RAC working group/R/19/2024
Final

7 May 2024

Report
of the 19th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation
(RAC AfA working group)

(Telakkakatu 6, Helsinki)
via WebEx

Tuesday 7 May
starts at 10.00 ends at 15.00

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 31 participants to the 19th 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 Arnis Ludboržs.

The Chair thanked all members and advisers for very high contribution to the RAC written consultations on draft opinions prior to the meeting of the working group and reminded that the July working group has been cancelled. It is very important that there will be sufficient number of comments on draft opinions during written consultations over the summer to allow to A-list some opinions without any discussion.

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

2. Adoption of the Agenda

The Chair introduced the agenda for the meeting (RAC working group/A/19/2024), 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. Declaration of a potential conflict of interest to the agenda items by one participant was added to Annex IV (declared at previous meetings).

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 specific draft opinions on the six Review Reports and Applications covering ten uses considered at this meeting are listed in Annex I.

5. Any other business

Horizontal issues:

The Secretariat presented the state of play of the AfA pipeline and how the Secretariat intends to process the AfAs in 2024.

6. Adoption of the report of the working group

Before the chair of the working group Arnis Ludboržs 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 19th meeting**
Annex III	**List of participants of the 19th 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:

CA	chromic acid
CT	chromium (VI) trioxide
DEHP	bis(2-ethylhexyl) phthalate
DtC	dichromium tris(chromate)
ED	endocrine disruption
ERC	environmental release category
ES	exposure scenario
HvE	Humans via environment
LEV	local exhaust ventilation
NPE	4-Nonylphenol, branched and linear, ethoxylated
OC	operational condition
OPE	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated
PBT	persistent, bioaccumulative and toxic
PD	potassium dichromate
PPE	personal protective equipment
RMM	risk management measure
RPE	respiratory protective equipment
RR	review report
SD	sodium dichromate
STP	sewage treatment plant
TEL	tetraethyl lead
WWTP	wastewater treatment plant
vPvB	very persistent, very bioaccumulative

Summary of the recommendation	**Action Points**
04.06. 353_TEL_Shell (1 use)	
Use1: *Use of tetraethyl lead in the formulation of aviation fuel.* The working group discussed: - Risk management measures, specifically a lack of vapour recovery system for unloading of tetraethyl lead, use of RPE, including its cleaning and disposal; - Additional conditions for the authorisation (see below for Section 7 of DO); - Monitoring conditions – reporting of the monitoring results (for Sections 8 and 9 of DO).	**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-69 plenary meeting.

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. The working group supports: Section 7: additional conditions for the authorisation (Request to rapporteurs to consider feasibility study on technical RMMs to avoid spillages). 1. The applicant shall provide additional training to the workers involved in the transfer tasks to ensure that the risk of spillage of TEL solutions during disconnection of the hose after the transfer is further minimised. Such training shall be conducted within 6 months of the granting of an authorisation for this use and repeated regularly thereafter. 2. Without prejudice the point 1 above, the applicant shall carry out and document a detailed feasibility study on the implementation of a vapour recovery system for the unloading of TEL solutions from the ISO containers to the storage tank. 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 minimise the workers' exposure to TEL 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. Section 9: recommendations for the review report. The working group recommends to discuss at the RAC plenary following points of the Draft opinion: - additional conditions for the authorisation.	
04.05. 352_DEHP_Baxter (3 uses)	

Use 1: *Formulation of DEHP mixtures for application in immediate packaging of medicines and medical devices.* Use2: *Use of DEHP-containing plastics for immediate packaging of medicinal products.* Use 3: *Use of DEHP-based mixtures as a lubricating/sealing agent for the insertion of port closures into empty bags and assembly/connection of parts, that are used in immediate packaging of medicines.* The working group discussed: - Risk management measures, specifically LEV systems in place across all the industrial sites; - Risk characterisation, minimisation of exposure due to ED effects, and importance to address both reprotoxic (threshold) effects and ED (non-threshold) effects in the draft opinion; - Further use(s) of the pellets manufactured by the applicants in the use 2; - Additional conditions and monitoring arrangements, for authorisation, including a biomonitoring program for the exposed workers. The working group supported request to continue annual monitoring as committed by the applicant and proper use proper reporting format in potential review report; - Scope of RAC assessment of service life of articles from uses 2 and 3. The working group recommends that the draft opinions should be fully discussed at the RAC-69 plenary.	**Rapporteurs** together with **SECR** to edit the draft opinions according to the discussion of the working group and information provided by the applicant in answers to RAC questions. **SECR** to schedule three draft opinions for agreement at the RAC-69 plenary meeting.
04.04. 351_PD_Turdus (1 use)	
Use1: *Industrial use of a potassium dichromate-based mixture for the manufacture of single-use chemical breathalysers.* The working group supported the draft opinion as proposed by the Rapporteur.	**SECR** to schedule the draft opinion for agreement at the RAC-69 plenary meeting via the A-listing procedure.

