include pre- and post-shift sampling. This data should be considered for further exposure assessment and included in any subsequent review report. The results of the measurements referred to in sections 7 and 8 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with sections 7 and 8 paragraph 2, should be documented and included in any subsequent review report. The working group recommended to discuss at the RAC plenary following points of the Draft opinion: 1. Section 7 2. Section 8 3. Section 9.	

Annex II

1 February 2022
RAC WG/A/10/2022
Final

Agenda

Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group (RAC AFA WG) reporting to RAC-60

1 February 2022

WebEx meeting

Tuesday 1 February starts at 10.00
Tuesday 1 February ends at 18.25

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/10/2022
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

1. 236_SD_Robur (1 use)
2. 237_CT_Nobili (1 use)
3. 238_CT_Hueck (1 use)
4. 239_OPE_NPE_Prionics (1 use)
5. 240_OPE_Alexion (1 use)
6. 241_CT_Gessi (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 10th Meeting of the RAC AFA WG

RAC Members
Baranski Boguslaw
Brovkina Julija
Chiurtu Elena (co-opted)
Deviller Geneviève (co-opted)
Doak Malcolm
Geoffroy Laure
Ginnity Bridget (co-opted)
Karadjova Irina
Moldov Raili
Printemps Nathalie
Schlüter Urs
Tobiassen Lea Stine
Užomeckas Žilvinas
Van der Haar Rudolf (co-opted)
Viegas Susana

Members' advisers
Beetstra Renske (adviser to Gerlienke Schuur)
De Kort Thijs (adviser to Betty Hakkert)
Seba Julie (adviser to Wendy Rodriguez)

RAC Regular Stakeholders
Janosi Amaya

European Commission
Dunauskiene Lina
Jezso Veronika
Roebben Gert

ECHA
Bowmer Tim
Karjalainen Anne-Mari
Klausbruckner Carmen
Lefevre Sandrine
Loukou Christina
Ludboržš Arnis
Mäkelä Petteri
Nicot Thierry
Nurmi Väinö
Peltola Jukka
Peltola-Thies Johanna
Pillet Monique
Portugal Laura
Regil Pablo
Schakir Yasmin
Sosnowski Piotr
Thierry-Mieg Morgane
Vazquez-Rodriguez Jesus
Väänänen Virpi
Zarogiannis Panagiotis

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 WG 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.