RAC/M/62/2022

28 September 2022

Minutes of the 62nd Meeting

of the Committee for Risk Assessment

(RAC-62)

Monday 12 September, 14.00 to Thursday 15 June 2022, 18.30

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

The Chair, Tim Bowmer, welcomed the members of the Committee in person to the ECHA conference centre and informed the Committee that the Johanna Peltola-Thies, Deputy Chair of RAC would chair some agenda items.

He noted that several items on the agenda were of a horizontal, scientific or regulatory nature and with the resumption of in-person meetings this year, it was now possible to catch up with capacity building and methodology. He noted that the highlight of the meeting would be the seminar on biomonitoring in the context of Authorisation and also that ECHA would outline its plans for the implementation of the Drinking Water Directive's European positive list, which will come to RAC from January 2025 onwards. The Committee would also be asked to agree on two notes for guidance, the first in a series to RAC documents to be published on various aspects of the committee's working methods.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/62/2022**) was adopted without amendment.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-62 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 2022.	
5.2 Annual update of RAC accredited stakeholders´ list The Committee decided on the updated stakeholder list	**Secretariat** to editorially finalise and publish the list on ECHA´s webpage.
6. Request under Article 77(3)(c)	
6.1 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 first version of the draft note. RAC discussed: - Starting points for DNEL derivation RAC expressed an initial preference for using DOTI:MOTI data for DNEL derivation over data on DOTE itself due to the use of less sensitive	**Rapporteurs** to prepare the revised draft note, taking into account the RAC-62 discussion. **Secretariat** to discuss with COM the note on effects on the immune system.

species and inadequate study details. However, as a first step the preference was to develop DNELs based on the DOTE and DOTI:MOTI studies and conclude on which DNEL to choose later. - Absorption RAC expressed some preference for the default absorption value of 10% for the dermal route unless further evaluation of the available data provides sufficient justification to lower this default value. RAC advised to consider 10% absorption value for the oral route and 50 % for the inhalation route. The discussion on the assessment factors, including the application of an additional assessment factor for severity for immune effects, will be further elaborated in the note and will be discussed in the next meeting. - Immunotoxicity RAC agreed that it would be important to include a paragraph on immunotoxic effects as these appear to be the most sensitive. RAC noted that developmental immunotoxic effects might be considered as developmental effects that could be used as PoD.	**Secretariat** to table the revised draft note for the RAC consultation and discussion at the October RAC CLH WG and at RAC-63.
7. Health based exposure limits at the workplace	
7.1.1 General OEL issues: Updated RAC Working procedure on opinion development	
RAC agreed on the updated Working procedure on OEL opinion development (as presented in the meeting document RAC/62/2022/02).	**Secretariat** to upload the updated Working procedure on the ECHA website.
7.2.1 Opinions for discussion: Cobalt – first draft 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.	
1. The Rapporteurs presented their first draft opinion on the scientific evaluation of limit values for cobalt and inorganic cobalt compounds at the workplace. The proposal	**Rapporteurs** to prepare the revised draft opinion, taking into account the RAC-62 discussions.

contains two distinct values for the respirable and inhalable fractions. 2. The Committee discussed: ~~(i)~~ the scope of the OEL and whether additional consideration of the hard metal industry as an important exposure setting should be incorporated; (ii) whether the poorly soluble compounds should be included in the scope; (iii) whether to include the available dose response information in the opinion; (iv) whether to propose BLV/ BGV in the opinion. 3. RAC agreed: (i) to consider if it is possible and justified to propose separate OEL values for the inhalable fraction specifically in relation to the hard metal and diamond polishing workplaces as opposed to other workplaces; (ii) all inorganic cobalt compounds should fall under the scope of the OEL, recognising that there is not enough scientific data to derive separate OELs for the poorly soluble and complex salts of cobalt, and that when measuring the air levels at workplaces it is not possible to distinguish between different cobalt compounds; (iii) that the cancer dose-response should be presented in the opinion in support of the further evaluation of OELs; (iv) to use a similar approach as was done for nickel and to not propose a BLV. A BGV will be proposed; (v) that no separate short-term limit value was considered necessary; (vi) to propose a skin sensitisation notation and a respiratory sensitisation notation, but not to propose a skin notation.	**Secretariat** to table the revised draft opinion for the RAC consultation and discussion at RAC-63.
The Eurometaux Regular Stakeholder Observer, the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers commented on the scope of the OEL. The WPC representative commented on the importance of the inclusion of dose-response in the RAC opinion. The experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers commented on biomonitoring and notations.	

7.2.2 Opinions for discussion: Polyaromatic hydrocarbons (PAHs) – first draft opinion

The Chair welcomed the representatives from the Government, Employers and Workers Interest Groups, the expert accompanying the CEFIC Regular Stakeholder Observers as well as the Occasional Stakeholder Observers from ECOPA and CONCAWE.

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 their first draft opinion on the scientific evaluation of limit values for PAH at the workplace. The Committee agreed on a non-threshold mode of action and to use BaP as an exposure indicator. The Committee agreed to use the meta-analysis of 39 epidemiological studies by Armstrong *et al.* (2003, 2004) to derive an exposure risk relationship (ERR) for lung cancer. The Rapporteurs were asked to include in the RAC opinion the correlation tables between the biomonitoring markers (urine 1-OHP and 3-OHBaP) and BaP air concentration. A BGV for 1-OHP is proposed. The Committee agreed on including a skin notation and no STEL was proposed.	**Rapporteurs** to prepare the revised draft opinion, taking into account the RAC-62 discussions. **Secretariat** to table the revised draft opinion for the RAC consultation and discussion at RAC-63.

The COM representative and the expert accompanying the CEFIC Regular Stakeholder Observer commented on biomonitoring.

8. Harmonised classification and labelling (CLH)

8.1.1 Report from the July 2022 RAC CLH WG

The Secretariat presented the Report of the 6th Meeting of the Committee for Risk Assessment Working Group on CLH held on 4-5 July 2022.	

The 7th Meeting of the RAC Working Group on CLH will be held on 24-27 October 2022.	

8.1.2 Guidance on assessing physical hazards in the CLH dossiers

RAC agreed on the revised Guidance note on assessing physical hazards as part of CLP, with modifications agreed at RAC-62 (choosing Option 2 from the three options presented in Section 2.1 Explosives in the meeting document RAC/62/2022/04).	**Secretariat** to do the final editing of the document and upload on the ECHA website.

8.1.3 Addressing developmental neurotoxicity and neurotoxicity under the current CLP hazard classes

The Secretariat presented the RAC Guidance note on addressing developmental neurotoxicity and neurotoxicity under the current CLP hazard classes, revised after the discussion at the previous RAC plenary meeting (meeting document RAC/62/2022/05) and the comments received during the RAC consultation conducted prior to RAC-62 and the consultation of ECHA's legal team. RAC agreed on the document with modifications to be included which were agreed at RAC-62.	**Secretariat** to do the final editing of the document and upload on the ECHA website.

The expert accompanying the CropLife Regular Stakeholder Observer commented on the document.

8.2 CLH dossiers

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

1. Perboric acid, sodium salt [1]; perboric acid, sodium salt, monohydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, monohydrate; sodium peroxoborate [3]; sodium perborate [4] (EC 234-390-0 [1]; 234-390-0 [2]; 239-172-9 [4]; CAS 11138-47-9 [1]; 12040-72-1 [2]; 10332-33-9 [3]; 15120-21-5 [4]): *acute toxicity, reproductive toxicity*
2. Perboric acid ($H_3BO_2(O_2)$), monosodium salt trihydrate [1]; perboric acid, sodium salt, tetrahydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, tetrahydrate; sodium peroxoborate, hexahydrate [3] (EC 239-172-9 [1]; 234-390-0 [2]; CAS 13517-20-9 [1]; 37244-98-7 [2]; 10486-00-7 [3]): *acute toxicity, reproductive toxicity*
3. Sodium peroxometaborate (EC 231-556-4; CAS 7632-04-4): *acute toxicity, reproductive toxicity*
4. Trimethyl borate (EC 204-468-9; CAS 121-43-7): *reproductive toxicity*
5. 1*H*-benzotriazole (EC 202-394-1; CAS 95-14-7): *hazardous to the aquatic environment*

6. Methyl-1*H*-benzotriazole (EC 249-596-6; CAS 29385-43-1): *hazardous to the aquatic environment*
7. Sodium 3-(allyloxy)-2-hydroxypropanesulphonate (EC 258-004-5; CAS 52556-42-0): *serious eye damage/eye irritation, reproductive toxicity*
8. *N*,*N*'-methylenediacrylamide (EC 203-750-9; CAS 110-26-9): *germ cell mutagenicity*
9. Ethanethiol; ethyl mercaptan (EC 200-837-3; CAS 75-08-1): *physical hazards, acute toxicity via oral route*

2. Substances with hazard classes for agreement in plenary session

1. Perboric acid, sodium salt [1]; perboric acid, sodium salt, monohydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, monohydrate; sodium peroxoborate [3]; sodium perborate [4] (EC 234-390-0 [1]; 234-390-0 [2]; 239-172-9 [4]; CAS 11138-47-9 [1]; 12040-72-1 [2]; 10332-33-9 [3]; 15120-21-5 [4]): *reproductive toxicity note on additivity*
2. Perboric acid ($H_3BO_2(O_2)$), monosodium salt trihydrate [1]; perboric acid, sodium salt, tetrahydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, tetrahydrate; sodium peroxoborate, hexahydrate [3] (EC 239-172-9 [1]; 234-390-0 [2]; CAS 13517-20-9 [1]; 37244-98-7 [2]; 10486-00-7 [3]): *reproductive toxicity note on additivity*
3. Sodium peroxometaborate(EC 231-556-4; CAS 7632-04-4): *reproductive toxicity note on additivity*
4. Trimethyl borate (EC 204-468-9; CAS 121-43-7): *reproductive toxicity note on additivity*
5. Ethanethiol; ethyl mercaptan (EC 200-837-3; CAS 75-08-1): *acute toxicity via inhalation route*

