RAC/M/66/2023

14 September 2023

Minutes of the 66th Meeting

of the Committee for Risk Assessment

(RAC-66)

Monday, 11 September at 14.00
Thursday, 14 September ends at 17.30

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

The Chair of RAC, Roberto Scazzola opened the meeting and provided some opening remarks considering his recent appointment as Chair of the Committee, including outlining the main priorities for his mandate.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/66/2023**) was adopted without amendment.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-66 minutes.
4. Appointment of (co-)rapporteurs	
4.1. Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for harmonised classification and labelling (CLH) dossiers, applications for authorisation, occupational exposure limit (OEL) requests and Article 77(3)(c) requests as listed in the restricted document in the Interact collaboration tool. The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted dossiers for the above-mentioned processes.	
5. Report from other ECHA bodies and activities	
5.1. RAC work plan for all processes The Chair presented the RAC work plan until end of 2023.	
5.2. Annual update of RAC accredited stakeholders´ list	
The Committee decided on the updated stakeholder list.	**SECR** to editorially finalise and publish the list on ECHA´s webpage.
6. Request under Article 77(3)(c)	
The Secretariat briefly presented the two Article 7(3)(c) requests received recently – on the harmonised classification and labelling of Methyl methacrylate and Lithium.	

The Members were encouraged to volunteer as Rapporteurs for these dossiers.	

7. Health based exposure limits at the workplace

7.1.1. Nitrosamines (N-nitrosodiethylamine (diethylnitrosamine) (EC 200-226-1; CAS RN 55- 18-5) - N-nitrosodimethylamine (dimethylnitrosamine) (EC 200-549-8; CAS RN 62-75-9) - N-nitroso di-n-propylamine (EC 210-698-0 ; CAS RN 621-64-7) - N-nitrosodiethanoamine (2,2'-(nitrosoimino)bisethanol) (EC 214-237-4; CAS RN 1116-54-7))

The Chair welcomed the representatives from the Government and Workers Interest Groups Working Party on Chemicals and of DG Employment. He informed that the Commission had requested ECHA to evaluate **nitrosamines,** in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 18 April 2023 until 16 June 2023 and the deadline for this request is 22 February 2024.

The Rapporteurs presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for nitrosamines. RAC agreed to use a non-threshold-approach for the derivation of OELs for nitrosamines. RAC agreed to base the exposure-risk relationship (ERR) on animal data and not on human data (with a more detailed rationale to be added in the draft opinion on the justification for that choice). For NDMA, RAC agreed to use the Klein et al. (1991) inhalation study, as considered it more relevant. The Peto et al. (1991) oral study might underestimate the respiratory tract tumours. RAC agreed to rely on a carcinogenic dose-response derivation based on a key study (rather than on CPDB-derived TD_{50} harmonic means). RAC in general agreed to derive an 8 hr TWA value for non-cancer liver effects only. RAC in general agreed to conclude on one cancer ERR for exposure to a combination of nitrosamines based on the most potent one and to define the additive effects. RAC in general agreed to derive a second ERR for exposure to only NDELA; mechanistic information – if different - should be considered. RAC agreed not to propose a STEL. RAC agreed that BGV or BLV are not proposed. RAC agreed to propose a Skin notation.	**Rapporteurs** to revise the opinion in accordance with the agreed modifications at RAC-66 and to provide it to SECR. **SECR** to organise a RAC consultation on the revised draft RAC opinion. **SECR** to table the opinion for the final discussion and adoption at RAC-67.

7.1.2. 2-chloro-1,3-butadiene (chloroprene) (EC 204-818-0; CAS 126-99-8) The Chair welcomed the representatives from the Government and Workers Interest Groups of the Working Party on Chemicals and of DG Employment. He informed that the Commission had requested ECHA to evaluate **2-chloro-1,3-butadiene (chloroprene),** in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 26 January 2023 until 28 March 2023 and the deadline for this request is 22 February 2024.	
The Rapporteurs presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for chloroprene. RAC agreed that no threshold can be currently identified for carcinogenicity of chloroprene and therefore an exposure-risk relationship (ERR) is to be derived. RAC agreed to consider the oral cavity tumours in Fischer rat in the NTP study as the basis for the ERR. RAC agreed to use the AGS (2019) derived BMD10 of 34.5 ppm without survival adjustment as PoD for the ERR (which is similar to T10) and to add more justifying details to the opinion. RAC agreed on the ERR, as presented in the draft opinion. RAC agreed on a 8hr TWA of 0.16 ppm for non-cancer effects based on the necrosis of olfactory epithelium observed in the 2-year NTP study in rats. RAC agreed that a 15-min STEL is needed to protect from respiratory irritation effects. RAC agreed that a BLV and BGV are not proposed. RAC agreed that the three air monitoring methods currently mentioned in the draft opinion can be described and their limitations mentioned, but no specific method should be recommended. RAC agreed to propose a Skin notation. RAC adopted by consensus its opinion (with the modifications agreed at RAC-66).	**Rapporteurs** to revise the opinion in accordance with the agreed modifications at RAC-66 and to provide it to SECR. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.
8. Harmonised classification and labelling (CLH)	
8.1. General CHL issues	
8.1.1. Report from the July CLH Working Group	
The Secretariat presented the Report of the 10th Meeting of the Committee for Risk Assessment	

Applications for Classification and Labelling Working Group which took place on 3-5 July 2023. RAC took note of the Report.	

8.1.2. New hazard classes under CLH

The Secretariat presented and RAC took note of the ECHA work in relation to the new hazard classes under CLH and the RAC role. The RAC Members were encouraged to provide comments on the new guidance documents currently open for the RAC consultation.	

8.2. CLH dossiers

8.2.1. Hazard classes for agreement without plenary debate (A-list)

- **Clopyralid (ISO):** *skin corrosion/irritation, STOT RE, reproductive toxicity (fertility) aquatic toxicity*
- **2-bromo-3,3,3-trifluoroprop-1-ene:** *STOT SE, reproductive toxicity*
- **2,3-epoxypropyl o-tolyl ether:** *skin sensitisation*
- **2-methyl-2*H*-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2 thiazol-3-one hydrochloride:** *physical hazards, acute toxicity, ski corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, ski sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity aquatic toxicity, hazard to the ozone layer*
- **Methyl oct-2-ynoate:** *skin sensitisation*
- **Dinotefuran (ISO):** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, aquatic toxicity*
- **Proquinazid (ISO):** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, aquatic toxicity, hazard to the ozone layer*
- **3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate:** *acute inhalation toxicity, aquatic toxicity*
- **Captan (ISO):** *acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, mutagenicity, aquatic hazards*

8.2.2. Hazard classes for agreement with plenary debate

8.2.2.1. Clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid (EC: 216-935-4;CAS: 1702-17-6): reproductive toxicity (development)

