RAC/M/67/2023_REV 1.1

22 January 2024

Minutes of the 67th Meeting

of the Committee for Risk Assessment

(RAC-67)

Monday, 27 November at 14.00
Thursday, 30 November end at 16.20

Summary Record of the Proceedings,

Conclusions and action points

Chair's opening address

The Chair of RAC, Roberto Scazzola opened the meeting and provided some opening remarks including on the appointment of RAC deputy Chair Piotr Sosnowski.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/67/2023**) was adopted without amendment.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-67 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, 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 and early 2024.	
5.2. Mandate for recruitment of RAC co-opted members (closed session)	
RAC took note of and discussed the restricted meeting document on co-opted members (RAC/67/2023/01.) RAC agreed on proposals for the required competences and selection procedure for co-opting additional members.	**SECR** to take note of discussions on the call for expression of interest on the appointment of co-opted members. **Members** to advertise the call within the relevant networks to get as many potential candidates as possible.

Furthermore, RAC agreed on the members of the Selection and Appeal panels.	
6. Request under Article 77(3)(c)	
n/a	
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 representative from the WPC Government Interest Group commented on the next steps after the RAC opinion development and the scope of the proposed OEL. The representative form the WPC Workers Interest Group commented on the scope of the proposed OEL.	
The Rapporteurs presented and RAC discussed the revised draft opinion on the scientific evaluation of limit values for nitrosamines. RAC agreed with the BMD-modelling approach (omitting the top dose) for NDMA inhalation study data. RAC agreed to use the ERR derived for NDMA based on inhalation data with BMDL as PoD, for NDMA, NDEA, and NMor. This PoD is considered conservative enough to compensate for the uncertainties introduced by the differences in potency of NDEA, NDMA, and NMor. RAC agreed to derive a separate ERR for NDELA and to apply a factor of 100 for NDELA's ERR to address the uncertainties due to a higher potency of NDMA following inhalation compared to oral exposure. RAC agreed to base the 8hr TWA value for non-cancer liver effects on decreased iron-binding capacity (0.08 µg/m^3). RAC agreed to apply the ERR from NDMA, for exposure to NDMA, NDEA and/or NMor.	**Rapporteurs** to revise the opinion in accordance with the agreed modifications at RAC-67 and to provide it to SECR. **SECR** to organise a written consultation in RAC on the final RAC opinion. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

RAC agreed on the two ERRs (NDMA and NDELA), but the Rapporteurs were asked to clarify better in the RAC final opinion how to apply these. RAC adopted by consensus its opinion (with the modifications agreed at RAC-67). It was agreed that a short consultation will be carried out on the applicability of the proposed ERRs - if relevant comments will be provided, a final RAC written consultation on those modifications will be carried out, ahead of the deadline of February 2024.	

8. Harmonised classification and labelling (CLH)

8.1. General CLH issues

8.1.1. Report from the October CLH Working Group

The Secretariat presented the Report of the 11th Meeting of the Committee for Risk Assessment Applications for Classification and Labelling Working Group which took place on 23-25 October 2023. RAC took note of the Report.	

8.2. CLH dossiers

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

- **Flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulfonyl)urea (EC -; CAS 104040-78-0):** *physical hazards, acute toxicity (oral, dermal, inhalation), skin irritation, eye irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity (fertility, lactation), STOT SE, STOT RE (kidney), aspiration hazard, aquatic hazards, hazard to the ozone layer*
- **Fosthiazate (ISO); *S*-*sec*-butyl *O*-ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate (EC -; CAS 98886-44-3):** *physical hazards, acute toxicity, serios eye damage/eye irritation, STOT RE, reproductive toxicity (fertility, lactation), aquatic hazards*
- **Tetra(sodium/potassium)7-[(*E*)-{2-acetamido-4-[(*E*)-(4-{[4-chloro-6-({2-[(4- fluoro-6-{[4-(vinylsulfonyl)phenyl]amino}-1,3,5-triazine-2-yl)amino]propyl} amino)-1,3,5-triazine-2-yl]amino}-5-sulfonato-1-naphthyl)diazenyl]-5-methoxyphenyl}diazenyl]-1,3,6-naphthalenetrisulfonate; [substance having a complex composition with <80% of the above constituents and other reaction side products]; Reactive Brown 51 (EC 466-490-7; CAS -):** *skin sensitisation, reproductive toxicity*
- **Metyltetraprole (ISO);1-[2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5*H*-tetrazol-5-one (EC - ; CAS 1472649-01-6):** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, reproductive toxicity, STOT SE, STOT RE, aquatic hazards, hazard to the ozone layer*

- **Methacrylic acid, monoester with propane-1,2-diol; [HPMA] (EC 248-666-3; CAS 27813-02-1):** *serious eye damage/eye irritation, skin sensitisation, respiratory sensitisation, STOT SE, Note D*
- **2-hydroxyethyl methacrylate; [HEMA] (EC 212-782-2; CAS 868-77-9):** *respiratory sensitisation, STOT SE*
- **4-phenylbenzophenone (EC 218-345-2; CAS 2128-93-0):** *skin sensitisation, reproductive toxicity, aquatic hazards*
- ***Melaleuca alternifolia*, ext. [1] *Melaleuca alternifolia*, essential oil; tea tree oil [2] (EC 285-377-1 [1]; CAS 85085-48-9 [1] CAS 68647-73-4 [2]):** *physical hazards, aspiration hazard, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT RE, mutagenicity, carcinogenicity, lactation*
- **Penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole (EC 266-275-6; CAS 66246-88-6):** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazard to the ozone layer*

8.2.2. Hazard classes for agreement with plenary debate

8.2.2.1. Flazasulfuron (ISO) (EC -; CAS 104040-78-0)

The Chair welcomed the Dossier Submitter representative and an expert accompanying regular stakeholder, and provided some general information on the uses of **flazasulfuron (ISO)**, existing harmonized classification, proposed classification by the Dossier Submitter (ES) and legal deadline.
Explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides, corrosive to metals, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, aquatic hazards and hazards for the ozone layer were the hazard classes open for comments during the Consultation.

