RAC WG/R/8/2021
Final
5 May 2021
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Report
of the 8th 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 4 May at 10.00
to
Wednesday 5 May at 15.00

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 28 participants to the 8th 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 Tim Bowmer.

He thanked all on behalf of ECHA for their commitment to prepare on time good quality documents and presentations. That constant commitment to all meeting of the RAC AFA WG results that the RAC AFA WG has been a great success and substantial support to RAC.

The Chair reminded the working group that the scope of the mandate, which has been extend until September 2021, was primarily to support the work of the appointed rapporteurs in preparing the Application for Authorisation cases and ensuring the consistency of the outcomes of the evaluations. He reminded all that the WG will be requested to adopt its report at the end of the meeting.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/A/8/2021), 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. One participant of the meeting declared a potential conflict of interest on cases scheduled for the discussion as presented in Annex IV to this Report. The Chair and co-Chairs declared that they had no potential interests related to any of the agenda points for the meeting.

4. Authorisation applications

The recommendations by the working group on the 9 applications for authorisation and opinions on 12 uses 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. The WG in July 2021 will not be held and the four opinions for that meeting will be discussed in RAC 58.

The Secretariat also informed the WG about the upcoming RAC and SEAC consultation on the approach for the review report, and the main aspects of this approach. The WG raised the question on how to treat AfAs submitted well after the sunset date by DUs for uses that are already granted to upstream actors with additional conditions and monitoring arrangements. The Secretariat reminded the WG that such authorisation decisions are quite recent and that a major enforcement project (REF-9) will be launched during the 2nd half of 2021.

The Secretariat presented the main changes that are being made to the opinion format especially on sections 7, 8 and 9. Members discussed the usefulness of comparison tables (AfA vs review report) in section 2 and 3 as comparison of numbers is not always straightforward. The COM also reminded the Secretariat about the issue of the presentation in the opinion text of maximum risk levels. Some RAC members will be consulted on this revised format before it is presented in RAC 57 in June and tentatively be used for draft opinions tabled for agreement in RAC 58 in September 2021.

The Secretariat will consider how to organise after summer capacity building / training e.g. on approach to evaluate measured data, modelled data and EUSES.

6. Adoption of the report of the working group

Before the Chair Tim Bowmer thanked the participants and closed the meeting, the working group adopted its report of the 8th 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**

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
CT	chromium (VI) trioxide
ERC	environmental release category
ES	exposure scenario
HvE	Humans via environment
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. 218_CT_DOURECA (2 uses)	
Use1: *Industrial use of chromium trioxide for a pre-treatment step (etching) in the electroplating process for automotive applications.* The working group supported the Draft opinion as proposed by the Rapporteur. The working group recommends to RAC that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report.	**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-57 plenary meeting via the A-listing procedure.

The highest combined inhalation exposure (8h adjusted TWA) to workers was estimated to be 0.078 µg Cr(VI)/m^3 (exposure estimate for Use 1 and Use 2 combined). For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to the general population was estimated to be (inhalation, local) 3.2 × 10^{-3} µg Cr(VI)/m^3 per 24h and (oral, local) 5.2 × 10^{-3} µg Cr(VI)/kg bw/d (Use 1 and Use 2 combined). The excess lifetime cancer risk for workers is estimated to be 3.1 × 10^{-4} (inhalation, 8h TWA exposure for 40 years, combined highest value, without the effect of the conditions) and 9.2 × 10^{-5} (inhalation, local, for 24h exposure for 70 years, without the effect of the conditions) for the general population. The working group supported: 1. no additional conditions for the authorisation 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 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; (v) include contextual information about the tasks performed during sampling; (vi) include the determination of the background concentrations at the plating line and onsite WWTP working area; (b) Environmental releases: (i) the applicants shall continue their	

monitoring programme for Cr(VI) emission of wastewater by conducting measurements twice a year; (ii) the applicants 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 applicants' site. 2. The information gathered via the measurements referred to in paragraph 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) 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 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. 5. The applicant should act upon the outcomes of the measurements of the background exposure levels in such a way that the use of RPE by the workers involved in WCS 3 and WCS 9 will be minimised. 3.recommendations for the review report. The results of the measurements referred to in section 8.1 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report.	

