RAC/M/64/2023

16 March 2023

Minutes of the 64th Meeting

of the Committee for Risk Assessment

(RAC-64)

Monday, 13 March at 14.00
Thursday, 16 March ends at 17.10

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

The Chair of RAC, Tim Bowmer welcomed the members to the first RAC plenary of 2023 and announced that the three remaining plenaries for this year would be held in person in Helsinki.

He noted that ECHA's call to the EU/EEA member states in December to nominate experts to a RAC standing Working Group on drinking water had yielded positive responses from 12 countries, with the possibility of one or two more still to decide; the names of about 18 experts were put forward, some already appointed as advisors to RAC members, which makes a strong link to the Committee. The working group will meet for the first time on 1 and 2 June.

At this meeting, the Chair informed that the Committee would be invited to consider the conformity of the 'Universal-PFAS' restriction dossier, following a presentation by the Dossier Submitter. Then, for the June meeting, the detailed recommendations for the Dossier Submitter

will be presented and stakeholders will have an opportunity to make statements/declare their positions. He further noted that the first draft opinion is expected to be ready for September.

Looking forward to RAC-65 in June, the Chair informed that ECHA will host the regular session of the Scientific Committee on Consumer Safety the SCCS, which will run in parallel with our meeting. To mark this special occasion, ECHA will provide an opportunity for scientific exchange between the members of the two Committees. The Chair then wished the participants a successful and productive meeting.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/64/2022**) was adopted without amendment.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-64 minutes.
4. Appointment of (co-)rapporteurs	
4.1 Appointment of (co-)rapporteurs for CLH 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 occupational exposure limit (OEL) 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 for 2023.	
6. Request under Article 77(3)(c)	
There were no items tabled.	
7. Health based exposure limits at the workplace	
7.1.1 1,2-dichloropropane – first draft opinion	
The Chair informed that the Commission had requested ECHA to evaluate, **1,2-dichloropropane** in accordance with the Directive 2004/37/EC. The ECHA scientific report was	

open for comments from 19 October until 19 December 2022 and the deadline for this request is 22 February 2024.

The Rapporteur presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for 1,2-dichloropropane. RAC agreed with the assessment of 1,2-dichloropropane, as proposed in the draft opinion: OEL as 8-hour TWA: None RAC agreed to propose no BGV, BLV and STEL. RAC agreed to propose a "Skin" notation. RAC agreed on the cancer exposure-risk relationship (ERR) as presented in the opinion. The Rapporteur was asked to specifically point out the uncertainties related to human cancer findings versus the exposure response relationship calculations based on animal data (and also to explain these uncertainties in the Summary section of the Opinion). RAC adopted by consensus its opinion (with the modifications agreed at RAC-64).	**Rapporteur** to revise the opinion in accordance with the agreed modifications in RAC-64 and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur and to ensure that the Annex and the RCOM are in line with the adopted opinion. **SECR** to organise a RAC consultation on the draft final RAC opinion after RAC-64. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

7.1.2 1,2,3-trichloropropane – first draft opinion

The Chair informed that the Commission had requested ECHA to evaluate, **1,2,3-trichloropropane** in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 19 October until 19 December 2022 and the deadline for this request is 22 February 2024.

The Rapporteur presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for 1,2,3-trichloropropane. RAC agreed with the assessment of 1,2,3-trichloropropane, as proposed in the draft opinion: OEL as 8-hour TWA: None RAC agreed to propose no BGV, BLV and STEL.	**Rapporteur** to revise the opinion in accordance with the agreed modifications in RAC-64 and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur and to ensure that the Annex and the RCOM are in line with the adopted opinion. **SECR** to organise a RAC consultation on the draft final RAC opinion after RAC-64.

RAC agreed to propose a "Skin" notation. RAC agreed to present a cancer exposure-risk relationship (ERR). The Rapporteur was asked to update the ERR and use the median values of the four data sets. RAC adopted by consensus its opinion (with the modifications agreed at RAC-64).	**SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

8. Harmonised classification and labelling (CLH)

8.1.1. Renewal of the RAC CLH WG mandate

The Secretariat presented the renewal of the RAC CLH Working Group mandate (meeting document RAC/64/2023/01). No changes were proposed to the current mandate.	**SECR** to publish the renewed mandate on the ECHA website.

8.1.2 Report from the January 2023 RAC CLH WG

The Secretariat presented the Report of the 8th Meeting of the Committee for Risk Assessment Working Group on CLH held on 23-26 January 2023. The 9th Meeting of the RAC Working Group on CLH will be held on 24-28 April 2023.	

8.2 CLH dossiers

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

- 2-ethylhexanoic acid, monoester with propane-1,2-diol: *reproductive toxicity*
- 2-phenylpropene: *skin sensitisation, Note D, STOT RE, carcinogenicity*
- Aqueous extract from the germinated seeds of sweet *Lupinus albus*: *all hazard classes*
- *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide: *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, aquatic toxicity, hazard to the ozone layer*
- *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents: *physical*

hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, aquatic toxicity, hazard to the ozone layer

- *N*-1-naphthylaniline; *N*-phenylnaphthalen-1-amine: *acute toxicity (oral and dermal routes of exposure), STOT SE, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT RE*
- Pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide: *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, respiratory sensitisation, STOT SE, STOT RE, mutagenicity, reproductive toxicity, aquatic toxicity, hazard to the ozone layer*
- Tetrairon tris(pyrophosphate); ferric pyrophosphate: *all hazard classes*
- Tetraphosphorus trisulphide; phosphorus sesquisulphide: *physical hazard (except for Explosives and Self-reactive substances), aquatic toxicity*
- α,α'-propylenedinitrilodi-*o*-cresol: *mutagenicity, reproductive toxicity*
- Ozone: *carcinogenicity, SCLs for STOT SE and STOT RE*
- *Propyl 4-hydroxybenzoate: reproductive toxicity*
- *Dinitrogen oxide: STOT SE, STOT RE, reproductive toxicity*

8.2.2. Hazard classes for agreement with plenary debate

8.2.2.1. 2-phenylpropene (EC: 202-705-0; CAS: 98-83-9)

The Chair welcomed the Dossier Submitter representative and an expert accompanying the CEFIC Regular Stakeholder Observer. He informed that **2-phenylpropene** is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance has current Annex VI entry as Flam. Liq. 3; H226, Eye Irrit. 2; H319, STOT SE 3; H335 (C ≥ 25 %) and Aquatic Chronic 2; H411.
The DS (DE) proposes to add Carc. 2; H351, Skin Sens. 1B; H317 and note D.
Skin sensitisation, germ cell mutagenicity, carcinogenicity and STOT RE were the hazard classes open for comments in the Consultation.
The deadline for the adoption of an opinion is 17 September 2023.

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Skin Sens. 1B; H317, Carc. 2; H351, Note D] RAC agreed on no classification for mutagenicity.	**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 Rapporteur. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

8.2.2.2. Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide (EC: 289-699-3; CAS: 89997-63-7)

The Chair welcomed the Dossier Submitter representatives, an expert accompanying the AISE Regular Stakeholder Observer, an expert accompanying the CropLife Regular Stakeholder Observer, an expert accompanying the CEFIC Regular Stakeholder Observer, as well as two observers from EFSA. He informed that *chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical CO_2 or hydrocarbon solvents, is intended to be used as insecticide against a wide range of flying and crawling pests except those that are plant parasitic, in various applications, sites in- and outdoor. Within the current CLH dossier the use against flies and mosquitoes is intended. The substance is a biocidal active substance, but also a PPP active substance under the name pyrethrins. The substance has no current Annex VI entry. The DS (ES) proposes to classify the substance as Acute Tox. 4; H332 (ATE=700 mg/kg bw), Acute Tox. 4; H332 (ATE=2.5 mg/L (dusts and mists)), Skin Sens. 1B; H317, Aquatic Acute 1; H400 (M=100) and Aquatic Chronic 1; H410 (M=10). Relevant physical hazards (explosives, flammable liquids, self-reactive substances, pyrophoric liquids, substances which in contact with water emit flammable gases, oxidising liquids, organic peroxides, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, hazardous to the aquatic environment and hazardous to the ozone layer were the hazard classes open for comments in the Consultation. The deadline for the adoption of an opinion is 31 August 2023.	
RAC agreed on the following classification: [Acute Tox. 4; H302 (ATE=730 mg/kg bw), Acute Tox. 4; H332 (ATE=2.6 mg/L (dusts and mists)), Skin Sens. 1; H317, Aquatic Acute 1; H400 (M=1000), Aquatic Chronic 1; H410 (M=100)] *STOT SE* RAC provisionally agreed to classify the substance as STOT SE 1; H370 (nervous system). In relation to the classification for STOT SE 3; H335, some RAC members were of the opinion that the observed respiratory irritation might merit classification for STOT RE rather than STOT SE 3. The rapporteur was asked to look at the data again, if there would be more indications of the human data (effect types, repeated exposure). This discussion will be finalised at the RAC-65 CLH WG. Industry was asked to provide the human surveillance data referred to in their invervention. *STOT RE*	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to organise the RAC consultation on the pending HH hazard classes (mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and aspiration hazard) and to table the opinion for further discussion at RAC-65 CLH WG and RAC-65.

