

RAC working group/R/17/2023 Final 11 October 2023

Report

## of the 17<sup>th</sup> Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC AfA working group)

(Telakkakatu 6, Helsinki) via WebEx

## Tuesday 10 October starts at 10.00 Wednesday 11 October ends at 17.30

#### Summary Record of the Proceedings

#### 1. Welcome and apologies

The Chair, Piotr Sosnowski, welcomed the 33 participants to the 17<sup>th</sup> Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. He informed the group that sections of the meeting would also be chaired by Arnis Ludboržs, Roberto Scazzola and Thierry Nicot.

He reminded all that the working group has been established based on the RAC Mandate and the purpose of the working group meeting is to discuss AfA cases and to provide recommendations to RAC if they can be agreed via the A-listing procedure or if they require discussion during the plenary. This allows to save time and discuss in the plenary only more complex issues. He reminded that the working group will be requested to adopt its report at the end of the meeting.

#### 2. Adoption of the Agenda

The Chair introduced the agenda for the meeting (RAC working group/A/17/2023), 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. Declaration of a potential conflict of interest to the agenda items by one participant was added to Annex IV (declared at previous meetings). The Chairs all declared that they had no potential conflicts of interest related to any of the agenda points of the meeting.



#### 4. Authorisation applications

The recommendations by the working group on draft opinions on the 14 Applications covering 15 uses considered at this meeting are listed in Annex I.

## 5. Any other business

#### Horizontal issues:

The Secretariat presented the state of play of the AfA pipeline and how the Secretariat intends to process the AfAs in 2024 while preparing a Restriction proposal for the uses of certain chromium compounds. In this context the Commission will publish soon a questions and answers document.

The Secretariat also reminded the working group about the conformity check performed by RAC and SEAC during the opinion-making process, and about the tips presented in RAC 66 to streamline the opinion making by RAC (including consideration on a consistent way of representing numbers in terms of digits).

#### 6. Adoption of the report of the working group

Before the Chair Roberto Scazzola 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 17<sup>th</sup> meeting
- Annex III List of participants of the 17<sup>th</sup> Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation
- Annex IV Declarations of potential conflicts of interest
- Annex V Standard text for Section 8: monitoring arrangements for the authorisation and Section 9: recommendation for the review report.



## Annex I

## Working group recommendations

## Abbreviations used

| CA   | chromic acid                          |
|------|---------------------------------------|
| СТ   | chromium (VI) trioxide                |
| DtC  | dichromium tris(chromate)             |
| ERC  | environmental release category        |
| ES   | exposure scenario                     |
| HvE  | Humans via environment                |
| LEV  | local exhaust ventilation             |
| 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                |
| WWTP | wastewater treatment plant            |
| vPvB | very persistent, very bioaccumulative |
|      |                                       |

| Summary of the recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Action Points                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| 1. 311_SD_Liebherr-Aerospace (1 use)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                      |
| <ul> <li>Use1: Industrial use of sodium dichromate for the sealing after anodizing of aluminium alloys and passivation of metallic coatings of actuation and landing gear system parts for the aviation industry that meet the airworthiness certification requirements.</li> <li>The working group discussed: <ul> <li>workers exposure values during the weighing process (WCS 2),</li> <li>conditions for the authorisation regarding the use of RPE and use of disposable protection clothes,</li> <li>monitoring arrangements for the authorisation.</li> </ul> </li> </ul> | Rapporteur<br>together with<br>SECR to edit<br>the draft<br>opinion<br>according to<br>the<br>discussion of<br>the working<br>group. |
| The working group supported the draft opinion as proposed by the Rapporteur.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | schedule the<br>draft opinion<br>for                                                                                                 |
| 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 to workers.                                                                                                                                                                                                                                                                                                                                                                                 | agreement at<br>the RAC-67<br>plenary<br>meeting via                                                                                 |

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UROPEAN CHEMICALS AGENCY Regarding the reproductive hazards associated with the use of the A-listing sodium dichromate, the working group recommends to RAC that procedure. the risk assessment presented in the application demonstrates adequate control of risk from the use applied for, provided that the operational conditions and risk management measures described in the application are adhered to. The working group recommends to RAC that the OCs and RMMs related to environmental release minimisation are appropriate and effective in limiting the risk to the general population via the environment. The working group supports: Section 7: additional conditions for the authorisation 1. The applicant shall implement technical improvements to the OCs and RMMs during weighing of solid SD (e.g. installation of LEV in room where weighing is performed), within 12 months of the granting of an authorisation for this use, followed by a measurement campaign to validate the effectiveness of the applied technical improvements. 2. The applicant shall ensure that workers involved in surface treatment activities and bath sampling use appropriate RPE, with due consideration for the duration of the tasks and the comfort of the workers during their use. The use of RPE could stop if the additional technical improvements to the OCs and RMMs (e.g. physical separation between the loading/unloading working area and the treatment lines, removal of the workers from the plating area through remote operations of hoists, automated system or closed sampling system etc.) will be implemented at the site.