The expert accompanying the CropLife Regular Stakeholder Observer commented on STOT RE and on developmental toxicity.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Repr. 2; H361d, STOT RE 2; H373 (liver, muscle), Aquatic Acute 1; H400 (M=1000), Aquatic Chronic 1; H410 (M=100)]	**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. Fosthiazate (ISO) (EC -; CAS 98886-44-3)	
The Chair welcomed the Dossier Submitter representatives, the EFSA observer and an expert accompanying the regular stakeholder observer, and provided some general information on the uses of **fosthiazate (ISO)**, existing harmonized classification, proposed classification by the Dossier Submitter (DE) and legal deadline. Physical hazards, acute toxicity via all routes, serious eye damage/eye irritation, reproductive toxicity, STOT SE, STOT RE, and aquatic hazards were the hazard classes open for comments during the Consultation. The expert accompanying the CropLife Regular Stakeholder Observer and the CropLife Regular Stakeholder Observer commented on developmental toxicity and STOT RE. The expert accompanying the CropLife Regular Stakeholder Observer commented on STOT SE and STOT RE.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Acute Tox. 3; H301 (ATE=57 mg/kg bw), Acute Tox. 3; H331 (ATE=0,56 mg/L (dusts/mists)), Acute Tox. 3; H311 (ATE=860 mg/kg bw), Eye Irrit. 2; H319, Repr. 1B; H360Df, Lact.; H362, STOT RE 1; H372 (nervous system), STOT RE 2; H373 (adrenals), Aquatic Acute 1; H400 (M=1), 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.
8.2.2. 3. Metyltetraprole (ISO) (EC - ; CAS 1472649-01-6)	
The Chair welcomed the Dossier Submitter representative and an expert accompanying regular stakeholder, and provided some general information on the uses of **metyltetraprole (ISO)**, proposed classification by the Dossier Submitter (FR) and legal deadline. All relevant hazard classes were open for comments during the Consultation. The expert accompanying the CropLife regular stakeholder observer and the CropLife regular stakeholder observer commented on carcinogenicity.	
RAC preliminary agreed on the following classification: [Carc. 2; H351 (pending), Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=1)] Carcinogenicity will be finalised at RAC-68 in March 2024 (pending the submission of the additional data by Industry).	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **SECR** to table the updated opinion for adoption at RAC-68 (carcinogenicity only).

8.2.2.4. Methacrylic acid, monoester with propane-1,2-diol; [HPMA] (EC 248-666-3; CAS 27813-02-1)

The Chair welcomed the Dossier Submitter representative and an expert accompanying regular stakeholder, and provided some general information on the uses of **methacrylic acid (HPMA)**, proposed classification by the Dossier Submitter (FR) and legal deadline.
STOT SE, serious eye damage/eye irritation, respiratory sensitisation and skin sensitisation were the hazard classes open for comments during the Consultation.

The expert accompanying the CropLife regular stakeholder observer commented on derivation of SCLs.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Eye Irrit. 2; H319, Skin Sens. 1; H317, STOT SE 3; H335 with SCL of 10%, Note D]	**Rapporteur** 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.

8.2.2.5. 2-hydroxyethyl methacrylate; [HEMA] (EC 212-782-2; CAS 868-77-9)

The Chair welcomed the Dossier Submitter representative and an expert accompanying regular stakeholder, and provided some general information on the uses of **2-hydroxyethyl methacrylate (HEMA)**, existing classification, proposed classification by the Dossier Submitter (FR) and legal deadline.
STOT SE and respiratory sensitisation were the hazard classes open for comments during the Consultation.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [STOT SE 3; H335 with SCL of 10%]	**Rapporteur** 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.

8.2.2.6. Melaleuca alternifolia, ext. [1] Melaleuca alternifolia, essential oil; tea tree oil [2] (EC 285-377-1 [1]; (CAS 85085-48-9 [1] CAS 68647-73-4 [2]

The Chair welcomed the occasional stakeholder representatives (IFRA and EFEO) with their accompanying experts, an expert accompanying the CropLife regular stakeholder observer and an occasional stakeholder observer from PETA Science Consortium International. He then provided some general information on the uses of **tea tree oil**, proposed classification by the Dossier Submitter (PL) and legal deadline.

All relevant hazard classes, except for respiratory sensitisation and hazard to the ozone layer, were open for comments during the Consultation. The expert accompanying the IFRA occasional stakeholder observer, the expert accompanying the CropLife regular stakeholder observer and the expert accompanying the EFEO occasional stakeholder observer commented on fertility. The expert accompanying the CropLife regular stakeholder observer commented on the aquatic toxicity.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Flam. Liq. 3; H226, Asp. Tox. 1; H304, Acute Tox. 4; H302 (ATE=1050 mg/kg bw), Acute Tox. 4; H332 (ATE=3.60 mg/L (dusts/mists)), Skin Irrit. 2; H315, Skin Sens. 1B; H317, Repr. 1B; H360Fd, STOT SE 3; H336, Aquatic Acute 1; H400 (M=1), Aquatic Chronic 2; H411]	**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.
8.2.2.7. Penconazole (ISO) (EC 266-275-6; CAS 66246-88-6)	
The Chair welcomed the Dossier Submitter representative, and provided some general information on the uses of **penconazole (ISO)**, existing harmonized classification, proposed classification by the Dossier Submitter (No) and legal deadline. All relevant hazard classes, except for respiratory sensitisation and aspiration hazard, were open for comments during the Consultation.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Acute Tox. 4; H302 (ATE=970 mg/kg bw), STOT RE 2; H373 (liver), Repr. 2; H361d, Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=10)]	**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. Restriction dossiers in preparation	
The Secretariat presented and RAC took note of the presentation of the restriction dossiers	**SECR** to launch the calls for expression of interest for rapporteurs in 2024. **RAC members** to come forward as volunteers to the pools of (co-) rapporteurs for upcoming restriction proposals.

in preparation which will be submitted in 2024.	

9.2. Restriction Annex XV dossiers

9.2.1. Opinion Development

9.2.1.1. Universal per- and polyfluoroalkyl substances (UPFAS) – Overview of third-party consultation outcome and the work plan for 2024

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 AISBL, Animal Health Europe, CEWEP, COCIR, CONCAWE, EuChemS, EPEE, EURATEX EuPC, EurEau, ETRMA FIPRA, FEC, HEAL, TEPPFA, Plastics Recyclers Europe and SEMI Europe, and the accompanying experts to the regular stakeholder observers from Cefic, CropLife Europe, Eurometaux, MedTech 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 Animal Health Europe, CEFIC, CONCAWE, CropLife Europe, EEB, EurEau, EuPC, FEC, MedTech Europe, Plastics Recyclers Europe, PlasticsEurope and TEPPFA commented on number of issues covering procedural aspects, including timelines (i.e. BD updates, uses and sectors covered, assessment of third-party consultation comments).

RAC was provided with an overview of the comments submitted in the third-party consultation, including the next steps for opinion development. Furthermore, the Committee was informed that the opinion deadlines will be extended for this dossier in accordance with Article 72(1) of the REACH Regulation, due to the complexity and breadth of the proposal and due to high volume of consultation comments received.	**SECR** to communicate the full workplan as soon as it is agreed. **SECR** to table further discussions as follows: → RAC-68 (and REST RAC-68 WG) in March 2024: • Discussion of next draft opinion • Focus on Hazard, Consumer mixtures, Cosmetics, Ski wax

10. Authorisation

10.1. General authorisation issues

10.1.1. Report from the October AFA Working Group

The Secretariat presented the Report of the 17th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group which took place on 10-11 October 2023. RAC took note of the Report.	

