RAC/M/63/2022

1 December 2022

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Minutes of the 63rd Meeting

of the Committee for Risk Assessment

(RAC-63)

Monday, 28 November starts at 14.00
Thursday, 1 December ends at 15.00

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

The Chair noted that he has informed the Committee of ECHA's plans for the implementation of the 'positive list' of the Drinking Water Directive which will officially start in RAC from January 2025. He announced that an invitation to nominate experts to a dedicated RAC working group will be sent to the Drinking Water Competent Authorities in the coming weeks, containing an explanation of the purpose of the Working Group, ways of nominating experts, terms of reference and a short work programme for 2023 and 2024. A first meeting is envisaged in will update you on further developments at the March 2023 plenary. He noted that this working group will operate in the same way as the current three standing working groups and emphasised that ECHA was looking for fresh expertise.

The Chair referred to the General Court's ruling on the Annex VI of CLP entry for titanium dioxide as Carc. 2which was recommended by RAC in 2017 and noted that the Commission, supported by the Agency was considering their response. Recognising that some members were keen to discuss the implications of the ruling for RAC, he proposed to table this for discussion at the CLH Working Group planned from 23-26 January, reporting back to plenary at RAC 64 in March.

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/63/2022**) was adopted without amendment.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-63 minutes.
4. Appointment of (co-)rapporteurs	
4.1 Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for CLH dossiers, restriction dossiers, applications for authorisation and 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, focussing mainly on the first half of the year.	
6. Request under Article 77(3)(c)	
6.1. DNEL setting for DOTE/MOTE (Request to the Committee for Risk Assessment to set a DNEL for 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	
The Rapporteurs presented the final version of the draft RAC Note. RAC supported the following conclusions:	**Rapporteur** together with **SECR** to do the final editing of the Note, taking into account the RAC-63 discussion.

Absorption values: - 50 % for inhalation absorption - 20 % for oral absorption - 0.1 % for dermal absorption Most relevant studies for DNEL derivation: - The NOAEL for (slight) developmental effects from the rabbit PNDT study with DOTE of 20 mg DOTE/kg bw/day (9 mg DOT/kg bw/d) - The NOAEL for increase in stillbirths from the rat 2-generation study with DOTI:MOTI of about 1.6 mg DOTE/kg bw/day (0.7 mg DOT/kg bw/d / 1.6 mg DOTI:MOTI/kg bw/d) Assessment Factors (AFs) - Default AFs for interspecies and intraspecies and exposure duration - Quality of database: o AF 4 for rabbit study since less sensitive species o AF 1 for read-across (DOTE and DOTI close analogues) o AF 5 for immuno-developmental effects, which are not investigated in PoD studies, but shown for DOTC Resulting DNELs: - Worker, long-term inhalation: 0.025 mg DOTE/m^3 - Worker, long-term dermal: 1.80 mg DOTE/kg bw/day - General population, long-term oral: 0.0032 mg DOTE/kg bw/d RAC agreed the RAC Note by consensus.	**Secretariat** to publish the RAC note on the ECHA website.

6.2. Request to RAC to prepare to prepare a supplementary opinion on lead in outdoor shooting and fishing

The Chair welcomed the regular stakeholders from EEB and EUROMETAUX, and their accompanying experts, the invited experts from AEWA Technical Committee and UNEP_AEWA and the occasional stakeholder observers from FITASC and FACE. In June 2022, RAC received a request from the European Commission to prepare a supplementary opinion on the proposed restriction on lead in outdoor shooting and fishing, updating or confirming their conclusions on the risks posed by the intake of lead through consumption of game meat. As specified in the mandate, a three-month targeted consultation was organised between 6 July - 6 October 2022. Stakeholders were invited to provide comments and supporting evidence on a dataset of lead concentrations in game meat and game meat intake provided by the European Food Safety Authority ('EFSA dataset'). This had been used by the Dossier Submitter in their assessment of human health risks from lead ammunition, but the document had not made publicly available by EFSA prior to the closure of the consultation on the Annex XV report.

RAC rapporteur presented and RAC discussed the draft supplementary opinion on this Article 77(3)(c) request.	**Rapporteur** to make the final editorials to the adopted supplementary opinion,

Conclusions on game meat lead concentrations • Overall, RAC reiterates its earlier conclusion that the lead concentrations in small game used by the Dossier Submitter are likely to be underestimated. • Although the EFSA dataset on large game meat contains three samples with high lead concentrations, their inclusion/exclusion in the dataset does not have any effect on the conclusions of the risk and impact assessment as this is based on the data distribution rather than mean values and the Dossier Submitter considered all IQ losses above 1 as 1. RAC conclusions on game meat consumption • Although the consumption rates used by the Dossier Submitter for infants, toddlers and adults in hunter families are conservative, they are not unrealistic and are intended to reflect families with a high consumption of game meat. • RAC does not consider that the alternative assumptions on game meat consumption rates submitted as part of the targeted consultation represent reasonable worst-case conditions. • Possible conservativeness of the consumption figures is compensated for by an underestimation of small game lead concentrations. Overall, RAC reiterates its conclusion that there is a **moderate to high risk from game meat lead exposure for children (infants and toddlers) in hunter families**. Exposure of infants comes both from mothers' milk and from the direct game meat consumption starting typically at the age of six months. RAC reiterates its conclusion that **risks for adults are likely to be low.** RAC notes that the conclusions from the qualitative assessment on the risks posed by the intake of lead through consumption of game meat for pregnant women as presented in the previously adopted RAC	taking into account the RAC-63 discussion. **Secretariat** to send the RAC supplementary opinion to the Commission and to publish it on the ECHA website.

opinion are unchanged by this supplementary opinion since the qualitative assessment was not influenced by the EFSA dataset. RAC adopted the supplementary opinion by consensus.	
The occasional stakeholder observer (FACE) and the accompanying experts to regular stakeholder observers (EEB and Eurometaux) commented on game meat lead concentrations and consumption.	

7. Health based exposure limits at the workplace

7.1.1 Opinions for discussion: Cobalt – adoption of opinion

The Chair welcomed the representatives from the Government, Employers and Workers Interest Groups, of DG Employments Working Party on Chemicals, the experts accompanying the Eurometaux and the CEFIC Regular Stakeholder Observers as well as the Occasional Stakeholder Observer from ECOPA.
The Commission requested ECHA to evaluate, cobalt and inorganic cobalt compounds in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 11 April until 10 June 2022 and the deadline for this request is 23 December 2022.

The Rapporteurs presented and RAC discussed the revised draft opinion on the scientific evaluation of limit values for cobalt and inorganic cobalt compounds. RAC confirmed that the Nemery (1992) study is highly relevant for Co limit value derivation (inhalable fraction). RAC agreed with the airborne occupational exposure limit values for cobalt and inorganic cobalt compounds, as proposed in the draft opinion: OEL as 8-hour TWA: 1 µg Co/m^3 (inhalable fraction); 0.5 µg Co/m^3 (respirable fraction) The values are applicable to all occupational settings, including hard metal and diamond polishing workplaces. RAC agreed to propose BGV of 2 µg Co/L urine for females and 0.7 µg Co/L urine for males. RAC agreed to not recommend a BLV.	**Rapporteurs** to revise the opinion in accordance with the agreed modifications in RAC-63 and to provide it to SECR. **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 and its annex to COM and publish it on the ECHA website.

RAC agreed to propose a "Skin sensitisation" and a "Respiratory sensitisation" notation. RAC adopted by consensus its opinion (with the modifications agreed at RAC-63).	

The experts accompanying the Eurometaux and the CEFIC Regular Stakeholder Observers commented on the derivation of OELs. The expert accompanying the Eurometaux Regular Stakeholder Observer commented on the scope of the OEL and reprotoxicity. The expert accompanying the Cefic Regular Stakeholder Observer commented on the link with the German AGS derivation.

7.1.2 Opinions for discussion: Polyaromatic hydrocarbons (PAHs) – adoption of opinion

The Chair welcomed the representatives from the Government, Employers and Workers Interest Groups, the expert accompanying the CEFIC Regular Stakeholder Observer as well as the Occasional Stakeholder Observer from ECOPA.
The Commission requested a scoping study to identify and assess approaches to monitoring exposure to combinations of different PAH and to recommend the most appropriate approach and to include a recommendation on, whether an airborne occupational exposure limit for benzo-a-pyrene (CAS 50-32-8) (and/or other substance (s)) is a suitable marker of overall PAH exposure. If appropriate, an occupational exposure limit(s) (OEL(s)) shall be complemented by other limit values (BLV/BGV) and notations. The deadline of this request is 31 December 2022.
The ECHA scientific report was open for comments from 10 May until 11 July 2022.
During the opinion development process, the ECHA scientific report will be transferred into an Annex to the RAC opinion.