8.2.2.1 Perboric acid, sodium salt [1]; perboric acid, sodium salt, monohydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, monohydrate; sodium peroxoborate [3]; sodium perborate [4]

The Chair welcomed the Dossier Submitter representative and informed that sodium per(oxo)borates mono- and tetrahydrates are used as oxidising and bleaching agents mainly in detergents (household detergents as well as detergents for institutional uses) and in cleaning products (stain removers in form of bleach booster tablets and dishwashing tablets). Per(oxo)borates are used in both regular and compact heavy-duty laundry powders.
The substances are currently classified with a split entry – Ox. Sol. 3; H272, Repr. 1B; H360Df, Acute Tox. 4*; H302, STOT SE 3; H335 and Eye Dam. 1; H318 for [1], [2], [3], [4], containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm, Ox. Sol. 3; H272, Repr. 1B; H360Df, Acute Tox. 3*; H331, Acute Tox. 4*; H302, STOT SE 3; H335 and Eye Dam. 1; H318 for [1], [2], [3], [4], containing = 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm, Ox. Sol. 2; H272, Repr. 1B; H360Df, Acute Tox. 4*; H302, STOT SE 3; H335 and Eye Dam. 1; H318 for [1], [2], [4], containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm, and Ox. Sol. 2; H272, Repr. 1B; H360Df, Acute Tox. 3*; H331, Acute Tox. 4*; H302, STOT SE 3; H335 and Eye Dam. 1; H318 for [1], [2], [4], containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm.
The DS (SE) proposes to merge the entries into one and modify Repr. 1B; H360FD, Acute Tox. 3; H331 (ATE=0.75 mg/L) and Acute Tox. 4; H302 (ATE=890 mg/kg bw/day).

Acute toxicity via all routes and reproductive toxicity were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 26 March 2023.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Acute Tox. 3; H331 (ATE=0.75 mg/L (dusts or mists)), Acute Tox. 4; H302 (ATE=890 mg/kg bw/day), Repr. 1B; H360FD + removal of SCL] RAC agreed on no classification for acute dermal toxicity and lactation. RAC agreed to the proposal to include a specific note to apply additivity for boron compounds that exert their reproductive toxicity through the same toxic entity (boric acid/borate ion). The final wording of this note will be adopted by the Commission.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteur. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.2 Perboric acid ($H_3BO_2(O_2)$), monosodium salt trihydrate [1]; perboric acid, sodium salt, tetrahydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, tetrahydrate; sodium peroxoborate, hexahydrate [3]	
The Chair welcomed the Dossier Submitter representative and informed that **sodium per(oxo)borates mono- and tetrahydrates** are used as oxidising and bleaching agents mainly in detergents (household detergents as well as detergents for institutional uses) and in cleaning products (stain removers in form of bleach booster tablets and dishwashing tablets). **Per(oxo)borates** are used in both regular and compact heavy-duty laundry powders. The substances are currently classified with a split entry – **Repr. 1B; H360Df, STOT SE 3; H335 and Eye Dam. 1; H318** for [1], [2], [3], containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm and **Repr. 1B; H360 Df, Acute Tox. 4*; H332, STOT SE 3; H335 and Eye Dam. 1; H318** for [1], [2], [3], containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm. The DS (SE) proposes to merge the two entries into one and modify Repr. 1B; H360FD and Acute Tox. 4; H332 (ATE=1.16 mg/L). Acute toxicity via all routes and reproductive toxicity were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 5 April 2023.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Acute Tox. 4; H332 (ATE=1.2 mg/L (dusts or mists)), Repr. 1B; H360FD + removal of SCL]	**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.

RAC agreed on no classification for acute dermal and oral toxicity and lactation. RAC agreed to the proposal to include a specific note to apply additivity for boron compounds that exert their reproductive toxicity through the same toxic entity (boric acid/borate ion). The final wording of this note will be adopted by the Commission.	**Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.3 Sodium peroxometaborate (EC 231-556-4; CAS 7632-04-4)	
The Chair welcomed the Dossier Submitter representative and informed that **sodium per(oxo)borates mono- and tetrahydrates** are used as oxidising and bleaching agents mainly in detergents (household detergents as well as detergents for institutional uses) and in cleaning products (stain removers in form of bleach booster tablets and dishwashing tablets). **Per(oxo)borates** are used in both regular and compact heavy-duty laundry powders. Sodium perborate, sodium peroxometaborate and sodium peroxoborate, containing = 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm, are currently classified as **Ox. Sol. 2; H272, Repr. 1B; H360Df, Acute Tox. 4*; H302, STOT SE 3; H335 and Eye Dam. 1; H318**. Sodium perborate, sodium peroxometaborate and sodium peroxoborate, containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm, are classified as **Ox. Sol. 2; H272, Repr. 1B; H360Df, Acute Tox. 3*; H331, Acute Tox. 4*; H302, STOT SE 3; H335 and Eye Dam. 1; H318**. The DS (SE) proposes to merge the two entries into one and modify Repr. 1B; H360FD, Acute Tox. 3; H331 (ATE=0.62 mg/L) and Acute Tox. 4; H302 (ATE=918 mg/kg bw/day) (after the Consultation the DS changed the ATE to 730 mg/kg). Acute toxicity via all routes and reproductive toxicity were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 8 April 2023.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Acute Tox. 4; H302 (ATE=730 mg/kg bw), Acute Tox. 3; H331 (ATE=0.62 mg/L (dusts or mists)), Repr. 1B; H360FD + removal of SCL] RAC agreed on no classification for lactation. RAC agreed to the proposal to include a specific note to apply additivity for boron compounds that exert their reproductive toxicity through the same toxic entity (boric acid/borate ion). The final wording of this note will be adopted by the Commission.	**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 Trimethyl borate	

The Chair welcomed the Dossier Submitter representative and informed that **trimethyl borate** is used in the following products: welding & soldering products, and laboratory chemicals in building & construction and scientific research & development. This substance is also used by professional workers in the production of metal products, formulation of mixtures (welding & soldering products) and as intermediate in the manufacturing of chemicals (welding & soldering products) at industrial sites. Trimethyl borate has a current Annex VI entry as Flam. Liq. 3; H226 and Acute Tox. 4*; H312. The DS (NL) proposes to add Repr. 1B; H360FD to the current classification. Reproductive toxicity was the only hazard class open for comments during the Consultation. The legal deadline for the adoption of an opinion is 4 February 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] RAC agreed on no classification for lactation. RAC agreed to the proposal to include a specific note to apply additivity for boron compounds that exert their reproductive toxicity through the same toxic entity (boric acid/borate ion). The final wording of this note will be adopted by the Commission.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.5 Ethanethiol; ethyl mercaptan	
The Chair informed that **ethanethiol** may be used as odorant for natural gas, intermediate and starting material in manufacture of plastics, insecticides and antioxidants. The substance has current Annex VI entry as Flam. Liq. 2; H225, Acute Tox. 4*; H332, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The DS (AT) proposes <u>to add</u> to the current classification Acute Tox. 4; H302 (ATE(oral) = 680 mg/kg bw) and <u>to modify</u> Flam. Liq. 1; H224 and Acute Tox. 3; H331 (ATE(inhalation) = 7.1 mg/L (vapours)). Flammable liquid and acute inhalation and oral toxicity were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 27 May 2023.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Flam. Liq. 1; H225, Acute Tox. 3; H332 (ATE=7.1 mg/L (vapours)), Acute Tox. 4; H302 (ATE=680 mg/kg bw)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur.

	SECR to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

9. Restrictions

9.1 General Restriction issues

1. Report from the August 2022 RAC REST WG

RAC took note of the Report of the 6th meeting of the Committee for Risk Assessment Working Group on restrictions held on 17-18 August 2022. The 7th meeting of the RAC Working Group on restrictions will be held during on 8-9 November 2022.	

2. Updated Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers

The Secretariat presented and RAC discussed the updated working procedure for the RAC and SEAC on developing opinions on Annex XV restriction dossiers.	**SECR** to make the minor modifications ("This flexible procedure would be decided on a case by case basis by the Chair, in consultation with the (co-)rapporteurs and the Secretariat") as agreed at RAC62 and publish it on ECHA website.

9.2 Restriction Annex XV dossiers

9.2.1 Conformity check and key issues discussion

1. Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17

The Deputy Chair welcomed the Dossier Submitter's representatives from ECHA, the regular stakeholder observers with their accompanying expert (Inovyn) and the occasional stakeholder observer (EDENA). The dossier has been submitted by ECHA 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.

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. **SECR** to inform the Dossier Submitter on the outcome of the conformity check.

The expert (Inovyn) accompanying the CEFIC regular stakeholder commented on the complexity of the substance identity and development of analytical methods.

9.2.2 Opinion development

1. Terphenyl, hydrogenated – first 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 17 and 18 August 2022, RAC-62 agreed on the: • Scope of the restriction proposal • Hazard assessment as the hazard has already been established by the MSC and no further evaluation is needed	**Rapporteurs** to prepare the second draft opinion, taking into account the discussion the RAC-62 Working Group on restrictions. **Secretariat** to table the second draft opinion for discussion at the RAC-63 Working Group on restrictions in November 2022.