RAC provisionally agreed on no classification for STOT RE for neurotoxicity. RAC agreed to discuss the respiratory effects further at RAC-65 CLH WG (see STOT SE). *Mutagenicity* RAC provisionally agreed on no classification. *Carcinogenicity* RAC provisionally agreed on no classification. *Reproductive toxicity* RAC provisionally agreed on no classification for fertility and development and for effects on or via lactation. *Aspiration hazard* RAC provisionally agreed on no classification.	
The expert accompanying the CropLife Regular Stakeholder commented on STOT SE, STOT RE and carcinogenicity.	

8.2.2.3. Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents (EC: 289-699-3; CAS: 89997-63-7):

The Chair welcomed the Dossier Submitter representatives, an expert accompanying the AISE Regular Stakeholder Observer, an expert accompanying the CropLife Regular Stakeholder Observer, an expert accompanying the CEFIC Regular Stakeholder Observer, as well as two observers from EFSA. He informed that *chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical CO_2 or hydrocarbon solvents, is intended to be used as insecticide against a wide range of flying and crawling pests except those that are plant parasitic, in various applications, sites in- and outdoor. Within the current CLH dossier the use against flies and mosquitoes is intended. The substance is a biocidal active substance, but also a PPP active substance under the name pyrethrins. The substance has no current Annex VI entry. The DS (ES) proposes to classify the substance as Acute Tox. 4; H332 (ATE=700 mg/kg bw), Acute Tox. 4; H332 (ATE=2.5 mg/L (dusts and mists)), Skin Sens. 1B; H317, Aquatic Acute 1; H400 (M=100) and Aquatic Chronic 1; H410 (M=10). Relevant physical hazards (explosives, flammable liquids, self-reactive substances, pyrophoric liquids, substances which in contact with water emit flammable gases, oxidising liquids, organic peroxides, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, hazardous to the aquatic environment and hazardous to the ozone layer were the hazard classes open for comments in the Consultation. The deadline for the adoption of an opinion is 31 August 2023.	
RAC agreed on the following classification:	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat.

[Acute Tox. 4; H302 (ATE=730 mg/kg bw), Acute Tox. 4; H332 (ATE=2.6 mg/L (dusts and mists)), Skin Sens. 1; H317, Aquatic Acute 1; H400 (M=1000), Aquatic Chronic 1; H410 (M=100)] *STOT SE* RAC provisionally agreed to classify the substance as STOT SE 1; H370 (nervous system). In relation to the classification for STOT SE 3; H335, some RAC members were of the opinion that the respiratory irritation might merit classification for STOT RE rather than STOT SE 3. Rapporteur was asked to have a look at the data again, if there would be more indications of the human data (effect types, repeated exposure). The discussion on this will be finalised at the RAC-65 CLH WG. The Industry was asked to provide the human surveillance data. *STOT RE* RAC provisionally agreed on no classification for STOT RE for neurotoxicity. RAC agreed to discuss the respiratory irritation further at the RAC-65 CLH WG (see STOT SE). *Mutagenicity* RAC provisionally agreed on no classification. *Carcinogenicity* RAC provisionally agreed on no classification. *Reproductive toxicity* RAC provisionally agreed on no classification for fertility and development and for effects on or via lactation. *Aspiration hazard* RAC provisionally agreed on no classification.	**Secretariat** to organise the RAC consultation on the pending HH hazard classes (mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and aspiration hazard) and to table the opinion for further discussion at RAC-65 CLH WG and RAC-65.
The expert accompanying the CropLife Regular Stakeholder commented on STOT SE, STOT RE and carcinogenicity.	
8.2.2.4. Dinitrogen oxide (EC: 233-032-0; CAS: 10024-97-2)	

The Chair welcomed an expert accompanying the CEFIC Regular Stakeholder Observer and an observer from EFSA. He informed that **dinitrogen oxide** has been used for more than 150 years in surgery, as an adjuvant in inhalational general anaesthesia. N_2O is also an industrial chemical used as a food additive (E942). Furthermore, N_2O is a propellant in canister used in many preparations and uses (e.g. aerate whipping cream, inflate balloons). It is also an additive to rocket fuels to increase available oxygen for combustion. In addition, N_2O is used in laboratory as an oxidizing agent in atomic flame absorption spectrometry. The substance has no current Annex VI entry.
The DS (FR) proposes to classify the substance as Repr. 1B; H360Df, STOT RE 1; H372 (nervous system), STOT SE 3; H336, Ozone 1; H420.
Reproductive toxicity, STOT SE, STOT RE and hazardous to the ozone layer were the hazard classes open for the Consultation.
The deadline for the adoption of an opinion is 25 October 2023.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Repr. 1B; H360Df, STOT SE 3; H336, STOT RE 1; H372 (nervous system), Ozone 1; H420]	**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.

The expert accompanying the CEFIC Regular Stakeholder commented on the hazard to the ozone layer.

8.2.2.5. Pethoxamid (ISO); 2-chloro-N-(2-ethoxyethyl)-N-(2-methyl-1-phenylprop-1-enyl)acetamide (EC: - ; CAS: 106700-29-2): carcinogenicity

The Chair welcomed the Dossier Submitter representative and an expert accompanying the CropLife Regular Stakeholder Observer. He noted that **pethoxamid** is intended to be used as a pre-emergence herbicide in soybeans and both a pre-emergence and early postemergence herbicide in maize for the control of mono and dicotyledonous weeds. Pethoxamid, is a member of the chemical class of the chloroacetamides. The substance has a current Annex VI entry as Acute Tox. 4*; H302, Skin Sens. 1; H317, Aquatic Acute 1; H400 (M=100) and Aquatic Chronic 1; H410.
The DS (AT) proposes to modify Acute Tox. 4; H302 (ATE=983 mg/kg bw), Skin Sens. 1A; H317 and to retain Aquatic Acute 1; H400 (M=100) and Aquatic Chronic 1; H410 (but to add M=10).
Relevant physical hazards (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 via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment and hazardous to the ozone layer were the hazard classes open for comments during the Consultation.
The deadline for the adoption of an opinion is 10 September 2023.

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=980 mg/kg bw), Skin Sens. 1A; H317, Aquatic Acute 1; H400 (M=100), Aquatic Chronic 1; H410 (M=10)] RAC agreed on no classification for carcinogenicity.	**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.
The expert accompanying the CropLife Regular Stakeholder commented on carcinogenicity.	

8.2.2.6. Tetraphosphorus trisulphide; phosphorus sesquisulphide (EC: 215-245-0; CAS: 1314-85-8)

The Chair welcomed the DS representative and informed that **tetraphosphorus trisulphide; phosphorus sesquisulphid** is an inorganic compound whose main and only application is in the industry of "strike anywhere" matches, where it totally replaced white and yellow phosphorus that were formerly used in the 19th century. The substance has a current Annex VI entry as Flam. Sol. 2; H228, Water-react. 1; H260, Acute Tox. 4*; H302, Aquatic Acute 1; H400 and Note T.
The DS (IT) proposes to modify Flam. Sol. 1; H228, to add Self-heating Sol. 1; H251, to retain Note T and to remove Water-react. 1; H260 and Aquatic Acute 1; H400.
Relevant physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals) and hazardous to the aquatic environment were the hazard classes open for the Consultation.
The deadline for the adoption of an opinion is 22 October 2023.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Flam. Sol. 1; H228, Self-heat. 1; H251, Note T]	**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 Rapporteur. **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. Renewal of the RAC RESTR WG mandate

The Secretariat presented and RAC agreed on the renewal of the mandate of the RAC Working Group (meeting document RAC/64/2023/03). No changes were proposed to the current mandate.	**SECR** to publish the renewal of the Mandate on the ECHA website.
9.1.2. Report from the February Restriction Working Group	
RAC took note of the Report of the 8th meeting of the Committee for Risk Assessment Working Group on restrictions held on 14-16 February 2023 (meeting document RAC/64/2023/04). **NOTE: the RAC-65 Working Group on restrictions (10-11 May 2023) will be cancelled.**	**SECR** to table the relevant restriction dossiers for discussion and adoption at RAC-65 plenary in June 2023.
9.2. Restriction Annex XV dossiers	
9.2.1. Conformity check and key issues discussion	
9.2.1.1. Universal PFAS (UPFAS)	
The Chair welcomed the dossier submitter representatives from Denmark, Germany, Netherlands, Norway and Sweden, as well as the occasional stakeholder observers from EPEE, HEAL, ORO, EUROFEU and CHEM Trust and the regular stakeholder observers together with their accompanying experts to Cefic, PlasticsEurope, Eurometaux, CropLIfe Europe, A.I.S.E, MedTech Europe and EEB. The dossier has been submitted in January 2023 and concerns on restricting manufacture, placing on the market and use of PFAS i.e. universal PFAS (UPFAS). The restriction covers the entire PFAS class.	
RAC agreed that the dossier conforms to the Annex XV requirements: → Proposed restriction → Information on hazards and risks → Information on alternatives → Justification that action is required on an EU-wide basis → Justification that the restriction is the most appropriate EU-wide measure → Information on stakeholder consultations	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC. **Rapporteurs** to present the key issues and recommendations to the Dossier Submitter at RAC-65. **Interested stakeholder observers** are invited to register their written position statements for RAC-65 in advance.

The accompanying expert to the regular stakeholder observer from PlasticsEurope asked for clarification on how the discussions will be divided between the working groups and the plenary meetings.

9.2.2. Opinion development

9.2.2.1. Creosote, and creosote related substances – first draft opinion

The Chair welcomed the Dossier Submitter's representatives from France, the regular stakeholder observers from Cefic with their accompanying expert. The restriction proposal was submitted in October 2022 and aims at reducing health and environmental risks associated with the reuse and second-hand use of wood treated with creosote (CAS 8001-58-9, EC 232-287-5) and creosote-related substances.