The Rapporteurs presented and RAC discussed the revised draft opinion on the scientific evaluation of limit values for PAH. RAC agreed with the airborne occupational exposure limit values for PAH, as proposed in the draft opinion: OEL as 8-hour TWA[1]: None RAC agreed on the Cancer exposure-risk relationship (ERR) as described in the draft opinion. RAC agreed that once an OEL is recommended by the Working Party on Chemicals of the DG-EMPL Advisory Committee on Safety and health (WPC-ACSH), based on the ERR recommended by RAC, a corresponding BLV using the metabolite 3-OHBaP in urine could be set using the appropriate correlation equation presented in the RAC opinion.	**Rapporteurs** to revise the opinion in accordance with the agreed modifications in RAC-63 and to provide it to SECR. **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 and its annex to COM and publish it on the ECHA website.

[1] The proposed OEL is based on a mode of action-based threshold for the carcinogenicity of cobalt compounds.

RAC agreed to recommend a Biological Guidance Value (BGV) for the metabolite 1-OHP in urine which can be selected either based on the European level data or, when available, on National data. RAC agreed to propose a "Skin" notation. RAC adopted its opinion (with modifications agreed at RAC-63) by consensus.	

The expert accompanying the CEFIC Regular Stakeholder Observer and the CONCAWE Regular Stakeholder Observer commented on the OEL derivation.

8. Harmonised classification and labelling (CLH)

8.1 Report from the October 2022 RAC CLH WG

The Secretariat presented the Report of the 7th Meeting of the Committee for Risk Assessment Working Group on CLH held on 24-27 October 2022. The 8th Meeting of the RAC Working Group on CLH will be held on 23-26 January 2022.	

8.2 CLH dossiers

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

- 1,4-Dichloro-2-nitrobenzene: *carcinogenicity, germ cell mutagenicity*
- Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl: *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, STOT RE, STOT SE, mutagenicity, carcinogenicity, reproductive toxicity (fertility and lactation), hazards to the aquatic environment, hazard to the ozone layer*
- Dibenzoyl peroxide; benzoyl peroxide: *hazards to the aquatic environment*
- Fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine: *physical hazards, acute toxicity, STOT SE (respiratory irritation), skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity (fertility and lactation), hazards to the aquatic environment*
- *n*-Hexane: *STOT RE*
- Ozone: *physical hazards, acute toxicity, STOT SE (respiratory system and nervous system, except SCL values), STOT RE (respiratory system and nervous system, except SCL values), mutagenicity, reproductive toxicity (fertility and development), skin irritation/corrosion, serious eye damage/eye irritation, respiratory sensitisation, hazards to the aquatic environment*
- Pyraclostrobin (ISO); methyl N-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate: *physical hazards, hazards to the aquatic environment, hazard to the ozone layer, acute inhalation and dermal toxicity, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, reproductive toxicity (fertility and lactation)*

- Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol (glycerol formal): *reproductive toxicity (fertility, development and lactation)*
- *tert*-butyl 2-ethylperoxyhexanoate: *reproductive toxicity (fertility and lactation), skin sensitisation*
- Cyclohex-3-ene-1-carbaldehyde derivatives: *skin sensitisation*

8.2.2 Hazard classes for agreement in plenary session

1. Copper (EC: 231-159-6; CAS: 7440-50-8): *hazards to the aquatic environment*
2. Ozone (EC: 233-069-2; CAS: 10028-15-6): *reproductive toxicity (lactation), STOT SE (cardiovascular system and SCL values for respiratory system and nervous system), STOT RE (cardiovascular system and SCL values for respiratory system and nervous system)*
3. *tert*-butyl 2-ethylperoxyhexanoate (EC: 221-110-7; CAS: 3006-82-4): *reproductive toxicity (development)*
4. Pyraclostrobin (ISO); methyl N-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate (EC: -; CAS: 175013-18-0): *acute oral toxicity, skin irritation, carcinogenicity, STOT SE, STOT RE, reproductive toxicity (development)*
5. Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl(EC: 201-993-5; CAS: 90-43-7): *skin sensitisation, reproductive toxicity (development)*
6. Fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine (EC: 614-049-6; CAS: 67306-00-7): *STOT SE (narcotic effects), reproductive toxicity (development)*

8.2.2.1 **Copper** (EC: 231-159-6; CAS: 7440-50-8)

The Chair welcomed the Dossier Submitter's representative, the Occasional Stakeholder Observer from the European Copper Institute as well as the expert accompanying the Eurometaux Regular Stakeholder Observer. He informed that **copper** has a large variety of uses in the metallurgy, building, transport and electronics sectors amongst many others. Consumer and professional uses of copper consist of, for example: metals, metal working fluids, welding and soldering products, cosmetics and personal care products, modelling clay, and metal surface treatment products. Furthermore, copper is also used as an active substance in biocidal products.

Unlike many copper salts, copper metal (Cu^0) does not have a current harmonised classification.

There are two exceptions: copper flakes (coated with aliphatic acid) are classified as Acute Tox. 4; H302, Eye Irrit. 2; H319, Acute Tox. 3; H331, Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410, while granulated copper [particle length: from 0,9 mm to 6,0 mm; particle width: from 0,494 to 0,949 mm] also has an existing Annex VI entry as Aquatic Chronic 2; H411. Some uses of both of the above active substances are currently approved in biocidal products.

The DS (SE) proposes to classify copper as: Copper ≤ 0.67 mm^2/mg (massive, equivalent to a copper sphere of 1mm diameter) – No Classification, and Copper > 0.67 mm^2/mg (powder) - Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=1).

The DS further proposed to amend the entries for copper flakes and granulated copper accordingly, since both forms would be fully covered by the entry proposed for copper. However, this is considered to be outside the remit of RAC and will be addressed by COM.

Hazards to the aquatic environment were the only hazard classes open for comments during the Consultation.

The deadline for the adoption of an opinion is 4 May 2023.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. Copper [specific surface area > 0.67 mm^2/mg] - [Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=1)] Copper [specific surface area ≤ 0.67 mm^2/mg] – no classification.	**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.

The Eurometaux Regular Stakeholder Observer highlighted the importance of the presented advanced Specific Surface Approach for future metal assessments and the Occasional Stakeholder Observer from the European Copper Institute commented on the RAC assessment and the agreed classification.

8.2.2.2 Ozone (EC: 233-069-2; CAS: 10028-15-6)

The Chair welcomed a representative of the Dossier Submitter (Germany). The Chair informed that **ozone** is generated in situ as a biocidal active substance from oxygen and used to disinfect water and ambient air. There are also several non-biocidal uses by operation of an ozonation device utilising the oxidative action of ozone e.g. (non-exhaustive): ozonation of mineral water and drinking water or water for swimming pools: removal of iron, manganese, arsenic and nitrite, pharmaceutical, medicine, cosmetics, and food industry: production of (ultra-)pure process water, pulp and paper bleaching, semiconductor industry: production of (ultra-)pure process water, off-gas treatment, laminating and coating, sludge reduction, soil and groundwater remediation, ozonation of wastewater. The substance has no current Annex VI entry.

The DS (DE) proposes to classify ozone as Ox. Gas 1; H270, Acute Tox. 1; H330, Muta. 2; H341, Carc. 2; H351, STOT SE 1; H370, STOT SE 3; H335, STOT RE 1; H372, Aquatic Acute 1; H400 (M = 100), Aquatic Chronic 1; H410 (M = 1).

All hazard classes (physical hazards as well as hazards to human health and the environment) with the exception of skin sensitisation, aspiration hazard and/or hazardous to the ozone layer, in the event that there are no data for these hazard classes were open for comments during the Consultation.

The legal deadline for the adoption of an opinion is 30 August 2023.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling. STOT SE 1; H370 (cardiovascular system) RAC agreed to classify STOT SE 1; H370 (cardiovascular system) based on cardiovascular effects after considering the likely co-existing adverse and non-adverse effects reported in the studies (animal and human data). However, multitude of effects reported on cardiovascular system were still considered as adverse by nature. RAC agreed to include SCLs for the adopted STOT SE and STOT RE classifications but revisit the SCL calculations for gases in RAC-64. Lact. – no classification [Ox. Gas 1; H270, Acute Tox. 1; H330 (ATE=10 ppmV), Muta. 2; H341, STOT SE 1; H370 (respiratory system, nervous system, cardiovascular system), STOT RE 1; H372 (respiratory system, nervous system), Aquatic Acute 1; H400 (M=100), Aquatic Chronic 1; H410 (M=1)]	**Rapporteur** to finalise ODD (carcinogenicity and SCL values for STOT SE 1 and STOT RE 1). **Secretariat** to organise a commenting round on the new section and table it for the discussion at RAC-64 CLH WG.

8.2.2.3 *tert*-butyl 2-ethylperoxyhexanoate (EC: 221-110-7; CAS: 3006-82-4)

The Chair informed that ***tert*-butyl 2-ethylperoxyhexanoate** is used in polymers and plastic products by consumers, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The industrial uses reported are the following: industrial use of organic peroxides as polymerisation initiators, cross linking agents or curing agents; other industrial uses of organic peroxides; use of reactive processing aid at industrial site (no inclusion into or onto article); industrial use of chemicals for polymer processing; industrial use of coatings and paints; industrial use as polymerisation initiator and cross-linking agent; use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into /onto article). Regarding consumer uses, the substance is used in adhesives and sealants, coating and paints, thinners, paint removers and fillers, putties, plasters, modelling clay. The substance has no current Annex VI entry.