The working group recommended that the Draft opinion is suitable for consideration via the A-listing procedure.	
Use2: *Industrial use of chromium trioxide for the electrolytic step to create a long-lasting and high durability chromium decorative surface on plastic substrates in the electroplating process for automotive applications* The working group supported the Draft opinion as proposed by the Rapporteur. The working group recommends to RAC that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The highest combined inhalation exposure (8h adjusted TWA) to workers was estimated to be 0.078 µg Cr(VI)/m^3 (exposure estimate for Use 1 and Use 2 combined). For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to the general population was estimated to be (inhalation, local) 3.2 × 10^{-3} µg Cr(VI)/m^3 per 24h and (oral, local) 5.2 × 10^{-3} µg Cr(VI)/kg bw/d (Use 1 and Use 2 combined). The excess lifetime cancer risk for workers is estimated to be 3.1 × 10^{-4} (inhalation, 8h TWA exposure for 40 years, combined highest value, without the effect of the conditions) and 9.2 × 10^{-5} (inhalation, local, for 24h exposure for 70 years, without the effect of the conditions) for the general population. The working group supported: 1. no additional conditions for the authorisation 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 their monitoring programmes for Cr(VI) exposure, which shall:	**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-57 plenary meeting via the A-listing procedure.

(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; (vi) include the determination of the background concentrations at the plating line and onsite WWTP working area; (b) Environmental releases: (i) the applicants shall continue their monitoring programme for Cr(VI) emission of wastewater by conducting measurements twice a year; (ii) the applicants 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 applicants' site. 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) 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 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 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 applicants, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant should act upon the outcomes of the measurements of the background exposure levels in such a way that the use of RPE by the workers involved in WCS 3 and WCS 9 will be minimised. 3. recommendations for the review report. RAC recommends, and in line with the applicant's commitment, that the applicant should continue to investigate the possibility to use liquid CrO_3 solution instead of solid CrO_3 (WCS 6). The results of this investigation 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. 219_CT_HusqvarnaAB (1 use)	
Use: *Industrial use of a mixture containing Chromium Trioxide in functional chrome plating of the saw chain cutter links in order to meet stay sharp and durability requirements for use with chainsaws.* 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	**Rapporteurs** together with **SECR** to edit the Draft opinion according to the discussion of the working group on results of biomonitoring and personal and static measurements. **SECR** to schedule the Draft opinion for agreement at the RAC-

adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The highest combined exposure to workers was estimated to be 0.0089 µg Cr(VI)/m^3 (average exposure value for one worker corrected for RPE, duration and frequency, 8h-TWA value). For reference, the current binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is: 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to the general population via inhalation was estimated to be 1.98×10^{-4} µg Cr(VI)/m^3 while via the oral route it was estimated to be 8.87×10^{-5} mg Cr(VI)/kg bw/day. Based on the above exposures, the highest excess lifetime cancer risk for workers (inhalation route) is estimated to be 3.58×10^{-5} over 40 years per worker, and for general population (inhalation and oral route combined, individual) 5.81×10^{-6}. The working group supported: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicant shall continue to conduct the following monitoring programmes for Cr(VI): a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: • be conducted at least annually for the exposed workers to Cr(VI); • be based on relevant standard methodologies or protocols; • comprise personal and / or static inhalation exposure sampling; • be representative of: ✓ the range of tasks undertaken where exposure to Cr(IV) is possible; ✓ the OCs and RMMs typical for each of these tasks; ✓ the number of workers potentially exposed. b) Environmental releases: • the applicant shall continue to conduct air emission measurements at least annually	57 plenary meeting via the A-listing procedure.

or more frequently following any possible changes in the process; • the monitoring programme for air emissions shall: ✓ be based on relevant standard methodologies or protocols and ✓ 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 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. 3. recommendations for the review report The information gathered via the measurements referred to in section 8 points (a) and (b) 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.	
3. 220_CT_SRG Global (2 uses)	
Use1: *Chromium trioxide-based etching as pre-treatment step for electroplating of plastics for transportation applications.* The working group supported the Draft opinion as	**Rapporteur** together with **SECR** to edit the Draft opinion according to the discussion of the working group.