Based on the recommendations of the Restriction Working Group which met on 14-16 February, RAC-64 agreed on the: • Scope of the risk assessment • Hazard(s) • Evaluation of emissions • Existing operational conditions (OCs) and risk management measures (RMMs) • Risk characterisation	**Rapporteurs** to prepare the second draft opinion, taking into account the outcome of the third party consultation, and the discussions in the RAC-64 Working Group on restrictions and at RAC-64 plenary. **Secretariat** to table the next draft opinion for discussion at RAC-66 REST WG/RAC-66 in August/September 2023.

No interventions by stakeholder observers were made.

9.2.2.2. BPA+ - first draft opinion

The Chair welcomed the Dossier Submitter's representatives from Germany and the occasional stakeholders from CHEM Trust, EDANA, EURATEX and EUPC and the regular stakeholders, including the accompanying experts to the regular (CEFIC, EEB, EUROMETAUX, PlasticsEurope) stakeholders.

The participants were informed that the restriction dossier had been submitted in October 2022 and relates to the placing on the market of mixtures and articles where the concentration is equal to or greater than 10 ppm (0.001 % by weight) with several derogations.

Based on the recommendations of the Restriction Working Group which met on 14-16 February, RAC-64 agreed that: The scope of the risk assessment is clear and is justified in sufficient detail. Hazards → Bisphenols with ED ENV properties should be provisionally treated as non-threshold substances for the purpose of risk assessment, subject to further scrutiny of the additional information provided via the third party	**Rapporteurs** to prepare the second draft opinion, taking into account the discussion the RAC-64 Working Group on restrictions and the discussions at RAC-64 plenary. **Secretariat** to table the next opinion for discussion at RAC66 REST WG/RAC-66 in August/September 2023.

consultation → RAC considers that this conclusion would reasonably apply to all bisphenols that in the future may be classified as ED for the environment Risk characterisation → Emissions of BPA and bisphenols of similar concern (BoSC) are a suitable proxy of risk to the environment (provisional conclusion) It was furthermore agreed that the following will need further clarification and/or scrutiny → Release estimates: Dossier Submitter answers to several clarifying questions on emissions (incl. excel) due on 17 March → the concentration limits for the different derogations → The provisional conclusion on lack of an ED threshold: further scrutiny of the additional information provided via the third-party consultation.	
The occasional stakeholder observer from ChemTrust commented on non-treshold nature of hazards, and the accompanying experts to PlasticsEurope, Cefic, and EEB commented on releases and emission estimates.	
9.2.2.3. Medium chain chlorinated paraffins (MCCP) – second draft opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA, the occasional stakeholder from EUPC as well as the accompanying expert to the Cefic regular stakeholder observer (Inovyn). The dossier has been submitted in July 2022 and concerns restricting the manufacture, use and placing on the market of substances, mixtures and articles containing C14-17 chloroalkanes with PBT- and/or vPvB-properties.	
Based on the recommendations of the Restriction Working Group which met on 14-16 February, RAC-64 agreed that: Action required on EU wide basis: → any necessary action to address the identified risks should be implemented at an EU wide level. Risks of alternatives: → Some available alternatives seem to have a better hazard profile than the substances to be restricted, from a	**Rapporteurs** to prepare the third draft opinion, taking into account the outcome of the third party consultation, the discussions in the RAC-64 Working Group on restrictions and at RAC-64 plenary. **SECR** to table the third draft opinion for discussion and adoption at RAC-65 plenary inJune 2023. **Stakeholders** to submit additional information on the challenges of

human health and an environmental perspective. → The Dossier Submitter's assessment of risks of alternatives, based on their human health and environmental concerns, poses no major shortcomings or uncertainties related to the methodology used. Most appropriate EU wide measure: → The proposed restriction is the most appropriate risk management measure for 'CA:C14-17 with PBT and/or vPvB properties'. → The other, mainly higher chlorinated vP congeners are considered to present similar risks to those having PBT and/or vPvB properties and are present as constituents in the same substances as 'CA:C14-17 with PBT and/or vPvB properties', thus the restriction measure should consider all congeners of concern. → Effectiveness: the restriction is targeted to the effects or exposures that cause the risks identified, capable of reducing these risks within a reasonable period of time and proportional to the risk posed by CA:C14-17 in substances, mixtures and articles. → Practicality and monitorability: the restriction is in general implementable, enforceable, practical and manageable. It is also monitorable.	manufacturing congeners via the third-party consultation on the Annex XV dossier.
The expert accompanying the Cefic regular stakeholder observer commented on the practicalities noting that the manufacture of congeners with only a high level of chlorination is a hypothetical scenario only.	
9.2.2.4. Terphenyl, hydrogenated – third draft opinion	
The RAC Chair welcomed the Dossier Submitter's representative from Italy and the expert accompanying CEFIC. The chair informed the participants that the restriction dossier had been submitted in April 2022 and concerns the restriction of the placing on the market and use of terphenyl, hydrogenated.	
The Rapporteurs presented and RAC discussed the revised draft opinion with changes based on comments provided by the members and	**Rapporteurs** to revise the opinion in accordance with the agreed modifications in RAC-64 and to provide it to SECR.

the remaining open topics from the working group: • RAC agreed that currently no suitable alternatives to terphenyl, hydrogenated exist for the HTF use, but notes that the assessment is mainly based on the information provided by the DS. • RAC agreed that the derogation proposed by the DS for aerospace and defense applications cannot be supported. • RAC agreed that the derogation proposed by the DS for thermostats cannot be supported. • RAC agreed with the conclusions of the rapporteurs on the analytical methods and, in particular, that standard methods need to be developed further. • RAC supported the recommendations from the Working Group and adopted its opinion (with modifications agreed at RAC-64) by consensus.	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs and to ensure that the Annex and the RCOM are in line with the adopted opinion. **SECR** to forward the adopted opinion to COM and publish it on the ECHA website.
The DS and the expert accompanying CEFIC commented on the time limited HTF derogation.	
9.2.2.5. N,N-dimethylacetamide and 1-ethylpyrrolidin-2-one – third draft opinion	
The RAC Chair Tim Bowmer welcomed the Dossier Submitter's representative from the Netherlands. He also welcomed the regular CEFIC and MedTech Europe stakeholders including their accompanying experts. The chair informed the participants that the restriction dossier had been submitted in April 2022 and concerns occupational exposure to DMAC and NEP and proposes harmonised DNELs for workers.	
Based on the recommendations of the Restriction RAC-64 Working Group which met on 14-16 February 2023, RAC adopted its opinion by consensus.	**The rapporteurs,** together with **SECR,** to do the final editing of the adopted RAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.
No interventions by stakeholder observers were made.	
9.2.2.6. PFAS in fire-fighting foams (PFAS-FFF) – third draft opinion	

The RAC Chair Tim Bowmer welcomed the Dossier Submitter's representatives from ECHA and their invited experts. The Chair also welcomed the regular stakeholders from CropLife Europe, Cefic, Eurometaux, PlasticsEurope and EEB including their accompanying experts. He further welcomed the occasional stakeholder from Eurofeu and their accompanying expert. He informed the participants that the restriction dossier had been submitted in January 2022 and concerns PFAS in firefighting foams.	
Based on the recommendations of the Restriction RAC-64 Working Group which met on 14-16 February 2023, RAC agreed the following issues: **Hazard assessment** - not to include an assessment of fluoropolymers and fluorinated gases as this could not be robust enough in the context of this proposed restriction. **Effectiveness** - to introduce an additional condition into paragraph 4(d) and 6 that refers specifically to waste from cleaning (without the word "routine") and sets a concentration limit of 1 mg/L for waste from cleaning. - to introduce a reworded condition into paragraph 4(d) and 5 to specify biological wastewater treatment and an incineration temperature of 1 100C for adequate treatment. - to remove the recommendation for investigating a return and reuse scheme. **Practicality** - to introduce a reworded condition into paragraph 6 to clarify that cleaning waste is included in the scope. - to introduce an additional condition into paragraph 6 that sets a concentration limit of 1 mg/L for waste from cleaning. **Monitorability** - to include a recommendation for reporting by formulators during the transitional period. - to ask SEAC to evaluate the aforementioned reporting.	**The rapporteurs,** together with **SECR,** to do the final editing of the adopted RAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.