- 3. The applicant shall ensure that workers perform a 'fit check' of the seal of their RPE before taking on relevant tasks and workers shall be trained to do this test adequately.
- 4. Without prejudice to points 1, 2 and 3 above, the applicant shall carry out and document a detailed feasibility study on:
  - the replacement of solid SD crystals by a liquid solution of SD, or the implementation of a closed/automated system to perform the dilution of solid SD (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent refilling of the baths with liquid solutions (e.g. fix-piping from the containers or mixing tanks, to the baths);
  - the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen;
  - the installation of a physical separation between the treatment lines and loading/unloading areas;
  - the installation of a LEV system that triggers automatically appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) treatment bath(s), in case the local exhaust ventilation is not functioning properly).



| The feasibility studies 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.<br>Section 8: monitoring arrangements for the authorisation as given in Annex V.<br>Section 9: recommendations for the review report as given in Annex V.<br>The working group recommends that the draft opinion is suitable for consideration via the A-listing procedure.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2. 312_CT_Metalplast (2 uses)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                |
| <ul> <li>Use1: Industrial use of hexavalent chromium for a pre-treatment step (etching) in the electroplating process for plastic materials with various applications.</li> <li>Use2: Industrial use of chromium trioxide for plating on plastic materials to create a long-lasting high durability chromium decorative surface in the electroplating process for various applications.</li> <li>The working group discussed: <ul> <li>manual etching and related concerns at the Metalplast site, conclusion on RMMs and OCs,</li> <li>feasibility study versus hard conditions to automatise the dipping process at the Metalplast site,</li> <li>lack of an emissions abatement system (e.g. a wet scrubber) for the chimney at the CO.BE site for both uses and the consequences and related changes in the draft opinions,</li> <li>separation of conclusions on RMMs and OCs for HH and HvE (not appropriate for HvE).</li> </ul> </li> <li>The working group recommends that the draft opinion is suitable for general discussion (with emphasis to the possible automatisation of the process) and agreement at the RAC plenary.</li> </ul> | Rapporteur<br>together with<br>SECR to edit<br>the draft<br>opinion<br>according to<br>the<br>discussion of<br>the working<br>group.<br>SECR to<br>schedule the<br>draft opinion<br>for discussion<br>and<br>agreement at<br>the RAC-67<br>plenary<br>meeting. |
| 3. 313_CT_BWI-Poland (1 use)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                |
| <b>Use1:</b> Industrial use of chromium trioxide for the functional                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Rapporteurs                                                                                                                                                                                                                                                    |

**Use1:** *Industrial use of chromium trioxide for the functional* **Rapporteurs** *chrome plating of shock absorber rods and strut rods, cylinders* together with



*and reservoir tubes mounted on passive or semi-active dampers* **SECR** to edit the draft

The working group discussed:

- number of operation days a year of the plating lines,
- semi-closed system for sampling,
- high limit of quantification of the analytical method used by the applicant for long-term worker exposure measurements,
- irregular tasks by the workers,
- relatively prolonged use of RPE by the workers.

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 generally 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

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

- (a) the replacement of solid CrO<sub>3</sub> flakes by a liquid solution of CrO<sub>3</sub>, or the implementation of a closed/automated system to perform the dilution of solid CrO<sub>3</sub> (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 (for the FIAMMA line), where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.
- (c) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and or/the shutdown of the plating operation, in case the local ventilation is not functioning properly (for the FIAMMA 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.

Section 9: recommendations for the review report

The results of the feasibility study and actions as mentioned in section 7 and the measurements referred to in section 8.1 as

the draft opinion according to the discussion of the working group.

SECR to schedule the draft opinion for agreement at the RAC-67 plenary meeting via the A-listing procedure.



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.

The working group recommends that the draft opinion is suitable for consideration via the A-listing procedure.

