

RAC working group/R/16/2023

Final

7 July 2023

**Report
of the 16th Meeting of the Committee for Risk Assessment
Working Group on Applications for Authorisation
(RAC AfA working group)**

**(Telakkakatu 6, Helsinki)
via WebEx**

**Thursday 6 July starts at 9.30
Friday 7 July ends at 17.00**

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 25 participants to the 16th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. He informed the group that sections of the meeting would also be chaired by Roberto Scazzola, Thierry Nicot and Tim Bowmer.

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 working group/A/16/2023), which was adopted unchanged and is attached to this Report as Annex II.

3. Declarations of conflicts of interests to the Agenda

The Chair requested all participants to declare any potential conflicts of interest to any of the agenda items. None of the participants declared a potential conflict of interest to the agenda items. The Chairs all declared that they had no potential conflicts of interest related to any of the agenda points of the meeting.

4. Authorisation applications

The recommendations by the working group on draft opinions on the 13 Applications covering 13 uses considered at this meeting are listed in Annex I.

5. Any other business

Horizontal issues:

The Secretariat presented the state of play of the application pipeline and how the AfAs will be prioritised.

The working group discussed how to best report exposures for short-duration tasks. The rapporteurs should assess the applicant's calculations and assumptions and verify in as far as possible that they are correct (including, for instance, whether other tasks involving exposure for Cr(VI) are carried out during the sampling time, conversion to TWA, etc.). The overall goal is to assess the reliability of such data but does not require a full reconstruction of the applicant's calculations.

The working group also discussed the standard phrase for personal and static sampling containing 'and/or' in section 8. The Secretariat informed that the 'and/or' mainly means 'or'. Section 8 is generally designed to address shortcomings at the level of the overall exposure assessment (i.e. the workplace as a whole), and not at the level of each individual WCS or task. Therefore the 'or' is in general more appropriate as not all WCS/tasks would systematically need both personal and static sampling.

The Secretariat will nevertheless update the RAC's Lines-To-Take so that both options [personal or static] and [personal and static] can be distinguished more clearly. The 'and' can be used when RAC has major concerns with regard to the OCs/RMMs or the exposure assessment (for instance for cases where the working conditions are not acceptable).

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, requesting the Secretariat to make any necessary editorial changes.

- Annex I Working group recommendations**
- Annex II Agenda of the 16th meeting**
- Annex III List of participants of the 16th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation**
- Annex IV Declarations of potential conflicts of interest**
- Annex V Standard text for Section 8: monitoring arrangements for the authorisation and Section 9: recommendation for the review report.**

Annex I

Working group recommendations

Abbreviations used

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. 297_CT_Acciaierie_Italia (1 use)	
<p>Use1: <i>Use of Chromium (VI) Trioxide for Electrolytic Chromium Coating of Steel (ECCS).</i></p> <p>The working group discussed:</p> <ul style="list-style-type: none"> - If the facility operates only when LEV is working; it was confirmed during the discussion, - RMMs for protection of the soil pollution. <p>The working group supported the draft opinion as proposed by the Rapporteur.</p> <p>The working group recommends to RAC that the operational conditions and risk management measures described in the</p>	<p>SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.</p>

<p>application are appropriate and effective in limiting the risk, provided that they are adhered to.</p> <p>The working group supports: Section 7: additional conditions for the authorisation 1. The applicant shall carry out and document a detailed feasibility study on:</p> <ul style="list-style-type: none"> - the implementation of a closed/automated system to perform passivation tank sampling tasks. <p>The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.</p> <p>Section 8: monitoring arrangements for the authorisation as given in Annex V. Section 9: recommendations for the review report as given in Annex V.</p> <p>The RAC AFA working group recommends to A-List the draft opinion.</p>	
2. 298_CT_Bjerringbro_Fornikling (1 use)	
<p>Use1: <i>Electroplating (by a job plater) of metal substrates using chromium trioxide to achieve functional surfaces.</i></p> <p>The working group requested to set the deadline to improve RMMs on 31 December 2023 in line with the applicant's commitment.</p> <p>The working group supported the draft opinion as proposed by the Rapporteur with mentioned changes.</p> <p>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.</p> <p>The working group supports: Section 7: additional conditions for the authorisation 1. The applicant shall implement the RMM wall segregation proposals contained in the applicant update of 16th May 2023 by 31 December 2023 as declared in the updated CSR 2. The applicant shall implement the RMM lids fitting proposals for both electroplating lines contained in the applicant update of 16th May 2023 by 31 December 2023 as declared in the updated CSR</p>	<p>Rapporteur together with SECR to edit the draft opinion according to the discussion of the working group.</p> <p>SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.</p>