No interventions by stakeholder observers were made.

2. N,N-dimethylacetamide and 1-ethylpyrrolidin-2-one – first 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, EDANA). 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 17-18 August 2022, RAC-62 agreed on the:
 	
• Scope of the restriction proposal
• DNELs:
  ○ DMAC: Systemic long-term inhalation DNEL of 13 mg/m3
  ○ NEP: Systemic long-term inhalation DNEL of 4 mg/m3
  ○ NEP: Systemic long-term dermal DNEL of 2.4 mg/kg bw/day
  ○ NEP: Biomarker DNEL of 20 mg /L for combined urinary excretion of 5-HNEP plus 2-HESI
 	
The rapporteurs then presented and RAC briefly discussed the 1st draft opinion.
 	
RAC supported the WG recommendation to further evaluate the hazard assessment and in particular the systemic long-term dermal DNEL for DMAC, the Biomarker DNEL for DMAC and the acute inhalation DNEL for NEP. RAC supported further evaluation of the exposure data. RAC also supported alignment of the justification related to assessment factors for
	Rapporteurs to prepare the second draft opinion, taking into account the discussions of RAC-62 and the RAC-62 Working Group on restrictions.
	
	Secretariat to table the second draft opinion for discussion at the RAC-63 Working Group on restrictions in November 2022.

developmental effects with previous opinions on aprotic solvents.	
The accompanying expert to the regular CEFIC stakeholder observers and an occasional stakeholder observer (CIRFS) commented on the Annex XV report consultation. The accompanying expert to occasional EDANA stakeholder observer commented on the hazard assessment.	
3. Per- and polyfluoroalkyl substances (PFASs) in fire-fighting foams – Second draft opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA and their invited experts (WFVD, Lastfire), the regular stakeholder observers, and their accompanying experts (Cefic, EEB, CropLife Europe, ClientEarth) as well as the occasional stakeholder observers (EUROFEU, EPEE and CONCAWE) and their accompanying experts (EPEE). He informed the participants that the dossier has been submitted by ECHA in January 2022 and aims to restrict the formulation, placing on the market and use of PFASs for the use in fire-fighting foams.	
Based on the recommendations of the Restriction Working Group which met on 17-18 August 2022, RAC-62 agreed on the: • Scope of the restriction proposal • Hazard assessment • Risk characterisation • Action required on Union-wide basis The rapporteurs then presented and RAC briefly discussed the 2nd draft opinion. RAC supported the WG recommendation to further evaluate the effectiveness of the restriction options including the effectiveness of different disposal options as well as a possible additional ban of the placing on the market for handheld devices.	**Rapporteurs** to prepare the third draft opinion, taking into account the discussions of RAC-62 and the RAC-62 Working Group on restrictions. **Secretariat** to table the third draft opinion for discussion at the RAC-63 Working Group on restrictions in November 2022.
The regular CropLife Europe and Plastics Europe stakeholder observers commented on the scope of the restriction proposal. The accompanying experts to a regular stakeholder observer (EEB) and a occasional stakeholder observer (Eurofeu) commented on the effectiveness of the proposal in reducing the risk.	
4. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting – third draft opinion	
The Deputy Chair welcomed the Dossier Submitter's representatives from ECHA, the regular stakeholder observers, and their accompanying expert (Coal Chemicals Europe sector group). She informed the participants that the dossier has been submitted by ECHA in October 2021 and concerns on the placing on the market and use of substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting.	
Based on the recommendations of the Restriction Working Group which met on 17-18 August 2022, RAC adopted its opinion by consensus (with minor editorials as agreed at RAC-62).	**The rapporteurs,** together with **SECR,** to do the final editing of the adopted RAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion.

	SECR to forward the adopted opinion and its supporting documentation to SEAC.
No interventions by stakeholder observers were made.	
10. Authorisation	
10.1 General authorisation issues	
1. Report from the July AFA Working Group	
The Secretariat presented the Report of the 12th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group which took place on 7-8 July 2022. RAC took note of the Report.	
2. Update on incoming/future applications	
The ECHA Secretariat presented the information on incoming/future applications, expected workload in 2022 and timelines. The RAC rapporteurs were encouraged to shorten opinions to the essential arguments and to follow the technical guidance for rapporteurs (the LTT document) while drafting opinions. RAC discussed on optimising the process *inter alia:* - To delay the sending of the 1st round of questions to applicants, as well as presenting the key issues - To include references to CSR in opinions instead of copy and paste information - To revise the check list for applicants. RAC took note of the information.	**SECR** to consider further communication to applicants to remind them about the expected quality of submitted information. **SECR** to work on improvement in the AFA process to increase efficiency of opinions development.
3. Renewal of the RAC AFA WG Mandate	
The ECHA Secretariat presented the Mandate for RAC Working Group on AfA and requested RAC to extend the mandate until September 2023. RAC agreed the Mandate for RAC Working Group on AfA by consensus.	**SECR** to publish the Mandate on the ECHA website.
4. Seminar on biomonitoring	

Following a series of presentations by fellow emebers and invited experts, the group discussed the following issues: 1. Where to go with biomonitoring and what extra effort would need to be put into our evaluations against the possible benefits to the authorisation process? 2. Are there other ways of improving exposure monitoring? 3. If we make changes, how will we implement them? The group noted that initiating European-wide biomonitoring programmes for hundreds of workplaces could have unforeseen consequences and would also raise concerns about equal treatment for applicants. The group also noted that with such diverse National legislations and practices related to worker protection, exposure to dangerous chemicals and biomonitoring in place, it was questioned whether widespread biomonitoring at an EU level is even supported under REACH. It was suggested that enhanced monitoring in specific cases where needed, as opposed to just adding biomonitoring might provide a way forward. It was then proposed to examine workplaces of greatest concern with electroplating in particular and identify where such enhanced monitoring could allow OCs and RMMs to be evaluated more effectively. This was broadly supported by RAC as a way forward. Finally, the meeting agreed that biomonitoring might need to be reconsidered and with a different emphasis where other SVHC that could be placed in Annex XIV in the future are concerned.	**The Commission** agreed to investigate this further in the case of SVHC on Annex XIV in general. **SECR** to develop a set of criteria for identifying such workplaces. This will be reflected in the next version of the RAC's Lines-to-take. The secretariat will also investigate where further guidance on HBM can be provided to companies.
10.2 Authorisation applications	
10.2.1. Discussion on key issues	
1. **11 applications for authorisation (chromium (VI) substances) and 1 review report (diglyme) from May 2022 submission window**	
RAC discussed the key issues in 11 applications for authorisation (chromium (VI) substances) and 1 review report (diglyme) from May 2022 submission window	

The table was made available on the S-CIRCABC and on the Interact Portal.	

10.3 Agreement on draft opinions

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

1. 253_CT_GEA-Westfalia (1 use)
2. 254_CT_Ratier-Figeac (2 uses)
3. 255_CT_Chrom-Mueller (3 uses)
4. 257_CT_Qualipac (1 use)
5. 259_CT_ST-SRL (1 use))

The Chair informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 12th meeting the RAC AFA WG the 8 draft opinions have been proposed for agreement via the A-listing procedure. ECHA Secretariat presented the summary of the draft opinions.

RAC agreed by consensus the 8 draft opinions on the Application listed in Annex IV.

1. Draft opinions for agreement with plenary debate

256_CT_KaVo-Dental (1 use)

Use1: *Chromium trioxide based functional chrome plating of dental instruments applied by professionals for dental treatment.* RAC discussed: - The appropriates of the OCs and the RMMs. - A frequency of the monitoring programme for Cr(VI) emission to wastewater. - A time limit for the proposed additional conditions for the authorisation. - A need to ensure the proper protections of the workers until the proposed additional conditions for the authorisation will be implemented i.e. *"The applicant shall ensure that workers involved in WCS 2 use an appropriate RPE until the engineering measures are implemented and verified that guarantee the protection needed to the workers".* 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 (pending on adjustment according to the action points): Section 7. Proposed additional conditions for the authorisation	**Rapporteur** together with **SECR** to revise the proposed additional conditions for the authorisation by adding a deadline for its implementation and the requirement for the proper protection of workers in a transitional period (in line with the LTT document), to ensure to address in the final edits the annual frequency of the monitoring of the wastewater. **Rapporteur** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

1. Without prejudice to point 2 below, the applicant shall implement a technical solution to avoid the need for the operator to be close to the baths during the bath loading and unloading and to cover the baths when not loading/unloading. 2. The applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 flakes by liquid CrO_3; (b) the implementation of an automated system to replace the manual bath adjustments and the implementation of a closed/automatic system to replace the manual bath sampling tasks. The feasibility studies must be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period. Section 8. Proposed 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 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. 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 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 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 paragraphs 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 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 authorisation holder 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 biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 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. RAC agreed the Draft Opinion by consensus.	
258_CT_Schulte	
Use1: *Chromium trioxide-based functional chrome plating of large components and small components with complex geometries and/or requiring special approval procedures for their application in demanding sectors such as medical, aerospace, defence and mining industry*	**Rapporteur** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary and the LTT document. **SECR** to send the draft opinions to the applicant for commenting.