## 4. 314\_CT\_Benoni (1 use)

**Use 1:** Functional chrome plating of mechanical components (including hydraulic cylinders, columns, moulds and various machinery parts) using chromium trioxide.

The working group discussed:

- possible combined exposure to HvE.

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 not appropriate and effective in limiting the risk for workers for both sites and not appropriate and effective in limiting the risk to the general population at the Cristofoletti site.

The working group supports:

Section 7: additional conditions for the authorisation

- 1. The applicant shall implement, without delay technical improvements to the OCs/RMMs (e.g. improvement of the LEV functioning, covering the bath during the plating process, segregation of parts preparation, etc) to minimize the Cr(VI) concentration nearby the plating bath and reduce workers' exposure to Cr(VI) at both sites. These shall be implemented within 12 months of the granting of an authorisation for this use and be followed by a measurement campaign to validate the effectiveness of the applied technical improvements.
- 2. The applicant shall take further action related to the air emissions of the Cristofoletti site:
  - The applicant shall carefully analyse the results of the measurement campaign carried out in 2023 and recalculate the release factor for the air of the Cristofoletti site.
    - A release factor of a same level of magnitude or lower than the one derived for the Benoni site shall be achieved;
    - $_{\odot}$  . If the release factor is not of the same order of

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-67 plenary meeting via the A-listing procedure.



magnitude or lower than for Benoni, the applicant shall conduct a root cause analysis for the difference and implement immediately appropriate actions to improve the situation in terms of achieving a higher level of efficiency of the applied OCs and RMMs at the site for air release control. If necessary, additional RMMs shall be implemented to further reduce these releases to as low a level as technically and practically feasible.

- Control measurements shall be conducted to confirm the impact of any action. The "control measurement – analysis – action" cycle shall be continued until a release factor of the same level of magnitude or lower than Benoni is achieved.
- 3. The applicant shall carry out and document a detailed feasibility study on:
  - (a) the replacement of solid CrO<sub>3</sub> flakes by a liquid solution of CrO<sub>3</sub>, or the implementation of a closed/automated system to perform the dilution of solid CrO<sub>3</sub> (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.

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

The results of the feasibility study and actions as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1 and 7, 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 recommends that the draft opinion is suitable for consideration via the A-listing procedure.

## 5. 315\_CT\_Egal (1 use)

**Use1:** Industrial use of chromium trioxide for the pre-treatment **Rapporteur** 



| LOROFEAN CHEMICALS AGENCT                                                                                                             |                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| step (etching) in the electroplating process of small sized plastic items for various sectors.                                        | together with<br><b>SECR</b> to edit<br>the draft |
| The working group discussed:                                                                                                          | opinion                                           |
| - LEV: effectiveness of the mobile capturing hood,                                                                                    | according to                                      |
| - static sampling used for exposure assessment.                                                                                       | the                                               |
|                                                                                                                                       | discussion of                                     |
| The working group supported the draft opinion as proposed by the                                                                      | the working                                       |
| Rapporteur.                                                                                                                           | group.                                            |
|                                                                                                                                       |                                                   |
| The working group recommends to RAC that the operational                                                                              | SECR to                                           |
| conditions and risk management measures described in the                                                                              | schedule the                                      |
| application are appropriate and effective in limiting the risk,                                                                       | draft opinion                                     |
| provided that they are implemented and adhered to.                                                                                    | for                                               |
|                                                                                                                                       | agreement at                                      |
| The working group supports:                                                                                                           | the RAC-67                                        |
| Section 7: additional conditions for the authorisation                                                                                | plenary                                           |
| 1. The applicant shall carry out and document a detailed                                                                              | meeting via                                       |
| feasibility study on:                                                                                                                 | the A-listing                                     |
| a) the implementation of a physical segregation of the etching                                                                        | procedure                                         |
| tank (as planned by the applicant);                                                                                                   | (unless                                           |
| b) the implementation of a closed/automated system to                                                                                 | changes in                                        |
| perform bath sampling tasks, where exposure to Cr(VI) is                                                                              | the draft                                         |
| foreseen and which currently rely on the use of PPE.                                                                                  | opinion).                                         |
| 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 working every version do that the duaft evicing is suitable                                                                       |                                                   |
| The working group recommends that the draft opinion is suitable<br>for consideration via the A-listing procedure if no changes in the |                                                   |
| draft opinion after an additional consultation with the applicant.                                                                    |                                                   |
| arar opinion arter an additional consultation with the applicant.                                                                     |                                                   |
|                                                                                                                                       |                                                   |
|                                                                                                                                       |                                                   |
| 6. 316_CT_ASO-Cromsteel (1 use)                                                                                                       |                                                   |
|                                                                                                                                       |                                                   |
| <b>Use1:</b> Chromium trioxide based functional chrome plating of                                                                     | Rapporteur                                        |
| semi-finished steel products (bars, cylinder tubes and linear                                                                         | together with                                     |
| shafts) for the manufacture of hydraulic and pneumatic                                                                                | SECR to edit                                      |
| components.                                                                                                                           | the draft                                         |
| The working group discussed:                                                                                                          | opinion                                           |
|                                                                                                                                       | according to                                      |