The Chair welcomed the Dossier Submitter representative, an expert accompanying CropLife regular stakeholder organisation representative and PETA Science Consortium International occasional stakeholder, and provided some general information on the uses of **clopyralid**

(ISO), existing harmonized classification, proposed classification by the Dossier submitter (FI) and legal deadline. Reproductive toxicity, STOT RE, skin corrosion/irritation and aquatic hazards were the hazard classes open for comments during the Consultation. The expert accompanying the CropLife regular stakeholder observer commented on developmental toxicity.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Eye Dam. 1; H318, Aquatic Chronic 1; H410 (M=10), EUH066]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.2. Proquinazid (ISO); 6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one (EC: - ; CAS: 189278-12-4): STOT RE for liver and thyroid effects	
The Chair welcomed the Dossier Submitter representative and an expert accompanying regular stakeholder organisation representative, and provided some general information on the uses of **proquinazid**, existing harmonized classification, proposed classification by the Dossier submitter (SE) and legal deadline. All relevant hazard classes were open for comments during the Consultation, except for respiratory sensitisation. The CropLife regular stakeholder observer and the expert accompanying the CropLife regular stakeholder observer commented on STOT RE.	
Following an extensive discussion, RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Carc. 2; H351, STOT RE 1; H372 (thyroid), STOT RE 2; H373 (liver), Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=10)]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC (with a focus on the justification supporting the proposed classification as STOT RE) and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs and to organise a RAC consultation on the draft final opinion. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

8.2.2.3. Captan (ISO); 1,2,3,6-tetrahydro-N-(trichloromethylthio)phthalimide (EC: 205-087-0; CAS: 133-06-2): reproductive toxicity, STOT RE, carcinogenicity	
The Chair welcomed the Dossier Submitter representatives and an expert accompanying the CropLife regular stakeholder organisation representative, and provided some general information on the uses of **captan (ISO), 1,2,3,6-tetrahydro-N-(trichloromethylthio)phthalimide**, existing harmonized classification, proposed classification by the Dossier Submitter (AT) and legal deadline. Acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and hazardous to the aquatic environment were open for comments during the Consultation. The expert accompanying the CropLife regular stakeholder observer commented on reproductive toxicity.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Acute Tox. 2; H330 (ATE=0.22 mg/L (dusts/mists)), Eye Dam. 1; H318, Skin Sens. 1A; H317 (SCL=0.001%), Carc. 2; H351, STOT RE 1; H372 (respiratory tract), Repr. 2; H361f, Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=1)]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
9. Restrictions	
9.1. General restriction issues	
9.1.1. Report from the August Restriction Working Group	
RAC took note of the Report of the 9th meeting of the Committee for Risk Assessment Working Group on restrictions held on 23-24 August 2023 (meeting document RAC/66/2023/03). NOTE: the RAC-67 Working Group on restrictions in November is cancelled.	**SECR** to table the relevant restriction dossiers for discussion and adoption at RAC-67 plenary in November/December 2023.
9.2. Restriction Annex XV dossiers	
9.2.1. Opinion Development	
9.2.1.1. Universal per- and polyfluoroalkyl substances (U-PFAS) – First draft opinion with focus on hazard and food contact materials and packaging (FCM) and hazards	

The Chair welcomed the Dossier Submitter representatives from Denmark, Germany, the Netherlands, Norway and Sweden, as well as the occasional stakeholder observers together with their accompanying experts from CHEM Trust, EuChemS, EuPC, EurEau, FEC, HEAL and Plastics Recyclers Europe, and the accompanying experts to the regular stakeholder observers from Cefic, CropLife Europe, EEB, Eurometaux and PlasticsEurope. The dossier was submitted in January 2023 and proposes to restrict the manufacture, placing on the market and use of PFAS, i.e. universal PFAS (UPFAS). All uses of PFASs are covered by this restriction proposal except for the use of PFASs in fire-fighting foams, which is assessed in a separate restriction proposal.

The observers from Plastics Recyclers Europe, EuCHEMS, and CropLife commented on the substance scope. The observers from EEB, EuChemS, EurEau and Plastics Recyclers Europe and the Plastics Europe expert commented on hazards. The observers from Plastics Recyclers Europe, PlasticsEurope, EurEau and CropLife commented on release estimates.

The Dossier Submitter representatives provided clarifications with regard to the scope and hazards.

RAC had further preliminary discussions on the substance scope, hazard assessment as well as the restriction proposal with respect to FCM and packaging. RAC supported and overall agreed with the recommendations from the Restriction Working Group which met on 23-24 August regarding the scope, hazards, and the sector-by-sector approach. Pending the outcome of the third-party consultation, RAC will continue its assessment on the case and consider if the preliminary agreements reached at this meeting need to be revised.	**Rapporteurs** to take into account the plenary and WG discussions and the outcome of the third-party consultation in a revised draft opinion to be tabled for discussion at a future working group and plenary. **Interested stakeholder observers** to submit additional information via the ongoing third-party consultation by 25 September 2023, and to follow the agendas on the ECHA website for the upcoming RAC working group and plenary meetings. **Secretariat** to table further discussions as follows: → At RAC-67: • Overview of consultation input • Work plan for 2024 → RAC-68 (and REST RAC-68 WG): • Discussion of next draft opinion • Focus on Substance scope, Hazard, Consumer mixtures, Cosmetics, Ski wax

9.2.1.2. Creosote, and creosote related substances– adoption of the opinion

The Chair welcomed the Dossier Submitter's representatives from France and the regular stakeholders, including the accompanying expert to the regular CEFIC stakeholder.

The participants were informed that the restriction dossier had been submitted in October 2022 and concerns the placing on the market, re-use and secondary use of wood treated with creosote or related substances.

The CEFIC expert provided clarifications on substances included in the substance identity.	
RAC agreed with the recommendations from the Restriction Working Group which met on 23-24 August, regarding risk of alternatives, other regulatory risk management options, effectiveness, practicality, incl. enforceability, monitorability, the most appropriate EU-wide measure and uncertainties. Furthermore, RAC discussed and concluded that the restriction option 3 as introduced by SEAC, is the most appropriate restriction measure in reducing the risk. <u>RAC adopted by consensus</u> <u>the opinion</u> (with minor modifications as agreed at RAC-66 on reference to import, length of the transition period, wording of the restriction).	**The rapporteurs,** together with **SECR,** to do the final editing of the adopted RAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to the Commission.
10. Authorisation	
10.1. General authorisation issues	
10.1.1. Report from the July AFA Working Group	
The Secretariat presented the Report of the 16th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group which took place on 6-7 July 2023. RAC took note of the Report.	
10.1.2. Update on incoming/future applications and horizontal issues	
The Secretariat presented an update on AfA process: 1. AfAs and Review Reports pipeline 2. RAC Lines-To-Take (Chromates) It is proposed to be put on hold until the end of 2024. 3. 10 steps to streamline RAC AfA opinion-making process RAC discussed the quality of the applications, and the possibility to decline an application via the conformity check after the questions and answers round and putting on hold the LTT document versus regular updates. <u>RAC supported</u> the proposal by the Secretariat.	**Rapporteurs** to apply 10 steps to streamline RAC AfA opinion-making process.