Use2: *Chromium trioxide-based functional chrome plating of small components with simple geometries not requiring special approval procedures for their application in demanding sectors such as hydraulic systems, food, paper and chemical industry* RAC discussed: - wording of the proposed additional conditions for the authorisation and the proposed monitoring arrangements for the authorisation - the conditions concerning the task of removing the sludge from the emptied baths. 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 (pending on adjustment according to the action points): Section 7. Proposed additional conditions for the authorisation RAC stresses the importance of following the hierarchy of control for the protection of workers at both sites and proposes the following conditions for the authorisation: 1. The applicant shall: i) introduce additional OC/RMMs (e.g. bath coverage, in particular at the Iserlohn site where currently the baths are not covered, even during the plating process) to comply with the principles of hierarchy of control. ii) implement the necessary OCs and RMMs (e.g. physical segregation) to ensure that the exposure to Cr(VI) at the loading/ unloading working area is as low a level as technically and practically feasible. The changes must be implemented during the review period. 2. Without prejudice to point 1 above, the applicant shall carry out and document a detailed feasibility study on: i) the substitution of solid CrO_3 flakes by liquid CrO_3 to further limit exposure.	

ii) the implementation of an automated system to perform the bath adjustment and the implementation of a closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. iii) changing the way that the task of removing the sludge from the emptied baths is performed, preferably aiming to automation. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. 3. The applicant shall ensure that where RPE is needed to minimise exposure to chromium trioxide, it shall be used in accordance with standard procedures for use and maintenance. Those procedures shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards, and shall ensure training and medical fitness checking and supervision of the wearer and maintenance of the RPE. Section 8. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue to perform the following monitoring programmes for Cr(VI) at both sites: (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 air and 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 sites. 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 (air and wastewater) 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 authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. 7. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1 and paragraph 4, 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. RAC agreed the Draft Opinions by consensus.	
10.4 Adoption of opinions	
231_CT_Kesseboehmer (1 use)	
Use1: *Use of chromium trioxide for decorative/functional application in the furniture, sanitary and automotive sector* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. RAC agreed: Section 7. Proposed additional conditions for the authorisation The applicant shall investigate the feasibility to use RPE for workers during the manual tasks at the plating line for research and development. The applicant shall continue to investigate the feasibility to use liquid CrO_3 solution instead of solid CrO_3. Section 8. Proposed monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programme for Cr(VI): Occupational inhalation exposure The applicant shall implement their monitoring programmes for Cr(VI) exposure, which shall : (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of:	**SECR** to send the draft opinion to the applicant, the European Commission and MS CAs.

a. the range of tasks undertaken where exposure to Cr(IV) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling. 2. The information gathered via the measurements referred to in paragraphs 1 and related contextual information shall be used by the applicant annually 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) 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 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 paragraphs 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 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 shall continue to conduct their annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The measurements referred to in section 8.1 paragraph 1 and 5, 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.	

RAC adopted the Final Opinion by consensus.	
241_CT_Gessi (1 use)	
Use1: *Use of chromium trioxide for electroplating of metal substrates with the purpose of creating a long-lasting high durability surface with bright look for kitchen and bathroom sanitaryware (functional plating with decorative character).* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk at the Gessi site, provided that they are adhered to. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk at the San Marco site. RAC agreed: Section 7. Proposed additional conditions for the authorisation RAC acknowledges that the applicant has already evaluated the automation of tasks at both sites. However, the Committee stresses the importance of such automation for the protection of workers and proposes the following conditions for the authorisation: 1. Gessi site a. The applicant shall carry out and document a detailed feasibility study on: i. the substitution of solid CrO_3 flakes by liquid CrO_3. ii. the implementation of an automated system to replace the manual bath adjustments and the implementation of a closed/automatic system to replace the manual bath sampling tasks where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. b. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.

accordingly during the review period. 2. San Marco site a. Without prejudice to point 1 above, the applicant shall modify the RMMs at the site to ensure that they are in line with those in place at the Gessi site. The outcome of the feasibility study referred to in paragraph 1.a.ii shall also be taken into consideration. The changes must be implemented during the review period. Section 8. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue to perform the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes for Cr(VI), 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) (e.g. due to the increase of the substance use expected for San Marco site); (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and/or static sampling for workers for WCS that might imply exposure, including WCS 7; (iv) be representative of: a. the range of tasks undertaken where exposure to Cr(VI) is possible, particularly the short duration tasks that might imply higher exposure moments (e.g. baths sampling, dipping of jigs); b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) 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	

air and water. (ii) the applicant shall conduct air emission measurements more frequently (at least yearly), particularly if changes in the process justifies such as the expected increase of volume; (iii) the monitoring programmes for air and water 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 applicant shall use the information gathered via the measurements referred to in paragraph 1 and related contextual information to review 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. This review shall be conducted annually. 3. 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. 4. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The results of the feasibility study as mentioned in section 7 and the measurements referred to in section8.1 paragraph 1 and paragraph 4, 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 review report.	

RAC adopted the Final Opinion by consensus.	

11. AOB

11.1 Grouping and CLH

The Secretariat presented and RAC took note of two presentations: 1) ECHA`s Integrated Regulatory Strategy and Assessment of Regulatory Needs; 2) Read-across in CLH and RAC: 2017-2021 past learnings and future developments.	

The Eurometaux Regular Stakeholder Observer commented on the presentations.

11.2 Drinking Water Directive: Introducing the role of RAC

The Secretariat presented an introductionto the Drinking Water Directive and the envisaged role of RAC in the process of assessment of applications submitted for the purpose of inclusion into or removal from the European positive lists of starting substances, compositions or constituents. The following questions were raised by participants:

- The range of competences required to process applications under the Drinking Water Directive.
- Legal basis to nominate members for the work on the Drinking Water Directive and their renumeration.
- Questions related to the future structure of the Committee and status of a Drinking Water Directive a proposed working group and its affiliation with the Committee.
- Scope of the future assessment of applications, methodology and information requirements.
- Potential stakeholder involvement in the preparatory work for the Drinking Water Directive process.

12. Minutes of RAC-61

12.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-62

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-62 to CIRCA BC.

CLH opinions at RAC-62

1*H*-benzotriazole

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*H*-benzotriazole	202-394-1	95-14-7	Aquatic Chronic 2	H411	GHS09 Wng	H411			
RAC opinion		1*H*-benzotriazole	202-394-1	95-14-7	Aquatic Chronic 2	H411	GHS09 Wng	H411			
Resulting Annex VI entry if agreed by COM		1*H*-benzotriazole	202-394-1	95-14-7	Aquatic Chronic 2	H411	GHS09 Wng	H411			

Methyl-1*H*-benzotriazole

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	methyl-1*H*-benzotriazole	249-596-6	29385-43-1	Aquatic Chronic 2	H411	GHS09 Wng	H411			
RAC opinion	TBD	methyl-1*H*-benzotriazole	249-596-6	29385-43-1	Aquatic Chronic 2	H411	GHS09 Wng	H411			
Resulting Annex VI entry if agreed by COM	TBD	methyl-1*H*-benzotriazole	249-596-6	29385-43-1	Aquatic Chronic 2	H411	GHS09 Wng	H411			

Sodium 3-(allyloxy)-2-hydroxypropanesulphonate

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	Sodium 3-(allyloxy)-2-hydroxypropanesulphonate	258-004-5	52556-42-0	Repr. 1B Eye Dam. 1	H360F H318	GHS08 Danger	H360F H318			
RAC opinion	TBD	Sodium 3-(allyloxy)-2-hydroxypropanesulphonate	258-004-5	52556-42-0	Repr. 1B Eye Dam. 1	H360F H318	GHS08 GHS05 Dgr	H360F H318			
Resulting Annex VI entry if agreed by COM	TBD	Sodium 3-(allyloxy)-2-hydroxypropanesulphonate	258-004-5	52556-42-0	Repr. 1B Eye Dam. 1	H360F H318	GHS08 GHS05 Dgr	H360F H318			

N,N'-methylenediacrylamide

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	*N,N'*-methylenediacrylamide	203-750-9	110-26-9	Muta. 1B	H340	GHS08 Dgr	H340			
RAC opinion	TBD	*N,N'*-methylenediacrylamide	203-750-9	110-26-9	Muta. 1B	H340	GHS08 Dgr	H340			
Resulting Annex VI entry if agreed by COM	TBD	*N,N'*-methylenediacrylamide	203-750-9	110-26-9	Muta. 1B	H340	GHS08 Dgr	H340			

Perboric acid, sodium salt; [1] perboric acid, sodium salt, monohydrate; [2] perboric acid (HBO(O2)), sodium salt, monohydrate; sodium peroxoborate; [3] sodium perborate; [4]