| - RAC calculation of the stated effectiveness values for                                                                    | the               |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------|
| environmental RMMs to air,                                                                                                  | the discussion of |
| - individual excess risk level for HVE.                                                                                     | the working       |
|                                                                                                                             | -                 |
| The working every every ted the dueft eninion of purposed by the                                                            | group.            |
| The working group supported the draft opinion as proposed by the                                                            |                   |
| Rapporteur.                                                                                                                 | SECR to           |
|                                                                                                                             | schedule the      |
| The working group recommends to RAC that the operational                                                                    | draft opinion     |
| conditions and risk management measures described in the                                                                    | for               |
| application are appropriate and effective in limiting the risk,                                                             | agreement at      |
| provided that they are adhered to.                                                                                          | the RAC-67        |
|                                                                                                                             | plenary           |
| The working group supports:                                                                                                 | meeting via       |
| Section 7: additional conditions for the authorisation                                                                      | the A-listing     |
| The applicant shall carry out and document a detailed feasibility                                                           | procedure.        |
| study on:                                                                                                                   |                   |
| (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 (at both                                                                |                   |
| sites);                                                                                                                     |                   |
| (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 (at the Romanian site).                                                                         |                   |
| 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 working group recommends that the draft opinion is suitable                                                             |                   |
| for consideration via the A-listing procedure.                                                                              |                   |
| 5,                                                                                                                          |                   |
|                                                                                                                             | l                 |
|                                                                                                                             |                   |
| 7. 317_CA_Micron (1 use)                                                                                                    |                   |
|                                                                                                                             |                   |
| <b>Use1:</b> Dilution of chromic acid solution at concentrations lower                                                      | SECR to           |
|                                                                                                                             | JEUR LU           |
| than 0 10/ for the use in passivation baths                                                                                 | achodula tha      |
| than 0.1% for the use in passivation baths.                                                                                 | schedule the      |
|                                                                                                                             | draft opinion     |
| than 0.1% for the use in passivation baths.<br>The working group supported the draft opinion as proposed by the Rapporteur. |                   |



| The working group recommends to RAC that the operationalthe RAC-67The working group recommends to RAC that the operationalplenaryconditions and risk management measures described in the reviewmeeting viareport are appropriate and effective in limiting the risk, providedthe A-listingthat they are implemented and adhered to.procedure.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | /      |
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| The working group supports:<br>Section 7: additional conditions for the authorisation<br>None<br>Section 8: monitoring arrangements for the authorisation as given                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |        |
| in Annex V.<br>Section 9: recommendations for the review report as given in<br>Annex V.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |        |
| The working group recommends that the draft opinion is suitable for consideration via the A-listing procedure.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |        |
| 8. 318_CT_Sirio_Galv (1 use)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |        |
| <b>Use1:</b> Industrial use of Chromium Trioxide for the functional <b>Rapporter</b> together with decorative character for different applications. <b>SECR</b> to economic of the second | ith    |
| The working group discussed: the draft                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |        |
| <ul> <li>calculations of workers exposure,</li> <li>representativeness of static measurements for specific according t</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 0      |
| tasks, the<br>- if the combined exposure can be validated by static discussion                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |        |
| <ul> <li>measurements,</li> <li>wording of the authorisation condition concerning LEV group.</li> <li>control.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 9      |
| The working group supported the draft opinion as proposed by the<br>Rapporteurs.SECR to<br>schedule th<br>draft opinion<br>for                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |        |
| The working group recommends to RAC that the operational agreement conditions and risk management measures described in the the RAC-67                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 7      |
| application are appropriate and effective in limiting the risk, plenary provided that they are implemented and adhered to. meeting via the A-listing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | g      |
| provided that they are implemented and adhered to.<br>The working group supports:<br>meeting via<br>the A-listing<br>procedure.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | g      |
| provided that they are implemented and adhered to. meeting via the A-listing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | g      |



in case anomalies are detected by the of LEV flow controller.