10.1.2. Update on incoming/future applications and horizontal issues	
The Secretariat presented an update: - on AfAs and Review Reports pipeline, - on preparation of the dossier on restriction of use of Cr(VI), - on the AFA Task Force. The Secretariat presented summary of approach to conditions of authorisation in DOs on AFA where manual task are performed by workers.	
10.1.3. New Opinion format	
The ECHA Secretariat presented the new opinion format. RAC requested to discuss at the next RAC AFA WG the use of the new opinion format. RAC requested some detailed discussion how to present data in the opinion during the next RAC AFA WG meeting especially concerning RAC opinions on review reports.	**SECR** to distribute the new opinion format in Q1 2024. **Rapporteurs** to use the new opinion format for preparation of opinions on AFA starting from the Nov 2023 batch or the Feb 2024 batch.
10.2. Discussion on key issues	
10.2.1. 23 applications for authorisation from May 2023 submission window	
RAC rapporteurs presented Key issues in 23 applications for authorisation from May 2023 submission window.	**RAC members** to provide comments during 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. 311_SD_Liebherr-Aerospace (1 use) 2. 313_CT_BWI-Poland (1 use) 3. 314_CT_Benoni (1 use) 4. 315_CT_Egal (1 use) 5. 316_CT_ASO-Cromsteel (1 use) 6. 317_CA_Micron (1 use) 7. 318_CT_Sirio_Galv (1 use) 8. 320_CT_Fratelli-Creola (1 use) 9. 321_CT_LMC (1 use) 10. 322_CT_ArcelorMittal_plating (1 use) 11. 323_CT_HDO-Druckguss (1 use)	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicants for commenting.

12. 324_CT_Tecnofiniture (1 use) RAC agreed by consensus the 12 draft opinions on the Application listed in Annex IV.	
10.3.2. Draft opinions for discussion and agreement with plenary debate	
312_CT_Metalplast (2 uses)	
Use1: *Industrial use of hexavalent chromium for a pre-treatment step (etching) in the electroplating process for plastic materials with various applications.* RAC discussed: - feasibility study versus hard conditions to automatise the dipping process at the Metalplast site taking into consideration frequency and duration of the task and low exposure data, - additional condition to cover all baths to reduce the exposure of workers. 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 at the CO.BE site, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. However, RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to the general population at the CO.BE site. 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. 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 at the Metalplast site. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. RAC concluded that the operational conditions and risk management measures	**Rapporteur** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary - to add request for regular biomonitoring of workers performing manual tasks during the etching process. **SECR** to send the draft opinions to the applicant for commenting.

described in the application are appropriate and effective in limiting the risk to the general population at the Metalplast site. RAC agreed: Section 7: additional conditions for the authorisation At the CO.BE site, the applicant shall: - install an emissions abatement system (e.g. a wet scrubber) for the chimney currently missing such a system These conditions should be implemented within 12 months of the granting of an authorisation for this use. The applicant shall carry out and document a detailed feasibility study for both sites on: - automatise the dipping process to minimise workers exposure in proximity of the etching bath during the surfaces dipping process; - the replacement of solid CrO_3 flakes by a liquid solution of CrO_3 at both sites, 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 etching baths); - 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 physical segregation between the etching baths and the loading/unloading areas that will prevent the exposure of indirectly exposed workers; - covering of all baths to reduce the exposure of workers performing tasks near the baths; - 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) etching 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. 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. **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.* 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 (at both sites), provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. However, RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to the general population at the CO.BE site. 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. For the Metalplast site, the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk to the general population. RAC agreed: Section 7: additional conditions for the authorisation At the CO.BE site, the applicant shall install an emissions abatement system (e.g. a wet scrubber) for the chimney currently missing such a system.	

This condition should be implemented within 12 months of the granting of an authorisation for this use. The applicant shall carry out and document a detailed feasibility study for both sites on: - the replacement of solid CrO_3 flakes by a liquid solution of CrO_3 at both sites, 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); - 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 physical segregation between the plating baths and the loading/unloading areas that will prevent the exposure of indirectly exposed workers; - covering of all baths to reduce the exposure of workers performing tasks near the baths; - 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 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. RAC agreed the draft opinions by consensus.	
319_CT_SK-Nexillis (1 use)	

Use1: *Chromium trioxide use: Manufacture of passivated copper foil used in Lithium-ion batteries (LiB).* RAC discussed: - feasibility study versus hard conditions considering that this is the future use. RAC concluded that operational conditions and risk management measures described in the application are expected to be NOT appropriate and effective in limiting the risk. RAC agreed: Section 7: additional conditions for the authorisation The applicant shall: - implement a closed/automated system to perform the dilution of solid CrO_3 (e.g. a glove box to transfer flakes to a mixing tank). - implement a closed/automated system to perform make-up tank sampling tasks; - install a system that triggers automatically appropriate 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). This condition should be implemented within 12 months of the granting of an authorisation for this use. 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. RAC provisionally agreed the draft opinion.	**Rapporteur** together with **SECR** to do the editing of the draft opinions according to the discussion at the plenary. **SECR** to launch a short RAC consultation on the DO. Pending on the RAC members feedback: **SECR** to launch a written procedure to agree on the draft opinion or schedule the DO for discussion at the next RAC AFA WG and agreement at the RAC-68. **SECR** to send the draft opinion to the applicant for commenting.
10.4. Adoption of opinions	
10.4.1. 286_CT_Hartchrom-Beck (4 uses)	
Use1: *Chromium trioxide-based functional chrome plating of axially/rotationally symmetrical components requiring optimal tribological surface properties (resulting from microcracked surface) to ensure low surface friction under lubrication.*	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.

Use2: *Chromium trioxide-based functional chrome plating of axially/rotationally symmetrical components requiring high wear resistant surfaces to withstand abrasive forces occurring in their application.* **Use3:** *Chromium trioxide-based functional chrome plating of components with complex 3-dimensional geometry (not axially/rotationally symmetrical) requiring optimal tribological surface properties (resulting from microcracked surface) to ensure low surface friction under lubrication.* **Use4:** *Chromium trioxide-based functional chrome plating of components with complex 3-dimensional geometry (not axially/rotationally symmetrical) requiring high wear resistant surfaces to withstand abrasive forces occurring in their application.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk and that existing workplace conditions are not acceptable in terms of workers' health protection. RAC agreed: Section 7: additional conditions for the authorisation 1 The applicant shall implement without delay, technical improvements to the OCs and RMMs at the manual plating lines (e.g. automated systems to perform the dipping/immersion of the parts and sampling, bath coverage, use of mist suppressant and physical segregation), followed by a measurement campaign to validate the effectiveness of the applied technical improvements. The additional OCs and RMMs shall be implemented within 12 months of the granting of an authorisation for this use. 2. Until the implementation of the additional OCs and RMMs, the applicant shall ensure that workers involved in chrome plating activities in the proximity of the baths, use appropriate and properly fit-tested RPE, with due consideration for the duration of the tasks and the comfort of the workers during their use. The applicants shall also	

use the results of Human Biomonitoring (see section 8.1) to validate the appropriateness and effectiveness of the RPEs. 3. Without prejudice to points 1 and 2 above, the applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 by liquid solutions of CrO_3 (at 6 sites) to further limit exposure, (b) the implementation of an automated system to perform the bath concentration adjustment (at 8 sites), (c) the implementation of a closed/automated system to perform bath sampling tasks (at all sites), 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 all across the sites and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2 including point 8. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC adopted the final opinion by consensus.	
10.4.2. 288_CT_Leonardo (1 use)	
Use1: *Functional chrome plating of military gun barrels and outer jacket surfaces using chromium trioxide.* RAC concluded 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. RAC agreed: Section 7: additional conditions for the authorisation	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.

