RAC WG/R/9/2021
Final
12 October 2021

Report
of the 9th 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 12 October starts at 10.00
Tuesday 12 October ends at 18.15

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 26 participants to the 9th 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 Johanna Peltola-Thies.

The Chair reminded the working group of the revised scope of the mandate, which has been extend until September 2022 at RAC-58. The mandate is now to review and to do assessment of the Rapporteur's Draft opinions and to make recommendations on fast tracking, where relevant. Agenda of each working group meeting normally covers the Draft opinions scheduled for the subsequent RAC plenary meeting. The working group shall also maintain a list of relevant horizontal issues which the Committee and the Secretariat can request them to discuss and report.

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

Finally, he thanked all Rapporteurs on behalf of ECHA for their commitment to prepare on time good quality documents and presentations.

2. Adoption of the Agenda

The Chair introduced the agenda for the meeting (RAC WG/A/9/2021), 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 of the meeting declared a potential conflict of interest on cases scheduled for the discussion (see also Annex IV to this Report). The Chair and co-Chairs 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 5 applications considered at this meeting are listed in Annex I.

5. AOB

AfA horizontal issues:
The Secretariat presented a state of play of the AfA/RR pipeline. Due to the expected high number of AfA opinions to be issued in 2022 by RAC and SEAC, ECHA Secretariat presented how the workload in 2022 will be staggered so that a reasonable number of opinions are discussed and agreed per quarter (10 to 15 applications per meeting at maximum).

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 9th Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I	**Working Group Recommendations**
Annex II	**Agenda of the 8th meeting**
Annex III	**List of participants of the 9th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation**
Annex IV	**Declarations of potential conflicts of interest**
Annex V	**Conclusions of the Capacity Building Seminar on assessment of biomonitoring data**
Annex VI	**List of participants of the Capacity Building Seminar on assessment of biomonitoring data**

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. 231_CT_Kesseboehmer (1 use)	
Use1: *Use of chromium trioxide for decorative/functional application in the furniture, sanitary and automotive sector.* The working group supported the Draft opinion as proposed by the Rapporteurs. The working group recommends to RAC that RAC concluded 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.	**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-59 plenary meeting via the A-listing procedure.

The proposed additional conditions and 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 supported: 1. additional conditions for the authorisation [Conditions for the authorisation are proposed to ensure that the tests that the RPE is correctly fitting are always performed by workers before they enter the workplace, so that the intended level of protection is reached during use.]* The applicant should continue to investigate the possibility to use liquid CrO_3 solution instead of solid CrO_3. The applicant should use RPE for workers performing tasks under WCS4 – R&D line. 2. monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programme for Cr(VI): Occupational inhalation exposure The applicant shall implement their monitoring programmes for Cr(VI) exposure, which shall : (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of: a. the range of tasks undertaken where exposure to Cr(IV) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed;	

* The square brackets indicate that the finalisation of the detail is to be carried out by the Rapporteur, supported by ECHA-s.

(v) include contextual information about the tasks performed during sampling. 2. The information gathered via the measurements referred to in paragraphs 1 and related contextual information shall be used by the applicants 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) 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 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 monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and made available by the applicants, 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 potential exposed to Cr(VI). The biomonitoring should be specific to Cr(VI) exposure and include at least pre- and post-shift sampling. The results of the investigation in section 7 and 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.	
2. 232_DtC_Monroe (1 use)	
Use: *Use of dichromium tris(chromate) in a post-*	**Rapporteurs** together

treatment step of the autodeposition coating process of shock absorbers for automotive vehicles. 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 **not** 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 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 use applied for may result in up to 0.01 kg Cr(VI) per year releases of the substance to the environment. The working group supported: 1. additional conditions for the authorisation [Within [3][6] months from the decision granting authorisation][†] 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. The applicant shall introduce measures to control the exposure according to the hierarchy of control. The applicant shall introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment such as LEV and scrubbers to 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:	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-59 plenary meeting via the A-listing procedure.

[†] The square brackets indicate that the finalisation of the detail is to be carried out by the Rapporteur, supported by ECHA-s.

(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 WCSs 3-8) 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 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 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 specific to Cr(VI) exposure and used to support the exposure assessment.	