The DS (FR) proposes to classify *tert*-butyl 2-ethylperoxyhexanoate as Repr. 1B; H360FD, Skin Sens. 1B; H317.

Reproductive toxicity and skin sensitisation were open for comments during the Consultation.

The legal deadline for the adoption of an opinion is 13 July 2023.

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Repr. 1B; H360FD and Skin Sens. 1; H317]	**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.
8.2.2.4 Pyraclostrobin (ISO); methyl N-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate (EC: - CAS: 175013-18-0)	
The Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. He informed that exceptionally only physical hazards and ENV were discussed in the RAC-63 CLH WG, while the HH part of the draft opinion was prepared and consulted with the Committee prior to this RAC-63 plenary. The Chair noted that **pyraclostrobin** is used as a fungicidal agent in plant protection products. The substance has a current Annex VI entry as Acute Tox. 3 *; H331, Skin Irrit. 2; H315, Aquatic Acute 1; H400 (M=100) and Aquatic Chronic 1; H410. The DS (DE) proposes to modify the classification to Repr. 2; H361d, Acute Tox. 3; H331 (ATE = 0.58 mg/L (dusts or mists)), Acute Tox. 4; H302 (ATE = 450 mg/kg bw), STOT SE 3; H335, STOT RE 2; H373 (liver, gastrointestinal tract), Skin Irrit. 2; H315, Aquatic Acute 1; H400 (M=100) and Aquatic Chronic 1; H410 (M=100). Selected physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, desensitised explosives), 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 open for comments during the Consultation. The deadline for the adoption of an opinion is 22 March 2023.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Repr. 2; H361d, Acute Tox. 3; H331 (ATE = 0.58 mg/L (dusts or mists)), Acute Tox. 4; H302 (ATE = 450 mg/kg bw), Skin Irrit. 2; H315, STOT SE 3; H335, STOT RE 2; H373 (liver, gastrointestinal tract, nasal cavity), Aquatic Acute 1; H400 (M=100), Aquatic Chronic 1; H410 (M=100)]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

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

8.2.2.5 Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl (EC: 201-993-5; CAS: 90-43-7)

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the CropLife Regular Stakeholder Observer. He informed that **biphenyl-2-ol** is used as a post-harvest fungicide in citrus. The substance is currently classified as Skin Irrit. 2; H315, Eye Irrit. 2; H319, STOT SE 3; H335 and Aquatic Acute 1; H400.

The DS (ES) proposes to classify biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl as Skin Corr. 1; H314, Eye. Dam. 1; H318, Carc. 2; H351, Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=1).

Selected physical hazards (organic peroxides; 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), 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, hazards to the aquatic environment and hazards to the ozone layer were open for comments during the Consultation.

The deadline for the adoption of an opinion is 23 August 2023.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Carc. 2; H351, Skin Corr. 1; H314, Eye Dam. 1; H318, Skin Sens. 1B; H317, Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=1)]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the CropLife Regular Stakeholder Observer commented on skin sensitisation and developmental toxicity.

8.2.2.6 Fenpropidin (ISO); (R,S)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine (EC: 614-049-6; CAS: 67306-00-7)

The Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. He informed that **fenpropidin** is used as a fungicidal agent in plant protection products. The substance has no current Annex VI entry.

The DS (CZ, supported by DE) proposes to classify fenpropidin as Acute Tox. 4; H302, Acute Tox. 4; H332, Eye Dam. 1; H318, Skin Sens. 1B; H317, Repr. 2; H361d, STOT SE 3; H335, STOT RE 2; H373 (nervous system), Aquatic Acute 1; H400 (M=1000) and Aquatic Chronic 1; H410 (M=100).

Selected physical hazards (explosive, flammable liquid, self-reactive substance or mixture, pyrophoric liquid, self-heating substance, substance or mixture which in contact with water emits flammable gas, oxidising liquid, substance or mixture 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 and hazards to the aquatic environment were open for comments during the Consultation.

The deadline for the adoption of an opinion is 24 February 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=1330 mg/kg bw), Acute Tox. 4; H332, Skin Irrit. 2; H315, Eye Dam. 1; H318, Skin Sens. 1; H317, STOT SE 3; H335 (respiratory irritation) and H336 (narcotic effects), STOT RE 2; H373 (nervous system, eyes and lungs), Repr. 2; H361d, Aquatic Acute 1; H400 (M=1000), Aquatic Chronic 1; H410 (M=10000)]	**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 CropLife Regular Stakeholder Observer commented on STOT SE for narcotic effects. The expert accompanying the CropLife Regular Stakeholder Observer commented on developmental toxicity.

9. Restrictions

9.1 General Restriction issues

9.1.1 Report from the November 2022 RAC REST WG

RAC took note of the Report of the 7th meeting of the Committee for Risk Assessment Working Group on restrictions held on 8-9 November 2022. The 8th meeting of the RAC Working Group on restrictions will be held during on 14-16 February 2023.	

9.2 Restriction Annex XV dossiers

9.2.1 Conformity check and key issues discussion

9.2.1.1 BPA+ - Conformity check and key issues discussion

The Deputy Chair welcomed the Dossier Submitter's representatives from Germany, the regular stakeholder observers (Cefic, PlasticsEurope) with their accompanying experts (Olin Chemical Business) and the occasional stakeholder observer (CHEM Trust). The dossier has been submitted in October 2022 and concerns a) restricting the use as an additive and the content

in articles (0.02% by weight) b) restricting content of residues (unreacted monomer) in articles – also for imported goods (0.02% by weight) c) restricting the use of mixtures with content of 0.02% by weight for non-automated processes and d) introducing release rates for BPA from articles (products and subassemblies) during service life (weathering, leaching due to cleaning action) preventing release into the environment and/or (direct) migration to organisms.	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC discussed the recommendations to the Dossier Submitter, and recommended additional issue to be added (e.g. to clarify emissions estimates for five uses).	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
The regular stakeholder observer asked for clarifications regarding the concentration limit of 10ppm and environmental releases (migration limits). Experts accompanying the regular stakeholder observers from the PlasticsEurope and Cefic asked to further clarify the methodology regarding migration test requirements and commented that the testing methods should be, i.a., able to cover the articles in the scope and the preceding relevant life-cycle steps. Cefic will submit input on this via the third-party consultation.	
9.2.1.2. Creosote, and creosote related substances	
The Chair welcomed the Dossier Submitter's representatives from France, the regular stakeholder observers from Cefic with their accompanying expert (Koppers). 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.	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC discussed the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
The Commission observer noted that creosote treated wood as waste is out of the scope of REACH. Furthermore, the expert accompanying CEFIC commented on the scope of the restriction, suggesting that substances other than creosote should not be in the scope. The Chair encouraged to submit these specific comments via the third-party consultation on the Annex XV dossier which will be launched on 21 December 2022, if the dossier is confirmed to be in conformity in both Committees.	
9.2.2. Opinion development	
9.2.2.1 Medium chain chlorinated paraffins (MCCP) – first draft opinion	
The Deputy Chair welcomed the Dossier Submitter's representatives from ECHA as well as the accompanying expert to the Cefic regular stakeholder observer (CPIA). 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 8 and 9 November 2022, RAC-63 agreed on the:	**Rapporteurs** to prepare the second draft opinion, taking into account the discussion the RAC-63 Working Group on restrictions.

• The scope of the risk assessment is clear and is justified in sufficient detail. • Hazard(s) • Evaluation of emissions • Existing OCs and RMMs • Risk characterisation	**Secretariat** to table the second draft opinion for discussion at the RAC-64 Working Group on restrictions in February 2023.
The expert accompanying the Cefic regular stakeholder observer commented on the substance identification (e.g. related to materials, manufacturing process etc).	
9.2.2.2. Terphenyl, hydrogenated – second draft opinion	
The Deputy Chair welcomed the Dossier Submitter's representatives from Italy, and the regular stakeholder observers. She informed the participants that the dossier has been submitted by Italy in April 2022 and concerns the restriction of the use of Terphenyl, hydrogenated.	
Based on the recommendations of the Restriction Working Group which met on 8-9 November 2022, RAC-63 agreed that: • the emissions may be used as a proxy for risk. • the quantitative emission assessment was not reliable • despite the uncertainties in the emission estimates, releases and exposures from current uses occur and there is hence a risk to address • current operational conditions and risk management measures are not effective to control the risks from terphenyl, hydrogenated in HTF systems • despite the uncertainties, Action is required on Union-wide basis inter alia due to vPvB status of the substance and wide dispersiveness of uses. The rapporteurs then presented, and RAC briefly discussed the 2nd draft opinion and the possibility of a qualitative approach to evaluate the case as recommended by RAC-63 Working Group for discussion at RAC-63. • RAC-63 supported the rapporteurs would derive a qualitative approach to evaluation as proposed by the rapporteurs.	**Rapporteurs** to prepare the third draft opinion, taking into account the discussion the RAC-63 Working Group on restrictions and the discussions at RAC-63. **Rapporteurs** to further explore the qualitative approach and incorporate their findings in the 3rd DO. **Secretariat** to table the third draft opinion for discussion at the RAC-64 Working Group on restrictions in February 2023.
No interventions by stakeholder observers were made.	
9.2.2.3. N,N-dimethylacetamide and 1-ethylpyrrolidin-2-one – second draft opinion	

The Chair welcomed the Dossier Submitter's representatives from the Netherlands, the regular stakeholder observers and their accompanying experts (Cefic), the occasional stakeholder observers (CIRFS, EDANA) and their accompanying experts (CIRFS). He informed the participants that the dossier has been submitted by the Netherlands in April 2022 and concerns occupational exposure to N,N-dimethylacetamide and 1-ethylpyrrolidin-2-one.

