RAC WG/R/11/2022
Final
11 May 2022

Report
of the 11th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC-AFA working group)

ECHA Conference Centre
(Telakkakatu 6, Helsinki)
via Webex

Tuesday 10 May starts at 10.00
Wednesday 11 May ends at 15.20

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 30 participants to the 11th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. He informed them that sections of the meeting would also be chaired by Thierry Nicot and by Johanna Peltola-Thies, the Deputy Chair of RAC.

The Chair summarised the members 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 WG/A/11/2022), 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 9 AFA cases 10 uses and 2 RRs on 2 uses considered at this meeting are listed in Annex I.

5. AOB

AfA horizontal issues:

The Secretariat informed the working group about applications for authorisation and review reports, which are expected to be received in 2022 and in 2023.

The Secretariat informed the group about the outcome of the RAC consultation on the technical guidance ('Lines to take') document. In addition, the Secretariat presented the actions taken to address the comments received from RAC members and representatives of the European Commission.

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 11th Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I	**Working group Recommendations**
Annex II	**Agenda of the 11th meeting**
Annex III	**List of participants of the 11th 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
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. 242_RR1_TCE_Microporous (1 use)	
Use1: *Trichloroethylene used as extraction solvent in the manufacture of polyethylene separators for lead-acid batteries.* The Working Group proposed to add to the monitoring arrangements details for biomonitoring sampling campaigns. 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	**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-61 plenary meeting via the A-listing procedure.

described in the review report are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.
The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently.

The working group supported:
Section 7: no additional conditions for the authorisation
Section 8: monitoring arrangements for the authorisation

1. The authorisation holder shall implement a continuous monitoring of TCE workplace concentrations in the extraction units and shall continue to perform a continuous monitoring of TCE workplace concentrations in the production and finishing areas and conduct an annual monitoring programme of occupational exposure for trichloroethylene of workers, directly or indirectly involved in the production of polyethylene separators for lead-acid batteries, using a sufficiently sensitive analytical method for inhalation exposure measurement and for biomonitoring. 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 within all worker contributing scenarios identified where exposure to trichloroethylene is possible, including tasks involving maintenance 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 maintain the continuous TCE measurements in exhaust air using a sufficiently sensitive analytical method and the continuous measurement of exhaust air volume flow of the active carbon plant chimney, to obtain a more accurate statement about the air emission.
3. The information gathered via the measurements referred to in paragraphs 1 and 2, as well as related contextual information, shall be used by

the authorisation holder to confirm the effectiveness of OCs and RMMs and to review regularly the effectiveness of OCs and RMMs in place and to introduce measures to further reduce workplace exposure, respectively air emissions to TCE, to as low a level as technically and practically feasible. 4. The information from the monitoring programmes referred to in paragraphs 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 authorisation holder, upon request, to the competent authority, and included in any subsequent authorisation review report. 5. The authorisation holders may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. Section 9: recommendation for the review report. The results of the measurements referred to in section 8, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8, should be documented and included in any subsequent review report. The RAC-AFA working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	

2. 243_RR1_TCE_DOMO	
Use1: *Industrial use as an extraction solvent for the purification of caprolactam from caprolactam oil.* The Working Group discussed a few elements in the monitoring arrangements part of the draft opinion. 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 review report 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 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: Section 7: additional conditions for the authorisation 1. The authorisation holder shall implement the OCs and RMMs as planned, for example the extension of the vent system with integration of a vessel and a separation tube, to seal the system and prevent the TCE emissions. 2. The authorisation holder shall carry out and document a feasibility study to further limit fugitive emissions. Section 8: monitoring arrangements for the authorisation 1. The authorisation holder shall continue to conduct regular occupational exposure measurements relating to the use of TCE described in this review	**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-61 plenary meeting via the A-listing procedure.

report. (a) Occupational inhalation exposure monitoring programmes, which shall: (i) take place at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to trichloroethylene.; (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 trichloroethylene is possible, i.e. including production and maintenance workers; 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 authorisation holder shall continue conducting their monitoring programme for TCE emission to air and wastewater monitoring before discharging the wastewater to the WWTP; (ii) the authorisation holder 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 authorisation holder's site. 2. The authorisation holder shall use the information gathered via the measurements referred to in Section 8.1 including the contextual information to review annually the effectiveness of the risk management measures and operational conditions and to introduce measures to reduce worker's exposure to trichloroethylene as well as emissions to the environment to as low a level as technically and	

practically feasible.