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 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 RAC adopted the final opinion by consensus.	
10.4.3. 3.289_CT_Beretta (2 uses)	
Use1: *Chromium trioxide based functional plating of gun barrel bores and auxiliary parts for assault rifles, carbines and pistols for non-civilian uses.* **Use2:** *The use of Chromium trioxide based functional chrome plating of gun barrel bores and auxiliary parts for semi-automatic shotguns, over/under, side-by-side shotguns, pistols and carbines for civilian uses.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk to workers and general population, provided that they 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 (WCS 6), due to the potential for exposure to Cr(VI). 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.	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.

RAC adopted the final opinion by consensus.	
11. Drinking Water Directive	
11.1. Report from the October DWD Working Group	
The Secretariat presented: - the Report from RAC DWD working group meeting on 4 October 2023 including information on the next meeting of the working group, - an update on development with draft guidance documents, RAC discussed alignment between different guidance documents, concerns that some clarifications are provided in the guidance documents but not in the legal text, reference to EN standards which are not publicly accessible, - an update on developments with DWD draft implementing legislation.	**SECR** to investigate a possibility to provide access to RAC members to EN standards for the purpose of work on the DWD guidance documents and to prepare to assess future applications.
12. AOB	
12.1 Operations of RAC (Caracal 50)	
RAC took note of the presentation on the operations of RAC.	
12.2. Update on recent upgrades to IT tools	
RAC took note of the presentations on the recent upgrades to IT tools.	
12.3 Presentation by European Environmental Bureau (EEB)	
RAC took note of the presentation by the EEB on the regulatory processes.	
13. Minutes of RAC-66	
13.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-67	
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-67 to CIRCA BC.

CLH opinions at RAC-67

1. tetra(sodium/potassium) 7-[(E)-{2-acetamido-4-[(E)-(4-{[4-chloro-6-({2-[(4-fluoro-6-{[4-(vinylsulfonyl)phenyl]amino}-1,3,5-triazine-2-yl)amino]propyl}amino)-1,3,5-triazine-2-yl]amino}-5-sulfonato-1-naphthyl)diazenyl]-5-methoxyphenyl}diazenyl]-1,3,6-naphthalenetrisulfonate;[substance having a complex composition with <80% of the above constituents and other reaction side products]; Reactive Brown 51

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	tetra(sodium/potassium) 7-[(*E*)-{2-acetamido-4-[(*E*)-(4-{[4-chloro-6-({2-[(4-fluoro-6-{[4-(vinylsulfonyl)phenyl]amino}-1,3,5-triazine-2-yl)amino]propyl}amino)-1,3,5-triazine-2-yl]amino}-5-sulfonato-1-naphthyl)diazenyl]-5-methoxyphenyl}diazenyl]-1,3,6-naphthalenetrisulfonate;[substance having a complex composition with <80% of the above constituents and other reaction side products]; Reactive Brown 51	466-490-7	-	Repr. 1B Skin Sens. 1A	H360F H317	GHS08 GHS07 Dgr	H360F H317			
RAC opinion	TBD	tetra(sodium/potassium) 7-[(*E*)-{2-acetamido-4-[(*E*)-(4-{[4-chloro-6-({2-[(4-fluoro-6-{[4-(vinylsulfonyl)phenyl]amino}-1,3,5-triazine-2-yl)amino]propyl}amino)-1,3,5-triazine-2-yl]amino}-5-sulfonato-1-naphthyl)diazenyl]-5-methoxyphenyl}diazenyl]-1,3,6-naphthalenetrisulfonate;[substance having a complex composition with <80% of the above constituents and other reaction side products]; Reactive Brown 51	466-490-7	-	Repr. 1B Skin Sens. 1A	H360F H317	GHS08 GHS07 Dgr	H360F H317			
Resulting Annex VI entry if agreed by COM	TBD	tetra(sodium/potassium) 7-[(*E*)-{2-acetamido-4-[(*E*)-(4-{[4-chloro-6-({2-[(4-fluoro-6-{[4-(vinylsulfonyl)phenyl]amino}-1,3,5-triazine-2-yl)amino]propyl}amino)-1,3,5-triazine-2-yl]amino}-5-	466-490-7	-	Repr. 1B Skin Sens. 1A	H360F H317	GHS08 GHS07 Dgr	H360F H317			

		sulfonato-1-naphthyl)diazenyl]-5-methoxyphenyl}diazenyl]-1,3,6-naphthalenetrisulfonate;[substance having a complex composition with <80% of the above constituents and other reaction side products]; Reactive Brown 51									

2. 4-phenylbenzophenone

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	4-phenylbenzophenone	218-345-2	2128-93-0	Repr. 1B Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H360FD H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360FD H317 H410		M = 10 M = 1	
RAC opinion	TBD	4-phenylbenzophenone	218-345-2	2128-93-0	Repr. 1B Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H360FD H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360FD H317 H410		M = 10 M = 1	
Resulting Annex VI entry if agreed by COM	TBD	4-phenylbenzophenone	218-345-2	2128-93-0	Repr. 1B Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H360FD H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360FD H317 H410		M = 10 M = 1	

3. flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)- 3-(3-trifluoromethyl-2-pyridylsulfonyl)urea

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	016-085-00-2	flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)- 3-(3-trifluoromethyl-2-pyridylsulfonyl)urea	-	104040-78-0	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitters proposal	016-085-00-2	flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)- 3-(3-trifluoromethyl-2-pyridylsulfonyl)urea	-	104040-78-0	**Retain** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H400 H410	**Retain** GHS09 Wng	**Retain** H410		**Add** M = 1000 M = 100	
RAC opinion	016-085-00-2	flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)- 3-(3-trifluoromethyl-2-pyridylsulfonyl)urea	-	104040-78-0	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2 STOT RE 2	**Retain** H400 H410 **Add** H361d H373 (liver, muscle)	**Retain** GHS09 Wng **Add** GHS08	**Retain** H410 **Add** H361d H373 (liver, muscle)		**Add** M = 1000 M = 100	
Resulting Annex VI entry if agreed by COM	016-085-00-2	flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)- 3-(3-trifluoromethyl-2-pyridylsulfonyl)urea	-	104040-78-0	Repr. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H361d H373 (liver, muscle) H400 H410	GHS08 GHS09 Wng	H361d H373 (liver, muscle) H410		M = 1000 M = 100	

4. fosthiazate (ISO); S-sec-butyl O-ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate

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	015-168-00-0	fosthiazate (ISO); *S*-sec-butyl *O*-ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate	-	98886-44-3	Acute Tox. 3* Acute Tox. 3* Acute Tox. 4* Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H301 H312 H317 H400 H410	GHS06 GHS09 Dgr	H331 H301 H312 H317 H410	EUH070		
Dossier submitters proposal	015-168-00-0	fosthiazate (ISO); *S*-sec-butyl *O*-ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate	-	98886-44-3	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Eye Irrit. 2 Repr. 2 Lact. STOT SE 1 STOT RE 2 **Modify** Acute Tox. 3 Acute Tox. 3 Acute Tox. 3	**Retain** H331 H301 H400 H410 **Add** H319 H361fd H362 H370 (nervous system) H373 (adrenals) **Modify** H311	**Retain** GHS09 Dgr **Add** GHS08	**Retain** H331 H301 H410 **Add** H319 H361fd H362 H370 (nervous system) H373 (adrenals) **Modify** H311	**Retain** EUH070	**Add** inhalation: ATE = 0,53 mg/L (dusts or mists) dermal: ATE = 861 mg/kg bw oral: ATE = 57 mg/kg bw STOT SE 1; H370 (nervous system): C ≥ 1 % STOT SE 2; H371 (nervous system): 0.2 % ≤ C < 1 % M = 1 M = 1	
RAC opinion	015-168-00-0	fosthiazate (ISO); S-sec-butyl O-ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate	-	98886-44-3	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Eye Irrit. 2 Repr. 1B Lact. STOT RE 1 **Modify** Acute Tox. 3 Acute Tox. 3 Acute Tox. 3	**Retain** H331 H301 H400 H410 **Add** H319 H360Df H362 H372 (nervous system, adrenals) **Modify** H312	**Retain** GHS09 Dgr **Add** GHS08	**Retain** H331 H301 H410 **Add** H319 H360Df H362 H372 (nervous system, adrenals) **Modify** H312	**Retain** EUH070	**Add** inhalation: ATE = 0,56 mg/L (dusts or mists) dermal: ATE = 860 mg/kg bw oral: ATE = 57 mg/kg bw M = 1 M = 1	

Resulting Annex VI entry if agreed by COM	015-168-00-0	fosthiazate (ISO); S-sec-butyl O-ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate	-	98886-44-3	Repr. 1B Lact. Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 STOT RE 1 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H360Df H362 H331 H311 H301 H372 (nervous system, adrenals) H317 H319 H400 H410	GHS08 GHS06 GHS09 Dgr	H360Df H362 H331 H311 H301 H372 (nervous system, adrenals) H317 H319 H410	EUH070	inhalation: ATE = 0,56 mg/L (dusts or mists) dermal: ATE = 860 mg/kg bw oral: ATE = 57 mg/kg bw M = 1 M = 1	

5. methacrylic acid, monoester with propane-1,2-diol [HPMA]

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	methacrylic acid, monoester with propane-1,2-diol [HPMA]	248-666-3	27813-02-1	STOT SE 3 Eye Irrit. 2 Resp. Sens. 1 Skin Sens. 1	H335 H319 H334 H317	GHS08 GHS07 Wng	H335 H319 H334 H317			
RAC opinion	TBD	methacrylic acid, monoester with propane-1,2-diol [HPMA]	248-666-3	27813-02-1	STOT SE 3 Eye Irrit. 2 Skin Sens. 1	H335 H319 H317	GHS07 Wng	H335 H319 H317		STOT SE 3, H335: C ≥ 10 %	D
Resulting Annex VI entry if agreed by COM	TBD	methacrylic acid, monoester with propane-1,2-diol [HPMA]	248-666-3	27813-02-1	STOT SE 3 Eye Irrit. 2 Skin Sens. 1	H335 H319 H317	GHS07 Wng	H335 H319 H317		STOT SE 3, H335: C ≥ 10 %	D

6. 2-hydroxyethyl methacrylate; [HEMA]

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	607-124-00-X	2-hydroxyethyl methacrylate	212-782-2	868-77-9	Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1	H315 H319 H317	GHS07 Wng	H315 H319 H317			D
Dossier submitters proposal	607-124-00-X	2-hydroxyethyl methacrylate; [HEMA]	212-782-2	868-77-9	**Add** STOT SE 3 Resp. Sens. 1	**Add** H335 H334	**Add** GHS08 **Modify** Dgr	**Add** H335 H334			
RAC opinion	607-124-00-X	2-hydroxyethyl methacrylate; [HEMA]	212-782-2	868-77-9	**Add** STOT SE 3	**Add** H335		**Add** H335		**Add** STOT SE 3, H335: C ≥ 10 %	
Resulting Annex VI entry if agreed by COM	607-124-00-X	2-hydroxyethyl methacrylate; [HEMA]	212-782-2	868-77-9	STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1	H335 H315 H319 H317	GHS07 Wng	H335 H315 H319 H317		STOT SE 3, H335: C ≥ 10 %	D

7. Melaleuca alternifolia, ext. [1] Melaleuca alternifolia, essential oil; tea tree oil [2]

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	Melaleuca alternifolia, ext. [1] *Melaleuca alternifolia*, essential oil; tea tree oil [2]	285-377-1 [1] - [2]	85085-48-9 [1] 68647-73-4 [2]	Flam. Liq. 3 Repr. 2 Acute Tox. 4 Acute Tox. 4 Asp. Tox. 1 Skin Irrit. 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 3	H226 H361f H332 H302 H304 H315 H317 H400 H412	GHS02 GHS08 GHS07 GHS09 Dgr	H226 H361f H332 H302 H304 H315 H317 H410		inhalation: ATE= 3.64 mg/L (dust/mist) oral: ATE = 1049 mg/kg bw M = 1	
RAC opinion	TBD	Melaleuca alternifolia, ext. [1] *Melaleuca alternifolia*, essential oil; tea tree oil [2]	285-377-1 [1] - [2]	85085-48-9 [1] 68647-73-4 [2]	Flam. Liq. 3 Repr. 1B Acute Tox. 4 Acute Tox. 4 STOT SE 3 Asp. Tox. 1 Skin Irrit. 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 2	H226 H360Fd H332 H302 H336 H304 H315 H317 H400 H411	GHS02 GHS08 GHS07 GHS09 Dgr	H226 H360Fd H332 H302 H336 H304 H315 H317 H410		inhalation: ATE= 3.60 mg/L (dust/mist) oral: ATE = 1050 mg/kg bw M = 1	
Resulting Annex VI entry if agreed by COM	TBD	Melaleuca alternifolia, ext. [1] *Melaleuca alternifolia*, essential oil; tea tree oil [2]	285-377-1 [1] - [2]	85085-48-9 [1] 68647-73-4 [2]	Flam. Liq. 3 Repr. 1B Acute Tox. 4 Acute Tox. 4 STOT SE 3 Asp. Tox. 1 Skin Irrit. 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 2	H226 H360Fd H332 H302 H336 H304 H315 H317 H400 H411	GHS02 GHS08 GHS07 GHS09 Dgr	H226 H360Fd H332 H302 H336 H304 H315 H317 H410		inhalation: ATE= 3.60 mg/L (dust/mist) oral: ATE = 1050 mg/kg bw M = 1	

8. penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1H-1,2,4-triazole

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	613-317-00-X	penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole	266-275-6	66246-88-6	Repr. 2 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H361d H302 H400 H410	GHS08 GHS07 GHS09 Wng	H361d H302 H410		 M = 1 M = 1	
Dossier submitters proposal	613-317-00-X	penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole	266-275-6	66246-88-6	**Retain** Repr. 2 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT RE 2	**Retain** H361d H302 H400 H410 **Add** H373 (liver)	**Retain** GHS08 GHS07 GHS09 Wng	**Retain** H361d H302 H410 **Add** H373 (liver)		**Retain** M = 1 M = 1 **Add** oral: ATE = 970 mg/kg bw	
RAC opinion	613-317-00-X	penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole	266-275-6	66246-88-6	**Retain** Repr. 2 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT RE 2	**Retain** H361d H302 H400 H410 **Add** H373 (liver)	**Retain** GHS08 GHS07 GHS09 Wng	**Retain** H361d H302 H410 **Add** H373 (liver)		**Retain** M = 1 **Add** oral: ATE = 970 mg/kg bw **Modify** M = 10	
Resulting Annex VI entry if agreed by COM	613-317-00-X	penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole	266-275-6	66246-88-6	Repr. 2 Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H361d H302 H373 (liver) H400 H410	GHS08 GHS07 GHS09 Wng	H361d H302 H373 (liver) H410		oral: ATE = 970 mg/kg bw M = 1 M = 10	