The results of the measurements referred to in sections 7 and 8 paragraph 1, and section 9 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 that the Draft opinion is suitable for consideration via the A-listing procedure.	
3. 233_CT_Betz-Chrom (1 use)	
Use1: *Chromium trioxide-based functional chrome plating of components with diverse geometries and dimensions, requiring specialized equipment and process knowledge, for applications in demanding industry sectors such as mechanical engineering, metalworking and processing, aerospace, automotive, and medical technology.* 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 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 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 supported: 1. additional conditions for the authorisation The applicant shall continue the efforts to minimize the workers' exposure to Cr(VI) by implementing state of the art RMMs. 2. monitoring arrangements for the authorisation 1. The applicant shall continue to monitor by implementing the following programmes for	**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-59 plenary meeting via the A-listing procedure.

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; 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. 3. 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. 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. 3. recommendations for the review report The applicant should conduct annual biomonitoring programme for the workers potential exposed to Cr(VI). The biomonitoring should be specific to Cr(VI) exposure. The applicant should select the type of RPE (if required) considering also the comfort of the workers during the use. The results of the measurements referred to in sections 8 paragraph 1, and 9 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 paragraph 2, should be documented and included in any subsequent review report. The working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	
1. 234_CT_Kwalter (2 uses)	
Use1: *Formulation of chromium trioxide-based electrolyte for electroplating process.* 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	**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-59 plenary meeting via the A-listing procedure.

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 supported: 1. additional conditions for the authorisation The formulator shall • ensure that workers perform the sealing test[‡] of their respiratory protective equipment (RPE) before taking on relevant tasks and workers will be trained to do this test adequately, • investigate the feasibility to enclose the area around the filling point of the mixing tank with solid CrO_3 as maximum possible with a guaranteed effectiveness of the LEV system. 2. monitoring arrangements for the authorisation The formulator shall implement the following monitoring programmes: (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and/or static inhalation exposure sampling; (iv) be representative of: a. the range of all tasks undertaken where exposure to Cr(IV) is possible; b. the operational conditions and risk management measures typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed and their frequency during measurements; (b) Environmental releases:	

[‡] It was agreed that ECHA-s will clarify and implement across the relevant opinions which terminology to use for the tests of the RPE and other PPEs to ensure no leakage.

(i) the formulator shall continue conducting their monitoring programme for Cr(VI) emission of wastewater; (ii) the formulator shall conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the formulator 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 formulator shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The formulator shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in 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 formulator, 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 results of the feasibility study as mentioned in section 7 and 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. In addition, any subsequent authorisation review report should contain clear information that	

supports the air and wastewater abatement efficiencies. The working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	
Use2: *Chromium trioxide-based functional chrome plating of cylinders used in the rotogravure printing and embossing industry.* 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 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 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 supported: 1. additional conditions for the authorisation In relation to the concerns and comments about the OCs and RMMs the applicant should: • regularly inform all their downstream users about the requirements to comply with the RMMs and OCs as outlined in the CSR, • inform and promote the implementation of the new dosing systems and of the valve and pump system for sampling once being developed and the use of wetting agents. 2. monitoring arrangements for the authorisation 1. The downstream users shall implement the following monitoring programmes: (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the	**SECR** to request the applicant for further clarification on RMMs and OCs required from DUs. **Rapporteurs** together with **SECR** to edit the Draft opinion according to the discussion of the working group. **SECR** to schedule the Draft opinion for discussion and agreement at the RAC-59 plenary meeting.

measurements should be increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and/or static inhalation exposure sampling; (iv) be representative of: a. the range of all tasks undertaken where exposure to Cr(IV) is possible; b. the operational conditions and risk management measures typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed and their frequency during measurements; (b) Environmental releases: (i) the downstream users shall conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process; (i) 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 downstream users' sites. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the downstream users to confirm the effectiveness of the operational conditions and risk management measures in place at their sites 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 downstream users shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The downstream users shall ensure that the application of RMMs 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 downstream users, upon request, to the competent national authority of the Member State where the downstream user is located. 3. recommendations for the review report. In relation to the concerns and comments about the OCs and RMMs the applicant should perform a new survey among their downstream users two years before the end of the review period, a survey that should be designed in such a way that a maximum and representative response is obtained. The results of the new survey and the measurements referred to in section 8.1 paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 3, should be documented and included in any subsequent authorisation review report. The working group recommended that the Draft opinion is suitable for full discussion and agreement at the RAC plenary.	
5. 235_CA_Neoperl (1 use)	
Use1: *The use of chromic acid in the functional electroplating of brass-made sanitary articles with the specific purpose of obtaining a final Cr(0) coating that provides a surface with high durability and chemical resistance.* 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 proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational	**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-59 plenary meeting via the A-listing procedure.