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 information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The highest combined inhalation exposure (8h adjusted TWA) to workers was estimated by RAC to be 0.32 µg Cr(VI)/m^3 (exposure estimate for Use 1). For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to the general population was estimated to be (inhalation, local) 1.0 × 10^{-3} µg Cr(VI)/m^3 per 24h and (oral, local) 4.9 × 10^{-3} µg Cr(VI)/kg bw/d (exposure estimate for Use 1). The excess lifetime lung cancer risk for workers for Use 1 is estimated to be 1.3 × 10^{-3} (inhalation, 8h TWA exposure for 40 years, combined highest value, without the effect of the conditions) and 3.0 × 10^{-5} (inhalation, local, for 24h exposure for 70 years, without the effect of the conditions) for the general population. The excess lifetime intestinal cancer risk is estimated to be 3.9 × 10^{-6} (oral, local indirectly exposed over 70 years, without the effect of the conditions) for the general population. The working group supported: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programmes for Cr(VI): (a) 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;	**SECR** to schedule the Draft opinion for agreement at the RAC-57 plenary meeting via the A-listing procedure.

(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; (vi) include the determination of the background concentrations at the plating line, loading / unloading working areas and the onsite WWTP working area. (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 both emission points 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 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 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. 3. recommendations for the review report The results of 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.	
Use2: *Functional chrome plating with decorative character for transportation applications.* The working group supported the Draft opinion as proposed by the Rapporteur. The working group recommends to RAC that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The highest combined inhalation exposure (8h adjusted TWA) to workers was estimated by RAC to be 0.32 µg Cr(VI)/m^3 (exposure estimate for Use 2). For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to the general population was estimated to be (inhalation, local) 5.5 × 10^{-4} µg Cr(VI)/m^3 per 24h and (oral, local) 2.6 × 10^{-3} µg Cr(VI)/kg bw/d (exposure estimate for Use 2). The excess lifetime cancer risk for workers for Use 2 is estimated to be 1.3 × 10^{-3} (inhalation, 8h TWA exposure for 40 years, combined highest value, without the effect of the conditions) and 1.6 × 10^{-5} (inhalation, local, for 24h exposure for 70 years, without the effect	**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-57 plenary meeting via the A-listing procedure.

of the conditions) for the general population.
The excess lifetime intestinal cancer risk is estimated to be 2.1 × 10^{-6} (oral, local indirectly exposed over 70 years, without the effect of the conditions) for the general population.

The working group supported:

1. no additional conditions for the authorisation
2. monitoring arrangements for the authorisation
    1. The applicant shall implement the following monitoring programmes for Cr(VI):
    (a) 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;
    (v) include contextual information about the tasks performed during sampling;
    (vi) include the determination of the background concentrations at the plating line, loading /unloading working areas and the onsite WWTP working area.
    (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 both emission points 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 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 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 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 RAC recommends that the applicant should perform a study on the feasibility to implement a closed and automated transfer system for the refilling of the electroplating baths (Use 2). The results of 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. 221_CT_SD_USSK (1 use)	
Use1: *Use of Chromium Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP).*	**Rapporteurs** together with **SECR** to edit the

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. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The working group supported: 1. additional conditions for the authorisation RAC proposes that the current investigation performed by the applicant in order to clarify if the higher exposure in WCS 9 compared to other tasks is due to unsuitable measurements or ineffective ventilation to be concluded without delay. The result shall be detailed in an updated CSR. If ventilation is found to be the cause of higher exposure values, the system shall be re-evaluated starting with the original design and completed with additional ventilation measurements. In addition, the effectiveness of the ventilation shall be periodically evaluated by means of annual campaigns of measurements. 2. monitoring arrangements for the authorisation a) The applicant shall continue and implement at least annual occupational/workers' exposure monitoring programmes for Cr(VI). Those programmes shall be based on relevant standard methodologies or protocols, comprise static and/or personal inhalation exposure sampling and be representative of: i. the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance workers; ii. the OCs and RMMs typical for each of these tasks; iii. the number of workers potentially exposed. b) The applicant shall continue and implement monitoring of Cr(VI) emissions to wastewater	Draft opinion according to the discussion of the working group especially providing a timeframe/deadline for the applicant to fulfil requirements of additional conditions for the authorisation. **SECR** to schedule the Draft opinion for general agreement at the RAC-57 plenary meeting.