Part III. List of Attendees of the RAC-67 meeting

RAC members	
Angeli	Karine
Aquilina	Gabriele
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
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
Piña	Benjamin
Pribu	Mihaela
Rakkestad	Kirsten Eline
Rodriguez	Wendy
Santonen	Tiina
Schlüter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sørensen	Peter Hammer
Spetseris	Nikolaos
Tekpli	Nina
Tobiassen	Lea Stine
Tsitsimpikou	Christina
Užomeckas	Žilvinas
van der Haar	Rudolf
Varnai	Veda Marija
Viegas	Susana

Members' advisers		Nominated by
Beestra	Renske	Hakkert Betty and Schuur Gerlienke
Bjorge	Christine	Kirsten Rakkestad
Broederick	Mike	Brendan Murray
Catone	Tiziana	Aquilina Gabriele
Granato	Giuseppe	Dania Esposito
Hoffmann	Frauke	Schulte Agnes
Houlihan	Margarete	Brendan Murray
Jankowska	Agnieszka	Peczkowska Beata
McCann	Andrew	Brendan Murray
Moilanen	Marianne	Leinonen Riitta
Panieri	Emiliano	Dania Esposito
Rehl	Anna-Lena	Manuel Facchin
Russo	Maria Teresa	Aquilina Gabriele
Saksa	Jana	Moldov Raili
Smith	Jenny	Murray Brendan
Suutari	Tiina	Leinonen Riitta
Van Herwijnen	Rene	Betty Hakkert
Woutersen	Marjolijn	Gerlinke Schuur

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

Invited experts		Role/Substance
Kloslova	Zuzana	Future RAC member
Levy	Patrick	WPC, Government Interest group (OELs)
Musu	Tony	ETUI
Stalter	Daniel	Future RAC member
Wildemann	Tanja	Future RAC member

Dossier submitters		Substance
August	Christina	(DE) - UPFAS
Averbeck	Frauke	(DE) – UPFAS
Baumbusch	Angelika	(NO) - UPFAS
Borg	Daniel	(SE) – UPFAS, Reactive Brown 51
Charles	Sandrine	(FR) – HEMA/HPMA
Dannenberg	Carl	(DE) - UPFAS
De Kort	Thijs	(NL) – UPFAS
Detjens	Marc	(DE) - UPFAS
Drost	Wiebke	(DE) - UPFAS
Gall	Andrea	(DE) - Fosthiazate
Heggelund	Audun	(NO) – UPFAS
Heise	Tanja	(DE) - Fosthiazate
Johansson	Tommy	(SE) – UPFAS
Kupprat	Franziska	(DE) – UPFAS
Sanders	Marion	(NL) - UPFAS
Sanz	Manuel	(ES) - Flazasulfuron
Sehbar	Khalaf	(DK) - UPFAS

Simpson	Peter	(NL) - UPFAS
Stalter	Daniel	(DE) - UPFAS
Willenbockel	Tobias	(DE) - Fosthiazate

Regular stakeholder observers		
De Backer	Liisi	Cefic
Duguy	Hélène	ClientEarth
Hermann	Christine	EEB
Lemetayer	Loreleï	MedTech Europe
Mueller	Patrik	PlasticsEurope
Robin	Nicolas (alternate)	PlasticsEurope - UPFAS
Robinson	Jan	AISE
Ruelens	Paul	CropLife Europe
Santos	Tatiana	EEB
Van De Broeck	Steven	Cefic
Verougstraete	Violaine	Eurometaux

Occasional stakeholders		**Substance**
Cingotti	Natacha (HEAL)	UPFAS
Corridori	Ricardo (COCIR)	UPFAS
Dainelli	Dario (FEC)	UPFAS
De Badereau	Vincent (EPEE)	UPFAS
De Bruycker	Leen (WECEP)	UPFAS
De Kort	Patrick (PRE)	UPFAS
Di Caprio	Elisabetta (Concawe)	UPFAS
Dvorakova	Dana (IFRA)	Tea Tree oil
Engelbrecht	Vera (PSCI)	DWD
Glüge	Juliane (EuChemS)	UPFAS
Kaup	Triin (EURATEX)	UPFAS
Loebel	Oliver (EurEau)	UPFAS, DWD
Orlando	Stefano Ramundo (SEMI Europe)	UPFAS
Taverne	Jean-Pierre (TEPPFA)	UPFAS
Tillieux	Geoffroy (EuPC)	UPFAS, AfA general issues
Van den Eede	Christel (Animal Health Europe)	UPFAS
Zippel	Maja (EFEO)	Tea Tree oil

Stakeholder experts		**Substance**
Ahlskog	Jan (COCIR)	UPFAS
Barber	David (CropLife Europe)	UPFAS
Bock	Ronald (PlasticsEurope)	UPFAS
Consoli	Elisa (Eurometaux)	UPFAS
Fourneau	Virginie (EPEE)	UPFAS
Fukunaga	Satoki (CropLifeEurope)	Metyltetrapole
Lindner	Sabine (Plastics Europe)	DWD

Moclair	Fiona (Intel, SEMI Europe)	UPFAS
Mutter	Corinna (MedTech Europe)	UPFAS
Natsch	Andreas (IFRA)	Tea Tree oil
Nielsen	Jesper Bo (EFEO)	Tea Tree oil
Nodler	Karsten (EurEau)	UPFAS
Pemberton	Mark (Cefic)	HEMA/HPMA
Samuels	Scott (CropLife Europe)	Fosthiazate
Schmeinck	Sina (CropLife Europe)	Tea Tree oil
Speziale	Lighea (CEWEP)	UPFAS
Stein	Jurgen (CropLife Europe)	Flazasulfuron
van Melkebeke	Gabrielle (IOGP, CONCAWE)	UPFAS
Van Wely	Eric (CEFIC)	UPFAS

European Commission		**DG**
Beekman	Martijn	DG GROW
Bertato	Valentina	DG ENV
Ceridono	Mara	DG ENV
Dunauskiene	Lina	DG GROW
Faraulo	Fabio	DG EMPL (OELs)
Kusendila	Christophe	DG GROW
Roebben	Gert	DG GROW
EU Agency Observers		
Parra Morte	Juan	EFSA