4. The European Commission (DG GROW) reported on the recent Court case on AFA submitted by CTAC RAC took note of the information by the Commission.	
10.1.3. Renewal of the RAC AFA WG mandate	
The ECHA Secretariat presented the Mandate for RAC Working Group on AfA and requested RAC to extend the mandate until March 2024. RAC agreed the Mandate for RAC Working Group on AfA by consensus.	**SECR** to publish the Mandate on the ECHA website.
10.2. Discussion on key issues	
10.2.1. 14 applications for authorisation from February 2023 submission window	
RAC rapporteurs presented Key issues in 14 applications for authorisation from February 2023 submission window.	**RAC members** to provide comments during still open RAC consultations on draft opinions.
10.3. Agreement on draft opinions	
10.3.1. Draft opinions for agreement with or without plenary debate (A-list)	
ECHA Secretariat presented the summary of the draft opinions for agreement without plenary debate (A-list): 1. 297_CT_Acciaierie_Italia (1 use) 2. 298_CT_Bjerringbro_Fornikling (1 use) 3. 299_OPE_MeiraTGX (1 use) 4. 300_CT_Weber-Hydraylic (1 use) 5. 303_CT_Rubinetterie_Stella (1 use) 6. 304_SD_Acciaierie (1 use) 7. 305_CT_Meoni_e_Bartoletti (1 use) 8. 306_CT_Galvanica_Pasotti – confirmed by ATM (1 use) 9. 307_CT_Vinzia – confirmed by ATM (1 use) 10. 309_CT_Cromatura-Staff (1 use) 11. 310_CT_Cromotecnica_Fida (1 use) <u>RAC agreed by consensus the 11 draft opinions</u> on the Application listed in Annex IV.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicants for commenting.
10.3.2. Draft opinions for discussion and agreement with plenary debate	
301_CT_SD_Liberty_Liege (1 use)	
Use1: *Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP).*	**Rapporteur** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary.

Regarding the exposure to Cr(VI) associated with use of chromium trioxide and sodium dichromate, RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. Regarding the reproductive hazards associated with the use of Sodium dichromate, RAC concluded that the risk assessment presented in the application demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the application are adhered to. RAC agreed: Section 7: additional conditions for the authorisation 1. 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. 2. The applicant shall ensure that for any task conducted in the cellar (including bath sampling) appropriate RPE is worn, as long as the exposure measured in the cellar are higher than the value used for the exposure assessment of the sampling task (T2. 3. The applicant shall carry out and document a detailed feasibility study on: the implementation of an automated system to perform passivation tank sampling tasks, where exposure to Cr(VI) is foreseen. 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 IV Table 2. Non-standard point 7 Section 9: recommendations for the review report as given in Annex IV Table 2. <u>RAC agreed the draft opinions by consensus</u> with the request to the Rapporteur to complement the additional conditions for the	**SECR** to send the draft opinions to the applicant for commenting.

authorisation by linking the requirement to use RPE to results of monitoring data.	
302_CT_Thoma_Metallveredelung (1 use)	
Use1: *Functional chrome plating for hydraulic applications, other cylindrical components and further industrial applications.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall ensure that RPE is used in accordance with standard procedures for use and maintenance. Those procedures shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards, shall ensure training and medical fitness checking and supervision of the wearer and maintenance of the RPE. 2. The applicant shall ensure that appropriate RPE is worn during bath sampling due to the increased potential for exposure to CrO3. The use of RPE could stop if the task starts being performed with an automated or closed sampling system. 3. The applicant shall carry out and document a detailed feasibility study on: a) the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen. b) the covering of the automatic plating Line 1900 during the plating process. c) a (partial) physical separation between the loading/unloading working areas and the plating lines (both manual and automatic lines). 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	**Rapporteur** together with **SECR** to do the final editing of the draft opinion according to the discussion at the plenary. **SECR** to send the draft opinion to the applicants for commenting.

feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2 wit exemption of point 1: 1. The applicant shall implement the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes, which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) be based on relevant standard methodologies or protocols; (iii) ensure a sufficiently low limit of quantification; (iv) comprise personal or static inhalation exposure sampling; (v) be representative of: a. the full range and duration of tasks undertaken where exposure to Cr(IV) is possible, including the preparation of the chromium solution with the new formulation system and the loading/unloading of the racks; 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: - as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. <u>RAC agreed the draft opinion by consensus</u>.	
10.4. Adoption of opinions	
10.4.1. 283_CT_KYB (1 use)	
Use1: *Functional chrome plating of piston rods for shock absorbers for automotive applications.* RAC concluded that the operational conditions	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.

and risk management measures described in the application are appropriate and effective in limiting the risk at the Pardubice site (KMCZ), provided that they are adhered to. RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk to the workers but not appropriate and effective in limiting the risk to the general population at the Ororbia site (KYBSE). RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall align the RPE used at the **KMCZ** Pardubice site with that used at the **KYBSE** site to ensure the best protection level for the workers and consistency between the two sites. 2. The applicant shall take further action related to the air emissions of the **KYSBE** site: • At the latest within three months of the granting of an authorisation for this use, the applicant shall conduct a measurement campaign on all emission points for emissions of Cr(VI) to. This campaign shall be conducted in accordance to section 8.1, paragraph 1.b)iii. • The applicant shall carefully analyse the results of the measurement campaign and recalculate the release factor for the. o A release factor of a same level of magnitude or lower than the one derived for the KMCZ site shall be achieved; o If the release factor is not of the same order of magnitude or lower than for KMCZ, 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 **KMCZ** is achieved. All of the actions taken shall be reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report The results of the actions 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. RAC adopted the final opinion by consensus.	
11. Drinking Water Directive	
11.1. Report from the June DWD Working Group	
The Secretariat reported on Activities on the DWD since June 2023: → IUCLID training → Draft guidance documents → Commission comments on the draft legal acts → Next DWD WG meeting on 4 October. RAC took note of the Report.	
14. Minutes of RAC-66	
14.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-66	
RAC adopted the final minutes by consensus at the plenary meeting.	**SECR** to upload the table with Summary Record of the Proceedings and Conclusions and Action points from RAC-66 to CIRCA BC.