RAC supported the recommendations from the Working Group and adopted its opinion by consensus.	
Members, the Commission, the Dossier Submitter (ECHA), a regular stakeholder (CropLife Europe) and accompanying experts to regular stakeholders (Cefic, EEB) and to the Dossier Submitter (ECHA) commented on effectiveness. Members, the Commission and the Dossier Submitter (ECHA) also commented on practicality and monitorability.	
10. Authorisation	
10.1. General authorisation issues	
10.1.1 Report from the January/February AFA Working Group	
The Secretariat presented the Report of the 14th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group which took place on 31 January - 1 February 2023. RAC took note of the Report.	
10.1.2Report from the October AFA Working Group	
The ECHA Secretariat presented information on: - AfAs and Review Reports pipeline - Reminder Opinion-making: streamlining - RAC Lines-To-Take - Group TIS (teleconference based information session) RAC discussed: - topics discussed with potential applicants during the Group TIS - the purpose of Key issues presentations.	**SECR** to upload the latest version of the RAC Lines-To-Take document on the S-CIRCABC.
10.2. Discussion on key issues	
No cases under this agenda item (November 2022 submission window AfAs will be presented at RAC-65 plenary meeting in June 2023).	
10.3. Agreement on draft opinions	
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) 275_CT_Sicrom (1 use) 2) 276_CT_Osmaplast (2 uses) 3) 278_RR1_Diglyme_Isochem (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

4) 279_CT_GalvanoPlus (1 use) 5) 282_CT_Hazet_Werk (1 use) 6) 284_CT_CGS (1 use) RAC agreed by consensus the 7 draft opinions on the Application listed in Annex IV.	
Draft opinions for discussion and agreement	
273_CT_MikroMetal (1 use)	
Use1: *Electroplating of different types of substrates using Chromium Trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications.* 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 • The applicant shall implement, without delay, [technical] improvements on the OCs/RMMs at the manual line to minimise the exposure to Cr(VI) and eliminate the overreliance on RPE. [These shall be implemented within 12 months and be followed by a measurement campaign to validate the effectiveness of the applied technical improvements.] • The applicant shall install without delay a continuous flow control device connected at the LEV of all plating lines, as indicated in the response to RAC's questions. This control will activate an alarm system in case of a decrease and/or stopping of the suction flow. • The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure. b) the implementation of a automatic and closed system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths. The feasibility study shall be concluded within 12 months of the granting of an authorisation	**Rapporteur** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary. **SECR** to send the draft opinions to the applicants for commenting.

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 opinion by consensus.	
274_CT_SD_ArcelorMittal (2 uses)	
Use1: *Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP)* RAC discussed: - adjustment of the conditions concerning the quality of the air intake Regarding the exposure to Cr(VI) associated with use of chromium trioxide and sodium dichromate, RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. Regarding the reproductive hazards associated with the use of Sodium dichromate, RAC concluded that the risk assessment presented in the application demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the application are adhered to. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall implement technical measures to stop addition of solid CT pellets at Basse-Indre and Etxebarri by the end of 2024. 2. In the event that T8 (Dissolution of solid CT/SD) is undertaken at any site during the review period, the applicant shall implement	**Rapporteur** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary. **SECR** to send the draft opinions to the applicants for commenting.

appropriate OC/RMMs to reduce workplace exposure to Cr(VI) in addition to those proposed in the CSR. As a minimum, the following RMMs shall be implemented: - Install a local exhaust ventilation system or an air extraction system to reduce dust generation during dissolution of solid CT/SD. - Restrict access to the area where the dissolution will take place. - Ensure operators that carry out the activity are trained in how to minimise exposure. - Monitor exposure of the operators by air monitoring and biomonitoring. The potential for exposure shall be brought to as low a level as technically and practically feasible prior to commencement of the activity. 3. The applicant shall carry out and document a detailed feasibility study at all sites on: • 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 vacuum removal of sludge at all sites and the use of LEV in the interim. 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. 4. The applicant shall conduct a root cause analysis for the elevated release factor to air at Basse-Indre within three months of the granting of an authorisation for this use. Following this analysis, the applicant shall implement immediately appropriate actions to improve the efficiency of the applied OCs and RMMs at the site for air release control, implementing additional RMMs if required. 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 a similar magnitude or lower than in the other sites is achieved. 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:** *Use of Chromium (VI) Trioxide for Electrolytic Chromium Coating of Steel (ECCS); also known as Tin Free Steel (TFS)* 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. In the event that T8 (Dissolution of solid CT) is undertaken in Basse-Indre, during the review period, the applicant shall implement appropriate OC/RMMs to reduce workplace exposure to Cr(VI) in addition to those proposed in the CSR. As a minimum, the following RMMs shall be implemented: - Install a local exhaust ventilation system or an air extraction system to reduce dust generation. - Restrict access to the area where the dissolution will take place. - Ensure operators that carry out the activity are trained in how to minimise exposure. - Monitor exposure of the operators by air monitoring and biomonitoring. The potential for exposure shall be brought to as low a level as technically and practically feasible prior to commencement of the activity. 2. 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, in both sites.	

b. the substitution of solid CrO_3 flakes by liquid solutions of CrO_3, or if not feasible, pellets, to further limit exposure in Etxebarri. 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. 3. The applicant shall conduct a root cause analysis for the elevated release factor to air at Basse-Indre within three months of the granting of an authorisation for this use. Following this analysis, the applicant shall implement immediately appropriate actions to improve the efficiency of the applied OCs and RMMs at the site for air release control, implementing additional RMMs if required. Control measurements shall be conducted to confirm the impact of any action. The "control measurement – analysis – action" cycle shall be continued to reduce these releases to as low a level as technically and practically feasible. 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 opinions by consensus.	
277_CT_Ritmonio (1 use)	
Use1: *Chromium trioxide-based functional chrome plating of machine components for centrifugal separator and decanter centrifuges.* RAC discussed: - additional conditions for the authorisation that the applicant shall carry out and document a detailed feasibility study on segregation between the	**Rapporteur** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary. **SECR** to send the draft opinions to the applicants for commenting.

loading/unloading areas taking into consideration measurements below LoD. 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 substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure. b) the implementation of a closed/automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths c) the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen d) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s), in case the local exhaust ventilation is not functioning properly The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation. 1. The applicants 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(IV) 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 conduct air emission measurements at least annually or more frequently following any possible changes in the process; (ii) the monitoring programmes for air emissions shall: a) be based on relevant standard methodologies or protocols; and b) be representative of the OCs and RMMs used at the applicant's site. c) ensure a sufficiently low limit of quantification. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the OCs and RMMs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the studies and monitoring programmes referred to in	

paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans (i.e. workers and general population) has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers and HvE at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers and HvE continues to be reduced to as low a level as technically and practically possible. 7. The applicant shall continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9: recommendations for the review report as given in Annex IV Table 2. RAC agreed the opinion by consensus.	
280_CT_Tecnocrom_Industrial (2 uses)	
Use1: *Functional chrome plating of parts with at least one axis of symmetry and simple surface geometry* **Use2:** *Functional chrome plating of parts with complex surface geometry and requiring the use of an auxiliary anode.*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary. **SECR** to send the draft opinions to the applicants for commenting.

RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk, provided that they are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall implement without undue delay, technical improvements to the OCs and RMMs at the manual plating lines, 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. 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. 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 11 sites) to further limit exposure, (b) the implementation of an automated system to perform the bath concentration adjustment (at 11 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 1. The applicant shall continue to implement the following monitoring programmes for Cr(VI), at all 14 sites: a) Occupational inhalation exposure monitoring programme which shall: i. be conducted at least annually for the workers exposed to Cr(VI). The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI). 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 annual monitoring programme for Cr(VI) emission to wastewater. ii. the applicant shall conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process. iii. the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols, b. be representative of the OCs and RMMs used at the applicant's site, c. ensure a sufficiently low level of quantification.	

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the OCs and RMMs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their sites is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans (i.e. workers and general population) has been reduced to as low a level as technically and practically possible and that the OCs and RMMs corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5 any subsequent changes to the OCs or RMMs that may affect the exposure of workers and humans via environment at each of the sites where the use takes place shall be	

documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers and humans via environment continues to be reduced to as low a level as technically and practically possible. 7. The applicant shall continue the existing annual biomonitoring programmes for the workers potentially exposed to Cr(VI). This programme must consist, as a minimum, of pre- and post-shift urine samples (beginning of the week --> end of the week), using valid existing standard methodologies such as e.g. HSE, HBM4EU. This annual biomonitoring programme must be synchronised with the annual occupational air monitoring campaign specified in 1.a above. The results of the biomonitoring programme can be reported following the "Format for reporting of occupational exposure data by downstream users", in the respective Excel sheet for biomonitoring, as it can be found on the ECHA homepage. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC agreed the opinions by consensus.	
281_CT_Electro_Durocrom (1 use)	
Use1: *Industrial use of chromium trioxide for the hard chromium plating of moulds, dies and custom-made finished parts on any metal base, in order to provide hardness, wear resistance, corrosion resistance, demoulding properties, low friction ratio, for the manufacture of high-quality metal parts in several sectors as automotive, pharmaceutical, food and packaging industries* 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. RAC concluded that the OCs and RMMs related to environmental release minimisation are	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary. **SECR** to send the draft opinions to the applicants for commenting.

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 additional OCs and RMMs, such as segregation (e.g. reconfiguration/redesign) of the chrome plating area from other work areas to avoid that loading and unloading activities are performed in the vicinity of the plating baths and remote operations of hoists to reduce presence of workers in proximity of plating baths. The implementation of these additional measures complies with the hierarchy of control principles. The additional OCs and RMMs shall be implemented without undue delay 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 (WCS 2) 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. 3. Without prejudice to points 1 and 2 above, 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 all across the sites and reviewed during the review period. Section 8: monitoring arrangements for the authorisation	

1. The applicant shall implement the following monitoring programmes for Cr(VI): a) Occupational inhalation exposure monitoring programme, which shall: i. be conducted *within 6 months of the granting of an authorisation on this use, and at least annually afterwards,* for the workers exposed to Cr(VI). The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI). ii. be based on relevant standard methodologies or protocols. iii. ensure a sufficiently low limit of quantification with which to assess minimisation of emissions. iv. comprise personal and 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 conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process. ii. the monitoring programmes for air emissions shall: a. be based on relevant standard methodologies or protocols. b. be representative of the OCs and RMMs used at the applicant's site. c. ensure a sufficiently low level of quantification. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the OCs and RMMs in place and, if needed, to introduce measures to further reduce workplace exposure to	

Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans (i.e. workers and general population) has been reduced to as low a level as technically and practically possible and that the OCs and RMMs corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5 any subsequent changes to the OCs or RMMs that may affect the exposure of workers and humans via environment at the site where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers and humans via environment continues to be reduced to as low a level as technically and practically possible.	