ECHA staff	
Atanasova	Marina
Barnewitz	Greta
Bichlmaier	Bohumila
Bin	Essi
De La Flor Tejero	Ignacio
Di Bastiano	Augusto
Doyle	Simone
Etholen	Anita
Fabjan	Evelin
Frattini	Stefano
Gmeinder	Michael
Hammer	Jort
Hellsten	Niko
Henrichson	Sanna
Husa	Stine
Kiakos	Konstantinos
Korjus	Pia
Lehto Hurlimann	Mikko
Lisboa	Patricia
Logtmeijer	Christiaan
Loukou	Christina
Ludborzs	Arnis
Makela	Petteri
Manassakis	Vasilis
Marquez-Camacho	Mercedes
Mattiuzzo	Marco
Mushtaq	Fesil
Myohanen	Kirsi
Nicot	Thierry
Niemela	Helena
Orispää	Katja
O'Rourke	Regina
Peltola	Jukka
Perazzolo	Chiara
Pillet	Monique
Portugal	Laura
Prevedouros	Konstantinos
Richarz	Andrea
Roberts	Julian
Sadam	Diana
Salo	Marta
Scazzola	Roberto (Chair)
Schakir	Yasmin
Sosnowski	Piotr
Stockmann-Juvala	Helene
Tai	Kaihsu
Tarvainen	Emma
Thierry-Mieg	Morgan

Vaananen	Virpi
Vitcheva	Vessela
Zarogiannis	Panos
Zeiger	Bastian
Zhivin	Sergey

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-67 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-67 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-67 meeting

ANNEX IV List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-67 meeting without plenary debate (A-list)

Annex I

27 November 2023
RAC/A/67/2023

Final Agenda
67th meeting of the Committee for Risk Assessment
(RAC-67)

27-30 November 2023

Face-to-face/Hybrid meeting[1]

Monday, 27 November starts at 14.00
Thursday, 30 November ends at 16.20

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/67/2023
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 – General RAC procedures

5.1 RAC Work Plan for all processes

For information

5.2 Mandate for recruitment of RAC co-opted members (closed session)

For discussion and agreement
RAC/67/2023/01
Restricted
Closed session

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

n/a

Item 7 –Health based exposure limits at the workplace

7.1 Opinions for discussion

1. *N*-nitrosodiethylamine (diethylnitrosamine) (EC 200-226-1; CAS 55-18-5)

For discussion and adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

1. Report from the October CLH Working Group

For information
RAC/67/2023/02

8.2 CLH dossiers

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

- **Flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulfonyl)urea (EC -; CAS 104040-78-0):** *physical hazards, acute toxicity (oral, dermal, inhalation), skin irritation, eye irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity (fertility, lactation), STOT SE, STOT RE (kidney), aspiration hazard, aquatic hazards, hazard to the ozone layer*
- **Fosthiazate (ISO); *S*-*sec*-butyl *O*-ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate (EC -; CAS 98886-44-3):** *physical hazards, acute toxicity, serios eye damage/eye irritation, STOT RE, reproductive toxicity (fertility, lactation), aquatic hazards*
- **Tetra(sodium/potassium)7-[(*E*)-{2-acetamido-4-[(*E*)-(4-{[4-chloro-6-({2-[(4- fluoro-6-{[4-(vinylsulfonyl)phenyl]amino}-1,3,5-triazine-2-yl)amino]propyl} amino)-1,3,5-triazine-2-yl]amino}-5-sulfonato-1-naphthyl)diazenyl]-5-methoxyphenyl}diazenyl]-1,3,6-naphthalenetrisulfonate; [substance having a complex composition with <80% of the above constituents and other reaction side products]; Reactive Brown 51 (EC 466-490-7; CAS -):** *skin sensitisation, reproductive toxicity*
- **Metyltetraprole (ISO);1-[2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5*H*-tetrazol-5-one (EC - ; CAS 1472649-01-6):** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin*

sensitisation, mutagenicity, reproductive toxicity, STOT SE, STOT RE, aquatic hazards, hazard to the ozone layer

- **Methacrylic acid, monoester with propane-1,2-diol; [HPMA] (EC 248-666-3; CAS 27813-02-1):** *serious eye damage/eye irritation, skin sensitisation, respiratory sensitisation, STOT SE, Note D*
- **2-hydroxyethyl methacrylate; [HEMA] (EC 212-782-2; CAS 868-77-9):** *respiratory sensitisation, STOT SE*
- **4-phenylbenzophenone (EC 218-345-2; CAS 2128-93-0):** *skin sensitisation, reproductive toxicity, aquatic hazards*
- ***Melaleuca alternifolia*, ext. [1] *Melaleuca alternifolia*, essential oil; tea tree oil [2] (EC 285-377-1 [1]; CAS 85085-48-9 [1] CAS 68647-73-4 [2]):** *physical hazards, aspiration hazard, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT RE, mutagenicity, carcinogenicity, lactation*
- **Penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole (EC 266-275-6; CAS 66246-88-6):** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazard to the ozone layer*

2. Hazard classes for agreement with plenary debate

1. **Flazasulfuron (ISO)** (EC -; CAS 104040-78-0): *STOT RE (liver, thymus, skeletal muscle), reproductive toxicity (development)*
2. **Fosthiazate (ISO)** (EC -; CAS 98886-44-3): *STOT SE and STOT RE for nervous system and adrenals, developmental toxicity*
3. **Metyltetraprole (ISO)** (EC - ; CAS 1472649-01-6): *carcinogenicity*
4. **Methacrylic acid, monoester with propane-1,2-diol; [HPMA]** (EC 248-666-3; CAS 27813-02-1): *SCL for STOT SE 3; H335*
5. **2-hydroxyethyl methacrylate; [HEMA]** (EC 212-782-2; CAS 868-77-9): *SCL for STOT SE 3; H335*
6. ***Melaleuca alternifolia*, ext. [1] *Melaleuca alternifolia*, essential oil; tea tree oil [2] (EC 285-377-1 [1]**; (CAS 85085-48-9 [1] CAS 68647-73-4 [2]): *STOT SE, reproductive toxicity (fertility, development), aquatic toxicity*
7. **Penconazole (ISO)** (EC 266-275-6; CAS 66246-88-6): *aquatic hazards*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Restriction dossiers in preparation

For information

9.2 Restriction Annex XV dossiers

1. Opinion development

    1. Universal per- and polyfluoroalkyl substances (U-PFAS) – Overview of third-party consultation outcome and the work plan for 2024

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the October AFA Working Group

For information
RAC/67/2023/03

2. Update on incoming/future applications and horizontal issues

For information/discussion

3. New Opinion format

For information

10.2 Authorisation applications

1. Discussion on key issues

1. 325_ADCR_Anodise_sealing (1 use)
2. 326_ADCR_Anodising (1 use)
3. 327_ADCR_Chemical_conversion_coating (1 use)
4. 328_ADCR_Chromate_rinsing (1 use)
5. 329_ADCR_Electroplating (1 use)
6. 330_ADCR_Finish_stripping (1 use)
7. 331_ADCR_Formulation (1 use)
8. 332_ADCR_Passivation_metallic_coatings (1 use)
9. 333_ADCR_Pre-treatments (1 use)
10. 334_ADCR_Stainless_steel_passivation (1 use)
11. 335_ADCR_RR_Anodising (1 use)
12. 336_ADCR_RR_Anodise_sealing (1 use)
13. 337_ADCR_RR_Chemical_conversion_coating (1 use)
14. 338_ADCR_RR_Chromate_rinsing (1 use)
15. 339_ADCR_RR_Electroplating (1 use)
16. 340_ADCR_RR_Finish_stripping (1 use)
17. 341_ADCR_RR_Formulation (1 use)
18. 342_ADCR_RR_Passivation_metallic_coatings (1 use)
19. 343_ADCR_RR_Pre-treatments (1 use)
20. 344_ADCR_RR_Slurry_coating (1 use)
21. 345_ADCR_RR_Stainless_steel_passivation (1 use)
22. 346_CT_Safran_landing_systems (2 uses)
23. 347_CT_Safran_Aircraft_Engines (1 use)