CLH opinions at RAC-66

1. 2-bromo-3,3,3-trifluoroprop-1-ene

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	2-bromo-3,3,3-trifluoroprop-1-ene	-	1514-82-5	Repr. 1B STOT SE 3 STOT SE 3	H360FD H335 H336	GHS08 GHS07 Dgr	H360FD H335 H336			
RAC opinion	TBD	2-bromo-3,3,3-trifluoroprop-1-ene	-	1514-82-5	Repr. 1B STOT SE 3 STOT SE 3	H360FD H335 H336	GHS08 GHS07 Dgr	H360FD H335 H336			
Resulting Annex VI entry if agreed by COM	TBD	2-bromo-3,3,3-trifluoroprop-1-ene	-	1514-82-5	Repr. 1B STOT SE 3 STOT SE 3	H360FD H335 H336	GHS08 GHS07 Dgr	H360FD H335 H336			

2. 2,3-epoxypropyl o-tolyl ether

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	603-056-00-X	2,3-epoxypropyl o-tolyl ether	218-645-3	2210-79-9	Muta. 2 Skin Irrit. 2 Skin Sens. 1 Aquatic Chronic 2	H341 H315 H317 H411	GHS08 GHS07 GHS09 Wng	H341 H315 H317 H411			Note C
Dossier submitters proposal	603-RST-VW-Y	2,3-epoxypropyl o-tolyl ether	218-645-3	2210-79-9	**Modify** Skin Sens. 1A	**Retain** H317		**Retain** H317			
RAC opinion	603-RST-VW-Y	2,3-epoxypropyl o-tolyl ether	218-645-3	2210-79-9	**Modify** Skin Sens. 1A	**Retain** H317		**Retain** H317			
Resulting Annex VI entry if agreed by COM	603-RST-VW-Y	2,3-epoxypropyl o-tolyl ether	218-645-3	2210-79-9	Muta. 2 Skin Irrit. 2 Skin Sens. 1A Aquatic Chronic 2	H341 H315 H317 H411	GHS08 GHS07 GHS09 Wng	H341 H315 H317 H411			Note C

3. 2-methyl-2*H*-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2- thiazol-3-one hydrochloride

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	2-methyl-2*H*-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride	247-499-3	26172-54-3	Acute Tox. 3 Skin Corr. 1A Eye Dam. 1 Skin Sens. 1A Acute Aquatic 1 Acute Chronic 1	H301 H314 H318 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	H301 H314 H317 H410	EUH071	oral: ATE = 175 mg/kg bw Skin. Sens 1A; H317: C ≥ 0,0015% M=1 M=1	
RAC opinion	TBD	2-methyl-2*H*-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride	247-499-3	26172-54-3	A. Acute Tox. 2 B. Acute Tox. 3 C. Acute Tox. 3 D. Skin Corr. 1 E. Eye Dam. 1 F. Skin Sens. 1A G. Acute Aquatic 1 H. Acute Chronic 1	H330 H311 H301 H314 H318 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	H330 H311 H301 H314 H317 H410	EUH071	inhalation: ATE = 0,15 mg/L dermal: ATE = 320 mg/kg bw oral: ATE = 180 mg/kg bw Skin. Sens 1A; H317: C ≥ 0,0015% M=10 M=1	
Resulting Annex VI entry if agreed by COM	TBD	2-methyl-2*H*-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride	247-499-3	26172-54-3	I. Acute Tox. 2 J. Acute Tox. 3 K. Acute Tox. 3 L. Skin Corr. 1 M. Eye Dam. 1 N. Skin Sens. 1A O. Acute Aquatic 1 Acute Chronic 1	H330 H311 H301 H314 H318 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	H330 H311 H301 H314 H317 H410	EUH071	inhalation: ATE = 0,15 mg/L dermal: ATE = 320 mg/kg bw oral: ATE = 180 mg/kg bw Skin. Sens 1A; H317: C ≥ 0,0015% M=10 M=1	

4. Methyl oct-2-ynoate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	methyl oct-2-ynoate	203-836-6	111-12-6	Skin Sens. 1A	H317	GHS07 Wng	H317			
RAC opinion	TBD	methyl oct-2-ynoate	203-836-6	111-12-6	Skin Sens. 1A	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	methyl oct-2-ynoate	203-836-6	111-12-6	Skin Sens. 1A	H317	GHS07 Wng	H317			

5. dinotefuran (ISO); (*RS*)-1-methyl-2-nitro-3-(tetrahydro-3- furylmethyl)guanidine

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	**Chemical name**	**EC No**	**CAS No**	**Classification**		**Labelling**			**Specific Conc. Limits, M-factors and ATE**	**Notes**
					Hazard Class and Category Code(s)	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement Code(s)**	**Suppl. Hazard statement Code(s)**		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	dinotefuran (ISO); (*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine		165252-70-0	P. Aquatic Acute 1 Aquatic Chronic 1	Q. H400 H410	GHS09 Wng	H410		R. M=10 M= 10	
RAC opinion	TBD	dinotefuran (ISO); (*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine		165252-70-0	S. Acute Tox. 4 T. Aquatic Acute 1 Aquatic Chronic 1	U. H302 V. H400 H410	GHS07 GHS09 Wng	W. H302 H410		X. oral: Y. ATE = 2000 mg/kg bw Z. M=10 M= 10	
Resulting Annex VI entry if agreed by COM	TBD	dinotefuran (ISO); (*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine		165252-70-0	AA. Acute Tox. 4 BB. Aquatic Acute 1 Aquatic Chronic 1	CC. H302 DD. H400 H410	GHS07 GHS09 Wng	EE. H302 H410		FF. oral: GG. ATE = 2000 mg/kg bw HH. M=10 M= 10	

6. 3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butyl-carbamate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	616-212-00-7	3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butyl-carbamate	259-627-5	55406-53-6	Acute Tox. 3 Acute Tox. 4 STOT RE 1 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H302 H372 (larynx) H318 H317 H400 H410	GHS06 GHS08 GHS05 GHS09 Dgr	H331 H302 H372 (larynx) H318 H317 H410		M =10 M = 1	
Dossier submitters proposal	616-212-00-7	3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butyl-carbamate	259-627-5	55406-53-6	**Retain** Aquatic Acute 1 **Modify** Acute Tox. 2 Aquatic Chronic 1	**Retain** H400 H410 **Modify** H330		**Retain** H410 **Modify** H330		**Retain** M = 10 **Add** inhalation: ATE = 0,31 mg/L (dusts or mists) **Modify** M = 10	
RAC opinion	616-212-00-7	3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butyl-carbamate	259-627-5	55406-53-6	**Retain** Aquatic Acute 1 **Modify** Acute Tox. 2 Aquatic Chronic 1	**Retain** H400 H410 **Modify** H330	**Retain** GHS06 GHS08 GHS05 GHS09 Dgr	**Retain** H410 **Modify** H330		**Add** inhalation: ATE = 0,17 mg/L (dusts or mists) **Retain** M = 10 **Modify** M = 10	
Resulting Annex VI entry if agreed by COM	616-212-00-7	3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butyl-carbamate	259-627-5	55406-53-6	Acute Tox. 2 Acute Tox. 4 STOT RE 1 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H330 H302 H372 (larynx) H318 H317 H400 H410	GHS06 GHS08 GHS05 GHS09 Dgr	H330 H302 H372 (larynx) H318 H317 H410		inhalation: ATE = 0.17 mg/L (dusts or mists) M = 10 M = 10	

7. clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-231-00-1	clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid	216-935-4	1702-17-6	Eye Dam. 1	H318	GHS05 Dgr	H318			
Dossier submitters proposal	607-231-00-1	clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid	216-935-4	1702-17-6	**Add** Repr. 2 STOT RE 2 Aquatic Chronic 1	**Add** H361d H373 H410	**Add** GHS08 GHS09	**Add** H361d H373 H410	**Add** EUH066	**Add** M = 10	
RAC opinion	607-231-00-1	clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid	216-935-4	1702-17-6	**Add** Aquatic Chronic 1	**Add** H410	**Add** GHS09	**Add** H410	**Add** EUH066	**Add** M = 10	
Resulting Annex VI entry if agreed by COM	607-231-00-1	clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid	216-935-4	1702-17-6	Eye Dam. 1 Aquatic Chronic 1	H318 H410	GHS05 GHS09 Dgr	H318 H410	EUH066	M = 10	

8. proquinazid (ISO) 6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	606-211-00-1	proquinazid (ISO) 6-iodo-2-propoxy-3-propylquinazolin-4(3*H*)-one		189278-12-4	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M = 1 M = 10	
Dossier submitters proposal	606-211-00-1	proquinazid (ISO); 6-iodo-2-propoxy-3-propylquinazolin-4(3*H*)-one		189278-12-4	**Retain** Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	**Retain** H351 H400 H410	**Retain** GHS08 GHS09 Wng	**Retain** H351 H410		**Retain** M = 1 M = 10	
RAC opinion	606-211-00-1	proquinazid (ISO); 6-iodo-2-propoxy-3-propylquinazolin-4(3*H*)-one		189278-12-4	**Retain** Carc. 2 Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT RE 1	**Retain** H351 H400 H410 **Add** H372 (liver, thyroid)	**Retain** GHS08 GHS09 Dgr	**Retain** H351 H410 **Add** H372 (liver, thyroid)		**Retain** M = 1 M = 10	
Resulting Annex VI entry if agreed by COM	606-211-00-1	proquinazid (ISO); 6-iodo-2-propoxy-3-propylquinazolin-4(3*H*)-one		189278-12-4	Carc. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H372 (liver, thyroid) H400 H410	GHS08 GHS09 Dgr	H351 H372 (liver, thyroid) H410		M = 1 M = 10	

9. captan (ISO); 1,2,3,6-tetrahydro-*N*-(trichloromethylthio)phthalimide

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-044-00-6 or TBD	captan (ISO); 1,2,3,6-tetrahydro-*N*-(trichloromethylthio)phthalimide	205-087-0	133-06-2	Carc. 2 Acute Tox. 3 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1	H351 H331 H318 H317 H400	GHS08 GHS06 GHS05 GHS09 Dgr	H351 H331 H318 H317 H400		M = 10	
Dossier submitters proposal	613-044-00-6 or TBD	captan (ISO); 1,2,3,6-tetrahydro-*N*-(trichloromethylthio)phthalimide	205-087-0	133-06-2	**Retain** Carc. 2 Eye Dam. 1 Aquatic Acute 1 **Add** STOT RE 1 Aquatic Chronic 1 **Modify** Acute Tox. 2 Skin Sens. 1A	**Retain** H351 H318 H317 H400 **Add** H372 H410 **Modify** H330	**Retain** GHS08 GHS06 GHS05 GHS09 Dgr	**Retain** H351 H318 H317 **Add** H372 **Modify** H330 H410		**Retain** M=10 **Add** inhalation: ATE = 0,22 mg/L (dusts and mists) Skin Sens. 1A: C ≥ 0,001% M = 1	
RAC opinion	613-044-00-6 or TBD	captan (ISO); 1,2,3,6-tetrahydro-*N*-(trichloromethylthio)phthalimide	205-087-0	133-06-2	**Retain** Carc. 2 Eye Dam. 1 Aquatic Acute 1 **Add** Repr. 2 STOT RE 1 Aquatic Chronic 1 **Modify** Acute Tox. 2 Skin Sens. 1A	**Retain** H351 H318 H317 H400 **Add** H361f H372 (respiratory tract) H410 **Modify** H330	**Retain** GHS08 GHS06 GHS05 GHS09 Dgr	**Retain** H351 H318 H317 **Add** H361f H372 (respiratory tract) **Modify** H330 H410		**Retain** M=10 **Add** inhalation: ATE = 0,22 mg/L (dusts and mists) Skin Sens. 1A: C ≥ 0,001% M = 1	
Resulting Annex VI entry if agreed by COM	613-044-00-6 or TBD	captan (ISO); 1,2,3,6-tetrahydro-*N*-(trichloromethylthio)phthalimide	205-087-0	133-06-2	Carc. 2 Repr. 2 Acute Tox. 2 STOT RE 1 Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H351 H361f H330 H372 (respiratory tract) H318 H317 H400 H410	GHS08 GHS06 GHS05 GHS09 Dgr	H351 H361f H330 H372 (respiratory tract) H318 H317 H410		inhalation: ATE = 0,22 mg/L (dusts and mists) Skin Sens. 1A: C ≥ 0,001% M = 10 M = 1	

Part III. List of Attendees of the RAC-66 meeting

RAC members	
Aquilina	Gabriele
Angeli	Karine
Baranski	Boguslaw
Biró	Anna
Brovkina	Julija
Chiurtu	Elena-Ruxandra
Christodoulou	Sotirios
Deviller	Genevieve
Docea	Anca Oana
Esposito	Dania
Facchin	Manuel
Fernández	Mariana
Geoffroy	Laure
Hakkert	Betty
Hartwig	Andrea
Kadiķis	Normunds
Karadjova	Irina
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Manusadzianas	Levonas
Martinek	Michal
Menard Srpčič	Anja
Mendas Starcevic	Gordana
Moeller	Ruth
Moldov	Raili
Murray	Brendan
Neumann	Michael
Peczkowska	Beata
Piña	Benjamin
Pribu	Mihaela
Rakkestad	Kirsten Eline
Rodriguez	Wendy
Santonen	Tiina
Schlüter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sørensen	Peter Hammer
Spetseris	Nikolaos
Tekpli	Nina
Tsitsimpikou	Christina
Tobiassen	Lea Stine
Užomeckas	Žilvinas
van der Haar	Rudolf
Varnai	Veda Marija
Viegas	Susana