and air from local exhaust ventilation at least annually. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the OCs and RMMs used at the applicants site. c) The information gathered via the measurements referred to in points (a) and (b) and related contextual information shall be used by the applicant to review and confirm the effectiveness of proposed RMM and OCs and, if needed, to introduce measures to further reduce workplace exposure to sodium dichromate and emissions to the environment to as low a level as technically and practically feasible. d) The applicant shall ensure that the application of RMMs at his site is in accordance with the hierarchy of control principles, and refine the worker and HvE assessments if necessary. e) The information from the measurements referred to in points (a) and (b), 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 point (c), 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 information gathered via the measurements referred to in section 8 points (a) and (b) as well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report The working group recommended that the Draft opinion is suitable for general agreement at the RAC plenary.	
5. 222_RR1_SD_Colle (1 use)	
Use1: *Use of Sodium dichromate as mordant in wool dyeing with dark colours.* The working group supported the Draft opinion as proposed by the Rapporteur.	**Rapporteurs** together with **SECR** to edit the Draft opinion according to the discussion of the working group.

The working group recommends to RAC that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure over the authorisation period. This information should also be included in the review report. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The exposure to workers was estimated to be 0.4 µg Cr(VI)/m^3 per 8h adjusted TWA via inhalation. For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to the local general population was estimated to be 6.54×10^{-7} µg Cr(VI)/m^3 via inhalation and 2.60×10^{-4} µg Cr(VI)/kg bw/day for the oral route. The excess lifetime lung cancer risk for workers is estimated to be 1.6×10^{-3} (inhalation; 8h TWA exposure for 40 years, highest combined exposure) and 1.89×10^{-8} (inhalation, local 24h exposure for 70 years) for the general population. The excess lifetime intestine cancer risk for the general population (oral, local 24h exposure for 70 years) is estimated to be 2.08×10^{-7}. The exposure to workers was estimated to be 0.69 µg Cr(VI)/kg bw/day via the dermal route. The RCR was estimated to be 1.6×10^{-2} for workers for the reprotoxic effect. The working group supported: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicant shall continue to conduct annual occupational exposure monitoring programmes for Cr(VI) with a sufficiently low LoD. 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: a. the range of tasks undertaken where exposure to chromium is possible, including tasks involving	**SECR** to schedule the Draft opinion for agreement at the RAC-57 plenary meeting.

maintenance/cleaning tasks; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed, including workers not directly using the substance. 2. The applicant shall continue to conduct at least annual Cr(VI) measurements in wastewater with a sufficiently low LoD. 3. The information gathered via the measurements referred to in paragraph 1 and 2 related contextual information shall be used by the applicant to confirm the effectiveness of operational conditions and risk management measures as well as to review regularly the effectiveness of operational conditions and risk management measures in place and, to introduce measures to further reduce workplace exposure respectively air emissions to Cr(VI) to as low a level as technically and practically feasible. 4. The information from the monitoring programmes referred to in paragraph 1 and 2, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 3 shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent authority. 3. recommendations for the review report • The information gathered via the measurements referred to in section 8 points 1 and 2 as well as the outcome and conclusions of the review and any action taken in accordance with point 3 shall be included in any subsequent authorisation review report. • Clear information that cleaning and maintenance do not result in potential exposure to Cr(VI) shall be included in any subsequent authorisation review report. The working group recommended to discuss at the RAC plenary following point of the Draft opinion: 1. compliance with the conditions from the Commission's authorisation decision.	

6. 223_RR1_EDC_Lanxess (1 use)	
Use1: *Industrial use as a swelling agent during the sulphonation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of strong acid cation exchange resins.* The working group supported the Draft opinion as proposed by the Rapporteur. The working group recommends to RAC that the alternative presented by the applicant, if implemented, would reduce the overall risks. 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. However, the proposed additional conditions for the authorisation are expected to further limit the risk. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The maximum inhalation exposure to workers was estimated to be 72 µg/m^3 (TWA-8-h; combined task exposure of WCS 1 and WCS 2) and the dermal exposure not more than 0.00039 µg/kg bw/day (TWA-8-h; combined task exposure WCS 5). The excess lifetime cancer risk for workers is estimated to be 4.3×10^{-5} (from combined dermal and inhalation exposure and tasks of WCS 1 and WCS 2), and 4.50×10^{-8} for the general population at the local scale and 7.68×10^{-11} at the regional scale. The working group supported: 1. additional conditions for the authorisation The authorisation holder should implement the improvements of the recovery of EDC from the exhaust gas before it reaches the TAR, as the authorisation holder has planned. In addition, the authorisation holder should investigate the reasons for the TAR failures and put in place measures to reduce the number of instances and duration of such failures. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report	**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-57 plenary meeting.