<p>3. Where RPE is needed to control exposure to chromium trioxide, it shall be used in accordance with standard procedures for use and maintenance. Those procedures shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards, shall ensure training and medical fitness checking and supervision of the wearer and maintenance of the RPE.</p> <p>Section 8: monitoring arrangements for the authorisation as given in Annex V.</p> <p>Section 9: recommendations for the review report as given in Annex V.</p> <p>The RAC AFA working group recommends to A-List the draft opinion.</p>	
3. 299_OPE_MeiraTGX (1 use)	
<p>Use1: <i>Use of 4-tert-OPhEO as a manufacturing aid in the production of gene therapies.</i></p> <p>The working group supported the draft opinion as proposed by the Rapporteur.</p> <p>The working group recommends to RAC that RAC concluded that the operational conditions and risk management measures described in the application are expected to be appropriate and effective in limiting the risk, provided that they will be implemented and adhered to.</p> <p>The use applied for may result in 0.00 kg per year releases of the substance to the environment.</p> <p>The working group supports: Section 7: additional conditions for the authorisation None Section 8: monitoring arrangements for the authorisation None. Section 9: recommendations for the review report None</p> <p>The RAC AFA working group recommends to A-List the draft opinion.</p>	<p>SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.</p>
4. 300_CT_Weber-Hydraulic (1 use)	
<p>Use1: <i>Chromium-trioxide-based functional chrome plating of solid</i></p>	<p>SECR to</p>

and hollow piston rods for hydraulic applications.

The working group supported the draft opinion as proposed by the Rapporteur.

The working group recommends to RAC that that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to.

The working group supports:

Section 7: additional conditions for the authorisation

The applicant shall ensure that workers perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before taking on relevant tasks and workers shall be trained to do this test adequately.

The applicant shall carry out and document a detailed feasibility study on:

- a) the implementation of a closed/automated system to perform the bath adjustment of the chromium baths at Pilot Galvanik 7203 line.

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex V.

Additionally point 8

The applicant shall implement an annual biomonitoring programme for the workers potentially exposed to Cr(VI). This programme must consist, as a minimum, of pre and post shift urine samples (beginning of the week --> end of the week), using valid existing standard methodologies such as e.g. HSE, HBM4EU. This annual biomonitoring program must be synchronised with the annual occupational air monitoring campaign specified in 1.a above. The results of the biomonitoring programme can be reported following the "Format for reporting of occupational exposure data by downstream users", in the respective Excel sheet for biomonitoring, as it can be found on the ECHA homepage.

Section 9: recommendations for the review report as given in Annex V.

The RAC AFA working group recommends to A-List the draft opinion.

schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.

5. 301_CT_SD_Liberty_Liege (1 use)

Use1: *Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP).*

The working group discussed:

- a condition to use RPE during baths sampling via valve fitted on the manifold of the passivation circuit and a feasibility study to automatise the sampling tasks,
- a statement in the draft opinion why the applicant decided to not use the biomonitoring data.

The working group recommends to RAC that regarding the exposure to Cr(VI) associated with use of chromium trioxide and sodium dichromate, 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.

Regarding the reproductive hazards associated with the use of sodium dichromate, that the risk assessment presented in the application demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the application are adhered to.

The working group supports:

Section 7: additional conditions for the authorisation

None

Section 8: monitoring arrangements for the authorisation as given in Annex V.

Section 9: recommendations for the review report as given in Annex V.

The RAC AFA working group recommends to discuss at the RAC plenary the following points of the draft opinion:

- 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-66 plenary.

6. 302_CT_Thoma_Metallverdelung (1 use)

Use1: *Functional chrome plating for hydraulic applications, other cylindrical components and further industrial applications.*

The working group discussed:

- Selection of static versus personal measurements by applicant for certain WCSs
- Justification for feasibility study on better measured