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 for the workers but they are appropriate and effective in limiting the risk for humans via environment. The working group supports: Section 7: additional conditions for the authorisation The applicant shall implement technical improvements to the OCs/RMMs, more specifically: a. The applicant shall install a fume hood with glass walls in the laboratory for preparation of the reagent (WSC 2) limiting the emission of Cr(VI) to the air of the working environment. The effectiveness of local ventilation system installed should be periodically checked to confirm the effectiveness of the operational conditions and risk management measures in place. This measure shall be implemented within 12 months of the granting of an authorisation for this use and be followed by a measurement campaign to validate the effectiveness of the applied technical improvements. 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 recommends that the draft opinion is suitable for consideration via the A-listing procedure.	
04.02. 349_RR1_OPE_Biomerieux (1 use)	
Use1: *Industrial use of 4-tert-OPnEO for its non-ionic detergent properties, used for the extraction of biological material which is further formulated and coated on articles intended for clinical and industrial in vitro testing applications.* The working group discussed:	**Rapporteur** together with **SECR** to edit the draft opinion according to the discussion of the working group. **SECR** to schedule both draft opinions for agreement at the

- A condition to put in place a monitoring program allowing to capture variability in the concentrations of 4-tert-OPnEO and its principal degradation products in the wastewater due to changes or operational fluctuations in the process is not fulfilled by the authorisation holder - a possibility to reduce the frequency of measurements, once the applicant can demonstrate to the competent authority of the Member State where the use takes place, that exposure of the environment has been reduced to as low a level as technically and practically possible. The working group supported the draft opinion as proposed by the Rapporteur. The working group recommends to RAC that that the operational conditions and risk management measures described in the review report are expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The use applied for result in 0 kg per year releases of the substance to the environment (according to qualitative assessment). The working group supports: Section 7: additional conditions for the authorisation None Section 8: monitoring arrangements for the authorisation 1. The authorisation holder shall continue with their plans to implement monitoring of the rinsing effluents generated during the cleaning operations of the non-disposable devices before sending to the glassware laundry. 4-tert-OPnEO concentration measurements (parent substance and its degradation products) will be performed on each rinsing water phases and, on the effluent produced after the final cleaning step with ES 7X solution. 2. The authorisation holder shall continue at least quarterly (4 times/year), the 24h-monitoring of 4-tert-OPnEO (parent substance and its degradation products) in wastewater prior to release to the local STP	RAC-69 plenary meeting via the A-listing procedure.

using an analytical method capable of adequately characterising the substance and at an appropriately low level of detection. 3. The information gathered via the measurements referred to in paragraphs 1 to 2, shall be used by the authorisation holder to confirm and to regularly review the effectiveness of OCs and RMMs in place to reduce the environmental emissions as low a level as technically and practically feasible. 4. The information from the monitoring programmes referred to in paragraphs 1 to 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 authorisation holder, upon request, to the competent authority, and included in any subsequent authorisation review report. ~~5~~. The authorisation holder may reduce the frequency of measurements, once he can demonstrate to the competent authority of the Member State where the use takes place, that exposure of the environment 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 scenario 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 the environment shall be documented. The authorisation holder shall assess the impact of such changes by monitoring to demonstrate that release to the environment continues to be reduced to as low a level as technically and practically possible.	