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

	Index No	International Chemical Identification	EC No.	CAS No.	Classification		Labelling			Specific Conc. Limits, M-factors	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 entries	005-019-00-8	perboric acid, sodium salt; [1] perboric acid, sodium salt, monohydrate; [2] perboric acid (HBO(O2)), sodium salt, monohydrate; [3] sodium peroxoborate; [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	234-390-0 [1] 234-390-0 [2] 231-556-4 [3]	11138-47-9 [1] 12040-72-1 [2] 10332-33-9 [3]	Ox. Sol. 3 Repr. 1B Acute Tox. 4 * STOT SE 3 Eye Dam. 1	H272 H360Df H302 H335 H318	GHS03 GHS05 GHS08 GHS07 Dgr	H272 H360Df H302 H335 H318		Repr. 1B; H360D: 6,5 % ≤ C < 9 % Repr. 1B; H60Df: C ≥ 9 % Eye Dam. 1; H318: C ≥ 22 % Eye Irrit. 2; H319: 14 % ≤ C < 22 %	
	005-019-01-5	perboric acid, sodium salt; [1] perboric acid, sodium salt; monohydrate [2] perboric acid (HBO(O2)), sodium salt, monohydrate; [3] sodium peroxoborate; [containing = 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	234-390-0 [1] 234-390-0 [2] 231-556-4 [3]	11138-47-9 [1] 12040-72-1 [2] 10332-33-9 [3]	Ox. Sol. 3 Repr. 1B Acute Tox. 3 * Acute Tox. 4 * STOT SE 3 Eye Dam. 1	H272 H360Df H331 H302 H335 H318	GHS03 GHS06 GHS05 GHS08 Dgr	H272 H360Df H331 H302 H335 H318		Repr. 1B; H360D: 6,5 % ≤ C < 9 % Repr. 1B; H360Df: C ≥ 9 % Eye Dam. 1; H318: C ≥ 22 % Eye Irrit. 2; H319: 14 % ≤ C < 22 %	
	005-017-00-7	sodium perborate; [1] sodium peroxometaborate;[2] sodium peroxoborate;	239-172-9 [1] 231-556-4 [2]	15120-21-5 [1] 7632-04-4 [2]	Ox. Sol. 2 Repr. 1B Acute Tox. 4 * STOT SE 3 Eye Dam. 1	H272 H360Df H302 H335 H318	GHS03 GHS05 GHS08 GHS07 Dgr	H272 H360Df H302 H335 H318		Repr. 1B; H360Df: C ≥ 9 % Repr. 1B; H360D: 6,5 % ≤ C < 9 % Eye Dam. 1; H318: C ≥ 22 %	

		[containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]								Eye Irrit. 2; H319: 14 % ≤ C < 22 %	
	005-017-01-4	sodium perborate; [1] sodium peroxometaborate; [2] sodium peroxoborate; [containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 231-556-4 [2]	15120-21-5 [1] 7632-04-4 [2]	Ox. Sol. 2 Repr. 1B Acute Tox. 3 * Acute Tox. 4 * STOT SE 3 Eye Dam. 1	H272 H360Df H331 H302 H335 H318	GHS03 GHS06 GHS05 GHS08 Dgr	H272 H360Df H331 H302 H335 H318		Repr. 1B; H360Df: C ≥ 9 % Repr. 1B; H360D: 6,5 % ≤ C < 9 % Eye Dam. 1; H318: C ≥ 22 % Eye Irrit. 2; H319: 14 % ≤ C < 22 %	
Dossier submitters proposal	**Merge:** 005-019-00-8 005-019-01-5 005-017-00-7 005-017-01-4	**<u>Retain</u>:** perboric acid, sodium salt; [1] perboric acid, sodium salt, monohydrate; [2] perboric acid (HBO(O2)), sodium salt, monohydrate; sodium peroxoborate; [3] sodium perborate; [4] **Remove:** sodium peroxometaborate [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] [containing = 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm	**Retain:** 234-390-0 [1] 234-390-0 [2] 239-172-9 [4] **Remove:** 231-556-4 [3]	**Retain:** 11138-47-9 [1] 12040-72-1 [2] 10332-33-9 [3] 15120-21-5 [4] **Remove:** 7632-04-4 [2]	**Modify:** Repr. 1B Acute Tox. 3 Acute Tox. 4	**Modify:** H360FD H331 H302	**Retain:** GHS06 GHS08 Dgr	**Modify:** H360FD H331 H302		**Remove:** Repr. 1B; H360D: 6,5 % ≤ C < 9 % Repr. 1B; H360Df: C ≥ 9 % **Add:** inhalation: ATE = 0.75 mg/L (dusts and mists) oral: ATE = 890 mg/kg bw/d	
RAC opinion	**Merge:** 005-019-00-8 005-019-01-5	**Retain:** perboric acid, sodium salt; [1] perboric acid, sodium salt, monohydrate; [2]	**Retain:** 234-390-0 [1] 234-390-0 [2]	**Retain:** 11138-47-9 [1] 12040-72-1 [2]	**Modify:** Repr. 1B Acute Tox. 3 Acute Tox. 4	**Modify:** H360FD H331 H302	**Retain:** GHS06 GHS08 Dgr	**Modify:** H360FD H331 H302		**Remove:** Repr. 1B; H360D: 6,5 % ≤ C < 9 % Repr. 1B; H360Df: C ≥ 9 %	

	005-017-00-7 005-017-01-4	perboric acid (HBO(O2)), sodium salt, monohydrate; sodium peroxoborate; [3] sodium perborate; [4] **Remove:** sodium peroxometaborate [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] [containing = 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm	239-172-9 [4] **Remove:** 231-556-4 [3]	10332-33-9 [3] 15120-21-5 [4] **Remove:** 7632-04-4 [2]						**Add:** inhalation: ATE = 0.75 mg/L (dusts and mists) oral: ATE = 890 mg/kg bw/d	
Resulting Annex VI entry if agreed by COM	TBD	perboric acid, sodium salt; [1] perboric acid, sodium salt, monohydrate; [2] perboric acid (HBO(O2)), sodium salt, monohydrate; sodium peroxoborate; [3] sodium perborate; [4]	234-390-0 [1] 234-390-0 [2] 239-172-9 [4]	11138-47-9 [1] 12040-72-1 [2] 10332-33-9 [3] 15120-21-5 [4]	Ox. Sol. 3 Repr. 1B Acute Tox. 3 Acute Tox. 4 STOT SE 3 Eye Dam. 1	H272 H360FD H331 H302 H335 H318	GHS03 GHS06 GHS05 GHS08 Dgr	H272 H360FD H331 H302 H335 H318		inhalation: ATE = 0.75 mg/L (dusts and mists) oral: ATE = 890 mg/kg bw/d Eye Dam. 1; H318: C ≥ 22 % Eye Irrit. 2; H319: 14 % ≤ C < 22 %	#

#The inclusion of a specific note to apply additivity for boron compounds that exert their reproductive toxicity through the same toxic entity (boric acid/borate ion) is supported.

Perboric acid (H3BO2(O2)), monosodium salt trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O2)), sodium salt, tetrahydrate sodium peroxoborate hexahydrate; [3]

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

	Index No.	International Chemical Identification	EC No.	CAS No.	Classification		Labelling			Specific Conc. Limits, M-factors	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 entries	005-018-00-2	perboric acid (H3BO2(O2)), monosodium salt trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O2)), sodium salt, tetrahydrate; [3] sodium peroxoborate hexahydrate; [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 234-390-0 [2] 231-556-4 [3]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. 1B STOT SE 3 Eye Dam. 1	H360Df H335 H318	GHS05 GHS08 GHS07 Dgr	H360Df H335 H318		Repr. 1B; H360Df: C ≥ 14 % Repr. 1B; H360D: 10 % ≤ C < 14 % Eye Dam. 1; H318: C ≥ 36 % Eye Irrit. 2; H319: 22 % ≤ C < 36 %	
	005-018-01-X	perboric acid (H3BO2(O2)), monosodium salt, trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O2)), sodium salt, tetrahydrate; [3] sodium peroxoborate hexahydrate; [containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 234-390-0 [2] 231-556-4 [3]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. 1B Acute Tox. 4 * STOT SE 3 Eye Dam. 1	H360Df H332 H335 H318	GHS05 GHS08 GHS07 Dgr	H360Df H332 H335 H318		Repr. 1B; H360Df: C ≥ 14 % Repr. 1B; H360D: 10 % ≤ C < 14 % Eye Dam. 1; H318: C ≥ 36 % Eye Irrit. 2; H319: 22 % ≤ C < 36 %	

Dossier submitters proposal	**Merge:** 005-018-00-2 005-018-01-X	**Retain:** perboric acid (H3BO2(O2)), monosodium salt trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O2)), sodium salt, tetrahydrate; [3] sodium peroxoborate hexahydrate; **Remove:** [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] [containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	**Modify:** 239-172-9 [1] 234-390-0 [2]	**Retain:** 13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	**Modify:** Repr.1B Acute Tox. 4	**Modify:** H360FD H332	**Retain:** GHS08 GHS07 Dgr	**Modify:** H360FD H332		**Remove:** Repr. 1B; H360Df: C ≥ 14 % Repr. 1B; H360D: 10 % ≤ C < 14 % **Add:** inhalation: ATE = 1.16 mg/L (dusts and mists)	
RAC opinion	**Merge:** 005-018-00-2 005-018-01-X	**Retain:** perboric acid (H3BO2(O2)), monosodium salt trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O2)), sodium salt, tetrahydrate; [3] sodium peroxoborate hexahydrate; **Remove:** [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] [containing ≥ 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	**Modify:** 239-172-9 [1] 234-390-0 [2]	**Retain:** 13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	**Modify:** Repr.1B Acute Tox. 4	**Modify:** H360FD H332	**Retain:** GHS08 GHS07 Dgr	**Modify:** H360FD H332		**Remove:** Repr. 1B; H360Df: C ≥ 14 % Repr. 1B; H360D: 10 % ≤ C < 14 % **Add:** inhalation: ATE = 1.2 mg/L (dusts and mists)	

Resulting Annex VI entry if agreed by COM	TBD	perboric acid ($H_3BO_2(O_2)$), monosodium salt trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid ($HBO(O_2)$), sodium salt, tetrahydrate sodium peroxoborate hexahydrate [3]	239-172-9 [1] 234-390-0 [2]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. 1B Acute Tox. 4 STOT SE 3 Eye Dam. 1	H360FD H332 H335 H318	GHS05 GHS08 GHS07 Dgr	H360FD H332 H335 H318		inhalation: ATE = 1.2 mg/L (dusts and mists) Eye Dam. 1; H318: C ≥ 36 % Eye Irrit. 2; H319: 22 % ≤ C < 36 %	#

#The inclusion of a specific note to apply additivity for boron compounds that exert their reproductive toxicity through the same toxic entity (boric acid/borate ion) is supported.