7. The applicant shall adapt and continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI). This programme must consist, as a minimum, of pre and post shift urine samples (beginning of the week --> end of the week), valid existing standard methodologies are e.g. HSE, HBM4EU, etc. This annual biomonitoring program must be synchronised with the annual occupational air monitoring campaign specified in 1.a above. Section 9: recommendations for the review report The results of the actions as mentioned in section 7 and the measurements referred to in section 8.1, the conclusions from the investigation on the source of measured concentration of Cr(VI) in wastewater referred in section 2.5, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1, should be documented and included in any subsequent authorisation review report. RAC agreed the opinion by consensus.	
283_CT_KYB (1 use)	
Use1: *Functional chrome plating of piston rods for shock absorbers for automotive applications.* RAC discussed: - concerns related to reliance on the RPE - concerns regarding emissions to env at KYBSE - additional conditions for the authorisation. RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk at the Pardubice site, provided that they are adhered to. RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk to the workers but not	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary. **SECR** to send the draft opinions to the applicants for commenting.

appropriate and effective in limiting the risk to the general population at the Ororbia site. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall align the RPE used at the KMCZ Pardubice site with that used at the KYBSE site to ensure the best protection level for the workers and consistency between the two sites. 2. The applicant shall continue to carry out and document a detailed feasibility study on the implementation of a closed/automated system to perform bath sampling tasks (at KYBSE Ororbia site), 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. 3. The applicant shall take further action related to the air emissions of the KYSBE site: • At the latest within three months of the granting of an authorisation for this use, the applicant shall conduct a measurement campaign on all emission points for emissions of Cr(VI) to air at the KYBSE site. This campaign shall be conducted in accordance to section 8.1, paragraph 1.b)iii. • The applicant shall carefully analyse the results of the measurement campaign and recalculate the release factor for the air of the KYBSE site. ○ A release factor of a same level of magnitude or lower than the one derived for the KMCZ site shall be achieved; ○ If the release factor is not of the same order of magnitude or lower than for KMCZ, the applicant shall conduct a root cause analysis for the difference and implement immediately appropriate	

actions to improve the situation in terms of achieving a higher level of efficiency of the applied OCs and RMMs at the site for air release control. If necessary, additional RMMs shall be implemented to further reduce these releases to as low a level as technically and practically feasible. ○ Control measurements shall be conducted to confirm the impact of any action. The "control measurement – analysis – action" cycle shall be continued until a release factor of the same level of magnitude or lower than KMCZ is achieved. All of the actions taken shall be reviewed during the review period. Section 8: monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programmes for Cr(VI) at both sites: a. Occupational inhalation exposure monitoring programme which shall: i. be conducted at least annually for the workers exposed to Cr(VI). The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI). 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, notwithstanding the monitoring requirements included in section 7.1:	

i. the applicant shall continue conducting their annual monitoring programme for Cr(VI) emission to wastewater. ii. the applicant shall conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process. iii. the monitoring programmes for wastewater and air emissions shall: a) be based on relevant standard methodologies or protocols. b) be representative of the OCs and RMMs used at the applicant's site. c) ensure a sufficiently low level of quantification. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the OCs and RMMs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of	

the Member State where the use takes place, that exposure of humans (i.e. workers and general population) has been reduced to as low a level as technically and practically possible and that the OCs and RMMs corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5 any subsequent changes to the OCs or RMMs that may affect the exposure of workers and humans via environment at the site where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers and humans via environment continues to be reduced to as low a level as technically and practically possible. 7. The applicant shall continue any existing biomonitoring programme at either site for the workers potentially exposed to Cr(VI). Section 9: recommendations for the review report as given in Annex IV Table 2. RAC agreed the opinion by consensus.	
11. Drinking Water Directive	
11.1 Mandate for the Committee for Risk Assessment Working Group on Drinking Water Directive	
The Secretariat presented the RAC Drinking Water Directive Working Group mandate. RAC discussed the role of the members advisers in the Drinking Water Directive and requested the Secretariat to add a note to the mandate concerning the expected scope of duties of the working group members. RAC agreed that the working group could consider criteria for grouping similar cases and for the A-listing. RAC members pointed that all RAC working groups should have the same scope of mandate and role in RAC processes.	**SECR** to update the mandate according to the RAC discussion and to publish the mandate on the ECHA website.

RAC discussed involvement of the stakeholders observers in the working group and their role in the DWD process in RAC. RAC asked the Secretariat to add to the wording (in line with DWD legal text) of the task to develop pilot projects. RAC agreed the mandate by consensus. The Eurometaux regular stakeholder observer commented that due to specific expertise required under the DWD it may be necessary to appoint new STO representatives (representing current regular RAC STO). The Chair agreed that this could be considered.	
12. AOB	
12.1. Court decision on titanium dioxide and other RAC-related cases, and their implications to RAC work	
The Secretariat presented and RAC took note of the update on the Court decision on titanium dioxide and other RAC-related cases, and their implications to RAC work.	
12.2 Update of CLP aquatic toxicity guidance: launch of a RAC consultation round	
The Secretariat informed RAC that the Committee will soon be consulted on the update of the CLP aquatic toxicity guidance.	
13. Minutes of RAC-64	
13.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-64	
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-64 to CIRCA BC.

CLH opinions at RAC-64

1. 2-ethylhexanoic acid, monoester with propane-1,2-diol
2. 2-phenylpropene; α-methylstyrene
3. Aqueous extract from the germinated seeds of *sweet Lupinus albus*
4. *N*-1-naphthylaniline; *N*-phenylnaphthalen-1-amine
5. Pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide
6. tetrairon tris(pyrophosphate); ferric pyrophosphate
7. Tetraphosphorus trisulphide; phosphorus sesquisulphid
8. α,α'-propylenedinitrilodi-*o*-cresol
9. Ozone
10. Propyl 4-hydroxybenzoate
11. Dinitrogen Oxide

2-ethylhexanoic acid, monoester with propane-1,2-diol

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	2-ethylhexanoic acid, monoester with propane-1,2-diol	285-503-5	85114-00-7	Repr. 1B	H360D	GHS08 Dgr	H360D			
RAC opinion	TBD	2-ethylhexanoic acid, monoester with propane-1,2-diol	285-503-5	85114-00-7	Repr. 1B	H360D	GHS08 Dgr	H360D			
Resulting Annex VI entry if agreed by COM	TBD	2-ethylhexanoic acid, monoester with propane-1,2-diol	285-503-5	85114-00-7	Repr. 1B	H360D	GHS08 Dgr	H360D			

2-phenylpropene; α-methylstyrene

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	601-027-00-6	2-phenylpropene; α-methylstyrene	202-705-0	98-83-9	Flam. Liq. 3 STOT SE 3 Eye Irrit. 2 Aquatic Chronic 2	H226 H335 H319 H411	GHS02 GHS07 GHS09 Wng	H226 H335 H319 H411		STOT SE 3; H335: C ≥ 25 %	
Dossier submitters proposal	601-027-00-6	2-phenylpropene; α-methylstyrene	202-705-0	98-83-9	**Add** Carc. 2 Skin Sens. 1B	**Add** H351 H317	**Add** GHS08	**Add** H351 H317			**Add** D
RAC opinion	601-027-00-6	2-phenylpropene; α-methylstyrene	202-705-0	98-83-9	**Add** Carc. 2 Skin Sens. 1B	**Add** H351 H317	**Add** GHS08	**Add** H351 H317			**Add** D
Resulting Annex VI entry if agreed by COM	601-027-00-6	2-phenylpropene; α-methylstyrene	202-705-0	98-83-9	Flam. Liq. 3 Carc. 2 STOT SE 3 Eye Irrit. 2 Skin Sens. 1B Aquatic Chronic 2	H226 H351 H335 H319 H317 H411	GHS02 GHS08 GHS07 GHS09 Wng	H226 H351 H335 H319 H317 H411		STOT SE 3; H335: C ≥ 25 %	D

Aqueous extract from the germinated seeds of *sweet Lupinus albus*

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	Aqueous extract from the germinated seeds of sweet *Lupinus albus*	-	-	No classification	-	-	-	-	-	-
RAC opinion	TBD	Aqueous extract from the germinated seeds of sweet *Lupinus albus*	-	-	No classification	-	-	-	-	-	-
Resulting Annex VI entry if agreed by COM	TBD	Aqueous extract from the germinated seeds of sweet *Lupinus albus*	-	-	No classification	-	-	-	-	-	-

N-1-naphthylaniline; *N*-phenylnaphthalen-1-amine

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	*N*-1-naphthylaniline; *N*-phenylnaphthalen-1-amine	201-983-0	90-30-2	Acute Tox. 4 Skin Sens. 1	H302 H317	GHS07 Wng	H302 H317		oral: ATE = 1231 mg/kg bw	
RAC opinion	TBD	*N*-1-naphthylaniline; *N*-phenylnaphthalen-1-amine	201-983-0	90-30-2	Acute Tox. 4 STOT RE 2 Skin Sens. 1	H302 H373 (blood system, liver) H317	GHS07 Wng	H302 H373 (blood system, liver) H317		oral: ATE = 1200 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	*N*-1-naphthylaniline; *N*-phenylnaphthalen-1-amine	201-983-0	90-30-2	Acute Tox. 4 STOT RE 2 Skin Sens. 1	H302 H373 (blood system, liver) H317	GHS07 Wng	H302 H373 (blood system, liver) H317		oral: ATE = 1200 mg/kg bw	

Pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	616-145-00-3	pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide		106700-29-2	Acute Tox. 4* Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H317 H400 H410	GHS07 GHS09 Wng	H302 H317 H410		M=100	
Dossier submitters proposal	616-145-00-3	pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide		106700-29-2	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Modify** Acute Tox. 4 Skin Sens. 1A	**Retain** H302 H317 H400 H410	**Retain** GHS07 GHS09 Wng	**Retain** H302 H317 H410		**Retain** M=100 **Add** oral: ATE = 983 mg/kg bw M=10	
RAC opinion	616-145-00-3	pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide		106700-29-2	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Modify** Acute Tox. 4 Skin Sens. 1A	**Retain** H302 H317 H400 H410	**Retain** GHS07 GHS09 Wng	**Retain** H302 H317 H410		**Retain** M=100 **Add** oral: ATE = 980 mg/kg bw M=10	
Resulting Annex VI entry if agreed by COM	616-145-00-3	pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide		106700-29-2	Acute Tox. 4 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H302 H317 H400 H410	GHS07 GHS09 Wng	H302 H317 H410		oral: ATE = 980 mg/kg bw M=100 M=10	

Tetrairon tris(pyrophosphate); ferric pyrophosphate

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	tetrairon tris(pyrophosphate); ferric pyrophosphate	233-190-0	10058-44-3	Eye Irrit. 2	H319	GHS07 Wng	H319			
RAC opinion	TBD	tetrairon tris(pyrophosphate); ferric pyrophosphate	233-190-0	10058-44-3	Eye Irrit. 2	H319	GHS07 Wng	H319			
Resulting Annex VI entry if agreed by COM	TBD	tetrairon tris(pyrophosphate); ferric pyrophosphate	233-190-0	10058-44-3	Eye Irrit. 2	H319	GHS07 Wng	H319			

Tetraphosphorus trisulphide; phosphorus sesquisulphide

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	015-012-00-1	tetraphosphorus trisulphide; phosphorus sesquisulphid	215-245-0	1314-85-8	Flam. Sol. 2 Water-react. 1 Acute Tox. 4* Aquatic Acute 1	H228 H260 H302 H400	GHS02 GHS07 GHS09 Dgr	H228 H260 H302 H400			T
Dossier submitters proposal	015-012-00-1	tetraphosphorus trisulphide; phosphorus sesquisulphid	215-245-0	1314-85-8	**Add** Self-heat. 1 **Modify** Flam. Sol. 1 **Remove** Water-react. 1 Aquatic Acute 1	**Retain** H228 **Add** H251 **Remove** H260 H400	**Retain** GHS02 GHS07 Dgr **Remove** GHS09	**Retain** H228 **Add** H251 **Remove** H260 H400			**Retain** T
RAC opinion	015-012-00-1	tetraphosphorus trisulphide; phosphorus sesquisulphid	215-245-0	1314-85-8	**Add** Self-heat. 1 **Modify** Flam. Sol. 1 **Remove** Water-react. 1 Aquatic Acute 1	**Retain** H228 **Add** H251 **Remove** H260 H400	**Retain** GHS02 GHS07 Dgr **Remove** GHS09	**Retain** H228 **Add** H251 **Remove** H260 H400			**Retain** T
Resulting Annex VI entry if agreed by COM	015-012-00-1	tetraphosphorus trisulphide; phosphorus sesquisulphid	215-245-0	1314-85-8	Flam. Sol. 1 Self-heat. 1 Acute Tox. 4*	H228 H251 H302	GHS02 GHS07 Dgr	H228 H251 H302			T

α,α'-propylenedinitrilodi-*o*-cresol

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	α,α'-propylenedinitrilodi-*o*-cresol	202-374-2	94-91-7	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
RAC opinion	TBD	α,α'-propylenedinitrilodi-*o*-cresol	202-374-2	94-91-7	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
Resulting Annex VI entry if agreed by COM	TBD	α,α'-propylenedinitrilodi-*o*-cresol	202-374-2	94-91-7	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

Ozone

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	ozone	233-069-2	10028-15-6	Ox. Gas 1 Carc. 2 Muta. 2 Acute Tox. 1 STOT SE 3 STOT SE 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H270 H351 H341 H330 H335 H370 (nervous system) H372 (cardiovascular, nervous, respiratory system) H400 H410	GHS03 GHS08 GHS06 GHS09 Dgr	H270 H351 H341 H330 H335 H370 (nervous system) H372 (cardiovascular, nervous, respiratory system H410		inhalation: ATE = 10 ppm (gases) M = 100 M = 1	
RAC opinion	TBD	ozone	233-069-2	10028-15-6	Ox. Gas 1 Carc. 2 Muta. 2 Acute Tox. 1 STOT SE 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H270 H351 H341 H330 H370 (nervous system, respiratory system, cardiovascular system) H372 (nervous system, respiratory system) H400 H410	GHS03 GHS08 GHS06 GHS09 Dgr	H270 H351 H341 H330 H370 (nervous system, respiratory system, cardiovascular system) H372 (nervous system, respiratory system) H410		inhalation: ATE = 10 ppmV STOT SE 1; H370: C ≥ 0,002 % STOT SE 2; H371: 0,0005 % ≤ C < 0,002 % STOT RE 1; H372: C ≥ 0,05 %	

										STOT RE 2; H373: 0,01 % ≤ C < 0,05 % M = 100 M = 1	
Resulting Annex VI entry if agreed by COM	TBD	ozone	233-069-2	10028-15-6	Ox. Gas 1 Carc. 2 Muta. 2 Acute Tox. 1 STOT SE 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H270 H351 H341 H330 H370 (nervous system, respiratory system, cardiovascular system) H372 (nervous system, respiratory system) H400 H410	GHS03 GHS08 GHS06 GHS09 Dgr	H270 H351 H341 H330 H370 (nervous system, respiratory system, cardiovascular system) H372 (nervous system, respiratory system) H410		inhalation: ATE = 10 ppmV STOT SE 1; H370: C ≥ 0,002 % STOT SE 2; H371: 0,0005 % ≤ C < 0,002 % STOT RE 1; H372: C ≥ 0,05 % STOT RE 2; H373: 0,01 % ≤ C < 0,05 % M = 100 M = 1	

Propyl 4-hydroxybenzoate

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	607-RST-VW-Y	propyl 4-hydroxybenzoate	202-307-7	94-13-3	Repr. 2	H361fd	GHS08 Wng	H361fd			
RAC opinion	607-RST-VW-Y	propyl 4-hydroxybenzoate	202-307-7	94-13-3	No classification						
Resulting Annex VI entry if agreed by COM	607-RST-VW-Y	propyl 4-hydroxybenzoate	202-307-7	94-13-3	No classification						

Dinitrogen oxide

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	dinitrogen oxide	233-032-0	10024-97-2	Repr. 1B STOT SE 3 STOT RE 1 Ozone 1	H360Df H336 H372 (nervous system) H420	GHS08 GHS07 Dgr	H360Df H336 H372 (nervous system) H420			
RAC opinion	TBD	dinitrogen oxide	233-032-0	10024-97-2	Repr. 1B STOT SE 3 STOT RE 1 Ozone 1	H360Df H336 H372 (nervous system) H420	GHS08 GHS07 Dgr	H360Df H336 H372 (nervous system) H420			
Resulting Annex VI entry if agreed by COM	TBD	dinitrogen oxide	233-032-0	10024-97-2	Repr. 1B STOT SE 3 STOT RE 1 Ozone 1	H360Df H336 H372 (nervous system) H420	GHS08 GHS07 Dgr	H360Df H336 H372 (nervous system) H420			

Part III. List of Attendees of the RAC-64 meeting

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

Viegas	Susana

Apologies RAC members	
Tsitsimpikou	Christina

Members' advisers		
Brett-Smith	Catharina	Neumann Michael
Catone	Tiziana	Aquilina Gabriele
Dumke	Carolin	Schlüter Urs, DMAC/NEP
Hoffmann	Frauke	Schulte Agnes
Jankowska	Agnieszka	Peczkowska Beata
Moilanen	Marianne	Leinonen Riitta
Nielsen	Peter Juhl	Tobiassen Lea Stine, PFAS FFF
Panieri	Emiliano	Esposito Dania
Russo	Maria Teresa	Aquilina Gabriele
Saksa	Jana	Moldov Raili
Stalter	Daniel	Schulte Agnes
Suutari	Tiina	Leinonen Riitta

SEAC Rapporteurs		
Cogen	Simon	UPFAS
Fankhauser	Simone	UPFAS
Kiiski	Johanna	PFAS FFF

Invited experts		**Role/Substance**
August	Christiana	(UPFAS) - PFAS FFF
Averbeck	Frauke	(UPFAS) – PFAS FFF
Baumbusch	Angelika	(UPFAS) – PFAS FFF
Dannenberg	Carl	(UPFAS) – PFAS FFF
Heggelund	Audun	(UPFAS) – PFAS FFF
Kupprat	Franziska	(UPFAS) – PFAS FFF
Peltzer	Eike	(UPFAS) - PFAS FFF
Schulze	Jona	(UPFAS) – PFAS FFF
Winther	Toke	(UPFAS) – PFAS FFF