Section 9: recommendations for the review report. RAC recommends the authorisation holder to further assess the feasibility to reduce the use of intermediate containers during the process in order to minimise as much as possible the generation of wastes and, act on the outcome of the feasibility study. RAC recommends the authorisation holder to continue its investigations on the sources of 4-tert-OPnEO common moieties measured at the on-site WWTP effluents. The information generated in accordance with section 8 and 9, should be documented and included in any subsequent review report. The working group recommends that the draft opinion is suitable for consideration via the A-listing procedure.	
04.01. 348_RR1_NPE_Chemetall (2 uses), 04.03. 350_RR1_OPE_PPG (2 uses)	
348_RR1_NPE_Chemetall **Use 1:** *The formulation of a hardener component containing NPE within Aerospace two-part polysulfide sealants.* **Use 2:** *Mixing, by Airbus, and their associated supply chains, including the Applicant, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1% w/w of OPE for Aerospace and Defence uses that are exempt from authorisation under REACH Art. 56(6)(a).* **350_RR1_OPE_PPG** **Use 1:** *Use applied for Repackaging hardener formulations containing OPE as a surfactant in a concentration above 0.1%, to be used within two-part polysulphide sealants by Airbus and their associated supply chains.* **Use 2:** *Use Mixing, by Airbus, and their associated supply chains, including the Applicant, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1% w/w of OPE for Aerospace and Defence uses that are exempt from authorisation under REACH Art. 56(6)(a).*	**SECR** to schedule four draft opinions for agreement at the RAC-69 plenary meeting via the A-listing procedure.

The working group supported four draft opinions as proposed by the Rapporteur. The working group recommends to RAC that that the operational conditions and risk management measures described in all four review reports are appropriate and effective in limiting the risk, provided that they are adhered to. The uses applied for results in 0 kg per year releases of the substances to the environment. The working group supports: Section 7: additional conditions for the authorisation None Section 8: monitoring arrangements for the authorisation None Section 9: recommendations for the review report None The working group recommends that the draft opinion is suitable for consideration via the A-listing procedure.	

25 March 2024
RAC WG/A/19/2024
Draft

Agenda

Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group (RAC AFA WG) reporting to RAC-69

7 May 2024

WebEx meeting

Tuesday 7 May
10:00 – 17:25

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/19/2024
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

1. 348_RR1_NPE_Chemetall
2. 349_RR1_OPE_Biomerieux
3. 350_RR1_OPE_PPG
4. 351_PD_Turdus
5. 352_DEHP_Baxter
6. 353_TEL_Shell

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 19th Meeting of the RAC AFA working group

RAC Members
Angeli Karine
Barański Bogusław
Brovkina Julija
Chiurtu Elena Ruxandra (co-opted)
Christodoulou Sotirios
Deviller Geneviève (co-opted)
Docea Anca Oana
Esposito Dania
Kadikis Normunds
Karadzhova Irina
Klöslova Zuzana
Leinonen Riitta
Manusadžianas Levonas
Menard Srpčič Anja
Rodriguez Wendy
Schlüter Urs
Tobiassen Lea
Tsitsimpikou Christina
Uzomeckas Zilvinas
van der Haar Rudolf (co-opted)
Viegas Susana
Wildemann Tanja

Members' advisers
Beetstra Renske (adv. to Gerlienke Schuur)
Catone Tiziana (adv. to Aquilina Gabriele)
Granato Giuseppe (adv. to Dania Esposito)
Jankowska Agnieszka (adv. to Peczkowska Beata)
Moilanen Marianne (adv. to Leinonen Riitta)
Panieri Emiliano (adv. to Esposito Dania)
Smith Jenny (adv. to Murray Brendan)
Dumke Carolin (adv. To Schlüter Urs)

European Commission
Kusendila Christophe
Roebben Gert
Jezso Veronika
Blass Rico Ana Maria
Fabbri Marco

ECHA
Ahtiainen Heini
Atanasova Marina
Barnewitz Greta
Etholen Anita
Gervasutti Simone
Kivelä Kalle
Lefevre Remi
Lisboa Patricia
Ludborzs Arnis
Mäkelä Petteri
Nicot Thierry
Parikka Petra
Pillet Monique
Portugal Laura
Regil Pablo
Scazzola Roberto
Sosnowski Piotr
Stoyanova Evgenia
Orispää Katja
Tarvainen Emma
Zellino Carolina

Stakeholder Occasional Industry Observer
Consoli Elisa

RAC Regular Stakeholders
Janosi Amaya
Santos Roumiana

Annex IV

Declaration of potential conflicts of interest

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

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

Annex V

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

Section 8: monitoring arrangements for the authorisation

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

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

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

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

5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans (i.e. workers and general 0population) has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.

6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers and humans via the environment at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues and humans via the environment to be reduced to as low a level as technically and practically possible

7. The applicant shall continue their existing [annual] biomonitoring programme for the workers potentially exposed to Cr(VI).

Section 9: recommendation for the review report.

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