Sodium peroxometaborate

	Index No	International Chemical Identification	EC No.	CAS No.	Classification		Labelling			Specific Conc. Limits, M-factors	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 entries	005-017-00-7	sodium perborate; [1] sodium peroxometaborate; [2] sodium peroxoborate; [containing = 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 231-556-4 [2]	15120-21-5 [1] 7632-04-4 [2]	Ox. Sol. 2 Repr. 1B Acute Tox. 4* STOT SE 3 Eye Dam. 1	H272 H360Df H302 H335 H318	GHS03 GHS05 GHS08 GHS07 Dgr	H272 H360Df H302 H335 H318		Repr. 1B; H360D: 6,5 % ≤ C < 9 % Repr. 1B; H360Df: C ≥ 9 % Eye Dam. 1; H318: C ≥ 22 % Eye Irrit. 2; H319: 14 % ≤ C < 22 %	
	005-017-01-4	sodium perborate; [1] sodium peroxometaborate; [2] sodium peroxoborate; [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 231-556-4 [2]	15120-21-5 [1] 7632-04-4 [2]	Ox. Sol. 2 Repr. 1B Acute Tox. 3* Acute Tox. 4* STOT SE 3 Eye Dam. 1	H272 H360Df H331 H302 H335 H318	GHS03 GHS06 GHS05 GHS08 Dgr	H272 H360Df H331 H302 H335 H318		Repr. 1B; H360D: 6,5 % ≤ C < 9 % Repr. 1B; H360Df: C ≥ 9 % Eye Dam. 1; H318: C ≥ 22 % Eye Irrit. 2; H319: 14 % ≤ C < 22 %	
Dossier submitters proposal	**Merge:** 005-017-00-7 & 005-017-01-4	**Modify:** sodium peroxometaborate; [2] **Remove:** sodium perborate; [1] sodium peroxoborate; [2] [containing = 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] [2] [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] [2]	**Retain:** 231-556-4 [2] **Remove:** 239-172-9 [1]	**Retain:** 7632-04-4 [2] **Remove:** 15120-21-5 [1]	**Modify:** Repr. 1B Acute Tox. 3 Acute Tox. 4	**Modify:** H360FD H331 H302	**Retain:** GHS06 GHS08 Dgr	**Modify:** H360FD H331 H302		**Remove:** Repr. 1B; H360D: 6,5 % ≤ C < 9 % Repr. 1B; H360Df: C ≥ 9 % **Add:** inhalation: ATE = 0.62 mg/L (dusts and mists) oral: ATE = 918 mg/kg bw/day	

RAC opinion	**Merge:** 005-017-00-7 & 005-017-01-4	**Modify:** sodium peroxometaborate; **Remove:** sodium perborate; [1] sodium peroxoborate; [2] [containing = 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] [2] [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] [2]	**Retain:** 231-556-4 [2] **Remove:** 239-172-9 [1]	**Retain:** 7632-04-4 [2] **Remove:** 15120-21-5 [1]	**Modify:** Repr. 1B Acute Tox. 3 Acute Tox. 4	**Modify:** H360FD H331 H302	**Retain:** GHS06 GHS08 Dgr	**Modify:** H360FD H331 H302		**Remove:** Repr. 1B; H360D: 6,5 % ≤ C < 9 % Repr. 1B; H360Df: C ≥ 9 % **Add:** inhalation: ATE = 0.62 mg/L (dusts and mists) oral: ATE = 730 mg/kg bw/day	
Resulting Annex VI entry if agreed by COM	TBD	sodium peroxometaborate	231-556-4	7632-04-4	Ox. Sol. 2 Repr. 1B Acute Tox. 3 Acute Tox. 4 STOT SE 3 Eye Dam. 1	H272 H360FD H331 H302 H335 H318	GHS03 GHS06 GHS05 GHS08 Dgr	H272 H360FD H330 H302 H335 H318		inhalation: ATE = 0.62 mg/L (dusts and mists) oral: ATE = 730 mg/kg bw/day Eye Dam. 1; H318: C ≥ 22 % Eye Irrit. 2; H319: 14 % ≤ C < 22 %	#

#The inclusion of a specific note to apply additivity for boron compounds that exert their reproductive toxicity through the same toxic entity (boric acid/borate ion) is supported.

Trimethyl borate

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	005-005-00-1	Trimethyl borate	204-468-9	121-43-7	Flam. Liq. 3 Acute Tox. 4*	H226 H312	GHS02 GHS07 Wng	H226 H312			
Dossier submitters proposal	005-005-00-1	Trimethyl borate	204-468-9	121-43-7	**Add** Repr. 1B	**Add** H360FD	**Add** GHS08 **Modify** Dgr	**Add** H360FD			
RAC opinion	005-005-00-1	Trimethyl borate	204-468-9	121-43-7	**Add** Repr. 1B	**Add** H360FD	**Add** GHS08 **Modify** Dgr	**Add** H360FD			#
Resulting Annex VI entry if agreed by COM	005-005-00-1	Trimethyl borate	204-468-9	121-43-7	Flam. Liq. 3 Acute Tox. 4* Repr. 1B	H226 H312 H360FD	GHS02 GHS07 GHS08 Dgr	H226 H312 H360FD			#

#The inclusion of a specific note to apply additivity for boron compounds that exert their reproductive toxicity through the same toxic entity (boric acid/borate ion) is supported.

Ethanethiol; ethyl mercaptan

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	016-022-00-9	ethanethiol; ethyl mercaptan	200-837-3	75-08-1	Flam. Liq. 2 Acute Tox. 4* Aquatic Acute 1 Aquatic Chronic 1	H225 H332 H400 H410	GHS02 GHS09 GHS07 Dgr	H225 H332 H410			
Dossier submitters proposal	016-022-00-9	ethanethiol; ethyl mercaptan	200-837-3	75-08-1	**Add** Acute Tox. 4 **Modify** Flam. Liq. 1 Acute Tox. 3	**Add** H302 **Modify** H224 H331	**Add** GHS06 **Remove** GHS07	**Add** H302 **Modify** H224 H331		**Add** oral: ATE = 680 mg/kg inhalation: ATE = 7.14 mg/L (vapours)	
Resulting Annex VI entry if agreed by COM	016-022-00-9	ethanethiol; ethyl mercaptan	200-837-3	75-08-1	Flam. Liq. 1 Acute Tox. 3 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H224 H331 H302 H400 H410	GHS02 GHS06 GHS09 Dgr	H224 H331 H302 H410		oral: ATE = 680 mg/kg inhalation: ATE = 7.1 mg/L (vapours)	

Part III. List of Attendees of the RAC-62 meeting

RAC members (physical attendance)	
Aquilina	Gabriele
Barański	Bogusław
Biró	Anna
Bjørge	Christine
Brovkina	Julija
Chiurtu	Elena (co-opted member)
Deviller	Geneviève (co-opted member)
Doak	Malcolm
Docea	Anca
Facchin	Manuel
Fernandez	Mariana
Geoffroy	Laure
Ginnity	Bridget (co-opted member)
Hakkert	Betty
Hartwig	Andrea (co-opted member)
Kadikis	Normunds
Karadjova	Irina
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Martinek	Michal
Menard Srpčič	Anja
Mendas	Gordana
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Murray	Brendan
Neumann	Michael
Paris	Pietro
Pęczkowska	Beata
Pribu	Mihaela
Printemps	Nathalie
Rodriguez	Wendy
Santonen	Tiina
Schlueter	Urs
Schulte	Agnes
Schuur	Gerlienke
Spetseris	Nikolaos
Tekpli	Nina Landvik
Tobiassen	Lea Stine
Tsitsimpikou	Christina
Uzomeckas	Žilvinas
van der Haar	Rudolf (co-opted member)
Varnai	Veda
Viegas	Susana

RAC members (remote attendance)	
Gebel	Thomas
Sørensen	Peter Hammer

Apologies RAC members	
Sogorb	Miguel
Xanthos	Theodore

Members' advisers (physical attendance)		
Esposito	Dania	(Pietro Paris)
Jankowska	Agnieszka	(Peczkowska Beata) Ethanethiol

Members' advisers (remote attendance)		
Beetstra	Renske	(Schuur Gerlienke) Biomonitoring seminar + some AfAs
Catone	Tiziana	(Gabriele Aquilina) CLH: Paracetic Acid
Dumke	Carolin	(Schlüter Urs)
Hoffmann	Frauke	(Agnes Schulte)
Huuskonen	Pasi	(Santonen Tiina)
Kohns	Kevin	(Gebel Thomas)
Nielsen	Peter Juhl	(Lea Stine Tobiassen) PFAS
Russo	Maria Teresa	(Gabriele Aquilina)
Saksa	Jana	(Moldov Raili)
Séba	Julie	(Rodriguez Wendy)
Stalter	Daniel	(Agnes Schulte)
Suutari	Tiina	(Riitta Leinonen)
Vriend	Jelle	(Schuur Gerlienke) Borates

SEAC Rapporteurs (remote attendance)		
Anastasiou	Christos	AfA: CT_Kesseboehmer
Brignon	Jean-Marc	Restrictions: PFAS
Jomini	Stéphane	Restrictions: Medium chain chlorinated paraffins (MCCP)
Kiiski	Johanna	Restrictions: PFAS in firefighting foams
Urban	Klaus	Restrictions: Medium chain chlorinated paraffins (MCCP)