Rapporteur together with **SECR** to edit the draft opinion according to the

<p>concentration measurements around the installation to prepare Cr(VI) solution. The working group proposed to address concerns via request proper monitoring campaign under section 8 of the draft opinion.</p> <p>The working group supported the draft opinion as proposed by the Rapporteur.</p> <p>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.</p> <p>The working group supports:</p> <p>Section 7: additional conditions for the authorisation</p> <ol style="list-style-type: none"> 1. The applicant shall ensure that RPE is used in accordance with standard procedures for use and maintenance. Those procedures shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards, shall ensure training and medical fitness checking and supervision of the wearer and maintenance of the RPE. 2. The applicant shall carry out and document a detailed feasibility study on: <ol style="list-style-type: none"> a) 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. b) the covering of the automatic plating Line 1900 during the plating process. c) a (partial) physical separation between the loading/unloading working areas and the plating lines (both manual and automatic lines). <p>The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.</p> <p>Section 8: monitoring arrangements for the authorisation as given in Annex V.</p> <p>With additional monitoring arrangements to clarify concerns on measured concentration during the use of the installation to prepare Cr(VI) solution.</p> <p>Section 9: recommendations for the review report as given in Annex V.</p> <p>The RAC AFA working group recommends to discuss at the RAC plenary the full draft opinion.</p>	<p>discussion of the working group.</p> <p>SECR to launch RAC consultations on the DO.</p> <p>SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting.</p>
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7. 303_CT_Rubinetterie_Stella (1 use)

Use1: *Electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector.*

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 implemented and adhered to.

The working group supports:

Section 7: additional conditions for the authorisation

1. The applicant shall implement, as planned:

- (a) the use of liquid CrO₃ instead of solid,
- (b) a dosing pump for automated addition of the liquid CrO₃ instead of the manual addition of flakes, to adjust the concentration in the bath,
- (c) a flow detector in the ventilation system, to ensure the correct functioning of the LEV.

2. The applicant shall carry out and document a detailed feasibility study on:

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

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex V.

Section 9: recommendations for the review report as given in Annex V.

The RAC AFA working group recommends to A-List the draft opinion.

SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.

8. 304_SD_Acciaierie (1 use)

Use1: *Use of Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP).*

Rapporteurs together with

<p>The working group discussed:</p> <ul style="list-style-type: none"> - Section 7 of the draft opinion. <p>The working group supported the draft opinion as proposed by the Rapporteurs.</p> <p>The working group recommends to RAC that Regarding the exposure to Cr(VI) associated with use of sodium dichromate, the operational conditions and risk management measures described in the application are generally appropriate and effective in limiting the risk to workers and general population, provided that they are adhered to.</p> <p>Regarding the reproductive hazards associated with the use of Sodium dichromate, the risk assessment presented in the application demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the application are adhered to.</p> <p>The working group supports:</p> <p>Section 7: additional conditions for the authorisation</p> <ol style="list-style-type: none"> 1. The applicant shall ensure that appropriate RPE is worn during baths sampling (T2), due to the potential for exposure to Cr(VI). 2. The applicant shall carry out and document a detailed feasibility study on: <ul style="list-style-type: none"> •the implementation of a closed/automated system to perform passivation tank sampling tasks, where exposure to Cr(VI) is foreseen RPE. <p>The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.</p> <p>Section 8: monitoring arrangements for the authorisation as given in Annex V.</p> <p>Section 9: recommendations for the review report as given in Annex V.</p> <p>The RAC AFA working group recommends to A-List the draft opinion.</p>	<p>SECR to edit the draft opinion according to the discussion of the working group.</p> <p>SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.</p>
<p>9. 305_CT_Meoni_e_Bartoletti (1 use)</p>	
<p>Use1: <i>Use of Chromium Trioxide for the hard-chrome plating of</i></p>	<p>SECR to</p>

hydraulic and pneumatic cylinders for various applications, and inner tubes of motorbike front suspension for the automotive industry.

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 review report **are** appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

The working group supports:

Section 7: additional conditions for the authorisation

- 1) The applicant shall ensure that workers perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before taking on relevant tasks and workers shall be trained to do this test adequately.
- 2) The applicant shall carry out and document detailed feasibility studies at current (Pistoia) and future (Pianoro) sites on:
 - a) the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of RPE.
 - b) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s)), in case the local exhaust ventilation is not functioning properly.

The feasibility studies shall be concluded within 12 months of granting an authorisation for this use. In accordance with the conclusion of the feasibility studies, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex V.

Point 8

The applicant holder shall conduct the monitoring programmes mentioned in 1.a and 1.b at the Pianoro site at least until the plant functions at full capacity to ensure the impacts of the expansion are closely monitored. Afterwards, the applicant holder may reduce the frequency of measurements, once they can clearly demonstrate to the national Competent Authority of the Member State where the use takes place, that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions function appropriately.

schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.