Based on the recommendations of the Restriction Working Group which met on 8-9 November 2022, RAC-63 agreed on the:

- **DNELs**:
  - DMAC: Systemic long-term dermal DNEL of 1.8 mg/kg bw/day
  - DMAC: Biomarker DNEL of 15 mg NMAC/g creatinine
  - NEP: acute inhalation DNEL not supported
  - NEP: Biomarker DNEL of 20 mg 5-HNEP+2-HESI/L urine
- DS **exposure estimates** as a basis for the risk characterisation
- **Risk characterisation**:
  - Risks for workers cannot be excluded and are not sufficiently controlled
  - Uncertainties lead to conservatism in the risk characterisation
- **Existing RMMs and OCs** cannot be evaluated due to lack of use-specific data
- **Action required on an EU-wide basis**
- **Risks of alternatives** are not analysed
- **Other regulatory RMOs**

The rapporteurs then presented and RAC briefly discussed the 2nd draft opinion.

RAC supported the WG recommendation to review monitoring data and contextual information if received as part of the consultation on the Annex XV report. RAC supported further work on uncertainties, effectiveness, practicality and monitorability of the proposed restriction options.

Rapporteurs to prepare the third draft opinion, taking into account the discussions of RAC-63 and the RAC-63 Working Group on restrictions.

Secretariat to table the third draft opinion for discussion at the RAC-64 Working Group on restrictions in February 2023.

Secretariat to consider updating the existing guidance on the NMP restriction for DMAC and NEP.

An occasional stakeholder observer (CIRFS) commented on the risk characterisation and existing RMMs and OCs.

10. Authorisation

10.1 General authorisation issues

10.1.1 Report from the October AFA Working Group	
The Secretariat presented the Report of the 13th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group which took place on 11-12 October 2022. RAC took note of the Report.	
10.1.2 Update on incoming/future applications	
The ECHA Secretariat presented information on proposed changes in AFA process concerning preparation of the Key issues presentation in month four of the AFA process and submission of questions to applicants after first draft of opinions. Generally, RAC supported proposed changed although RAC members proposed to further standardize the Key issues presentation. Some members requested the Secretariat to prepare a decision tree to support the rapporteurs in drafting opinions	**SECR** to consider outcome of the discussion and continue discussion at the next RAC AFA WG.
10.2 Authorisation applications	
10.2.1. Discussion on key issues	
10.2.1.1. 12 applications for authorisation (chromium trioxide) from August 2022 submission window	
RAC discussed the key issues in 12 applications for authorisation (chromium (VI) substances) from August 2022 submission window. The table was made available on the S-CIRCABC and on the Interact Portal.	
10.3 Agreement on draft opinions	
10.3.1 Draft opinions for agreement without plenary debate (A-list) 1. 261_CT_Metalbrass (1 use) 2. 262_CT_Cromoplastica (2 uses) 3. 264_CT_Cristina (1 use) 4. 265_TXP_EDF (2 uses) 5. 266_CT_Olivari (1 use) 6. 267_CT_SPGPrints (1 use) 7. 268_CT_Paffoni (1 use) 8. 269_CT_Rubinetterie3M (1 use) 9. 271_CT_Villeroy (1 use) 10. 272_CT_RIGHI (1 use) ECHA Secretariat presented the summary of the draft opinions.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicants for commenting.

RAC agreed by consensus the 12 draft opinions on the Application listed in Annex IV.	
10.3.2 Draft opinions for discussion and agreement	
1. 260_CT_SARREL (1 use) **2. 270_CT_Maier (2 uses)**	
RAC discussed the outcome of a review of LEV control systems in Cr(VI) Applications presented by the Secretariat. In 70% of the reviewed cases, an LEV control/ alarm system is in place and in 4% of the AfAs it is being implemented (opinions discussed by RAC in 2020-2022). RAC supported the approach proposed by the Secretariat: - Overview tables: information on LEV control systems was incorporated for all reviewed AfAs - A standard RAC question to be asked if information on LEV control systems is missing in the CSR - RAC lines-to-take: to be updated with standard text on a feasibility study as per CT-Hübner draft decision. **260_CT_Sarrel (1 use)** **Use1:** *Industrial use of chromium trioxide for the etching of plastics materials, as a pre-treatment step of the electroplating process, for automotive applications mostly.* 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 by liquid solutions of CrO_3 to further limit exposure; b) the implementation of an automated system to perform the concentration adjustment of the chromium baths and	**SECR** to implement conclusions of the RAC discussion on LEV in relevant documents. **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.

the implementation of a closed/automated system to perform bath sampling tasks where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. c) the installation of a system that continuously controls 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. 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. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. **270_CT_Maier (2 uses)** **Use1:** *Functional chrome plating with decorative character for automotive applications.* **Use2:** *Etching of plastics with chromium trioxide as pre-treatment step for electroplating of plastics for automotive applications.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to.	

RAC agreed: Section 7: additional conditions for the authorisation 1) The applicant shall ensure that 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 full substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure. b) the implementation of an automated system for sampling or sampling in a closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen. c) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and/or the shutdown of the plating operation in case the local exhaust ventilation is not functioning properly. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC agreed the draft opinions by consensus.	
3. 263_CT_Orelec (1 use)	
Use1: *Industrial use of chromium trioxide for the hard chrome plating of injection moulds in order to provide hardness, wear resistance and good demoulding properties, critical for the manufacture of high-quality plastic parts.*	**Rapporteur** together with **SECR** to do the final editing of the draft opinion according to the discussion at the plenary. **SECR** to send the draft opinion to the applicant for commenting.

RAC supported the draft opinion as proposed by the Rapporteur. 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 undue delay increased local enclosure (with lid, as described by Applicant in response to questions from RAC on the feasibility of additional risk management measures) of the bath to ensure that workers not performing activities directly associated with the bath (WCS 4) are protected from inhalation exposure. Within 12 months of the European Commission adopting the Decision, the Applicant shall implement segregation of the bath from the rest of the workshop or segregation of other activities from the bath (i.e. other activities when the bath is in use) to further reduce inhalation exposure of workers not performing activities directly associated with the bath (WCS 4). Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC agreed the draft opinion by consensus.	
10.4 Adoption of opinions	
10.4.1 242_RR1_TCE_Microporous (1 use)	
Use1: *Trichloroethylene used as extraction solvent in the manufacture of polyethylene separators for lead-acid batteries.* The Rapporteur presented the final draft opinion adapted after the authorisation holder comments. RAC concluded that the operational conditions and risk management measures described in	**SECR** to send the final opinion to the authorisation holder, the European Commission and MS CAs.