- 2. The applicant shall carry out and document a detailed feasibility study on:
  - (a) the replacement of solid CrO<sub>3</sub> flakes by a liquid solution of CrO<sub>3</sub>, 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

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 working group recommends that the draft opinion is suitable for consideration via the A-listing procedure.

## 9. 319\_CT\_SK-Nexilis (1 use)

**Use1:** Chromium trioxide use: Manufacture of passivated copper foil used in Lithium-ion batteries (LiB).

The working group discussed:

 additional conditions for the authorisation in consideration of the future use and whether to replace feasibility study by hard conditions.

The working group considered that the operational conditions and risk management measures described in the application are expected to be not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. the working group and provide proper justification of the changes.

The working group supports: Section 7: additional conditions for the authorisation SECR to edit

according to

discussion of

the draft

opinion

SECR to

schedule the

the



consistency

between

draft

opinions

concerning

the

the

The applicant shall: draft opinion implement a closed/automated system to perform the for discussion dilution of solid CrO<sub>3</sub> (e.g. a glove box to transfer flakes to and a mixing tank). agreement at implement of a closed/automated system to perform makethe RAC-67 up tank sampling tasks; plenary install of a system that triggers automatically appropriate meeting. and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) passivation bath(s), in case the local exhaust ventilation is not functioning properly). Section 8: monitoring arrangements for the authorisation as given in Annex V with following adjustments: 1. The applicant shall implement the following monitoring programmes: a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: • (i) be conducted within 3 months after the plant starts to be operational, and at least annually afterwards, for the workers exposed to Cr(VI). The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI) [....] b) Environmental releases: • (i) the applicant shall conduct monitoring programme for Cr(VI) emission to air and wastewater within 3 months after the plant starts to be operational, and at least annually afterwards *[....]* Section 9: recommendations for the review report as given in Annex V. The working group recommends discussing at the RAC plenary following points of the draft opinion: - overall conclusions on operational conditions and risk management measures as not appropriate and effective, - Section 7: additional conditions for the authorisation. 10. 320\_CT\_Fratelli-Creola (1 use) **Use 1:** Use of chromium trioxide for electroplating of metal Rapporteurs substrates with the purpose to creating a long-lasting high together with durability surface with bright (shiny) or matte look for sanitary and SECR to edit industrial applications. the draft opinion The working group discussed: according to



| EUROPEAN CHEMICALS AGENCY                                           |               |
|---------------------------------------------------------------------|---------------|
| calculation of workers exposure based on modelled data              | discussion of |
| and static measurements,                                            | the working   |
| - effectiveness of implementation of an additional LEV              | group.        |
| system.                                                             |               |
|                                                                     | SECR to       |
| The working group supported the draft opinion as proposed by the    | schedule the  |
| Rapporteurs.                                                        | draft opinion |
|                                                                     | for           |
| The working group recommends to RAC that the operational            | agreement at  |
| conditions and risk management measures described in the            | the RAC-67    |
| application are appropriate and effective in limiting the risk,     | plenary       |
| provided that they are implemented and adhered to.                  | meeting via   |
|                                                                     | the A-listing |
| The working group supports:                                         | procedure.    |
| Section 7: additional conditions for the authorisation              |               |
| 1. The applicant shall carry out and document a detailed            |               |
| feasibility study on:                                               |               |
| (a) the replacement of solid $CrO_3$ flakes by a liquid solution of |               |
| $CrO_3$ , or the implementation of a closed/automated               |               |
| system to perform the dilution of solid $CrO_3$ (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 additional LEV system nearby           |               |
| the chromium tank, as planned by the applicant, which               |               |
| consists of a movable arm capturing system, to minimize             |               |
| the spreading of Cr(VI),                                            |               |
| (c) the implementation of a closed/automated system to              |               |
| perform bath sampling tasks, where exposure to Cr(VI) is            |               |
| foreseen and which currently rely on the use of PPE.                |               |
| The feasibility study shall be concluded within 12 months of the    |               |
| granting of an authorisation for this use. 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 working group recommends that the draft opinion is suitable     |               |
| for consideration via the A-listing procedure.                      |               |
|                                                                     |               |
|                                                                     |               |
|                                                                     |               |
| 11. 321_CT_LMC (1 use)                                              |               |