Dossier submitters		**Substance**
Alivernini	Silvia	(IT) -Terphenyl
Averbeck	Frauke	(DE) – UPFAS, BPA+
Attias	Leonello	(IT) - Terphenyl
Brett-Smith	Catharina	(DE) – BPA+
Catone	Tiziana	(IT) - Terphenyl
Charles	Sandrine	(FR) – Court decision on titanium dioxide
Charron	Isabelle	(FR) - Creosote
De Kort	Thijs	(NL) – UPFAS
De Rivas	Ana	(ES) – Chrysanthemums
Drissi-Amraoui	Sammy	(FR) - Creosote
Galert	Wiebke	(DE) – BPA+
Hard	Sebastiana	(NL) – UPFAS
Heggelund	Audun	(NO) – UPFAS
Hofmaier	Tina	(AT) - Pethoxamid
Ivarsson	Jenny	(SE) – UPFAS

Johansson	Tommy	(SE) – UPFAS
Jomini	Stéphane	(FR) – Creosote, court decision on titanium dioxide
Jongeneel	Rob	(NL) - DMAC-NEP
Kupprat	Franziska	(DE) – UPFAS
Michel	Cecile	(FR) – Court decision on titanium dioxide
Orrù	Maria Antonietta	(IT) - Terphenyl
Schmeisser	Sebastian	(DE) – 2-phenylpropene
Unkelbach	Christian	(DE) - BPA+
Winther	Toke	(DK) – UPFAS

Regular stakeholder observers	
Barry	Frank (ETUC)
Cassart	Michel (PlasticsEurope)
Robin	Nicolas (PlasticsEurope) – UPFAS and PFAS FFF
De Backer	Liisi (Cefic)
Duguy	Hélène (ClientEarth)
Robinson	Jan (A.I.S.E)
Chhuon	Cindy (A.I.S.E) – replacement for 16 March
Romano Mozo	Dolores (EEB)
Ruelens	Paul (CropLife Europe)
Santos	Roumiana (MedTech Europe)
Verougstraete	Violaine (Eurometaux)

Occasional stakeholders		**Substance**
Barbu	Luminita (Edana)	BPA+
Cingotti	Natacha (HEAL)	UPFAS
De Badereau	Vincent (EPEE)	UPFAS
Doome	Roger (IMA-Europe)	Court decision on titanium dioxide
Drohmann	Dieter (OnlyRepresentatives)	UPFAS
Hannebaum	Peter (EUROFEU)	UPFAS
Kaup	Triin (EURATEX)	BPA+
Reineke	Ninja (CHEM Trust)	UPFAS, BPA+
Tillieux	Geoffroy (EuPC)	Report from the February REST WG, MCCP, BPA+

Stakeholder experts		**Substance**
Bock	Ronald (PlasticsEurope)	UPFAS
Bowen	Damian (Cefic)	Dinitrogen oxide
Consoli	Elisa (Eurometaux)	UPFAS, PFAS FFF
Eichler-Haeske	Jens-Olaf (Cefic)	DMAC/NEP
Ewald	Dirk (Eurometaux)	BPA+
Falcigno	Pasquale (CropLife Europe)	UPFAS, PFAS FFF
Gartland	Kevan (Cefic)	Chrysanthemums
Gestermann	Sven (PlasticsEurope)	BPA+
Hillwalker	Wendy (A.I.S.E)	Chrysanthemums, UPFAS, court case in titanium dioxide
Howick	Chris (Cefic)	MCCP
Hunziker	René (Cefic)	BPA+
Jackson	Ffion (MedTech Europe)	UPFAS
Johnson	David (CropLife Europe)	Pethoxamid
Kørner	Mads Boye (Cefic)	Creosote
Lockley	David (Cefic)	Court case on titanium dioxide
Pemberton	Mads (Cefic)	2-phenylpropene
Richmond	Emily (CropLife Europe)	Chrysanthemums
Schüller	Jan (Cefic)	Terphenyl
Veith	Tobias (MedTech Europe)	DMAC/NEP
Van Wely	Eric (Cefic)	UPFAS
Wietor	Jean-Luc (EEB)	UPFAS, PFAS FFF, BPA+

European Commission		**DG**
Beekman	Martijn	DG GROW
Bertato	Valentina	DG ENV
Fabbri	Marco	DG GROW
Dunauskiene	Lina	DG GROW
Kilian	Karin	DG ENV
Pinte	Jeremy	DG GROW
Roebben	Gert	DG GROW
Streck	Georg	DG GROW
Tosetti	Patrizia	DG GROW

EU Agency Observers		
Binaglia	Marco	EFSA
Castoldi	Anna F	EFSA
Rincon	Ana Maria	EFSA
Ruggeri	Laura	EFSA

ECHA staff	
Ahtiainen	Heini
Alami-Eerikinharju	Wafa
Barnewitz	Greta
Bowmer	Tim (Chair)
Broere	William
Di Bastiano	Augusto
Doyle	Simone
Gmeinder	Michael
Henricsson	Sanna
Klausbruckner	Carmen
Kokkola	Leila
Lazic	Nina
Lisboa	Patricia
Lefevre	Sandrine
Logtmeijer	Christiaan
Ludborzs	Arnis
Marquez-Camacho	Mercedes
Mattiuzzo	Marco
Mazzolini	Anna
Myöhänen	Kirsi
Mäkelä	Petteri
Nygren	Jonas
Orispää	Katja
O'Rourke	Regina
Peltola	Jukka
Pillet	Monique
Reuter	Ulrike
Roggeman	Maarten
Ryan	Paul
Sadam	Diana
Salo	Marta
Sosnowski	Piotr
Stockmann-Juvala	Helene
Thierry-Mieg	Morgane
Tunnela	Outi
Uphill	Simon
van Haelst	Anniek
Wilk	Mateusz
Zarogiannis	Panos
Zeiger	Bastian

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-64 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-64 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-64 meeting

ANNEX IV List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-64 meeting without plenary debate (A-list)

Annex I
13 March 2023
RAC/A/64/2023

Final Agenda
64th meeting of the Committee for Risk Assessment
(RAC-64)

13 – 16 March 2023

Virtual meeting

Monday, 13 March starts at 14.00
Thursday, 16 March ends at 18.20

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/64/2022
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 – Report from other ECHA bodies and activities

5.1 RAC Work Plan for all processes

For information

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

n/a

Item 7 –Health based exposure limits at the workplace

1. Opinion development

    1. 1,2-dichloropropane – first draft opinion

    2. 1,2,3-trichloropropane – first draft opinion

For discussion/adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

1. Renewal of the RAC CLH WG mandate

RAC/64/2023/01
For agreement

2. Report from the January CLH Working Group

RAC/64/2023/02
For information

8.2 CLH dossiers

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

- **2-ethylhexanoic acid, monoester with propane-1,2-diol:** *reproductive toxicity*
- **2-phenylpropene:** *skin sensitisation, Note D, STOT RE, carcinogenicity*
- **Aqueous extract from the germinated seeds of sweet *Lupinus albus*:** *all hazard classes*
- ***Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide:** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, aquatic toxicity, hazard to the ozone layer*
- ***Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents:** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, aquatic toxicity, hazard to the ozone layer*
- ***N*-1-naphthylaniline; *N*-phenylnaphthalen-1-amine:** *acute toxicity (oral and dermal routes of exposure), STOT SE, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT RE*
- **Pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide:** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye*

irritation, skin sensitisation, respiratory sensitisation, STOT SE, STOT RE, mutagenicity, reproductive toxicity, aquatic toxicity, hazard to the ozone layer

- **Tetrairon tris(pyrophosphate); ferric pyrophosphate:** *all hazard classes*
- **Tetraphosphorus trisulphide; phosphorus sesquisulphide:** *physical hazards (except for Explosives and Self-reactive substances), aquatic toxicity*
- **α,α'-propylenedinitrilodi-*o*-cresol:** *mutagenicity, reproductive toxicity*
- **Ozone:** *carcinogenicity, SCLs for STOT SE and STOT RE*
- ***Propyl 4-hydroxybenzoate**: reproductive toxicity*
- ***Dinitrogen oxide**: STOT SE, STOT RE, reproductive toxicity*

2. Hazard classes for agreement with plenary debate

1. 2-phenylpropene (EC: 202-705-0; CAS: 98-83-9): *mutagenicity*

2. *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide (EC: 289-699-3; CAS: 89997-63-7): *mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazards*

3. *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents (EC: 289-699-3; CAS: 89997-63-7): *mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazards*

4. Dinitrogen oxide (EC: 233-032-0; CAS: 10024-97-2): *hazard to the ozone layer*

5. Pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide (EC: - ; CAS: 106700-29-2): *carcinogenicity*

6. Tetraphosphorus trisulphide; phosphorus sesquisulphide (EC: 215-245-0; CAS: 1314-85-8) : *explosives, self-reactive substances*

For discussion/agreement/adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Renewal of the RAC RESTR WG mandate

RAC/64/2023/03
For agreement

2. Report from the February Restriction Working Group

RAC/64/2023/04
For information

9.2 Restriction Annex XV dossiers

1. Conformity check and key issues discussion
    1. Universal PFAS (UPFAS) – Conformity check and key issues discussion

For discussion and agreement

2. Opinion development

    1. Creosote, and creosote related substances – first draft opinion
    2. BPA+ - first draft opinion
    3. Medium chain chlorinated paraffins (MCCP) – second draft opinion

For discussion and agreement

    4. Terphenyl, hydrogenated – third draft opinion
    5. *N*,*N*-dimethylacetamide and 1-ethylpyrrolidin-2-one – third draft opinion
    6. PFAS in fire-fighting foams (PFAS-FFF) – third draft opinion

For discussion and adoption

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the January/February AFA Working Group

RAC/64/2023/05
For information

2. Update on incoming/future applications

For information/discussion

10.2 Authorisation applications

1. Discussion on key issues

No cases under this agenda item (November 2022 submission window AfAs will be presented at RAC-65 plenary meeting in June 2023).