<p>Section 9: recommendations for the review report as given in Annex V.</p> <p>The RAC AFA working group recommended to A-List the draft opinion.</p>	
10. 306_CT_Galvanica_Pasotti (1 use)	
<p>Use 1: <i>Industrial use of chromium trioxide for functional chrome plating with decorative character of items for the sanitary, hydro-sanitary, taps, household industries, and various other applications (such as handles/locks, pneumatic elements and electrical connection).</i></p> <p>The working group supported the draft opinion as proposed by the Rapporteur.</p> <p>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.</p> <p>The working group supports:</p> <p>Section 7: additional conditions for the authorisation</p> <ol style="list-style-type: none"> 1. The applicant shall carry out and document a detailed feasibility study for BOTH sites on: <ol style="list-style-type: none"> (a) the replacement of solid CrO₃ flakes by a liquid solution of CrO₃, or the implementation of a closed/automated system to perform the dilution of solid CrO₃ (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent (re-)filling of the baths with liquid solutions (e.g. fix-piping from the containers or mixing tanks, to the plating baths). (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. <p>The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.</p> <p>Section 8: monitoring arrangements for the authorisation as given in Annex V.</p> <p>With point 8.</p> <p>Section 9: recommendations for the review report as given in Annex V.</p>	<p>SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.</p>

<p>The RAC AFA working group recommends to A-List the draft opinion.</p>	
<p>11. 307_CT_Vinzia (1 use)</p>	
<p>Use1: <i>Industrial use of chromium trioxide for the functional chrome plating with the decorative character of brass or stainless-steel drain components for the tap industry to provide thickness, corrosion resistance.</i></p> <p>The working group supported the draft opinion as proposed by the Rapporteur.</p> <p>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.</p> <p>The working group supports: Section 7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on:</p> <ol style="list-style-type: none"> a) the replacement of solid CrO₃ flakes by a liquid solution of CrO₃, or the implementation of a closed/automated system to perform the dilution of solid CrO₃ (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent (re-)filling of the baths with liquid solutions using a closed and automatic system 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. c) the installation of a physical separation between the plating line and loading/unloading areas. d) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s) in case the local exhaust ventilation is not functioning properly. <p>The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.</p> <p>Section 8: monitoring arrangements for the authorisation as given in Annex V.</p>	<p>SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.</p>

<p>Section 9: recommendations for the review report as given in Annex V.</p> <p>The RAC AFA working group recommends to A-List the draft opinion.</p>	
12. 309_CT_Cromatura-Staff (1 use)	
<p>Use1: <i>Industrial use of chromium trioxide for the plating of brass valves destined for applications involving industrial and technical fluids and brass fittings for oxygen cylinders.</i></p> <p>The working group discussed:</p> <ul style="list-style-type: none"> - A need for the authorization condition to implement automated systems to perform the bath maintenance activities - A request to the applicant to investigate the origin of biomonitoring results above relevant thresholds and take the necessary measures to reduce the increase of Cr(VI) concentration in urine, between the beginning and the end of the work shift, below the acceptable thresholds <p>The working group recommended to apply in the opinion the standard text for section 8 as in the LTT document.</p> <p>The working group supported the draft opinion as proposed by the Rapporteur with proposed changes.</p> <p>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.</p> <p>The working group supports:</p> <p>Section 7: additional conditions for the authorisation</p> <p>The applicant shall carry out and document a detailed feasibility study on:</p> <ol style="list-style-type: none"> a) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s)), in case the local exhaust ventilation is not functioning properly) b) the replacement of solid CrO₃ flakes by a liquid solution of CrO₃, or the implementation of a closed/automated system to perform the dilution of solid CrO₃ (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent (re-)filling of the baths with liquid solutions (e.g. fix-piping from the containers or mixing tanks, to the plating baths) 	<p>Rapporteur together with SECR to edit the draft opinion according to the discussion of the working group.</p> <p>SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.</p>