3. The authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.
4. The authorisation holder shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.
5. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent national authority of the Member State where the authorised use will take place.
6. The authorisation holders 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.
7. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 6, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holder 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.
8. The authorisation holder shall continue their existing biomonitoring programme for the workers potentially exposed to trichloroethylene.

Section 9: recommendations for the review report.

The authorisation holder should document - in a potential further review report - the results of the monitoring programs and the optimisation of RMMs and OCs carried out in order to minimise the TCE emissions.

The working group recommended that the draft opinion

is suitable for consideration via the A-listing procedure.	
3. 244_CT_Cromaplast (2 uses)	
Use1: *Industrial use of CrO_3 in the pre-treatment (etch) in the chrome plating process of automotive plastic components.* **Use2:** *Industrial use of CrO_3 in the chrome plating of automotive plastic components.* The working group supported of the Draft opinion as proposed by the Rapporteur. The working group discussed wording of the additional conditions for the authorisation. The Rapporteur will adjust the wording accordingly and provide additional justification. The Rapporteur will correct parts of the draft opinion concerning the reduction factor of 97% for transformation of Cr(VI) to Cr(III) in line with the Lines to take document. 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 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: Section7: 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 CrO_3 to further limit exposure b) the implementation of a closed automatic system	**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-61 plenary meeting via the A-listing procedure.

with liquid CrO_3 solution to perform concentration adjustment of the chromium baths c) the implementation of an automatic system for drawing samples at the Line A1A2 d) the implementation of an automatic system to replace the manual tasks of skimming the etching baths and stirring the baths e) the coverage of the baths of the A1A2 line as in the new plating line (Line 2004). The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period Section 8: monitoring arrangements for the authorisation 1. The applicant shall continue their yearly monitoring programmes for Cr(VI) and considering the following: 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(IV) 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 yearly monitoring programme for Cr(VI) emission to wastewater and air; ii. the applicant shall conduct air emission measurements 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 paragraphs 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 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 authorisation holder may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as	

technically and practically possible. 7. The applicant shall continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9: recommendations for the review report The results of the feasibility studies as mentioned in Section 7 and the monitoring programmes referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall 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.	
4. 245_CT_Newform	
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 main conclusions (sections 1, 2 and 3 agreed) of the Draft opinion as proposed by the Rapporteur. The working group discussed: - concerns related to the activities on the manual plating line (WCS 3) with its fully open chromium baths and its process of hand dipping of pieces to be plated, - concerns related to separation of the plating lines from the loading and unloading area, - disposal of suits after the concentration adjustments, - the rapporteur proposal to set an authorisation condition to stop immediately the use of the manual plating line, - request to continue biomonitoring and regularly review the biomonitoring data - alternatively, to consider the possible wording for a negative opinion without any conditions for manual plating.	**Rapporteur** together with **SECR** to revise the draft opinion according to the discussion and recommendation by the working group. **SECR** to schedule the draft opinion for discussion and agreement at the RAC-61 plenary meeting.

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. **[Note**: depending on the outcome of section 7: 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 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 requested the rapporteur to revise the wording of sections 7 and 8. The working group recommended that the Draft opinion should be fully discussed at the RAC plenary.	
5. 246_MOCA_Courbis (1 use)	
Use1: *Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of hot cast polyurethane products.* The Secretariat noted that the RAC (2017) opinion on the ReachLaw Ltd. upstream application for authorisation concerning MOCA had provided a clear set of minimum OC and RMM conditions. The working group supported the Draft opinion as proposed by the Rapporteur. The working group discussed: - the potential impact of the tonnage used related to the exposure, - the need for clarification in section 1 of the draft opinion conditions of the previous authorisation, - the need for proper communication between	**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-61 plenary meeting.

sites.

