

**Minutes of the 68th Meeting
of the Committee for Risk Assessment
(RAC-68)**

**Monday, 11 March 2024 at 10.00
Thursday, 14 March end at 18.10**

**Summary Record of the Proceedings,
Conclusions and action points**

Chair's opening address

The Chair of RAC, Roberto Scazzola opened the meeting and provided some opening remarks related to the expected Committee's workload for 2024.

Agenda point	
Conclusions / agreements / adoptions	Action requested after the meeting (by whom/by when)
2. Adoption of the Agenda	
The Agenda (RAC/A/68/2024) was adopted without amendment.	SECR to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-68 minutes.
4. Appointment of (co-)rapporteurs	
4.1. Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for harmonised classification and labelling (CLH) dossiers, applications for authorisation, and the restriction dossiers as listed in the restricted document in the Interact collaboration tool. The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted dossiers for the above-mentioned processes.	
5. Report from other ECHA bodies and activities	
5.1. RAC work plan for all processes The Chair presented the RAC work plan until end of 2024 and early 2025.	
6. Request under Article 77(3)(c)	
6.1 Request to review the CLH Opinion on Lithium carbonate (LiCO₃), lithium chloride (LiCl), lithium hydroxide (LiOH)	
The Chair welcomed an expert accompanying the CEFIC Regular Stakeholder Observer and an expert accompanying the Eurometaux Regular Stakeholder Observer. He informed the Committee that ECHA received a request from the Commission on a new study (Boyle et al. (2017)) and also on any relevant additional data related to cardiac foetal malformations compared to the information considered in the opinion of RAC adopted on 16 September 2021 on lithium carbonate (EC number: 209-062-5), lithium chloride (EC number: 231-212-3) and	

lithium hydroxide (EC number: 215-183-4). RAC was asked to review the submitted information, clarify the evidence available and the association between exposure to lithium salts and cardiac foetal malformations, and, if necessary, amend its opinion.
 A targeted consultation on the new information was organised on the ECHA website.
 The deadline for the adoption of an opinion is 1 June 2024.
 The expert accompanying the CEFIC Regular Stakeholder Observer commented on read-across.

The Rapporteurs presented and RAC discussed the revised draft opinion on this Article 77(3)(c) request.

RAC noted that the Boyle et al. (2017) study is not intended to investigate the effect of lithium, analysis is not sufficiently informative for the risk of lithium during pregnancy, no support for the hypothesis that lithium use in the first trimester of pregnancy increases the risk of Ebstein's anomaly (EA), but neither does it reject the hypothesis.

RAC noted that all available studies have been considered and weighted according to their robustness and quality – the studies show an increase, albeit low, in cardiac malformations after lithium exposure during pregnancy. The newly added studies by Fornaro et al. (2020) and Hastie et al. (2021) further strengthen the case for Reprotoxicity category 1A for development.

RAC agreed that the classification for Toxic for reproduction category 1A for developmental toxicity is warranted, based on:

- Increased risk of congenital cardiac malformations following lithium exposure during pregnancy (especially in the first trimester) in some epidemiological studies;
- Association is dose-dependent;
- Although rare, malformations are considered as serious and therefore relevant for hazard classification;
- Increased risk is shown in comparison with general pregnant population as well as with population of pregnant women with mental disorder.

RAC agreed on read-across between the inorganic lithium compounds lithium carbonate, lithium chloride and lithium hydroxide, with regards to systemic toxicity including developmental toxicity.

RAC adopted by consensus the opinion on this Article 77(3)(c) request.

Rapporteurs to revise the opinion in accordance with the agreed modifications at RAC-68 and to provide it to SECR.

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

6.2 Request to review the CLH Opinion on Methyl methacrylate (MMA)

The Chair welcomed an expert accompanying the CEFIC Regular Stakeholder Observer and an Occasional Stakeholder Observer from EuPC. He reminded the Committee that on 18 March 2021, RAC adopted an opinion on methyl methacrylate (MMA, EC Number 201-297-1), concluding that the substance should be classified as Resp. Sens. 1; H334, in line with the

proposal from the DS (FR). Following the adoption and publication of the RAC opinion, manufacturers of the substance provided additional evidence, which could challenge the causality of the association between MMA exposure and occupational asthma. Based on a request from the Commission, the Executive Director of ECHA gave the mandate to RAC to review the opinion of 18 March 2021 in relation to the classification for respiratory sensitisation. A targeted consultation on the new information was organised on the ECHA website. The deadline for the adoption of an opinion is 1 September 2024. The expert accompanying the CEFIC Regular Stakeholder Observer commented on respiratory sensitisation.