| CROPEAN CHEMICALS AGENCY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| <b>Use1:</b> Industrial use of chromium trioxide for the functional chrome plating of food slicer's circular blades.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Rapporteur<br>together with                                                              |
| The working group discussed:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | SECR to edit the draft                                                                   |
| <ul> <li>high exposure data for workers (due to the conservative approach by the applicant),</li> <li>request to the applicant to cover baths, their answer and how it should be reflected in the draft opinion.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | opinion<br>according to<br>the<br>discussion of<br>the working                           |
| The working group supported the draft opinion as proposed by the Rapporteur.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | group.                                                                                   |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | SECR to<br>schedule the<br>draft opinion<br>for<br>agreement at<br>the RAC-67<br>plenary |
| <ul> <li>Section 7: additional conditions for the authorisation</li> <li>The applicant shall carry out and document a detailed feasibility study on: <ol> <li>the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently relies on the use of PPE.</li> <li>the physical segregation of the plating area (as per the applicant's commitment).</li> </ol> </li> <li>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.</li> <li>Section 8: monitoring arrangements for the authorisation as given in Annex V.</li> </ul> | meeting via<br>the A-listing<br>procedure.                                               |
| The working group recommends that the draft opinion is suitable for consideration via the A-listing procedure.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                          |
| 12. 322_CT_ArcelorMittal_plating (1 use)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                          |
| <b>Use1:</b> Industrial use of chromium trioxide for functional chrome plating of work rolls for use in the production of flat metal products.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | SECR to<br>schedule the<br>draft opinion<br>for                                          |

The working group supported the draft opinion as proposed by the agreement at



| EUROPEAN CHEMICALS AGENCY                                            |               |
|----------------------------------------------------------------------|---------------|
| Rapporteur.                                                          | the RAC-67    |
|                                                                      | plenary       |
| The working group recommends to RAC that the operational             | meeting via   |
| conditions and risk management measures described in the             | the A-listing |
| application are appropriate and effective in limiting the risk,      | procedure.    |
| provided that they are 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 a detailed             |               |
| feasibility study on 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.                                                      |               |
| 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 working group recommends that the draft opinion is suitable      |               |
| for consideration via the A-listing procedure.                       |               |
|                                                                      |               |
|                                                                      |               |
| 13.323_CT_HDO-Druckguss (1 use)                                      |               |
| lical: Electronisting (by a long term contractual cumplical) of      | Bannortouro   |
| <b>Use1:</b> Electroplating (by a long-term contractual supplier) of | Rapporteurs   |
| metal substrates using chromium trioxide to achieve functional       | together with |
| surfaces with decorative character.                                  | SECR to edit  |
|                                                                      | the draft     |
| The working group discussed:                                         | opinion       |
| - cleaning procedure of sludge removal from baths and                | according to  |
| related workers exposure,                                            | the           |
| - acceptable LOQ values,                                             | discussion of |
| - limited (not sufficient) number of measurements of                 | the working   |
| emissions to the air (one year only) and workers exposure            | group.        |
| and how it should be reflected in the draft opinion.                 | group.        |
|                                                                      |               |
|                                                                      | SECR to       |
| The working group supported the draft opinion as proposed by the     | schedule the  |



Rapporteurs. draft opinion for The working group recommends to RAC that the operational agreement at conditions and risk management measures described in the the RAC-67 application are appropriate and effective in limiting the risk, plenary provided that they are implemented and adhere to. meeting via the A-listing procedure. The working group supports: Section 7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: (a) the replacement of solid  $CrO_3$  flakes by a liquid solution of CrO<sub>3</sub>, or the implementation of a closed/automated system to perform the dilution of solid CrO<sub>3</sub> (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 system to perform the bath concentration adjustment, and 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 (at both sites). 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 working group conditionally recommends that the draft opinion is suitable for consideration via the A-listing procedure. Rapporteurs are requested to check if the workers are going inside the baths during the cleaning procedure and if necessary to add relevant feasibility study. 14. 324\_CT\_Tecnofiniture (1 use) **Use1:** Industrial use of chromium trioxide for the hard-chrome **Rapporteurs** plating of a wide variety of items with large dimensions and together with complex geometries used in energy generation and supply, off-SECR to edit shore oil and gas extraction and manufacturing industries. the draft opinion The working group discussed: according to effectiveness of the LEV system placed above the plating the



- bath,
- the condition for the authorisation of covering of the bath,
- the request to perform feasibility study on implementation of a closed/automated system to perform the bath adjustment.