conditions and risk management measures implemented and on trends in exposure and releases during the review period. This information should also be included in a possible review report. The working group supported: 1. additional conditions for the authorisation [For the WCS 9 the applicant shall to implement additional mobile LEV during operations for removing of Cr(VI) containing sludge from the baths. The applicants shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.][§] 2. monitoring arrangements for the authorisation 1. The applicants shall implement the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure: the applicant shall implement a monitoring programmes for Cr(VI) exposure, which shall: (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of: a. the range of tasks undertaken where exposure to Cr(IV) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue their quarterly monitoring programme for Cr(VI) emission of wastewater; (ii) the applicant shall conduct air emission measurements at least annually at emission point or more frequently in the periods following any possible changes in the	

[§] The square brackets indicate that the finalisation of this condition is to be carried out by the Rapporteur, supported by ECHA-s.

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 paragraphs 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.
3. The applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.
4. The information from the monitoring programmes referred to in paragraphs 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.

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 specific to Cr(VI) exposure and include at least pre and post-shift sampling. It should be used to support the exposure assessment.

The information gathered via the measurements referred to in section 8 points (a) and (b) and 9 paragraph 1, as well as the outcome and conclusions of the review and any action taken in accordance with section 8 paragraph 2 shall 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.

Annex II

RAC WG/A/9/2021
Final

Agenda

Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group (RAC AFA WG) reporting to RAC-59

12 October 2021

WebEx meeting

Tuesday 12 October starts at 10.00
Tuesday 12 October ends at 18.15

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/9/2021
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

1. 231_CT_Kesseboehmer (1 use)
2. 232_DtC_Monroe (1 use)
3. 233_CT_Betz-Chrom (1 use)
4. 234_CT_Kwalter (2 uses)
5. 235_CA_Neoperl (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 9th Meeting of the RAC AFA WG

RAC Members
Baranski Boguslaw
Bjørge Christine
Tsakovska Ivanka
Brovkina Julija
Chiurtu Elena (co-opted)
Doak Malcolm
Husa Stine
Kadiķis Normunds
Leinonen Riitta
Moldov Raili
Paris Pietro
Printemps Nathalie
Tsakovska Ivanka
Užomeckas Žilvinas
Van der Haar Rudolf (co-opted)
Viegas Susana

Invited Experts
Ginnity Bridget
Deviller Geneviève

Members' advisers
Giuseppe Granato (adviser to Pietro Paris)
Renske Beetstra (adviser to Gerlienke Schuur)
Panieri Emiliano (adviser to Pietro Paris)

RAC Regular Stakeholders
Janosi Amaya
Barry Frank
Duguy Helene

European Commission
Roebben Gert
Marco Fabbri

ECHA
Bowmer Tim
Henrichson Sanna
Lazic Nina
Ludboržš Arnis
Logtmeijer Christiaan
Makela Petteri
Mushtaq Fesil
Mbani Tytti
Nicot Thierry
Peltola Jukka
Peltola-Thies Johanna
Pillet Monique
Portugal Laura
Smilovici Simona
Sosnowski Piotr
Schakir Yasmin
Thierry-Mieg Morgane
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 WG MEETING(S)		
Applications for Authorisation		
none		

Annex V

Conclusions of the Capacity Building Seminar on assessment of biomonitoring data

ECHA Conference Centre
(Telakkakatu 6, Helsinki)
via Webex

Wednesday 13 October starts at 10.00
Wednesday 13 October ends at 17.15

Summary

A Capacity Building Seminar was organised at the suggestion of the participants of the 7th meeting Working Group on Applications for Authorisation to discuss the assessment of biomonitoring data in the context of the authorisation process under REACH.