For discussion

10.3 Agreement on draft opinions

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

9. 311_SD_Liebherr-Aerospace (1 use)
10. 313_CT_BWI-Poland (1 use)
11. 314_CT_Benoni (1 use)
12. 315_CT_Egal (1 use)
13. 316_CT_ASO-Cromsteel (1 use)
14. 317_CA_Micron (1 use)
15. 318_CT_Sirio_Galv (1 use)
16. 320_CT_Fratelli-Creola (1 use)
17. 321_CT_LMC (1 use)
18. 322_CT_ArcelorMittal_plating (1 use)
19. 323_CT_HDO-Druckguss (1 use)
20. 324_CT_Tecnofiniture (1 use)

For agreement

2. Draft opinions for agreement with plenary debate

1. 312_CT_Metalplast (2 uses)
2. 319_CT_SK-Nexillis (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 286_CT_Hartchrom-Beck (4 uses)
2. 288_CT_Leonardo (1 use)
3. 289_CT_Beretta (2 uses)

For discussion and adoption

Item 11 – Drinking Water Directive

1. Report from the October DWD Working Group

For information
RAC/67/2023/04

Item 12 – AOB

1. Operations of RAC (Caracal)
2. Update on recent upgrades to IT tools
3. Presentation by European Environmental Bureau (EEB)

Item 13 – Minutes of RAC-67

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-67

For adoption

Annex II

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

RAC/A/67/2023	RAC-67 final Draft Agenda
RAC/67/2023/01	Mandate for recruitment of RAC co-opted members (closed session)
RAC/67/2023/02	General CHL issues: Report from the October CLH Working Group
RAC/67/2023/03	General authorisation issues: Report from the October AFA Working Group
RAC/67/2023/04	General authorisation issues: Report from the October DWD Working Group

ANNEX III (RAC-67)

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 SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Restrictions		
Universal PFAS **DE**	Michael NEUMANN Urs SCHLUETER	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 SOERENSEN 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.
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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
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.
Harmonised classification & labelling		
Tea tree oil **PL**	Boguslaw BARANSKI	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. Personal involvement.
	Beata PECZKOWSKA	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. Personal involvement.
1) **Metyltetraprole (ISO);** 2) **HPMA;** 3) **HEMA** **FR**	Karine ANGELI	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.
	Laure GEOFFROY	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
Reactive Brown 51 **SE**	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.
	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.
Flazasulfuron (ISO) **ES**	Benjamin PINA	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.
Penconazole (ISO) **NO**	Kirsten RAKKESTAD	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.
	Nina TEKPLI	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
1) **Fosthiazate (ISO);** 2) **4-phenylbenzophenone** **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. Personal involvement in no 2.
	Michael NEUMANN	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.
	Urs SCHLUETER	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.

Annex IV

Table 1. List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-67 meeting without plenary debate (A-list).

Conclusions / agreements / adoptions
311_SD_Liebherr-Aerospace (1 use) **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.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to workers. 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 risk from the use applied for, provided that the operational conditions and risk management measures described in the application are adhered to. RAC concluded 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. RAC agreed: 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.

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.

313_CT_BWI-Poland (1 use)

Use1: *Industrial use of chromium trioxide for the functional chrome plating of shock absorber rods and strut rods, cylinders and reservoir tubes mounted on passive or semi-active dampers for automotive applications.*

RAC concluded 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.

RAC agreed:

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 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 IV Table 2.

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

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.

314_CT_Benoni (1 use)

Use1: *Functional chrome plating of mechanical components (including hydraulic cylinders, columns, moulds and various machinery parts) using chromium trioxide.*

RAC concluded 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.

RAC agreed:
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;
        - If the release factor is not of the same order of 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_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.

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

315_CT_Egal (1 use)

Use1: *Industrial use of chromium trioxide for the pre-treatment step (etching) in the electroplating process of small sized plastic items for various sectors.*

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

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

a) The implementation of a physical segregation of the etching tank (as planned by the applicant);
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.

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

316_CT_ASO-Cromsteel (1 use)

Use1: *Chromium trioxide based functional chrome plating of semi-finished steel products (bars, cylinder tubes and linear shafts) for the manufacture of hydraulic and pneumatic components..*

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 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 IV Table 2.

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

317_CA_Micron (1 use)

Use1: *Dilution of chromic acid solution at concentrations lower than 0.1% for the use in passivation baths.*

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

None

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.

318_CT_Sirio_Galv (1 use)

Use 1: *Industrial use of Chromium Trioxide for the functional chrome plating with decorative character for different 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 implemented and adhered to.

RAC agreed:

Section 7: additional conditions for the authorisation

1. Following the applicant's commitment as showed in the response to the question from RAC, the applicant shall implement, without delay:
   - a LEV flow controller connected to a visual and audible alarm to alert in case of suction interruption or flow decrease
   - a shutdown system of the chrome plating part of the process 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_3 flakes by a liquid solution of CrO_3, 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 IV Table 2.

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

320_CT_Fratelli-Creola (1 use)

Use1: *Use of chromium trioxide for electroplating of metal substrates with the purpose to creating a long-lasting high durability surface with bright (shiny) or matte look for sanitary and 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 implemented and adhered to.

RAC agreed:

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 IV Table 2.

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

321_CT_LMC (1 use)

Use1: *Industrial use of chromium trioxide for the functional chrome plating of food slicer's circular blades.*

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:

1. 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.
2. the physical segregation of the plating area (as per the applicant's commitment).

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.

322_CT_ArcelorMittal_plating (1 use)

Use1: *Industrial use of chromium trioxide for functional chrome plating of work rolls for use in the production of flat metal products.*

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

323_CT_HDO-Druckguss (1 use)

Use1: *Electroplating (by a long-term contractual supplier) of metal substrates using chromium trioxide to achieve functional surfaces with decorative character.*

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 adhere 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 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).

(c) for rare maintenance tasks performed under WCS8, to implement additional measures to reduce further the exposure of workers, considering the hierarchy of control principles, such as improved cleaning practices to minimise the exposure to Cr(VI) (e.g., reduce it to Cr(III) before workers can enter the bath to remove the sludge and remaining liquid).

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.

324_CT_Tecnofiniture (1 use)

Use1: *Industrial use of chromium trioxide for the hard-chrome plating of a wide variety of items with large dimensions and complex geometries used in energy generation and supply, off-shore oil and gas extraction and manufacturing industries.*

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, 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 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.

8. 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.
9. 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.
10. 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.
11. 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.
12. 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
13. 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.