the review report are appropriate and effective in limiting the risk, if they are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation None Section 8: monitoring arrangements for the authorisation 1. The authorisation holder shall implement a continuous monitoring of the air flow in the extraction units and install an alarm to be activated in case the air flow drops below the value which may lead to increase of concentration of TCE in the extraction unit. In addition to the airflow measurements, the actual TCE concentration in the extraction units shall be measured weekly with a handheld device, e.g. PID or Draeger tubes. The results shall be recorded in a manual logbook which shall be available on request. 2. The authorisation holder shall continue to perform a continuous monitoring of TCE workplace concentrations in the production and finishing areas and conduct an annual monitoring programme of occupational exposure for trichloroethylene of workers, directly or indirectly involved in the production of polyethylene separators for lead-acid batteries, using a sufficiently sensitive analytical method for inhalation exposure measurement and for biomonitoring. Samples for biomonitoring shall be taken at the end of the last shift of the working week, as recommended by the SCOEL when establishing the BLV for TCE. The monitoring programmes shall be based on relevant standard methodologies or protocols, comprise both static and personal inhalation exposure sampling, include detailed contextual information on the tasks performed, the duration of monitoring, the OCs and RMMs in place and be representative of: a. the range of tasks undertaken within all worker contributing scenarios identified where exposure to trichloroethylene is possible, including tasks involving maintenance tasks;	

b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed, including workers not directly using the substance. 3. The authorisation holder shall maintain the continuous TCE measurements in exhaust air using a sufficiently sensitive analytical method and the continuous measurement of exhaust air volume flow of the active carbon plant chimney, to obtain a more accurate statement about the air emission. 4. The information gathered via the measurements referred to in paragraphs 1 to 3, as well as related contextual information, shall be used by the authorisation holder to confirm the effectiveness of OCs and RMMs and to review regularly the effectiveness of OCs and RMMs in place and to introduce measures to further reduce workplace exposure, respectively air emissions of TCE, to as low a level as technically and practically feasible. 5. The information from the monitoring programmes referred to in paragraphs 1 to 3, 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 4, shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent authority, and included in any subsequent authorisation review report. 6. The authorisation holder may reduce the frequency of measurements, once he 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. 7. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 6, any subsequent changes	

to the operational conditions or risk management measures that may affect the exposure of workers at the site where the use takes place shall be documented. The authorisation holder 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, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8, should be documented and included in any subsequent review report. RAC adopted the final opinion by consensus.	
10.4.2. 243_RR1_TCE_DOMO (1 use)	
Use1: *Industrial use as an extraction solvent for the purification of caprolactam from caprolactam oil.* The Rapporteur presented the final draft opinion adapted after the authorisation holder comments. 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 adhered to. RAC agreed: Section 7: additional conditions for the authorisation 1. The authorisation holder shall implement the OCs and RMMs as planned, i.e. the further extension of the vent system with integration of vessel B636 a/b, to seal the system and further reduce TCE emissions. 2. The authorisation holder shall carry out and document a detailed feasibility study to further limit fugitive emissions. Section 8: monitoring arrangements for the authorisation 1. The authorisation holder shall continue to conduct regular occupational exposure	**SECR** to send the final opinion to the authorisation holder, the European Commission and MS CAs.

measurements relating to the use of TCE described in this review report. (a) Occupational inhalation exposure monitoring programmes, which shall: (i) take place at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to trichloroethylene.; (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 trichloroethylene is possible, i.e. including production and maintenance workers; 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 authorisation holder shall continue conducting their monitoring programme for TCE emission to air and wastewater monitoring before discharging the wastewater to the WWTP; (ii) the authorisation holder 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 authorisation holder's site. 2. The authorisation holder shall use the information gathered via the measurements referred to in Section 8.1 including the contextual information to review annually the effectiveness of the risk management	

measures and operational conditions and to introduce measures to reduce worker's exposure to trichloroethylene as well as emissions to the environment to as low a level as technically and practically feasible. 3. The authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 4. The authorisation holder shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 5. 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. 6. The authorisation holders 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. 7. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 6, 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 holder 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. 8. The authorisation holder shall continue their	

existing biomonitoring programme for the workers potentially exposed to trichloroethylene. Section 9: recommendations for the review report The authorisation holder should document - in a potential further review report - the results of the monitoring programs and the optimisation of RMMs and OCs carried out in order to minimise the TCE emissions. RAC adopted the final opinion by consensus.	
10.4.3. 249_CT_Tenneco_CZ (1 use) **10.4.4. 250_CT_Tenneco_ES (1 use)** **10.4.5. 251_CT_Tenneco_BE (1 use)** **10.4.6. 252_CT_Tenneco_PL (1 use)**	
Use1: *The use of Chromium Trioxide (EC 215-607-8) by Tenneco Automotive Europe BVBA in the functional chrome plating of shock absorber rods* The Rapporteur presented the final draft opinions adapted after the applicant comments. RAC concluded that the operational conditions and risk management measures described in the application are appropriate (*for PL and ES sites)/[*generally] appropriate (*for BE and CZ sites)* and effective in limiting the risk for workers and humans via the environment. RAC agreed: Section 7: additional conditions for the authorisation **249_CT_Tenneco_CZ (1 use)** The applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 flakes by liquid CrO_3 to further limit exposure, taking into account additional RMMs such as the use of a plastic sleeve adapter on the top of solid CrO_3 container to prevent exposure of the workers to CrO_3 dust. (b) the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the	**SECR** to send the draft opinions to the applicant, the European Commission and MS CAs.

use of PPE. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period. Until the implementation of the relevant actions according to feasibility study, the applicant shall consider additional RMMs (for example, the use of a plastic sleeve adapter on the top of solid CrO_3 container) to prevent exposure of the workers to CrO_3 dust. **250_CT_Tenneco_ES (1 use)** The applicant shall carry out and document a detailed feasibility study 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 feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period. **251_CT_Tenneco_BE (1 use)** The applicant shall carry out and document a detailed feasibility study on: (a) the automated/closed decanting of solid chromium trioxide into the pre-mixing tank (for example using a closed cabinet or glove box), (b) the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. The feasibility study shall be concluded within 12 months of the granting of the authorisation for this use. Relevant actions must be implemented accordingly during the review period. **252_CT_Tenneco_PL (1 use)** The applicant shall carry out and document a detailed feasibility study 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 feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be	

implemented accordingly during the review period. **For all four opinions:** Section 8: monitoring arrangements for the authorisation 1. The applicant shall continue to implement the following 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, including activities such as sampling and corrective maintenance (WCSs 7 and 9); (v) be representative of: a. the full range 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 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. 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 RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans 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. 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 applicant 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. 6. The applicant shall reimplement an annual	

biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9: recommendations for the review report The results of the measurements referred to in sections 8 paragraph 1 and 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 paragraph 2, should be documented and included in any subsequent review report. RAC adopted the final opinions by consensus.	
11. AOB	
No items were raised.	
12. Minutes of RAC-63	
12.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-63	
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-63 to CIRCA BC.

CLH opinions at RAC-63

1. 1,4-Dichloro-2-nitrobenzene

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	1,4-dichloro-2-nitrobenzene	201-923-3	89-61-2	Carc. 1B	H350	GHS08 Dgr	H350			
RAC opinion	TBD	1,4-dichloro-2-nitrobenzene	201-923-3	89-61-2	Carc. 1B	H350	GHS08 Dgr	H350			
Resulting Annex VI entry if agreed by COM	TBD	1,4-dichloro-2-nitrobenzene	201-923-3	89-61-2	Carc. 1B	H350	GHS08 Dgr	H350			

2. n-hexane

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	601-037-00-0	*n*-hexane	203-777-6	110-54-3	Flam. Liq. 2 Repr. 2 Asp. Tox. 1 STOT SE 3 STOT RE 2 * Skin Irrit. 2 Aquatic Chronic 2	H225 H361f*** H304H336 H373** H315 H411	GHS02 GHS08 GHS07 GHS09 Dgr	H225 H361f*** H304 H336 H373** H315 H411		STOT RE 2; H373: C ≥ 5%	
Dossier submitters proposal	601-037-00-0	*n*-hexane	203-777-6	110-54-3	**Modify** STOT RE 1	**Modify** H372 (nervous system)		**Modify** H372 (nervous system)		**Delete** STOT RE 2; H373: C ≥ 5%	
RAC opinion	601-037-00-0	*n*-hexane	203-777-6	110-54-3	**Modify** STOT RE 1	**Modify** H372 (nervous system)		**Modify** H372 (nervous system)		**Delete** STOT RE 2; H373: C ≥ 5%	
Resulting Annex VI entry if agreed by COM	601-037-00-0	*n*-hexane	203-777-6	110-54-3	Flam. Liq. 2 Repr. 2 Asp. Tox. 1 STOT SE 3 STOT RE 1 Skin Irrit. 2 Aquatic Chronic 2	H225 H361f*** H304 H336 H372 (nervous system) H315 H411	GHS02 GHS08 GHS07 GHS09 Dgr	H225 H361f*** H304 H336 H372 (nervous system) H315 H411			

3. Dibenzoyl peroxide; benzoyl peroxide

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	617-008-00-0	dibenzoyl peroxide; benzoyl peroxide	202-327-6	94-36-0	Org. Perox. B Eye Irrit. 2 Skin Sens. 1	H241 H319 H317	GHS01 GHS02 GHS07 Dgr	H241 H319 H317			
Dossier submitters proposal	617-008-00-0	dibenzoyl peroxide; benzoyl peroxide	202-327-6	94-36-0	**Add** Aquatic Acute 1 Aquatic Chronic 1	**Add** H400 H410	**Add** GHS09	**Add** H410		**Add** M = 10 M = 10	
RAC opinion	617-008-00-0	dibenzoyl peroxide; benzoyl peroxide	202-327-6	94-36-0	**Add** Aquatic Acute 1 Aquatic Chronic 1	**Add** H400 H410	**Add** GHS09	**Add** H410		**Add** M = 10 M = 10	
Resulting Annex VI entry if agreed by COM	617-008-00-0	dibenzoyl peroxide; benzoyl peroxide	202-327-6	94-36-0	Org. Perox. B Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H241 H319 H317 H400 H410	GHS01 GHS02 GHS07 GHS09 Dgr	H241 H319 H317 H410		 M = 10 M = 10	

4. Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol

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	reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol	-	-	Repr. 1B	H360Df	GHS08 Dgr	H360Df			
RAC opinion	TBD	reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol	-	-	Repr. 1B	H360Df	GHS08 Dgr	H360Df			
Resulting Annex VI entry if agreed by COM	TBD	reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol	-	-	Repr. 1B	H360Df	GHS08 Dgr	H360Df			

5. Cyclohex-3-ene-1-carbaldehyde derivatives

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	cyclohex-3-ene-1-carbaldehyde derivatives	-	-	Skin Sens. 1B	H317	GHS07 Wng	H317			
RAC opinion	TBD	cyclohex-3-ene-1-carbaldehyde derivatives	-	-	Skin Sens. 1	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	cyclohex-3-ene-1-carbaldehyde derivatives	-	-	Skin Sens. 1	H317	GHS07 Wng	H317			

6. Fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine

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	fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine	-	67306-00-7	Repr. 2 Acute Tox. 4 Acute Tox. 4 STOT SE 3 STOT RE 2 Eye Dam. 1 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H361d H332 H302 H335 H373 (nervous system) H318 H317 H400 H410	GHS08 GHS07 GHS05 GHS09 Dgr	H361d H332 H302 H335 H373 (nervous system) H318 H317 H410		M = 1000 M = 100	
RAC opinion	TBD	fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine	-	67306-00-7	Repr. 2 Acute Tox. 4 Acute Tox. 4 STOT SE 3 STOT SE 3 STOT RE 2 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H361d H332 H302 H335 H336 H373 (nervous system, eyes, lungs) H315 H318 H317 H400 H410	GHS08 GHS07 GHS05 GHS09 Dgr	H361d H332 H302 H335 H336 H373 (nervous system, eyes, lungs) H315 H318 H317 H410		oral: ATE = 1330 mg/kg bw M = 1000 M = 10000	
Resulting Annex VI entry if agreed by COM	TBD	fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine	-	67306-00-7	Repr. 2 Acute Tox. 4 Acute Tox. 4 STOT SE 3 STOT SE 3 STOT RE 2 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H361d H332 H302 H335 H336 H373 (nervous system, eyes, lungs) H315 H318 H317 H400 H410	GHS08 GHS07 GHS05 GHS09 Dgr	H361d H332 H302 H335 H336 H373 (nervous system, eyes, lungs) H315 H318 H317 H410		oral: ATE = 1330 mg/kg bw M = 1000 M = 10000	

7. Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl

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	604-020-00-6	biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl	201-993-5	90-43-7	STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Aquatic Acute 1	H335 H315 H319 H400	GHS07 GHS09 Wng	H335 H315 H319 H400			
Dossier submitters proposal	604-020-00-6	biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl	201-993-5	90-43-7	**Retain** Aquatic Acute 1 **Add** Carc. 2 Aquatic Chronic 1 **Modify** Skin Corr. 1 Eye Dam. 1 **Remove** STOT SE 3	**Retain** H400 **Add** H351 H410 **Modify** H314 H318 **Remove** H335	**Retain** GHS09 **Add** GHS08 GHS05 **Modify** Dgr **Remove** GHS07	**Add** H351 H410 **Modify** H314 **Remove** H335 H400		**Add** M = 1 M = 1	
RAC opinion	604-020-00-6	biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl	201-993-5	90-43-7	**Retain** Aquatic Acute 1 **Add** Carc. 2 Skin Sens. 1B Aquatic Chronic 1 **Modify** Skin Corr. 1 Eye Dam. 1 **Remove** STOT SE 3	**Retain** H400 **Add** H351 H317 H410 **Modify** H314 H318 **Remove** H335	**Retain** GHS09 **Add** GHS08 GHS05 **Modify** Dgr **Remove** GHS07	**Add** H351 H410 **Modify** H314 **Remove** H335 H400		**Add** M = 1 M = 1	
Resulting Annex VI entry if agreed by COM	604-020-00-6	biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl	201-993-5	90-43-7	Carc. 2 Skin Corr. 1 Eye Dam. 1 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H351 H314 H318 H317 H400 H410	GHS08 GHS05 GHS07 GHS09 Dgr	H351 H314 H317 H410		M = 1 M = 1	

8. tert-butyl 2-ethylperoxyhexanoate

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	*tert*-butyl 2-ethylperoxyhexanoate	221-110-7	3006-82-4	Repr. 1B Skin Sens. 1B	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			
RAC opinion	TBD	*tert*-butyl 2-ethylperoxyhexanoate	221-110-7	3006-82-4	Repr. 1B Skin Sens. 1	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			
Resulting Annex VI entry if agreed by COM	TBD	*tert*-butyl 2-ethylperoxyhexanoate	221-110-7	3006-82-4	Repr. 1B Skin Sens. 1	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			

9. Pyraclostrobin (ISO); methyl N-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-272-00-6	pyraclostrobin (ISO); methyl N-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate	-	175013-18-0	Acute Tox. 3* Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H331 H315 H400 H410	GHS06 GHS09 Dgr	H331 H315 H410		M=100	
Dossier submitters proposal	613-272-00-6	pyraclostrobin (ISO); methyl N-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate	-	175013-18-0	**Retain** Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2 Acute Tox. 4 STOT SE 3 STOT RE 2 **Modify** Acute Tox. 3	**Retain** H331 H315 H400 H410 **Add** H361d H302 H335 H373 (liver, gastrointestinal tract)	**Retain** GHS06 GHS09 Dgr **Add** GHS08	**Retain** H331 H315 H410 **Add** H361d H302 H335 H373 (liver, gastrointestinal tract)		inhalation: ATE = 0.58 mg/L (dusts or mists) oral: ATE = 450 mg/kg bw M = 100 M = 100	
RAC opinion	613-272-00-6	pyraclostrobin (ISO); methyl N-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate	-	175013-18-0	**Retain** Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2 Acute Tox. 4 STOT SE 3 STOT RE 2 **Modify** Acute Tox. 3	**Retain** H331 H315 H400 H410 **Add** H361d H302 H335 H373 (liver, gastrointestinal tract, nasal cavity)	**Retain** GHS06 GHS09 Dgr **Add** GHS08	**Retain** H331 H315 H410 **Add** H361d H302 H335 H373 (liver, gastrointestinal tract, nasal cavity)		inhalation: ATE = 0.58 mg/L (dusts or mists) oral: ATE = 450 mg/kg bw M = 100 M = 100	
Resulting Annex VI entry if	613-272-00-6	pyraclostrobin (ISO); methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-	-	175013-18-0	Repr. 2 Acute Tox. 3 Acute Tox. 4 STOT SE 3	H361d H331 H302 H335	GHS08 GHS06 GHS09 Dgr	H361d H331 H302 H335		inhalation: ATE = 0.58 mg/L (dusts or mists)	

agreed by COM		yloxymethyl]phenyl}(*N*-methoxy)carbamate			STOT RE 2 Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H373 (liver, gastrointestinal tract, nasal cavity) H315 H400 H410		H373 (liver, gastrointestinal tract, nasal cavity) H315 H410		oral: ATE = 450 mg/kg bw M = 100 M = 100	

10. Copper

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 ATEs	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 submitter's proposal	TBD	copper; [specific surface area >0.67 mm^2/mg]	231-159-6	7440-50-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 10 M = 1	
RAC opinion	TBD	copper; [specific surface area >0.67 mm^2/mg]	231-159-6	7440-50-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 10 M= 1	
Resulting Annex VI entry if agreed by COM	TBD	copper; [specific surface area >0.67 mm^2/mg]	231-159-6	7440-50-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 10 M= 1	

Part III. List of Attendees of the RAC-63 meeting

RAC members (physical attendance)	
Angeli	Karine
Biró	Anna
Brovkina	Julija
Chiurtu	Elena-Ruxandra
Deviller	Genevieve
Doak	Malcolm
Docea	Anca Oana
Facchin	Manuel
Fernández	Mariana F.
Geoffroy	Laure
Ginnity	Bridget
Hartwig	Andrea
Kadiķis	Normunds
Karadjova	Irina
Losert	Annemarie
Lund	Bert-Ove
Martinek	Michal
Menard Srpčič	Anja
Mendas Starcevic	Gordana
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Murray	Brendan
Paris	Pietro
Peczkowska	Beata
Rodriguez	Wendy
Santonen	Tiina
Schlüter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sogorb	Miguel A.
Sørensen	Peter Hammer
Spetseris	Nikolaos
Tekpli	Nina Landvik
Tobiassen	Lea Stine
Tsitsimpikou	Christina
Užomeckas	Žilvinas
van der Haar	Rudolf
Varnai	Veda Marija
Viegas	Susana

RAC members (remote attendance)	
Baranski	Boguslaw
Hakkert	Betty
Leinonen	Riitta
Neumann	Michael
Pribu	Mihaela
Rakkestad	Kirsten Eline