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 working group supported:
Section 7: additional conditions for the authorisation

RAC considers that the RMMs currently in place in the different sites are not in line with the principles of hierarchy of controls and are not appropriate and effective in limiting the risks.

1. Therefore, the applicant shall put in place, in all sites, the following RMMs:

<u>Engineering measures</u>

a) Glove boxes implemented for loading MOCA to all casting machines (this recommendation is for sites F and G);
b) LEV in place in all the casting benches (this recommendation is for sites G, H and J).
c) Curing should be done in closed ovens with suitable exhaust ventilation located inside the oven. The ovens should only be possible to open after the vapours being completely exhausted (this recommendation is for sites B, F, J and K).
d) In WCS 6 (Pouring of PU mixture to moulds in partially open system) all the sites should have LEV in place during casting step.
e) To control air emissions, suitable filters or other air abatement techniques need to be implemented in all the sites.

<u>Organizational Measures</u>

a) A regular cleaning and maintenance program

of the glove boxes, including the structural integrity of the gloves shall be implemented to eliminate the potential for dermal exposure. b) An adequate maintenance program of all the LEV systems in place and also for the ones to be installed; c) Workers perform the sealing test of their RPE before taking on relevant tasks and are trained to perform this test adequately; d) All sites should have a program to guarantee that all the working clothes are disposable or cleaned after a working day; e) Workers rotation to reduce biomonitoring levels should be eliminated at all the sites. <u>Personal Protective Equipment (RPE)</u> The use of RPE should be considered as the last resort in the hierarchy of controls. Other preventive and protective measures should be considered first, such as closed systems whenever possible, automating the process and/or by the use of engineering controls such as LEV. However, while the engineering measures listed are not fully in place and their efficacy not yet evaluated, RPE should be considered as a provisional measure to protect workers. Therefore, workers should use RPE: a) Near the casting benches until an appropriate LEV system is implemented; b) During curing or when opening the ovens after the curing process until all sites have installed closed ovens with suitable exhaust ventilation located inside; c) During the casting step in the sites that still do not have LEV systems in place. 2. The applicant shall carry out and document a feasibility study on substituting the semi-closed mixing chamber by a closed chamber in site D since this situation might result in workers exposure. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Any relevant action shall be implemented accordingly during the review period. Section 8: monitoring arrangements for the authorisation 1. To have a detailed overview of the exposure to MOCA at the different sites and workplaces the applicant shall implement a complementary monitoring programme, using simultaneously different exposure assessment methods that are	

describe below:

a) Biomonitoring:

(i) Exposure of all workers working within the premises in which MOCA is used shall be followed by twice yearly biomonitoring programmes, in which urinary total MOCA levels are measured from urinary samples collected on the Friday afternoon after the work week. If urinary levels are repeatedly low (below LoD using sensitive biomonitoring methods) frequency of monitoring may be reduced to once per year. The applicant should also provide contextual information that allows connecting the data with each WCS, RMMs in place and changes in the process (e.g. increase of the volume used).

b) Air monitoring for occupational exposure:

The applicant shall continue their monitoring programmes for MOCA exposure, which shall:

(i) be conducted at least annually for the workers exposed to MOCA. Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure due, for instance, to the foreseen increase of the volume used;

(ii) be based on relevant standard methodologies or protocols ensuring a sufficiently low limit of quantification;

(iii) comprise personal and / or static inhalation exposure sampling;

(iv) be representative of:

a. the range of tasks undertaken where exposure to MOCA 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.

c) Surface contamination monitoring:

(i) Surface measurements of surface contamination shall continue to be conducted at least twice per year in all sites in order to identify exposure sources and prevent exposure via the contaminated surfaces. This is especially important when biomonitoring shows measurable (above LoD) urinary MOCA levels but not limited to this criteria since the data provided should be used to take actions and

prevent exposure. Surface monitoring shall be targeted to surfaces located in workplaces with highest potential for dust formation and with higher frequency for hands contact. d) Environmental releases (i) the applicant shall conduct air emission measurements in all the sites at least yearly, particularly if changes in the process justifies; (ii) 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 sites. (iii) include contextual information about the RMMs and the process conditions in place when measurements were done. 2. The information gathered in the monitoring campaigns shall be used by the applicant to review and improve the RMMs and OCs to further reduce workers' exposure to MOCA. The outcomes and conclusions of this review, including those related to the implementation of any additional RMMs, must be documented. The results of the monitoring and of the review of the OCs and RMMs shall be maintained, be available to national enforcement authorities, and included in any subsequent authorisation review report submitted. Section 9: recommendations for the review report The applicant should continue to conduct annual biomonitoring, air monitoring and surface monitoring programmes for the workers potentially exposed to MOCA. These monitoring programmes should be used as complementary, since all provide different information concerning exposure, and should be based on validated methodologies and protocols for MOCA exposure. In case of biomonitoring, the urinary sampling should be performed in the end of the shift and week. All these datasets should be included in future exposure assessments and included in any subsequent review report. The same principles should be followed for environmental releases monitoring. 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: - need for clarification in the section 1 of the draft opinion conditions of the previous authorisation - need for proper communication between sites.	
6. 247_OPE_Boehringer_2 (1 use)	
Use1: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a detergent in the purification of lapidated OspA protein subsequently used for manufacturing of Lyme disease vaccine candidate.* 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 expected to allow RAC to evaluate a possible review report efficiently. The use applied for may result in up to 669 g per year releases of the substance to the environment. The working group proposed: Section 7: no additional conditions for the authorisation Section 8: monitoring arrangements for the authorisation As soon as the full-scale production commences the applicant shall monitor at least quarterly or 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 off-site WWTP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. 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.	**Rapporteur** together with **SECR** to edit section 8 of the draft opinion according to the discussion of the working group. **SECR** to schedule the draft opinion for agreement at the RAC-61 plenary meeting via the A-listing procedure.

The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. Section 9: 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.	
7. 248_NPE_OCV (1 use)	
Use1: *Mixing by the Applicant of a 4-NPnEO-containing epoxy resin, resulting in mixtures containing < 0.1% w/w of 4-NPnEO for the manufacture of glass fibre articles for critical composite helicopter parts, that is exempt from authorisation under REACH Art. 56(6)(a).* 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 **0 kg per year releases** of the substance to the environment. The working group proposed: Section 7: no additional conditions for the authorisation Section 8: no monitoring arrangements for the authorisation Section 9: no recommendations for the review report 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-61 plenary meeting via the A-listing procedure.

8. 249_CT_Tenneco_CZ (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 Rapporteurs. The working group requested the rapporteurs to add to the section 9 the outcome of the feasibility studies mentioned in the section 7. 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 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: 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 CrO_3 to further limit exposure, taking into account additional RMMs such as the use of a plastic sleeve adapter on the top of solid CrO_3 container to prevent exposure of the workers to CrO_3 dust (b) the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to	**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-61 plenary meeting via the A-listing procedure.

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. Relevant actions must be implemented accordingly during the review period.

Until the implementation of the relevant actions according to feasibility study, the applicant shall consider additional RMMs (for example, the use of a plastic sleeve adapter on the top of solid CrO_3 container) to prevent exposure of the workers to CrO_3 dust.

Section 8: monitoring arrangements for the authorisation

1. The applicant shall continue to implement 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) ensure a sufficiently low limit of quantification;

(iv) comprise personal and/or static inhalation exposure sampling, including sampling, preventative and corrective maintenance activities (WCSs 7, 8 and 10);

(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. 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 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.* *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.* 6. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9: recommendations for the review report	

The results of the measurements referred to in sections 8 paragraph 1, and 4, 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.	
9. 250_CT_Tenneco_ES (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 requested the rapporteurs to add to the section 9 the outcome of the feasibility studies mentioned in the section 7. 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. 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 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: Section 7: additional conditions for the authorisation The applicant shall carry out and document 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-61 plenary meeting via the A-listing procedure.

detailed feasibility study on the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period.