Members' advisers		
		Nominated by
Beestra	Renske	Hakkert Betty and Schuur Gerlienke
Capolupo	Marco	Esposito Dania
Catone	Tiziana	Aquilina Gabriele
Hoffmann	Frauke	Schulte Agnes
Jankowska	Agnieszka	Peczkowska Beata
Moilanen	Marianne	Leinonen Riitta
Russo	Maria Teresa	Aquilina Gabriele
Saksa	Jana	Moldov Raili
Schwanemann	Torsten	Neumann Michael
Smith	Jenny	Murray Brendan
Stalter	Daniel	Schulte Agnes
Suutari	Tiina	Leinonen Riitta

SEAC Rapporteurs		
Castan	Stephanie	UPFAS - adviser to Fankhauser Simone
Cogen	Simon	UPFAS
Fankhauser	Simone	UPFAS
Janssen	Martien	Creosote

Invited experts		**Role/Substance**
Levy	Patrick	WPC, Government Interest group (OELs)
Saarikoski	Sirkku	WPC, Government Interest group (OELs)

Dossier submitters		**Substance**
August	Christina	(DE) - UPFAS
Averbeck	Frauke	(DE) – UPFAS, BPA+
Baumbusch	Angelika	(NO) - UPFAS
Blodörn	Krister	(SE) - Proquinazid
Borg	Daniel	(SE) - UPFAS
Dannenberg	Carl	(DE) - UPFAS
De Blaeij	Arianne	(NL) - UPFAS
De Kort	Thijs	(NL) – UPFAS
Drissi	Sammy	(FR) - Creosote
Drost	Wiebke	(DE) - UPFAS
Fischer	Alexandra	(AT) - Captan
Hard	Sebastiana	(NL) - UPFAS
Heggelund	Audun	(NO) – UPFAS
Hrdina-Zoedl	Bettina	(AT) - Captan
Ivarsson	Jenny	(SE) – UPFAS
Johansson	Tommy	(SE) – UPFAS
Jomini	Stéphane	(FR) - Creosote
Kuittinen	Marko	(FI) - Clopyralid
Kupprat	Franziska	(DE) – UPFAS
Larsson	Kristin	(SE) – UPFAS
Nielsen Juhl	Peter	(DK) - UPFAS
Pasquier	Elodie	(FR) - Creosote
Sanders	Marion	(NL) - UPFAS
Sehbar	Khalaf	(DK) - UPFAS

Regular stakeholder observers		
Barry	Frank	ETUC
Di Caprio	Elisabetta	Concawe
De Backer	Liisi	Cefic
Duguy	Hélène	ClientEarth
Hermann	Christine	EEB
Lemetayer	Loreleï	MedTech Europe
Robin	Nicolas	PlasticsEurope - UPFAS
Robinson Janssis (alternate)	Jan Julie	AISE AISE
Romano Mozo	Dolores	EEB
Ruelens	Paul	CropLife Europe
Verougstraete	Violaine	Eurometaux

Occasional stakeholders		**Substance**
Cingotti	Natacha (HEAL)	UPFAS
De Kort	Patrick (PRE)	UPFAS, BPA
Engelbrecht	Vera (PSCI)	DWD
Glüge	Juliane (EuChemS)	UPFAS
Loebel	Oliver (EurEau)	DWD
Schneider	Julie (CHEM Trust)	UPFAS
Strehl	Gernot (FEC)	UPFAS
Tillieux	Geoffroy (EuPC)	UPFAS, BPA+

Stakeholder experts		**Substance**
Barber	David (CropLife Europe)	UPFAS
Bock	Ronald (PlasticsEurope)	UPFAS
Consoli	Elisa (Eurometaux)	UPFAS
Dainelli	Dario (FEC)	UPFAS
Hedfors	Cecilia (CHEMTrust)	UPFAS
Kent	Lauren (CropLife Europe)	Proquinazid
Kørner	Mads Boye (Cefic)	Creosote
Malvasi	Marco (Cefic)	UPFAS
Moxon	Mary (CropLife Europe)	Captan
Richmond	Emily (CropLife Europe)	Clopyralid

European Commission		**DG**
Beekman	Martijn	DG GROW
Bertato	Valentina	DG ENV
Blass Rico	Ana Maria	DG GROW
Dunauskiene	Lina	DG GROW
Faraulo	Fabio	DG EMPL (OELs)
Heras-Palomar	Nerea	DG EMPL (OELs)
Roebben	Gert	DG GROW
EU Agency Observers		
Binaglia	Marco	EFSA

ECHA staff	
Barnewitz	Greta
Bin	Essi
Bowmer	Tim
Broere	William
Gmeinder	Michael
Hoffstadt	Laurence
Kapanen	Anu
Karjalainen	Antti
Logtmeijer	Christiaan
Ludborzs	Arnis
Marquez-Camacho	Mercedes
Mushtaq	Fesil
Nicot	Thierry
Nygren	Jonas
Orispää	Katja
O'Rourke	Regina
Perazzolo	Chiara
Pillet	Monique
Portugal	Laura
Ryan	Paul
Sadam	Diana
Salo	Marta
Scazzola	Roberto (Chair)
Schakir	Yasmin
Simoes	Ricardo
Sosnowski	Piotr
Uphill	Simon
Van der Jagt	Katinka
Zarogiannis	Panos
Zeiger	Bastian

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-66 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-66 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-66 meeting

ANNEX IV List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-66 meeting without plenary debate (A-list)

1 September 2023
RAC/A/66/2023

Final Draft Agenda
66th meeting of the Committee for Risk Assessment
(RAC-66)

11-14 September 2023

Face-to-face/Hybrid meeting[1]

Monday, 11 September starts at 14.00
Thursday, 14 September ends at 17.30

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/66/2023
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

4.1 Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits

For agreement
Closed session

Item 5 – Work plan

5.1 RAC Work Plan for all processes

For information

5.2 Annual update of RAC accredited stakeholders´ list

The Secretariat will update you on the requests from stakeholder observers to attend RAC meetings since the last review of the RAC stakeholders. You will be invited to agree on the updated list of the accredited stakeholder organisations to RAC this year.

RAC/66/2023/01
Restricted
For agreement
Closed session

Item 6 – Requests under Article 77(3)(c)

No new requests.