Invited experts (physical attendance)		
Angeli	Karine	New RAC member (mandate starting 1.10)
Rakkestad	Kirsten Eline	New RAC member (mandate starting 1.10)

Invited experts (remote attendance)		Substance
August	Christina (UPFAS)	Restrictions: PFAS in firefighting foams
Beekman	Martijn (UPFAS)	Restrictions: PFAS in firefighting foams
Dannenberg	Carl (UPFAS)	Restrictions: PFAS in firefighting foams
Drost	Wiebke (UPFAS)	Restrictions: PFAS in firefighting foams
Duca	Radu	Seminar on biomonitoring
Elliott	Dave	Seminar on biomonitoring
Ivarsson	Jenny (UPFAS)	Restrictions: PFAS in firefighting foams
Levy	Patrick	OEL: Cobalt and PAHs

Musu	Tony	OEL: Cobalt and PAHs
Saarikoski	Sirkku	OEL: Cobalt and PAHs
Stalter	Daniel (UPFAS)	Restrictions: PFAS in firefighting foams
Verdonck	Jelle	Seminar on biomonitoring

Dossier submitters (remote participation)		**Substance**
Catone	Tiziana (IT)	Restrictions: Terphenyl, hydrogenated
Groothuis	Floris (NL)	trimethyl borate
Jongeneel	Rob (NL)	DMAC-NEP
Witasp Henriksson	Erika (SE)	Perboric acid, sodium salt; perboric acid, sodium salt, monohydrate; perboric acid ($HBO(O_2)$), sodium

Regular stakeholder observers (physical attendance)	
De Backer	Liisi (CEFIC)
Duguy	Hélène (ClientEarth)
Fernandez	Ana (EEB)
Ruelens	Paul (CropLife Europe)
Verougstraete	Violaine (Eurometaux)

Regular stakeholder observers (remote attendance)	
Barry	Frank (ETUI)
Evans	Benedict (MedTech Europe)
Robin	Nicolas (PlasticsEurope) Restrictions: PFAS in fire fighting foams
Robinson	Jan (A.I.S.E.)

Occasional stakeholders (remote participation)		**Substance**
Ballach	Jochen (CIRFS)	Restrictions: DMAC and NEP conformity check and CLH: silver
Barbu	Luminita (EDANA)	Restrictions: MCCP and DMAC
Hinkal	George (Concawe)	OEL: PAH
Moinet	Thierry (Eurofeu)	Restrictions: PFAS
Niemela	Helena (CONCAWE)	General administrative, general CLH, general restrictions items; CLH dossiers; restrictions: creosote, terphenyl, hydrogenated; PFAS, PAHs
Rizzo	Federica (EPEE)	Restrictions: PFAS
Costanza	Rovida (Ecopa)	OELs – general and the two opinions for discussion; CHL general issues

Stakeholder experts (remote participation)		**Substance**
Barber	David (CropLife Europe)	Restrictions: PFAS
Bock	Ronald (Cefic/ AGC)	Restrictions: PFAS
Bothe	Kathrin (CroplifeEurope / Bayer)	CLH: Hazard classes to address developmental neurotoxicity

Consoli	Elisa (EPEE / European Chemical Industry Council)	Restrictions: PFAS
Höke	Hartmut (Cefic/ Coal Chemicals Europe sector group)	OEL: PHAs and Cobalt; Restrictions: clay target
Howick	Chris (Cefic / Inovyn)	Restrictions: MCCP
McMillan	Neil (ClientEarth)	Restrictions: PFAS
Schneider	Klaus (Edana)	Restrictions: DMAC/NEP
Schrage	Arnhild (Cefic / BASF)	Restrictions: DMAC/NEP
Viegas	Vanessa (Eurometaux)	OEL: Cobalt
Wieske	Martin (Cefic)	OEL: Cobalt

European Commission (physical participation)		**DG**
Kusendila	Christophe	DG GROW

European Commission (remote participation)		**DG**
Bertato	Valentina	DG ENV
Dunauskiene	Lina	DG GROW
Morris	Alick	DG EMPL (OELs)
Podniece	Zinta	DG EMPL (OELs)
Roebben	Gert	DG GROW
Tailler	William	DG EMPL (OELs)

EU Agency Observers (remote participation)		
Rincon	Ana Maria	EFSA: CLH

ECHA staff (physical or remote participation)	
Bowmer	Tim (Chair)
Doyle	Simone
Franke	Greta
Hautamäki	Anne (legal: CLH: neurotoxicity)
Hellsten	Kati
Herbatschek	Nicolas
Hoffstadt	Laurance
Karjalainen	Anne-Mari
Karjalainen	Antti
Klausbruckner	Carmen
Kokkola	Leila
Korjus	Pia
Lazic	Nina
Lefevre	Sandrine

Logtmeijer	Christiaan
Loukou	Christina
Ludborzs	Arnis
Marquez-Camacho	Mercedes
Nicot	Thierry
Nurmi	Väinö (DS for restrictions PAHs)
Nygren	Jonas
Orispää	Katja
O'Rourke	Regina
Peltola	Jukka
Peltola-Thies	Johanna (Vice-Chair)
Perazzolo	Chiara
Pikk	Liisa
Pillet	Monique
Portugal	Laura
Reuter	Ulrike
Ryan	Paul
Sadam	Diana
Simoes	Ricardo
Simpson	Peter
Sosnowski	Piotr (DS: Restrictions: PFAS)
Stockmann-Juvala	Helene
Thierry-Mieg	Morgane (DS for restrictions PAHs)
van Haelst	Anniek
Väänänen	Virpi
Zarogiannis	Panagiotis
Zeiger	Bastian

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-62 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-62 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-62 meeting

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

Annex I

12 September 2022
RAC/A/62/2022

Final Agenda
62nd meeting of the Committee for Risk Assessment
(RAC-62)

12-15 September 2022

Face-to-face meeting[1]

Monday, 12 September starts at 14.00
Thursday, 15 September ends at 18.30

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/62/2022
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.

5.2 Annual update of RAC accredited stakeholders´ list

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

RAC/62/2022/01
Restricted document
For agreement
Closed session

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))

For discussion

Item 7 –Health based exposure limits at the workplace

7.1 General OEL issues

1. Updated RAC Working procedure on opinion development

RAC/62/2022/02
For agreement

7.2 Opinions for discussion

1. Cobalt – first draft opinion
2. Polyaromatic hydrocarbons (PAHs) – first draft opinion

For discussion

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the July CLH Working Group

RAC/62/2022/03
For information

2. Guidance on assessing physical hazards in the CLH dossiers

RAC/62/2022/04
For discussion/agreement

3. Addressing developmental neurotoxicity and neurotoxicity under the current CLP hazard classes

RAC/62/2022/05
For discussion/agreement

8.2 CLH dossiers

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

10. Perboric acid, sodium salt [1]; perboric acid, sodium salt, monohydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, monohydrate; sodium peroxoborate [3]; sodium perborate [4] (EC 234-390-0 [1]; 234-390-0 [2]; 239-172-9 [4]; CAS 11138-47-9 [1]; 12040-72-1 [2]; 10332-33-9 [3]; 15120-21-5 [4]): *acute toxicity, reproductive toxicity*
11. Perboric acid ($H_3BO_2(O_2)$), monosodium salt trihydrate [1]; perboric acid, sodium salt, tetrahydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, tetrahydrate; sodium peroxoborate, hexahydrate [3] (EC 239-172-9 [1]; 234-390-0 [2]; CAS 13517-20-9 [1]; 37244-98-7 [2]; 10486-00-7 [3]): *acute toxicity, reproductive toxicity*
12. Sodium peroxometaborate (EC 231-556-4; CAS 7632-04-4): *acute toxicity, reproductive toxicity*
13. Trimethyl borate (EC 204-468-9; CAS 121-43-7): *reproductive toxicity*
14. 1*H*-benzotriazole (EC 202-394-1; CAS 95-14-7): *hazardous to the aquatic environment*
15. Methyl-1*H*-benzotriazole (EC 249-596-6; CAS 29385-43-1): *hazardous to the aquatic environment*
16. Sodium 3-(allyloxy)-2-hydroxypropanesulphonate (EC 258-004-5; CAS 52556-42-0): *serious eye damage/eye irritation, reproductive toxicity*
17. *N*,*N*'-methylenediacrylamide (EC 203-750-9; CAS 110-26-9): *germ cell mutagenicity*
18. Ethanethiol; ethyl mercaptan (EC 200-837-3; CAS 75-08-1): *physical hazards, acute toxicity via oral route*

2) Hazard classes for agreement with plenary debate

6. Perboric acid, sodium salt [1]; perboric acid, sodium salt, monohydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, monohydrate; sodium peroxoborate [3]; sodium perborate [4] (EC 234-390-0 [1]; 234-390-0 [2]; 239-172-9 [4]; CAS 11138-47-9 [1]; 12040-72-1 [2]; 10332-33-9 [3]; 15120-21-5 [4]): *reproductive toxicity note on additivity*
7. Perboric acid ($H_3BO_2(O_2)$), monosodium salt trihydrate [1]; perboric acid, sodium salt, tetrahydrate [2]; perboric acid ($HBO(O_2)$), sodium salt, tetrahydrate; sodium peroxoborate, hexahydrate [3] (EC 239-172-9 [1]; 234-390-0 [2]; CAS 13517-20-9 [1]; 37244-98-7 [2]; 10486-00-7 [3]): *reproductive toxicity note on additivity*
8. Sodium peroxometaborate(EC 231-556-4; CAS 7632-04-4): *reproductive toxicity note on additivity*
9. Trimethyl borate (EC 204-468-9; CAS 121-43-7): *reproductive toxicity note on additivity*
10. Ethanethiol; ethyl mercaptan (EC 200-837-3; CAS 75-08-1): *acute toxicity via inhalation route*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the August Restriction Working Group