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 working group supports:

Section 7: additional conditions for the authorisation

- 1. The applicant shall implement, without undue delay, technical improvements to the OCs and RMMs at the manual plating lines and the plating bath (e.g., improvement of the LEV functioning, covering the bath during the plating process, etc.) to minimize the Cr(VI) concentration nearby the plating bath and the area where plated items are prepared. These shall be implemented within 12 months of the granting of an authorisation for this use and be followed by a measurement campaign to validate the effectiveness of the applied technical improvements.
- 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 adjustment,
  - (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 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 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 all across the sites 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 working group recommends that the draft opinion is suitable

discussion of the working group.

SECR to schedule the draft opinion for agreement at the RAC-67 plenary meeting via the A-listing procedure.



| a the A-listing procedure. |  |
|----------------------------|--|
|                            |  |



10 October 2023 RAC WG/A/17/2023 Final

## Agenda

## Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group (RAC AFA WG) reporting to RAC-67

10 - 11 October 2023

WebEx meeting

## **Tuesday 10 October starts at 10.00** Wednesday 11 October ends at 17.40

## Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

## RAC WG/A/17/2023 For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Authorisation applications

- 1. 311\_SD\_Liebherr-Aerospace
- 2. 312\_CT\_Metalplast
- 3. 313\_CT\_BWI-Poland
- 4. 314\_CT\_Benoni
- 5. 315\_CT\_Egal
- 6. 316\_CT\_ASO-Cromsteel
- 7. 317\_CA\_Micron
- 8. 318\_CT\_Sirio\_Galv
- 9. 319\_CT\_SK-Nexilis
- 10. 320\_CT\_Fratelli-Creola
- 11. 321\_CT\_LMC
- 12. 322\_CT\_ArcelorMittal\_plating
- 13. 323\_CT\_HDO-Druckguss



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 17<sup>th</sup> Meeting of the RAC AFA working group

| RAC Members                                   |
|-----------------------------------------------|
| Angeli Karine                                 |
| Barański Boguslaw                             |
| Brovkina Julija                               |
| Chiurtu Elena (co-opted)                      |
| Deviller Geneviève (co-opted)                 |
| Docea Anca                                    |
| Geoffroy Laure                                |
| Kadikis Normunds                              |
| Karadjova Irina                               |
| Leinonen Riitta                               |
| Menard Srpčič Anja                            |
| Moldov Raili                                  |
| Murray Brendan                                |
| Schlüter Urs                                  |
| Tekpli Nina Landvik                           |
| Užomeckas Žilvinas                            |
| Van der Haar Rudolf (co-opted)                |
| Viegas Susana                                 |
|                                               |
| Members' advisers                             |
| Beetstra Renske (adv. to Gerlienke<br>Schuur) |
| Dumko Carolin (adv. to Urs Schlütor)          |

Dumke Carolin (adv. to Urs Schlüter)

Granato Giuseppe (adv. to Dania Esposito)

Jankowska Agnieszka (adv. to Beata Peczkowska)

Moilanen Marianne (adv. to Riitta Leinonen)

Panieri Emiliano (adv. to Dania Esposito)

Seba Julie (adviser to Wendy Rodriguez)

#### **RAC Regular Stakeholders**

Janosi Amaya

| European Commission  |
|----------------------|
| Fabbri Marco         |
| Jezso Veronika       |
| Kusendila Christophe |
| Roebben Gert         |

## <u>ECHA</u>

Atanasova Marina Etholen Anita Hammer Jort

Henrichson Sanna

Lehto Hürlimann Mikko

Lisboa Patricia

Loukou Christina

Ludborzs Arnis

Nicot Thierry

Niemelä Helena

Mäkelä Petteri

Peltola Jukka

Pillet Monique

Portugal Laura

Regil Pablo

Richarz Andrea

Roberts Julian

Salo Marta

Scazzola Roberto

Schakir Yasmin

Sosnowski Piotr

Tarvainen Emma

Väänänen Virpi





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



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

#### Section 9: recommendation for the review report.

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