For adoption

Item 7 –Health based exposure limits at the workplace

7.1 Opinions for discussion

1. Nitrosamines (*N*-nitrosodiethylamine (diethylnitrosamine) (EC 200-226-1; CAS RN 55- 18-5) - *N*-nitrosodimethylamine (dimethylnitrosamine) (EC 200-549-8; CAS RN 62-75-9) - *N*-nitroso di-*n*-propylamine (EC 210-698-0 ; CAS RN 621-64-7) - *N*-nitrosodiethanoamine (2,2'-(nitrosoimino)bisethanol) (EC 214-237-4; CAS RN 1116-54-7))

2. 2-chloro-1,3-butadiene (chloroprene) (EC 204-818-0; CAS 126-99-8)

For discussion

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the July CLH Working Group

RAC/66/2023/02
For information

2. New hazard classes under CLH

For information and discussion

8.2 CLH dossiers

1. Hazard classes for agreement without plenary debate (A-list)

- **Clopyralid (ISO):** *skin corrosion/irritation, STOT RE, reproductive toxicity (fertility), aquatic toxicity*
- **2-bromo-3,3,3-trifluoroprop-1-ene:** *STOT SE, reproductive toxicity*
- **2,3-epoxypropyl o-tolyl ether:** *skin sensitisation*

- **2-methyl-2*H*-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2- thiazol-3-one hydrochloride:** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aquatic toxicity, hazard to the ozone layer*
- **Methyl oct-2-ynoate:** *skin sensitisation*
- **Dinotefuran (ISO):** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, aquatic toxicity*
- **Proquinazid (ISO):** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, aquatic toxicity, hazard to the ozone layer*
- **3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate:** *acute inhalation toxicity, aquatic toxicity*
- **Captan (ISO):** *acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, mutagenicity, aquatic hazards*

2. Hazard classes for agreement with plenary debate

1. **Clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid** (EC: 216-935-4; CAS: 1702-17-6): *reproductive toxicity (development)*
2. **Proquinazid (ISO); 6-iodo-2-propoxy-3-propylquinazolin-4(3*H*)-one** (EC: - ; CAS: 189278-12-4): *STOT RE for liver and thyroid effects*
3. **Captan (ISO); 1,2,3,6-tetrahydro-*N*-(trichloromethylthio)phthalimide** (EC: 205-087-0; CAS: 133-06-2): *reproductive toxicity, STOT RE, carcinogenicity*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the August Restriction Working Group

RAC/66/2023/03
For information

9.2 Restriction Annex XV dossiers

1. Opinion development

    1. Universal per- and polyfluoroalkyl substances (U-PFAS) – First draft opinion with focus on hazard and food contact materials and packaging

For discussion

2. Creosote, and creosote related substances – adoption of the opinion

For adoption

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the July AFA Working Group

RAC/66/2023/04
For information

2. Update on incoming/future applications and horizontal issues

For information/discussion

3. Renewal of the RAC AFA WG mandate

RAC/66/2023/05
For discussion and agreement

10.2 Authorisation applications

1. Discussion on key issues

1. 311_SD_Liebherr-Aerospace (1 use)
2. 312_CT_Metalplast (2 uses)
3. 313_CT_BWI-Poland (1 use)
4. 314_CT_Benoni (1 use)
5. 315_CT_Egal (1 use)
6. 316_CT_ASO-Cromsteel (1 use)
7. 317_CA_Micron (1 use)
8. 318_CT_Sirio_Galv (1 use)
9. 319_CT_SK-Nexillis (1 use)
10. 320_CT_Fratelli-Creola (1 use)
11. 321_CT_LMC (1 use)
12. 322_CT_ArcelorMittal_plating (1 use)
13. 323_CT_HDO-Druckguss (1 use)
14. 324_CT_Tecnofiniture (1 use)

For discussion

10.3 Agreement on draft opinions

1. Draft opinions for agreement without plenary debate (A-list)

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

For agreement

2. Draft opinions for agreement with plenary debate

1. 301_CT_SD_Liberty_Liege (1 use)
2. 302_CT_Thoma_Metallveredelung (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 283_CT_KYB (1 use)

Item 11 – Drinking Water Directive

1. Report from the June DWD Working Group

RAC/66/2023/06
For information

Item 12 – AOB

1. Any other business

Item 13 – Minutes of RAC-66

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-66

Annex II

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-66 meeting.

RAC/A/66/2023	RAC-66 final Draft Agenda
RAC/66/2023/01	Review of RAC accredited stakeholders
RAC/66/2023/02	General CHL issues: Report from the July CLH Working Group
RAC/66/2023/03	Restriction issues: Report from the August Restriction Working Group
RAC/66/2023/04	General authorisation issues: Report from the August AFA Working Group
RAC/66/2023/05	General authorisation issues: Renewal of the RAC AFA WG mandate
RAC/66/2023/06	Report from the June DWD Working Group

ANNEX III

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

ANNEX III (RAC-66)

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLÜTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Restrictions		
Universal PFAS **DE**	Michael NEUMANN Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
DE	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
DK	Peter Hammer SØRENSEN Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NL	Betty HAKKERT Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
NO	Kirsten Eline RAKKESTAD Nina TEKPLI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
SE	Bert-Ove LUND Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Creosote, and Creosote related substances **FR**	Karine ANGELI Laure GEOFFROY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Harmonised classification & labelling		
Clopyralid (ISO) **FI**	Tiina SANTONEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Riitta LEINONEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
1) **2,3-epoxypropyl o-tolyl ether** 2) **Methyl oct-2-ynoate** 3) **3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate** **DK**	Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Peter Hammer SØRENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Captan (ISO) **AT**	Annemarie LOSERT	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Manuel FACCHIN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Dinotefuran (ISO) **BE**	Wendy RODRIGUEZ	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Proquinazid (ISO) **SE**	Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	Bert-Ove LUND	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
2-methyl-2*H*-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride **SI**	Anja MENARD SRPČIČ	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
2-bromo-3,3,3-trifluoroprop-1-ene **ES**	Benjamin PIÑA	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Marieta FERNANDEZ	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

Annex IV

Table 1. List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-66 meeting without plenary debate (A-list).

Conclusions / agreements / adoptions
297_CT_Acciaierie_Italia (1 use) **Use1:** *Use of Chromium (VI) Trioxide for Electrolytic Chromium Coating of Steel (ECCS).* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall carry out and document a detailed feasibility study on: - the implementation of a closed/automated system to perform passivation tank sampling tasks. 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 IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2.
298_CT_Bjerringbro_Fornikling (1 use) **Use1:** *Electroplating (by a job plater) of metal substrates using chromium trioxide to achieve functional surfaces.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall implement the RMM wall segregation proposals contained in the applicant update of 16th May 2023, within 12 months after the authorisation has been granted for this use. 2. The applicant shall implement the RMM lids fitting proposals for both electroplating lines contained in the applicant update of 16th May 2023, within 12 months after the authorisation has been granted for this use. RAC notes that lids increase the effectiveness of the LEV when the line is in operation – covering the baths when not in operation has little or no effect. 3. Where RPE is needed to control exposure to chromium trioxide, it shall be used in accordance with standard procedures for use and maintenance. Those procedures shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards, shall ensure training and medical fitness checking and supervision of the wearer and maintenance of the RPE.

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2.
Section 9: recommendations for the review report as given in Annex IV Table 2.

299_OPE_MeiraTGX (1 use)

Use1: *Use of 4-tert-OPnEO as a manufacturing aid in the production of gene therapies.*

RAC concluded that the operational conditions and risk management measures described in the application are expected to be appropriate and effective in limiting the risk, provided that they will be implemented and adhered to.
The use applied for may result in 0.00 kg per year releases of the substance to the environment.