The authorisation holder should continue to conduct an annual occupational monitoring programme (including measurements for WCS 4 and WCS 5 with a sufficiently low LoD) and an annual monitoring programme for emissions to air for EDC. The results of the occupational measurements (including maintenance and sampling tasks) and air emission measurements, as well as the outcome and conclusions of the review and any action taken in accordance should be included in any subsequent authorisation review report. Since TAR failure is the main driver for releases to air, RAC recommends that information on the duration of the TAR failure as well as the flow rate of the vent gases and the EDC concentration in these vent gases should be provided in any review report. The working group recommended to discuss at the RAC plenary following points of the Draft opinion: 1. the proposal for the authorisation conditions while RMMs and OCs have been considered as appropriate and effective in limiting the risk.	
7. 224_RR1_EDC_Eurenco (1 use)	
Use1: *Industrial use of 1,2-dichloroethane as a solvent for the synthesis of Polyepichlorohydrin used as a precursor in the production of Glycidyl Azide Polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives.* The working group supported the Draft opinion as proposed by the Rapporteurs. RAC concluded that the operational conditions and risk management measures described in the review report 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. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The inhalation exposure to workers was estimated to be	**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-57 plenary meeting.

up to 0.413 mg/m³ (8h TWA combined tasks corrected for PPE and frequency), and the dermal exposure to workers up to 0.094 mg/kg bw/day (8h TWA combined tasks corrected for PPE and frequency). For reference, the current binding Occupational Exposure Limit (BOEL) for this substance is: 8.2 mg/m³ [2 ppm]. The exposure to the general population was estimated to be 3.4×10^{-5} mg/m³ on a local scale and 1.01×10^{-8} mg/m³ on a regional scale. The excess lifetime risk for workers is estimated to be up to 4.44×10^{-4} for 8h TWA combined exposures corrected for PPE and frequencies for 40 years, and 3.07×10^{-7} for 24h exposure for 70 years for the general population on a local scale and 7.10×10^{-11} on the regional scale for the general population. The working group supported: 1. additional conditions for the authorisation The authorisation holder shall use the information gathered via the measurements referred to in section **Error! Reference source not found.** to regularly review the effectiveness of the risk management measures and operational conditions, including the effectiveness and positioning of extraction ventilation, and to take action as appropriate, to further reduce workers' exposure and environmental exposure to 1,2-dichloroethane. In addition, the authorisation holder shall further assess, and document the feasibility to implement additional OCs and RMMs and act on the outcome of the feasibility study. Such action may encompass the implementation of an automatic transfer of 1,2-dichloroethane from a delivery truck to a reservoir. 2. monitoring arrangements for the authorisation The authorisation holder shall conduct regular occupational exposure measurements of 1,2-dichloroethane. Those measurements shall: (i) take place at least annually or, during the operation/production of PECH (i.e. when the use of 1,2-dichloroethane occurs); (ii) be representative of the range of tasks undertaken where exposure to 1,2-dichloroethane is possible and of the total number of workers that are potentially exposed – especially those involved in the collection of samples and their analysis; (iii) be based on relevant standard methodologies or protocols and use analytical methods with the lowest detection limit; (iv) include contextual information about the	