RAC/62/2022/06
For information

2. Updated Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers

RAC/62/2022/07
For agreement

9.2 Restriction Annex XV dossiers

1. Conformity check and key issues discussion

    1. Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17

For discussion and agreement

2. Opinion development

    1. Terphenyl, hydrogenated - first draft opinion
    2. *N*,*N*-dimethylacetamide and 1-ethylpyrrolidin-2-one – first draft opinion
    3. Per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams – second draft opinion

For discussion

    4. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting – third draft opinion

For discussion and adoption

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the July AFA Working Group

RAC/62/2022/08
For information

2. Update on incoming/future applications

For information/discussion

3. Renewal of the RAC AFA WG mandate

RAC/62/2022/09
For discussion and agreement

4. Seminar on biomonitoring

RAC/62/2022/10

For discussion and agreement

10.2 Authorisation applications

1. Discussion on key issues

1. 11 applications for authorisation (chromium (VI) substances) and 1 review report (diglyme) from May 2022 submission window

For discussion

10.3 Agreement on draft opinions

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

6. 253_CT_GEA-Westfalia (1 use)
7. 254_CT_Ratier-Figeac (2 uses)
8. 255_CT_Chrom-Mueller (3 uses)
9. 256_CT_KaVo-Dental (1 use)
10. 257_CT_Qualipac (1 use)
11. 258_CT_Schulte (2 uses)
12. 259_CT_ST-SRL (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 231_CT_Kesseboehmer (1 use)
2. 241_CT_Gessi (1 use)

For discussion and adoption

Item 11 – AOB

1. Grouping and CLH
2. Drinking Water Directive: Introducing the role of RAC

Item 12 – Minutes of RAC-62

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-62

For adoption

Annex II (RAC 62)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-62 meeting.

RAC/A/62/2022	RAC-62 final Draft Agenda
RAC/62/2022/01 *Restricted document*	Annual update of RAC accredited stakeholders´ list
RAC/62/2022/02	General OEL issues: Updated RAC Working procedure on opinion development
RAC/62/2022/03	General CHL issues: Report from the July CLH Working Group
RAC/62/2022/04	General CHL issues: Guidance on assessing physical hazards in the CLH dossiers
RAC/62/2022/05	General CLH issues: Addressing developmental neurotoxicity and neurotoxicity under the current CLH hazard classes
RAC/62/2022/06	General restriction issues: Report from the August Restriction Working Group
RAC/62/2022/07	General restriction issues: Updated Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers
RAC/62/2022/08	General authorisation issues: Report from the July AFA Working Group
RAC/62/2022/09	General authorisation issues: Renewal of the RAC AFA WG mandate
RAC/62/2022/10	General authorisation issues: Seminar on biomonitoring (Program)

ANNEX III (RAC-62)

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		
N,N-dimethylacetamide and NEP **NL**	Betty HAKKERT Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Terphenyl, hydrogenated **IT**	Gabriele AQUILINA	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
NEW DOSSIERS		
Harmonised classification & labelling		
1) Perboric acid, sodium salt, tetrahydrate **2) Perboric acid, sodium salts, monohydrate** **3) Sodium peroxometaborate** **4) *N,N'*-methylenediacrylamide** **SE**	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.
	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.
Trimethyl borate **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.
Ethanethiol **AT**	Annemarie LOSERT	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Manuel FACCHIN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Sodium 3-(allyloxy)-2-hydroxypropanesulphonate **FR**	Nathalie PRINTEMPS	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.
1) ***1H*-Benzotriazole** 2) **Methyl-*1H*-benzotriazole** **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.
	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Urs SCHLUTER	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
	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.

Annex IV (RAC 62)

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	**Action requested after the meeting (by whom/by when)**
254_CT_Ratier-Figeac (use 1) **Use1:** *Industrial use of chromium trioxide for functional chrome plating of aircraft safety critical steel ball screws used in airplane's actuators, to decrease friction ratio, and enhance wear, corrosion, and endurance resistance, enabling targeted service life* 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. Proposed additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 pellets by liquid CrO_3 to further limit 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; c) the automation of the HCP line and coverage of the chromium baths as in the CAA line (Use 2). 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.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

Section 8. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue their monitoring programmes for Cr(VI) and considering the following: 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: 1. the full range and duration of tasks undertaken where exposure to Cr(IV) is possible, including irregular maintenance activities (WCS 1.6); 2. the OCs and RMMs typical for each of these tasks; 3. the number of workers potentially exposed; and vi. include contextual information about the tasks performed during sampling. b. Environmental releases: i. the applicant shall continue conducting their yearly monitoring programme for Cr(VI) emission to air; ii. the applicant shall conduct air emission measurements more frequently following any possible changes in the process; iii. the monitoring programmes for air emissions shall:	

1. be based on relevant standard methodologies or protocols; 2. be representative of the OCs and RMMs used at the applicant's site; and 3. ensure a sufficiently low limit of quantification. 2. The information gathered via the measurements referred to in paragraphs 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 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 authorisation holder may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed	

in the chemical safety report function appropriately 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. Section 9. Recommendations for the review report The results of the feasibility studies as mentioned in Section 7 and the monitoring programmes referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent authorisation review report.	
254_CT_Ratier-Figeac (use 2) **Use1:** *Industrial use of chromium trioxide for the chromic acid anodizing of aluminium spars as critical surface preparation phase for bonding with aircraft safety critical propeller blades to secure reliable bonding performance and enhance spars corrosion resistance* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. RAC agreed: Section 7. Proposed additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 pellets by liquid CrO_3 to further limit exposure;	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

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 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. Proposed monitoring arrangements for the authorisation

1. The applicant shall continue their monitoring programmes for Cr(VI) and considering the following:

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:

1. the full range and duration of tasks undertaken where exposure to Cr(IV) is possible;

2. the OCs and RMMs typical for each of these tasks;

3. the number of workers potentially exposed; and

vi. include contextual information about the tasks performed during sampling.

b. Environmental releases: i. the applicant shall continue conducting their yearly monitoring programme for Cr(VI) emission to air; ii. the applicant shall conduct air emission measurements more frequently following any possible changes in the process; iii. the monitoring programmes for air emissions shall: 1. be based on relevant standard methodologies or protocols; 2. be representative of the OCs and RMMs used at the applicant's site; and 3. ensure a sufficiently low limit of quantification. 2. The information gathered via the measurements referred to in paragraphs 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 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 authorisation holder may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. Section 9. Recommendations for the review report The results of the feasibility studies as mentioned in Section 7 and the monitoring programmes referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent authorisation review report.	
255_CT_Chrom-Mueller (3 use) **Use1:** *Industrial use of chromium trioxide for high ratio aspects inside hard chromium coating of firearms barrel bores subject to thermal, mechanical and chemical stresses, in order to provide wear resistance properties, as well as low friction coefficient, hardness, resistance to corrosion and gas erosion properties.*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

Use2: *Industrial use of chromium trioxide in the hard chromium coating of complex outer surfaces of firearm auxiliary parts subject to mechanical, chemical and thermal stress in order to provide optimized sliding properties as well as heat, corrosion and wear resistance properties.* **Use3:** *Industrial use of chromium trioxide in the hard chromium coating of complex outer and inner surfaces of firearms auxiliary parts requiring a customised and selective coating technique and subject to thermal, mechanical and chemical stresses, in order to provide wear resistance and barrier properties, as well as post-processing capability and resistance to hot combustion gas erosion.* 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. Proposed additional conditions for the authorisation RAC proposes the following conditions for the authorisation: 1. The applicant shall continue to carry out their plan to fully automate the plating line by 2023. 2. 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. 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. Proposed monitoring arrangements for the authorisation	

1. The applicant shall implement (or continue) 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; (ii) the applicant shall continue conducting 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 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 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. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such	

changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible 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 study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1 and 7, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report.	
257_CT_Qualipac (1 use) **Use1:** *Industrial use of chromium trioxide for the etching of polypropylene (PP) substrates, as a pretreatment step of the electroplating process, for the luxury sector and other 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. Proposed 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 both at Graindorge and Qualipac; b. the automation of manual tasks at the treatment lines including the concentration adjustment of the chromium baths and the bath sampling at both sites, and the weighing of	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

chromium trioxide at Qualipac. 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 implement a regular maintenance programme of the LEV systems (at least annual). 3) 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. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue their following monitoring programmes for Cr(VI) at the Graindorge and the Qualipac sites: (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 static inhalation exposure sampling. In addition to the current personal measurements performed, static measurements at the vicinity of the	

baths and at far field from the baths are requested at both sites; (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; (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; 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. Section 9. Recommendations for the review report The results of the feasibility studies and of the implementation of OCs and RMMs requested in section 7 and of the monitoring arrangements 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 review report.	
259_CT_ST-SRL (1 use) **Use1:** *Use for electroplating of different types of substrates with the purpose to create a long-lasting high durability surface with bright (shiny) or matte look (functional electroplating with decorative character)* RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. RAC agreed: Section 7. Proposed additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on:	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

(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/automated system to perform bath testing/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. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue 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;	

(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 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 7. The applicant shall continue their existing biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1, and paragraph 4, 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.	