RAC agreed:
Section 7: additional conditions for the authorisation
None
Section 8: monitoring arrangements for the authorisation
None
Section 9: recommendations for the review report
None

300_CT_Weber-Hydraylic (1 use)

Use1: *Chromium-trioxide-based functional chrome plating of solid and hollow piston rods for hydraulic applications.*

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

RAC agreed:
Section 7: additional conditions for the authorisation

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

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

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

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

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2 with an additional point 8:

8. The applicant shall implement an annual biomonitoring programme for the workers potentially exposed to Cr(VI). This programme must consist, as a minimum, of pre and post shift urine samples (beginning of the week --> end of the week), using valid existing standard methodologies such as e.g. HSE, HBM4EU. This annual biomonitoring program must be synchronised with the annual occupational air monitoring campaign specified in 1.a above. The

results of the biomonitoring programme can be reported following the "Format for reporting of occupational exposure data by downstream users", in the respective Excel sheet for biomonitoring, as it can be found on the ECHA homepage.

Section 9: recommendations for the review report as given in Annex IV Table 2.

304_SD_Acciaierie (1 use)

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

Regarding the exposure to Cr(VI) associated with use of sodium dichromate, RAC concluded that the operational conditions and risk management measures described in the application are generally appropriate and effective in limiting the risk to workers and general population, provided that they are adhered to.

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

RAC agreed:

Section 7: additional conditions for the authorisation

1. The applicant shall ensure that appropriate RPE is worn during baths sampling (T2), due to the potential for exposure to Cr(VI).
2. The applicant shall carry out and document a detailed feasibility study on:
   - the implementation of a closed/automated system to perform passivation tank sampling tasks, where exposure to Cr(VI) is foreseen.

   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 IV Table 2.

Section 9: recommendations for the review report as given in Annex IV Table 2.

305_CT_Meoni_e_Bartoletti (1 use)

Use1: *Use of Chromium Trioxide for the hard-chrome plating of hydraulic and pneumatic cylinders for various applications, and inner tubes of motorbike front suspension for the automotive industry.*

RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

RAC agreed:

Section 7: additional conditions for the authorisation

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

2) The applicant shall carry out and document detailed feasibility studies at current (Pistoia) and future (Pianoro) sites on:
   a) the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.
   b) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s)), in case the local exhaust ventilation is not functioning properly.

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

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2 with an additional point 8:

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

Section 9: recommendations for the review report as given in Annex IV Table 2.

306_CT_Galvanica_Pasotti (1 use)

Use 1: *Industrial use of chromium trioxide for functional chrome plating with decorative character of items for the sanitary, hydro-sanitary, taps, household industries, and various other applications (such as handles/locks, pneumatic elements and electrical connection).*

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

RAC agreed:

Section 7: additional conditions for the authorisation

1. The applicant shall carry out and document a detailed feasibility study for BOTH sites 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 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 IV Table 2 with an additional point 8:

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

Section 9: recommendations for the review report as given in Annex IV Table 2.

309_CT_Cromatura-Staff (1 use)

Use1: *Industrial use of chromium trioxide for the plating of brass valves destined for applications involving industrial and technical fluids and brass fittings for oxygen cylinders.*

RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk.

RAC agreed:

Section 7: additional conditions for the authorisation

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

a) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s)), in case the local exhaust ventilation is not functioning properly)
b) the replacement of solid CrO3 flakes by a liquid solution of CrO3, or the implementation of a closed/automated system to perform the dilution of solid CrO3 (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent (re-)filling of the baths with liquid solutions (e.g. fix-piping from the containers or mixing tanks, to the plating baths).
c) the implementation of a closed/automated system to perform baths sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE

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 IV Table 2.

Section 9: recommendations for the review report as given in Annex IV Table 2.

310_CT_Cromotecnica_Fida (1 use)

Use1: *Functional chrome plating of hydraulic cylinders, stems, pistons and rollers using chromium trioxide.*

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

RAC agreed:
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_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 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.

c) the installation of a wall up to the rooftop between the preparation and plating/rinsing areas and a dedicated contact strip that will secure the coverage of the chromium baths during the plating process, as proposed by the applicant.

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 IV Table 2.
Section 9: recommendations for the review report as given in Annex IV Table 2.

303_CT_Rubinetterie_Stella (1 use)

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

RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

RAC agreed:
Section 7: additional conditions for the authorisation

1.The applicant shall implement, as planned:

(a) the use of liquid CrO_3 instead of solid,

(b) a dosing pump for automated addition of the liquid CrO_3 instead of the manual addition of flakes, to adjust the concentration in the bath,

(c) a flow detector in the ventilation system, to ensure the correct functioning of the LEV.

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

(a) the implementation of a closed/automated system to perform the bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of 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 IV Table 2.

Section 9: recommendations for the review report as given in Annex IV Table 2.

307_CT_Vinzia (1 use)

Use1: *Industrial use of chromium trioxide for the functional chrome plating with the decorative character of brass or stainless-steel drain components for the tap industry to provide thickness, corrosion resistance.*

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

RAC agreed:

Section 7: additional conditions for the authorisation

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

a) the replacement of solid CrO3 flakes by a liquid solution of CrO3, or the implementation of a closed/automated system to perform the dilution of solid CrO3 (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent (re-)filling of the baths with liquid solutions using a closed and automatic system
b) the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.
c) the installation of a physical separation between the plating line and loading/unloading areas.
d) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s) in case the local exhaust ventilation is not functioning properly.

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 IV Table 2.

Section 9: recommendations for the review report as given in Annex IV Table 2.

Table 2. Standard text for Section 8: monitoring arrangements for the authorisation and Section 9: recommendation for the review report.

Section 8: monitoring arrangements for the authorisation

1. The applicant shall implement the following monitoring programmes for Cr(VI):
   (a) Occupational inhalation exposure monitoring programmes, which shall:
      (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI).
      (ii) be based on relevant standard methodologies or protocols;
      (iii) ensure a sufficiently low limit of quantification;
      (iv) comprise personal and/or static inhalation exposure sampling;
      (v) be representative of:
         a. the full range and duration of tasks undertaken where exposure to Cr(VI) is possible;
         b. the OCs and RMMs typical for each of these tasks;
         c. the number of workers potentially exposed;
      (vi) include contextual information about the tasks performed during sampling.
   (b) Environmental releases:
      (i) the applicant shall continue conducting their (or "implement a") monitoring programme for Cr(VI) emission to wastewater;
      (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process;
      (iii) the monitoring programmes for wastewater and air emissions shall:
         a. be based on relevant standard methodologies or protocols; and
         b. be representative of the OCs and RMMs used at the applicant's site.
         c. ensure a sufficiently low limit of quantification.
9. 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.
10. 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.
11. 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.
12. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans (i.e. workers and general 0population) has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.
13. 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

14. 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.