The Rapporteurs presented and RAC discussed the revised draft opinion on this Article 77(3)(c) request; this included consideration of information provided late into the process by Industry.

The Committee agreed that the previous conclusion from the RAC MMA opinion (2021) is still considered valid; this is based on 4 SIC cases presented in Suojalehto et al. (2020) and Annex 5 of the RAC MMA opinion (2021) as well as the reply by Suojalehto dated 15 January 2024 to the questions from the RAC chair (D(2023) 1134), showing that MMA can induce respiratory sensitisation. This is supported by a further two cases reported by Walters et al. (2017) where MMA was considered as a causative agent for occupational asthma and other information provided in the RAC opinion.

RAC confirmed that classification for Respiratory Sensitisation in Category 1, H334, is warranted.

RAC adopted by consensus the opinion on this Article 77(3)(c) request.

Rapporteurs to revise the opinion in accordance with the agreed modifications at RAC-68 and to provide it to SECR.

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

7. Health based exposure limits at the workplace

7.1.1. 1,3-Butadiene (EC number: 203-450-8; CAS RN: 106-99-0)

The Chair welcomed the representatives from the Government and Industry Interest Groups Working Party on Chemicals, of DG Employment and an expert accompanying the CEFIC Regular Stakeholder Observer. He informed that the Commission had requested ECHA to evaluate **1,3-butadiene**, in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 21 September 2023 until 20 November 2023 and the deadline for this request is 23 February 2025.

The expert accompanying the CEFIC Regular Stakeholder Observer commented on cancer risk assessment.

The Rapporteurs presented and RAC discussed the first draft opinion on the scientific evaluation of occupational exposure limit values for 1,3-butadiene (1,3 -BD).

Rapporteurs to revise the opinion in accordance with the agreed modifications at RAC-68 and to provide it to SECR.

<p>RAC agreed that 1,3-BD acts via a non-threshold genotoxic mode of action (MoA), and this approach can be used for the derivation of ERRs for 1,3-BD.</p> <p>RAC agreed to base the cancer exposure-risk relationship (ERR) on human data rather than on animal data, recognising the uncertainties related to human data.</p> <p>RAC agreed to apply linear regression fitted on rate ratios (RR) calculated for each decile of exposure to 1,3-BD, from data from Sathiakumar et al. (2021b) group, and to use the obtained slope coefficient in the life-table analysis.</p> <p>RAC agreed to use the 1,3-butadiene concentration of 0.065 ppm (0.146 mg/m³) corresponding to excess risk 4x10⁻⁵ (calculated as an arithmetic mean of the concentrations corresponding to excess risk 4x10⁻⁵ based on the linear ERRs derived after the exclusion of the highest and two highest 1,3-butadiene exposure deciles).</p> <p>RAC confirmed that the most critical non-cancer effect is ovarian atrophy driven by DEB (MoA) and agreed that the species quantitative differences in the formation of DEB is well substantiated by available data.</p> <p>RAC agreed that comparative TK data are sufficient to propose a chemical-specific value of interspecies assessment factor (AF) lower than 1 (AFs are to be further discussed).</p> <p>RAC will continue and finalise its discussion on this dossier at RAC-69.</p>	<p>SECR to organise a RAC consultation on the revised draft RAC opinion.</p> <p>SECR to table the opinion for the final discussion and adoption at RAC-69.</p>
<p>7.1.2. Boron and its compounds (EC numbers: 233-139-2, 215-575-5, 215-540-4, 215-125-8 and CAS RN: 10043-35-3, 1332-77-0, 1330-43-4, 1303-86-2 respectively)</p> <p>The Chair welcomed the representatives from the Government and Industry Interest Groups Working Party on Chemicals, of DG Employment, an Occasional Stakeholder Observer from IMA-Europe and an Occasional Stakeholder Observer from EuPC. He informed that the Commission had requested ECHA to evaluate boron and its compounds, including boric acid, dipotassium tetraborate, disodium tetraborate and boric oxide, in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 31 October 2023 until 12 January 2024 and the deadline for this request is 23 February 2025.</p> <p>The Occasional Stakeholder Observer from IMA-Europe commented on the scope of the OEL, PoD for development, PoD for fertility and local irritant effects.</p>	
<p>RAC discussed the draft opinion on the scientific evaluation of occupational exposure limit values for 'boron and its compounds'.</p>	<p>Rapporteurs to revise the opinion in accordance with the agreed modifications at RAC-68 and to provide it to SECR.</p>