tasks with possible exposure to 1,2-dichloroethane and of the total number of workers that are potentially exposed. The authorisation holder shall continue to regularly measure emissions of 1,2-dichloroethane to the atmospheric compartment. They shall take place at least annually or, during the time of operation/production of PECH (i.e when the use of 1,2-dichloroethane occurs). Those measurements shall be based on relevant standard methodologies or protocols and use analytical methods with the lowest detection limit. 3. recommendations for the review report The results of the measurements referred to in section 8.1, as well as the outcomes and conclusions of the review and any actions taken in accordance with section 7, shall be documented and included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place. The working group recommended to discuss at the RAC plenary following points of the Draft opinion: 1. compliance with the Commission decision on authorisation, 2. sections 7, 8 and 9.	
8. 225_MOCA_LUC (2 uses)	
Use1: *Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors.* **Use2:** *Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for heavy-duty rollers, tensioner pads and spring blocks with high reliability requirements for offshore energy and renewables sectors.* The working group supported the Draft opinions as proposed by the Rapporteur.	**Rapporteur** together with **SECR** to edit the Draft opinions according to the discussion of the working group. **SECR** to schedule the Draft opinions for agreement at the RAC-57 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 appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure over the authorisation period The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The exposure to workers was estimated to be 3.66 µmol MOCA/mol creatinine (Use 1 and Use 2 combined) when measured from urinary samples collected on the Friday afternoon after the work week. This corresponds the daily intake of 12.22 µg/d (Use 1 and Use 2 combined). The excess lifetime cancer risk for workers is estimated to be **1.18×10^{-5}**, **2.7×10^{-7}** for the local population and **4.06×10^{-11}** for the regional population (Use 1 and Use 2 combined). The working group supported: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation • 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. • Measurement of surface contamination shall continue to be conducted 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. If urinary levels consistently show urinary levels below LOD, surface monitoring may not be needed. • The information gathered in the monitoring campaigns shall be used by the applicant to review and improve the risk management measures (RMMs) and operational conditions (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 and be available to national enforcement authorities. • Additional request to continue air monitoring for the workers. 3. recommendations for the review report The applicant shall continue monitoring of exposure and the information gathered in the monitoring campaigns shall be used by the applicant to review and improve the risk management measures (RMMs) and operational conditions (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 and included in any subsequent authorisation review report submitted. RAC recommends the applicant to perform a study on the feasibility to implement machine casting in all casting lines and include the result in any subsequent authorisation review report. The working group recommended that the Draft opinions are suitable for consideration via the A-listing procedure.	
9. 226_OPE_LETI (1 use)	
Use1: *Use of 4-tert-OPnEO in aqueous buffers during the manufacturing process of the active pharmaceutical ingredient (Protein Q) of the veterinary vaccine LetiFend®* 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 use applied for may result in 0 kg per year emissions of the substance to the environment. The working group supported: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation The applicant shall carry out a mass balance	**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-57 plenary meeting via the A-listing procedure.

analysis to confirm the appropriateness and effectiveness of the operational conditions and risk management measures in place. The mass balance shall be based on measurements for the relevant waste streams potentially containing 4-tert-OPnEO. 3. recommendations for the review report The information from the mass balance analysis, as well as the outcome and conclusions of any action taken regarding RMMs, 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.	

Annex II

4 May 2021
RAC WG/A/8/2021
Final

Agenda

8th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC-AFA WG-8)

4-5 May 2021
WebEx meeting

Tuesday 4 May starts at 10.00
Wednesday 5 May ends at 15.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/8/2021
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

1. 218_CT_DOURECA (2 uses)
2. 219_CT_HusqvarnaAB (1 use)
3. 220_CT_SRG Global (2 uses)
4. 221_CT_SD_USSK (1 use)
5. 222_RR1_SD_Colle (1 use)
6. 223_RR1_EDC_Lanxess (1 use)
7. 224_RR1_EDC_Eurenco (1 use)
8. 225_MOCA_LUC (2 uses)
9. 226_OPE_LETI (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 agreement

Annex III

List of Attendees of the 8th Meeting of RAC-AFA WG

RAC Members
Baranski Boguslaw
Bjørge Christine
Branisteanu Radu (co-opted)
Brovkina Julija
Chiurtu Elena (co-opted)
Doak Malcolm
Facchin Manuel
Geoffroy Laure
Husa Stine
Kadiķis Normunds
Kapelari Sonja
Leinonen Riitta
Moldov Raili
Printemps Nathalie
Santonen Tiina
Schlüter Urs
Užomeckas Žilvinas
Van der Haar Rudolf (co-opted)

Members' advisers
Beetstra Renske
Rother Dag
Seba Julie

Invited Experts
Viegas Susana

European Commission
Roebben Gert
Veronika Jezso

RAC Regular Stakeholders
Janosi Amaya

ECHA
Bowmer Tim
Gmeinder Michael
Kalle Kivelä
Lazic Nina
Lefevre Sandrine
Ludboržs Arnis
Logtmeijer Christiaan
Marquez-Camacho Mercedes
Mottet Denis
Nicot Thierry
Nurmi Vaino
Peltola Jukka
Pillet Monique
Richarz Andrea
Smilovici Simona
Sosnowski Piotr
Thierry-Mieg Morgane
Väänänen Virpi
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 WG MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chair.