1. Agenda of the Seminar

- Introduction. Use of HBM and ethical aspects - Tiina Santonen (Finnish Institute of Occupational Health)
- Usefulness of biomonitoring data for exposure and risk assessment. Case study in a Portuguese company dedicated to aircraft maintenance - Susana Viegas (National School of Public Health, NOVA University of Lisbon)
- Some technical aspects related to the interpretation of the biomonitoring data - Simo Porras (Finnish Institute of Occupational Health)
- Setting of biological limit values / reverse and forward calculation - Tiina Santonen (Finnish Institute of Occupational Health)
- Human biomonitoring study for ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate (ammonium salt of HFPO-DA) in volunteering workers - Wieneke Bil (RIVM, NL)
- RR1_TCE_ROQUETTE (TCE). Use as a processing aid in the biotransformation of starch to obtain betacyclodextrin. Biomonitoring data - Christine Bjørge (RAC member)

2. Summary of the Seminar

- Where there is a serious exposure concern, and sampling and analytical methods are available, RAC may recommend biomonitoring in section 8, allowing the European Commission the option of adding this to the decision. Such a recommendation needs to be robustly justified!
- RAC should generally not make biomonitoring a standard request.

- If there is a history of biomonitoring evident in an application, RAC can recommend to the applicant that they should continue and that they could use the data in anonymised form in the format provided as part of their future exposure assessment.
- Applicants may have less legal/personal data protection concerns if they are requested to provide biomonitoring data in an aggregated and anonymised form. Additionally, this type of information can be included in a confidential part of the AfA CSR.
- Potential exposure of bystanders (administrative workers, workers not covered by WCS) should be carefully scrutinised by RAC and applicants should be made aware of this. Detailed contextual information should also be provided by applicants.
- Adequately sensitive methods to measure general population exposure are available for some substances. Applicants should be encouraged to search and provide such data within applications if available.
- Applicants should request from laboratories providing biomonitoring services on reference values used including which data have been used to derived reference values and how old are those reference values.
- The Secretariat could consider preparing a check list for applicants and rapporteurs on how to prepare, communicate and assess biomonitoring data.
- The Secretariat is requested to add the template on reporting (bio)monitoring data to the CSR template
- The Secretariat is requested to consider preparing a standard text to request biomonitoring in Cr(VI) AfA cases, as this is mandatory in any case in some jurisdictions.

Annex VI

List of participants of the Capacity Building Seminar on assessment of biomonitoring data

RAC Members	
Surname	**Name**
Barański	Bogusław
Bjørge	Christine
Chiurtu	Elena (co-opted)
Doak	Malcolm
Husa	Stine
Kadikis	Normunds
Moeller	Ruth
Losert	Annemarie
Leinonen	Riitta
Moldov	Raili
Peczkowska	Beata
Rodriguez	Wendy
Santonen	Tiina
Schuur	Gerlienke
Sogorb	Miguel
Tobiassen	Lea Stine
Tsakovska Van der Haar	Ivanka Rudolf
Viegas	Susana

Invited Experts	
Surname	**Name**
Deviller	Geneviève
Ginnity	Bridget
Porras	Simo
De Knecht	Joop

Wieneke	Bil

RAC Members' advisers		
Surname	**Name**	**Nominated by**
Beetstra	Renske	Gerlinke Schuur
Granato	Giuseppe	Pietro Paris
Mahiout	Selma	Tiina Santonen

Regular Stakeholder Observers		
Surname	**Name**	**Organisation**
Barry	Frank	ETUC
Duguy	Helene	ClientEarth
Jànosi	Amaya	Cefic
Verougstraete	Violaine	Eurometaux

ECHA Staff	
Surname	**Name**
Bowmer	Tim
Henrichson	Sanna
Lazic	Nina
Ludborzs	Arnis
Makela	Petteri
Mustaq	Fesil
Orispää	Katja
Peltola-Thies	Johanna
Pillet	Monique
Portugal	Laura
Regil	Pablo
Rodriguez Vazquez	Jesus
Roberts	Julian
Rheinberger	Christoph
Richarz	Andrea
Schakir	Yasmin

Smilovici	Simona
Sosnowski	Piotr
Stoyanova	Evgenia
Thierry-Mieg	Morgane
Väänänen	Virpi
Wilk	Mateusz