For discussion

10.3 Agreement on draft opinions

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

1) 273_CT_MikroMetal (1 use)
2) 274_CT_SD_ArcelorMittal (2 uses)
3) 275_CT_Sicrom (1 use)
4) 276_CT_Osmaplast (2 uses)
5) 277_CT_Ritmonio (1 use)
6) 278_RR1_Diglyme_Isochem (1 use)
7) 279_CT_GalvanoPlus (1 use)
8) 280_CT_Tecnocrom_Industrial (2 uses)
9) 281_CT_Electro_Durocrom (1 use)
10) 282_CT_Hazet_Werk (1 use)
11) 283_CT_KYB (1 use)
12) 284_CT_CGS (1 use)

For discussion and agreement

10.4 Adoption of final opinions

No cases under this agenda item.

For discussion and adoption

Item 11 – Drinking Water Directive

1. Mandate for the Committee for Risk Assessment Working Group on Drinking Water Directive

RAC/64/2023/06
For agreement

Item 12 – AOB

1. Court decision on titanium dioxide and other RAC-related cases, and their implications to RAC work
2. Update of CLP aquatic toxicity guidance: launch of a RAC consultation round

For information

Item 13 – Minutes of RAC-64

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-64

For adoption

Annex II (RAC 64)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-64 meeting.

RAC/A/64/2023	RAC-64 final Draft Agenda
RAC/64/2023/01	General CLH issues: Renewal of the RAC CLH WG mandate
RAC/64/2023/02	General CHL issues: Report from the January CLH Working Group
RAC/64/2023/03	General restriction issues: Renewal of the RAC REST WG mandate
RAC/64/2023/04	General restriction issues: Report from the February Restriction Working Group
RAC/64/2022/05	General authorisation issues: Report from the January/February AFA Working Group
RAC/64/2022/06	Mandate for the Committee for Risk Assessment Working Group on Drinking Water Directive

ANNEX III (RAC-64)

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.
Harmonised classification & labelling		
Ozone **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. No personal involvement.
	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.
Restrictions		
NEW DOSSIERS		
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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
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.
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.
BPA+ **DE**	Agnes SCHULTE Urs SCHLUETER 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.
Creosote, and Creosote related substances **FR**	Karine ANGELI Laure GEOFFROY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
N,N-dimethylacetamide and NEP **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.
Terphenyl, hydrogenated **IT**	Gabriele AQUILINA Dania ESPOSITO	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		
1) **Aqueous extract from the germinated seeds of sweet *Lupinus albus*** 2) **α,α'-propylenedinitrilodi-*o*-cresol** **NL**	Betty HAKKERT	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.
	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.
1) **2-phenylpropene** 2) **N-1-naphthylaniline; N-phenylnaphthalen-1-amine** **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.
	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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	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.
Dinitrogen oxide **FR**	Karine ANGELI	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.
	Laure GEOFFROY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Pethoxamid (ISO) **AT**	Annemarie LOSERT	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Manuel FACCHIN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Propyl 4-hydroxybenzoate **BE**	Wendy RODRIGUEZ	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Tetrairon tris(pyrophosphate) **PL**	Boguslaw BARANSKI	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.
	Beata PECZKOWSKA	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. Personal involvement.
1) *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide **2) *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents** **3) 2-ethylhexanoic acid, monoester with propane-1,2-diol** **ES**	Marieta FERNANDEZ	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.
	Benjamin PINA	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.
Tetraphosphorus trisulphide **IT**	Dania ESPOSITO	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
	Gabriele Aquilina	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

Annex IV (RAC 63)

Table 1. List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-64 meeting without plenary debate (A-list).

Conclusions / agreements / adoptions
275_CT_Sicrom (1 use) **Use1:** *Functional chrome plating of hydraulic cylinders and swivel joints using chromium trioxide.* RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall ensure that workers perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before taking on relevant tasks and workers shall be trained to do this test adequately. 2. The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 flakes with liquid CrO_3 to further limit the exposure; b) the implementation of a closed automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths and 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 Table 2. Section 9: recommendations for the review report as given in Table 2.
276_CT_Osmaplast (2 uses) **Use1:** *Industrial use of hexavalent chromium for a pre-treatment step (etching) in the electroplating process for various applications.* **Use2:** *Industrial use of hexavalent chromium to create a long-lasting and high durability chromium decorative surface on plastic substrates in the electroplating process for various applications.*

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

RAC agreed:
Section 7: additional conditions for the authorisation

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

   a) the substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure;

   b) the implementation of a closed automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths;

   c) 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.

   d) the installation of a system that controls continuously the local exhaust ventilation and triggers and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s), in case the local exhaust ventilation is not functioning properly.

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

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

278_RR1_Diglyme_Isochem (1 use)

Use1: *Use of diglyme as a process solvent in one step of the manufacturing of an Active Pharmaceutical Ingredient used in an anti-protozoal drug.*

RAC concluded that the risk assessment presented in the review report demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the review report are implemented and adhered to.

RAC agreed:
Section 7: no additional conditions for the authorisation

Section 8: monitoring arrangements for the authorisation

1. The authorisation holder shall continue the following occupational inhalation exposure monitoring programmes for Diglyme, 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 Diglyme

(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 Diglyme 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.

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the authorisation holder to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Diglyme and emissions to the environment to as low a level as technically and practically feasible. While doing so, the authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.

3. The authorisation holder shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.

4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent national authority of the Member State where the authorised use will take place.

5. The authorisation holder 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 has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.

6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible.

Section 9: recommendations for the review report

The results of the measurements referred to in section 8.1 paragraph 1 as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report.

279_CT_GalvanoPlus (1 use)

Use1: *Industrial use of chromium trioxide for functional chrome plating with decorative character of sanitary equipment.*

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

RAC agreed:
Section 7: additional conditions for the authorisation

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

The applicant shall install without delay, as indicated in the response to RAC's questions:

- an automated system at Briga Novarese site for the transfer of jigs over the activation step to ensure that also this step, is automated. This is currently performed manually by workers who rely on RPE as a protective measure against exposure. An automatic system for the transfer of the jigs from the activation bath to the chrome plating bath is already installed in San Maurizio's site;
- a closed and automated supply system to transfer the CrO_3 solution directly into the baths in both sites (San Maurizio and Briga Novarese). This operation is currently performed manually by workers which rely on the use of RPE as a safety measure.

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

c) 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 RPE.

d) 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 exhaust ventilation is not functioning properly.

e) the physical separation between the loading/unloading working area and the plating 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

3. The applicant shall implement the following monitoring programmes:

(a) Occupational inhalation exposure monitoring programmes for Cr(VI) at both sites, which shall:

(i) be conducted at least annually for the workers exposed to Cr(VI). The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI);
(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(IV) is possible;
b. the operational conditions and risk management measures 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 at both sites conduct air emission measurements at least annually or more frequently following any possible changes in the process.;
(ii) the monitoring programmes for air emissions shall:
d) be based on relevant standard methodologies or protocols; and
e) be representative of the OCs and RMMs used at the applicant's site.
f) ensure a sufficiently low limit of quantification.

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the operational conditions and risk management measures in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.

3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.

4. The information from the studies and monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.

5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans (i.e. workers and general population) has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.

6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers and HvE at each of the sites where the use takes place shall be

documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers and HvE continues to be reduced to as low a level as technically and practically possible.

7. The applicant shall continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI).

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

282_CT_Hazet_Werk (1 use)

Use1: *Chromium trioxide-based functional chrome plating of hand tools to achieve a high level of abrasion resistance as well as corrosion and chemical resistance.*

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

RAC agreed:
Section 7: additional conditions for the authorisation

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 ensure that appropriate RPE is worn during bath sampling (WCS 4) due to the increased potential for exposure to CrO_3. The use of RPE could stop if the task starts being performed with an automated system or closed sampling system.
3. The applicant shall carry out and document a detailed feasibility study on:
   a) the segregation between the loading/unloading areas and the plating area, either by the introduction of a physical barrier or by the removal of loading/unloading from the plating area;
   b) the implementation of a closed/ automated system for sampling to perform bath sampling tasks, where exposure to Cr(VI) is foreseen.

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

Section 8: monitoring arrangements for the authorisation as given in Table 2.

Section 9: recommendations 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, shall be documented and included in any subsequent authorisation review report.

External workers potentially exposed to Cr(VI) at the site where the use applied for takes place shall be included in the risk assessment of any subsequent authorisation review report.

284_CT_CGS (1 use)

Use1: *Electroplating of different types of substrates using Chromium Trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications.*

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

RAC agreed:
Section 7: additional conditions for the authorisation

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

a) the substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure;

b) the implementation of an automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium bath, and the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE;

c) the installation of a 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;

d) the physical separation between the loading/unloading working area and the plating 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 Table 2.
Section 9: recommendations for the review report as given in 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.
7. 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.
8. 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.
9. 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.
10. 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.

11. 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
12. 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.