<p>c) the implementation of a closed/automated system to perform baths sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.</p> <p>The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.</p> <p>Section 8: monitoring arrangements for the authorisation as given in Annex V.</p> <p>Section 9: recommendations for the review report as given in Annex V.</p> <p>The RAC AFA working group recommends to A-List the draft opinion.</p>	
13. 310_CT_Cromotecnica_Fida (1 use)	
<p>Use1: <i>Functional chrome plating of hydraulic cylinders, stems, pistons and rollers using chromium trioxide.</i></p> <p>The working group discussed:</p> <ul style="list-style-type: none"> - the condition to install a dedicated contact strip as proposed by the applicant. <p>The working group supported the draft opinion as proposed by the Rapporteur.</p> <p>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.</p> <p>The working group supports:</p> <p>Section 7: additional conditions for the authorisation</p> <p>The applicant shall carry out and document a detailed feasibility study on:</p> <ol style="list-style-type: none"> a. the replacement of solid CrO₃ flakes by a liquid solution of CrO₃, or the implementation of a closed/automated system to perform the dilution of solid CrO₃ (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent (re-)filling of the baths with liquid solutions (e.g. fix-piping from the containers or mixing tanks, to the plating baths). b. the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. 	<p>Rapporteur together with SECR to edit the draft opinion according to the discussion of the working group.</p> <p>SECR to schedule the draft opinion for agreement at the RAC-66 plenary meeting via the A-listing procedure.</p>

- c. the installation of a physical separation between the plating and the preparation areas.
- d. the installation of a dedicated contact strip so that the plating process can only operate when the cover is properly secured.

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex V.

Section 9: recommendations for the review report as given in Annex V.

The RAC AFA working group recommended to A-List the draft opinion.

Agenda

Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group (RAC AFA WG) reporting to RAC-66

6 - 7 July 2023

WebEx meeting

Thursday 6 July starts at 9.30
Friday 7 July ends at 17.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/16/2023
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

1. 297_CT_Acciaierie_Italia
2. 298_CT_Bjerringbro_Fornikling
3. 299_OPE_MeiraTGX
4. 300_CT_Weber-Hydraylic
5. 301_CT_SD_Liberty_Liege
6. 302_CT_Thoma_Metallverdelung
7. 303_CT_Rubinetterie_Stella
8. 304_SD_Acciaierie
9. 305_CT_Meoni_e_Bartoletti
10. 306_CT_Galvanica_Pasotti
11. 307_CT_Vinzia
12. 309_CT_Cromatura-Staff
13. 310_CT_Cromotecnica_Fida

For discussion

Item 5 – AOB

1. AfA horizontal issues

For discussion

Item 6 – Adoption of the Report from the WG

For discussion and adoption

Annex III

List of participants of the 16th Meeting of the RAC AFA working group

<u>RAC Members</u>	<u>European Commission</u>
Angeli Karine	Roebben Gert
Barański Boguslaw	
Brovkina Julija	<u>RAC Regular Stakeholders</u>
Chiurtu Elena (co-opted)	Janosi Amaya
Christodoulou Sotirios	
Devilleur Geneviève (co-opted)	<u>ECHA</u>
Docea Anca	Ahtiainen Heini
Geoffroy Laure	Bowmer Tim
Leinonen Riitta	Di Bastiano Augusto
Menard Srpčič Anja	Etholen Anita
Moldov Raili	Henrichson Sanna
Pribu Mihaela	Lisboa Patricia
Tobiassen Lea Stine	Loukou Christina
Užomeckas Žilvinas	Ludborzs Arnis
Van der Haar Rudolf (co-opted)	Mushtaq Fesil
Viegas Susana	Mäkelä Petteri
	Nicot Thierry
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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		

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

Section 8: monitoring arrangements for the authorisation

1. The applicant shall implement the following monitoring programmes for Cr(VI):
 - (a) Occupational inhalation exposure monitoring programmes, which shall:
 - (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI).
 - (ii) be based on relevant standard methodologies or protocols;
 - (iii) ensure a sufficiently low limit of quantification;
 - (iv) comprise personal and/or static inhalation exposure sampling;
 - (v) be representative of:
 - a. the full range and duration of tasks undertaken where exposure to Cr(VI) is possible;
 - b. the OCs and RMMs typical for each of these tasks;
 - c. the number of workers potentially exposed;
 - (vi) include contextual information about the tasks performed during sampling.
 - (b) Environmental releases:
 - (i) the applicant shall continue conducting their (or “implement a”) monitoring programme for Cr(VI) emission to wastewater;
 - (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process;
 - (iii) the monitoring programmes for wastewater and air emissions shall:
 - a. be based on relevant standard methodologies or protocols; and
 - b. be representative of the OCs and RMMs used at the applicant’s site.
 - c. ensure a sufficiently low limit of quantification.
2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.
3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.
4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.

5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans (i.e. workers and general population) has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.
6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers and humans via the environment at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers and humans via the environment to be reduced to as low a level as technically and practically possible
7. The applicant shall continue their existing [annual] biomonitoring programme for the workers potentially exposed to Cr(VI).

Section 9: recommendation for the review report.

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