Section 8: monitoring arrangements for the authorisation

1. The applicant shall continue to implement 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) ensure a sufficiently low limit of quantification

(iv) comprise personal and/or static inhalation exposure sampling, including corrective maintenance activities (WCS 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.

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. 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.* *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.* 6. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9: recommendations for the review report The results of the measurements referred to in	

sections 8 paragraph 1, and 4, 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.	
10. 251_CT_Tenneco_BE (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 requested the rapporteurs to add to the section 9 the outcome of the feasibility studies mentioned in the section 7. 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. 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 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: 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 the RAC-61 plenary meeting via the A-listing procedure.

The applicant shall carry out and document a detailed feasibility study on: (a) the feasibility of automated/closed decanting of solid chromium trioxide into the pre-mixing tank (for example using a closed cabinet or glove box), (b) 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 the authorisation for this use. Relevant actions must be implemented accordingly during the review period. Section 8: monitoring arrangements for the authorisation 1. The applicant shall continue to implement 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) ensure a sufficiently low limit of quantification (iv) comprise personal and/or static inhalation exposure sampling, including activities such as sampling and corrective maintenance (WCSs 7 and 9); (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. 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. 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 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.* *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. 6. The applicant shall reimplement an annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9: recommendations for the review report The results of the measurements referred to in sections 8 paragraph 1 and 4, 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.	
11. 252_CT_Tenneco_PL (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 requested the rapporteurs to add to the section 9 the outcome of the feasibility studies mentioned in the section 7. 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. 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 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	**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-61 plenary meeting via the A-listing procedure.

report efficiently.

The working group proposed:

Section 7: additional conditions for the authorisation

The applicant shall carry out and document a detailed feasibility study on the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period.

Section 8: monitoring arrangements for the authorisation

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

(a) Occupational inhalation exposure monitoring programmes, which shall:

(i) be conducted quarterly (as performed currently). 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, including sampling and corrective maintenance activities (WCSs 7 and 9);

(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. 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. 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.* *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. 6. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9: recommendations for the review report The results of the measurements referred to in sections 8 paragraph 1, and 4, 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.	

Annex II

10 May 2022
RAC working group/A/11/2022
Final

Agenda

Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group (RAC AFA working group) reporting to RAC-61

10-11 May 2022

WebEx meeting

Tuesday 10 May starts at 10.00
Wednesday 11 May ends at 15.20

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC working group/A/11/2022
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

1. 242_RR1_TCE_Microporous
2. 243_RR1_TCE_DOMO
3. 244_CT_Cromaplast (2 uses)
4. 245_CT_Newform
5. 246_MOCA_Courbis
6. 247_OPE_Boehringer_2
7. 248_NPE_OCV
8. 249_CT_Tenneco_CZ
9. 250_CT_Tenneco_ES
10. 251_CT_Tenneco_BE
11. 252_CT_Tenneco_PL

For discussion

Item 5 – AOB

1. AfA horizontal issues

For discussion

Item 6 – Adoption of the Report from the working group

For discussion and adoption

Annex III

List of participants of the 11th Meeting of the RAC AFA working group

RAC Members
Baranski 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
Printemps Nathalie
Schlüter Urs
Strumylaite Loreta
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
Fernandez Ana
Janosi Amaya

European Commission
Dunauskiene Lina
Fabbri Marco
Jezso Veronika
Kusendila Christophe
Roebben Gert

ECHA
Bowmer Tim
Franke Greta
Gmeinder Michael
Klausbruckner Carmen
Loukou Christina
Ludboržš Arnis
Mushtaq Fesil
Mäkelä Petteri
Nicot Thierry
Peltola Jukka
Peltola-Thies Johanna
Pillet Monique
Portugal Laura
Regil Pablo
Schakir Yasmin
Sosnowski Piotr
Thierry-Mieg Morgane
Vazquez-Rodriguez Jesus

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.