Apologies RAC members	
Aquilina	Gabriele
Gebel	Thomas
Xanthos	Theodore

Members' advisers (physical attendance)		
Dumke	Carolin	Schlüter Urs, DMAC/NEP
Esposito	Dania	Paris Pietro
Jankowska	Agnieszka	Peczkowska Beata

Members' advisers (remote attendance)		
Dubois	Celine	Angeli Karine, Restrictions on 29.11.
Hoffmann	Frauke	Schulte Agnes
Huuskonen	Pasi	Santonen Tiina
Moilanen	Marianne	Leinonen Riitta
Rehrl	Anna-Lena	Facchin Manuel
Saksa	Jana	Moldov Raili
Seba	Julie	Rodriguez Wendy
Stalter	Daniel	Schulte Agnes
Suutari	Tiina	Leinonen Riitta

SEAC Rapporteurs (physical attendance)		
Janssen	Martien	Creosote
Jomini	Stephane	MCCP
Thiele	Karen	Art 77 Lead

SEAC Members' advisers (remote attendance)		
De Blaeij	Arianne	Janssen Martien, creosote

Invited experts (physical attendance)		
Piña	Benjamin	

Invited experts (remote attendance)		Role/Substance
Catone	Tiziana	Adviser to Gabriele Aquilina
Cromie	Ruth	AEWA: Art 77(3)c Lead
Kohns	Kevin	Adviser to Tom Gebel: OEL: PAH
Levy	Patrick	Employers Interest Group: OEL: Cobalt/PAH
Musu	Tony	Workers Interest Group: OEL: Cobalt/PAH
Russo	Maria Teresa	Adviser to Gabriele Aquilina

Dossier submitters (remote participation)		Substance
Alivernini	Silvia	Terphenyl
Arning	Jürgen	Bisphenols
Attias	Leonello	Terphenyl, hydrogenated
Čapková	Katarína	Fenpropidin
Catone	Tiziana	Terphenyl, hydrogenated
Charles	Sandrine	TBPEH
Charron	Isabelle	Creosote
Choi	Judy	Pyraclostrobin
Drissi-Amraoui	Sammy	Creosote
Falck	Jonas	Copper
Fanguet	Céline	Creosote
Fiore	Karine	Creosote
Galert	Wiebke	BPA Restriction
Hily	Emeline	Creosote
Jomini	Stéphane	Creosote
Jongeneel	Rob	DMAC-NEP
Kaßner	Franziska	BPA+
Maniere	Isabelle	TBPEH
Orru	Maria Antonietta	Terphenyl hydrogenated
Pasquier	Elodie	Creosote
Rudzok	Susanne	Ozone
Sanz	Manuel	Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl
Tenorio Gómez	María	Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl(EC: 201-993-5; CAS: 90-43-7)
Unkelbach	Christian	BPA+ (Restriction on BPA and bisphenols of similar concern for the environment)

Regular stakeholder observers (physical attendance)	
Barry	Frank (ETUC)
Duguy	Hélène (ClientEarth)
Ruelens	Paul (CropLife Europe)
Verougstraete	Violaine (Eurometaux)
Waeterschoot	Hugo (Eurometaux): CLH Copper

Regular stakeholder observers (remote attendance)	
Cassart	Michel (PlasticsEurope)
Evans	Benedict (MedTech Europe)

Hinkal	George (Concawe)
Robinson	Jan (A.I.S.E)
Romano Mozo	Dolores (EEB)
Van de Broeck	Steven (Cefic)

Occasional stakeholders (remote participation)		**Substance**
Baken	Stijn (European Copper Institute)	Copper
Ballach	Jochen (CIRFS)	9.2.2.2 N,N-dimethylacetamide and 1-ethylpyrrolidin-2-one – second draft opinion
Barbu	Luminita (edana)	Item 7– RAC Work Plan for Restriction, Authorisation and C&L processes
Palinkas	Jean-Francois (FITASC)	lead in outdoor shooting and fishing
Puustinen	Seppo (FACE)	lead in outdoor shooting and fishing
Reineke	Ninja (CHEM Trust)	bisphenols restrictions

Stakeholder experts (remote participation)		**Substance**
Gestermann	Sven (PlasticsEurope)	BPA+
Höke	Hartmut (Cefic)	PAH
Hunziker	René (Cefic)	BPA
Jaques	Andrew (Cefic)	MCCP
Kørner	Mads Boye (Cefic)	Creosote and creosote related substances
Mackie	Carol (Eurometaux)	Copper
Pain	Debbie (EEB)	Lead in ammunition
Schrage	Arnhild (Cefic)	DMAC/NEP
Schüller	Jan (Cefic)	Terphenyl, hydrogenated
Sebastiani	Giuliana (Eurometaux)	Lead article 77(3)
Tesh	Sheila (CropLife Europe)	Fenpropidin
Viegas	Vanessa (Eurometaux)	OEL: Cobalt
Walter	Sage (CropLife Europe)	Biphenyl-2-ol; 2-Phenylphenol
Werner	Christophe (CropLife Europe)	Pyraclostrobin
Wieske	Martin (Cefic)	Cobalt

European Commission (physical participation)		DG
Dunauskiene	Lina	DG GROW

European Commission (remote participation)		DG
Fabbri	Marco	DG GROW
Heras	Nerea	DG EMPL (OELs)
Kilian	Karin	DG ENV
Morris	Alick	DG EMPL (OELs)
Pinte	Jeremy	DG GROW
Podniece	Zinta	DG EMPL (OELs)
Roebben	Gert	DG GROW
SCHUTTE	Katrin	DG ENV
Streck	Georg	DG ENTR
Tailler	William	DG EMPL (OELs)
Tosetti	Patrizia	DG GROW

EU Agency Observers (remote participation)		
n/a	n/a	n/a

ECHA staff (physical or remote participation)	
Bowmer	Tim (Chair)
Doyle	Simone
Franke	Greta
Gmeinder	Michael
Hoffstadt	Laurance
Karjalainen	Antti
Klausbruckner	Carmen
Kokkola	Leila
Lazic	Nina
Lefevre	Sandrine
Logtmeijer	Christiaan
Ludborzs	Arnis
Marquez-Camacho	Mercedes
Mattiuzzo	Marco
Mushtaq	Fesil
Nicot	Thierry
Nurmi	Väinö
Nygren	Jonas
Orispää	Katja
O'Rourke	Regina
Peltola	Jukka
Peltola-Thies	Johanna (Vice-Chair)
Perazzolo	Chiara
Pikkarainen	Liisa
Pillet	Monique

Portugal	Laura
Prevedouros	Kostas
Rahkonen	Olli
Reuter	Ulrike
Roberts	Julian
Roggeman	Maarten
Ryan	Paul
Sadam	Diana
Simpson	Peter
Sosnowski	Piotr
Spjuth	Linda
Stockmann-Juvala	Helene
Thierry-Mieg	Morgane
Uphill	Simon
van Haelst	Anniek
Zeiger	Bastian

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-63 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-63 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-63 meeting

ANNEX IV List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-63 meeting without plenary debate (A-list)

Annex I

RAC/A/63/2022

28 November 2022
RAC/A/63/2022

Final Agenda
63rd meeting of the Committee for Risk Assessment
(RAC-63)

28 November-1 December 2022

Face-to-face meeting[1]

Monday, 28 November starts at 14.00
Thursday, 1 December ends at 15.45

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/63/2022
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

[1] Members are expected to attend in person.

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

1. DNEL setting for DOTE/MOTE (Request to the Committee for Risk Assessment to set a DNEL for 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE))
2. Request to RAC to prepare to prepare a supplementary opinion on lead in outdoor shooting and fishing

For discussion and adoption

Item 7 –Health based exposure limits at the workplace

7.1 Opinions for discussion

1. Cobalt – adoption of opinion
2. Polyaromatic hydrocarbons (PAH) – adoption of opinion

For discussion and adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the October CLH Working Group

RAC/63/2022/01
For information

8.2 CLH dossiers

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

- 1,4-Dichloro-2-nitrobenzene: *carcinogenicity, germ cell mutagenicity*
- Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl: *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, STOT RE, STOT SE, mutagenicity, carcinogenicity, reproductive toxicity (fertility and lactation), hazards to the aquatic environment, hazard to the ozone layer*
- Dibenzoyl peroxide; benzoyl peroxide: *hazards to the aquatic environment*
- Fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine: *physical hazards, acute toxicity, STOT SE (respiratory irritation), skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity (fertility and lactation), hazards to the aquatic environment*
- *n*-Hexane: *STOT RE*
- Ozone: *physical hazards, acute toxicity, STOT SE (respiratory system and nervous system, except SCL values), STOT RE (respiratory system and nervous system, except SCL values), mutagenicity, reproductive toxicity (fertility and development), skin irritation/corrosion, serious eye damage/eye irritation, respiratory sensitisation, hazards to the aquatic environment*
- Pyraclostrobin (ISO); methyl *N*-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate: *physical hazards, hazards to the aquatic environment, hazard to the ozone layer, acute inhalation and dermal toxicity, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, reproductive toxicity (fertility and lactation)*

- Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol (glycerol formal): *reproductive toxicity (fertility, development and lactation)*
- *tert*-Butyl 2-ethylperoxyhexanoate (TBPEH): *reproductive toxicity (fertility and lactation), skin sensitisation*
- Cyclohex-3-ene-1-carbaldehyde derivatives: *skin sensitisation*

2. Hazard classes for agreement with plenary debate

7. Copper (EC: 231-159-6; CAS: 7440-50-8): *hazards to the aquatic environment*
8. Ozone (EC: 233-069-2; CAS: 10028-15-6): *reproductive toxicity (lactation), STOT SE (cardiovascular system and SCL values for respiratory system and nervous system), STOT RE (cardiovascular system and SCL values for respiratory system and nervous system)*
9. *tert*-Butyl 2-ethylperoxyhexanoate (EC: 221-110-7; CAS: 3006-82-4): *reproductive toxicity (development)*
10. Pyraclostrobin (ISO); methyl *N*-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate (EC: - CAS: 175013-18-0): *acute oral toxicity, skin irritation, carcinogenicity, STOT SE, STOT RE, reproductive toxicity (development)*
11. Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl(EC: 201-993-5; CAS: 90-43-7): *skin sensitisation, reproductive toxicity (development)*
12. Fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine (EC: 614-049-6; CAS: 67306-00-7): *STOT SE (narcotic effects), reproductive toxicity (development)*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the November Restriction Working Group

RAC/63/2022/02
For information

9.2 Restriction Annex XV dossiers

1. Conformity check and key issues discussion
    1. BPA+ - Conformity check and key issues discussion
    2. Creosote, and creosote related substances - Conformity check and key issues discussion

For discussion and agreement

2. Opinion development

    1. Medium chain chlorinated paraffins (MCCP) – first draft opinion
    2. Terphenyl, hydrogenated – second draft opinion
    3. *N*,*N*-dimethylacetamide and 1-ethylpyrrolidin-2-one – second draft opinion

For discussion and agreement

4. Per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams - **not** for discussion at RAC-63

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the October AFA Working Group

RAC/63/2022/03
For information

2. Update on incoming/future applications

For information/discussion

10.2 Authorisation applications

1. Key issues

1. 12 applications for authorisation (chromium trioxide) from August 2022 submission window

For discussion

10.3 Agreement on draft opinions

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

11. 260_CT_SARREL (1 use)
12. 261_CT_Metalbrass (1 use)
13. 262_CT_Cromoplastica (2 uses)
14. 263_CT_Orelec (1 use)
15. 264_CT_Cristina (1 use)
16. 265_TXP_EDF (2 uses)
17. 266_CT_Olivari (1 use)
18. 267_CT_SPGPrints (1 use)
19. 268_CT_Paffoni (1 use)
20. 269_CT_Rubinetterie3M (1 use)
21. 270_CT_Maier (2 uses)
22. 271_CT_Villeroy (1 use)
23. 272_CT_RIGHI (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 242_RR1_TCE_Microporous (1 use)
2. 243_RR1_TCE_DOMO (1 use)
3. 249_CT_Tenneco_CZ (1 use)
4. 250_CT_Tenneco_ES (1 use)
5. 251_CT_Tenneco_BE (1 use)
6. 252_CT_Tenneco_PL (1 use)

For discussion and adoption

Item 11 – AOB

Item 12 – Minutes of RAC-63

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-63

For adoption

Annex II (RAC 63)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-63 meeting.

RAC/A/63/2022	RAC-63 final Draft Agenda
RAC/63/2022/01	General CHL issues: Report from the October CLH Working Group
RAC/63/2022/02	General restriction issues: Report from the November Restriction Working Group
RAC/63/2022/03	General authorisation issues: Report from the October AFA Working Group

ANNEX III (RAC-63)

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Restrictions		
NEW DOSSIERS		
BPA+ **DE**	Tom GEBEL	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.
Creosote, and Creosote related substances **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.
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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Terphenyl, hydrogenated **IT**	Gabriele AQUILINA	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		
Copper **SE**	Bert-Ove LUND	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.
	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.
1) Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol (glycerol formal) **2) 1,4-Dichloro-2-nitrobenzene** **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) *n*-Hexane **2) Ozone** **3) Cyclohex-3-ene-1-carbaldehyde derivatives** **4) Pyraclostrobin (ISO)** **5) Fenpropidin (ISO)**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement in no. 1 and 3.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
DE	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.
Tert-butyl 2-ethylperoxyhexanoate (TBPEH) **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.
Dibenzoyl peroxide; benzoyl peroxide **IE**	Brendan MURRAY	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.
	Malcolm DOAK	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
Fenpropidin (ISO) **CZ**	Michal MARTINEK	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.

Annex IV (RAC 63)

Table 1. List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-62 meeting without plenary debate (A-list).

Conclusions / agreements / adoptions
261_CT_Metalbrass (1 use) **Use1:** *Electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector.* RAC concluded that the operational conditions and risk management measures described in the application are generally appropriate and effective in limiting the risk, provided that they are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation 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 to further limit exposure, (b) the implementation of an automated system to perform the bath concentration adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. 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.
262_CT_Cromoplastica (2 uses) **Use1:** *Use of chromium trioxide for etching of plastic substrates as a key pre-treatment step for creating an electrically conductive surface to enable electroplating.* **Use2:** *Use of chromium trioxide for electroplating of plastic substrates to achieve a protective and durable surface with a silvery finish.* 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 detailed feasibility studies 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.

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

Section 8: monitoring arrangements for the authorisation

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

management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.

6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers and humans via the environment at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers and humans via the environment 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

The results of the feasibility studies 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.

264_CT_Cristina (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.

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 by liquid solutions of CrO_3 to further limit exposure;

(b) the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automatic system to perform manual 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.

265_TXP_EDF (2 uses)

Use1: *Industrial use as a hydraulic fluid in closed systems to drive and control the steam inlet valves of turbines.*

Use2: *Industrial use as a hydraulic fluid in closed systems to drive and control main steam isolation valves.*

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 implemented and adhered to.

RAC agreed:

Section 7: additional conditions for the authorisation

none

Section 8: monitoring arrangements for the authorisation

1. The applicant shall continue the following occupational inhalation exposure monitoring programmes for Trixylyl phosphate (TXP), 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 TXP
    (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 TXP 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 applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to TXP 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 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 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 applicant 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.

267_CT_SPGPrints (1 use)

Use1: *Use of Cr(VI) in an integrated process to create a hard surface with selective adhesion properties on mandrels used to manufacture screens for Rotary Screen Printing (RSP) for textile and other (printing) applications.*

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

RAC agreed:
Section 7: additional conditions for the authorisation
none
Section 8: monitoring arrangements for the authorisation as given in Table 2.
Section 9: recommendations for the review report as given in Table 2.

268_CT_Paffoni (1 use)

Use1: *Functional chrome plating with decorative character of metal substrates 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
1. The applicant shall carry out and document a detailed feasibility study on:
   (a) the substitution of solid CrO_3 flakes by 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 in both lines
   (c) the coverage of the baths.

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented 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.

269_CT_Rubinetterie3M (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

1) The applicant shall carry out and document feasibility studies on:
   a. The substitution of solid CrO_3 flakes by liquid CrO_3 to further limit worker exposure.
   b. The implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.

   The feasibility studies shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.
2) The applicant shall ensure that where RPEs are needed to control exposure to chromium trioxide, they used in accordance with standard procedures for use and maintenance. Those procedures shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards. The existing training, supervision of the wearer and maintenance of the RPE shall be continued. Medical fitness of the wearer shall be ensured.

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

270_CT_Maier (2 uses)

Use1: *Functional chrome plating with decorative character for automotive applications.*
Use2: *Etching of plastics with chromium trioxide as pre-treatment step for electroplating of plastics for automotive applications.*

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

RAC agreed:
Section 7: additional conditions for the authorisation

1) The applicant shall ensure that 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 full substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure.
   b) the implementation of an automated system for sampling or sampling in a closed system 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 as given in Table 2.
Additionally following recommendations:

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

271_CT_Villeroy (1 use)

Use1: *The use of chromium trioxide for electroplating of metal substrates with the purpose to create a long-lasting high durability surface with bright look for kitchen and bathroom sanitary ware*

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

RAC agreed:
Section 7: additional conditions for the authorisation

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

(a) the substitution of solid CrO_3 by liquid solutions of CrO_3 to further limit exposure (at the FMMMG site);

(b) the implementation of an automated system to perform the bath concentration adjustment at the FMMMG site, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE (at both sites).

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

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

272_CT_RIGHI (1 use)

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

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

RAC agreed:
Section 7: additional conditions for the authorisation

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 to further limit exposure.

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

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.
2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.
3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.
4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made

available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.

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

Section 9: recommendation for the review report.

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