<p>RAC agreed to recommend that the 8-h TWA value (OEL proposed) is applied to any compound releasing boric acid (for reproductive toxicity).</p> <p>RAC considered appropriate to use a PoD based on reduction in sperm quality parameters as a sensitive endpoint. Based on weight-of evidence, RAC agreed to use Yoshizaki (1999) to derive the PoD. The Rapporteurs were asked to elaborate more on the weight-of-evidence provided from the other studies.</p> <p>In the revised draft opinion, the Rapporteurs will provide more justification on the use of a time-extrapolation factor for fertility (between 2, 3 and 4 which were the most supported during plenary).</p> <p>RAC agreed to use Price et al. (1996) as the key study for PoD on development.</p> <p>RAC provisionally agreed to use an intraspecies AF of 10 for developmental toxicity. Indeed, RAC considers that the default AF 5 is not sufficient here, in view of protecting the unborn child (very young highly susceptible part of the general population) who is not part of the working population. The Rapporteurs were asked to include more justification on using an AF of 10 in the revised draft opinion, relying on the OEL guidance document (Annex to R8 Guidance).</p> <p>For the local irritant effects assessment, RAC agreed to use the Wegman et al. studies and provisionally agreed to use the lower value of 0.6 mg B/m³ as point of departure, and no additional AF.</p> <p>RAC will continue and finalise its discussion on this dossier at RAC-69.</p>	<p>SECR to organise a RAC consultation on the revised draft RAC opinion.</p> <p>SECR to table the opinion for the final discussion and adoption at RAC-69.</p>
<p>8. Harmonised classification and labelling (CLH)</p>	
<p>8.1. General CLH issues</p>	
<p>8.1.1. Renewal of the RAC CLH WG mandate</p>	
<p>The Secretariat presented and RAC agreed on the renewal of the RAC CLH Working Group until March 2025.</p>	<p>Secretariat to publish the renewed mandate on the ECHA website.</p>
<p>8.1.2. Report from the January CLH Working Group</p>	
<p>The Secretariat presented the Report of the 12th Meeting of the Committee for Risk Assessment Applications for Classification and Labelling Working Group which took place on 23-24 January 2024.</p> <p>RAC took note of the Report.</p>	

8.2. CLH dossiers

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

- **Pyriproxyfen (ISO):** all hazard classes, except for aquatic chronic toxicity
- **Undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]:** STOT RE, reproductive toxicity (fertility and lactation)
- **Benzobicyclon (ISO):** all hazard classes
- **Sodium bromide:** STOT SE, STOT RE (nervous system and adrenals)
- **Potassium bromide:** STOT SE, STOT RE (nervous system and adrenals)
- **Calcium bromide:** STOT SE, STOT RE (nervous system and adrenals)
- **1-amino-4-hydroxy-2-phenoxyanthraquinone:** skin sensitisation
- **Dimethachlor (ISO):** all hazard classes, except for carcinogenicity

8.2.2. Hazard classes for agreement with plenary debate

8.2.2.1. **Metyltetraprole (ISO); 1-[2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5H-tetrazol-5-one (EC - ; CAS 1472649-01-6) (EC - ; CAS 1472649-01-6): carcinogenicity**

The Chair welcomed an expert accompanying the CropLife Regular Stakeholder Observer, and provided some general information on the uses of **metyltetraprole (ISO)**, proposed classification by the Dossier Submitter (FR) and legal deadline.

All relevant hazard classes were open for comments during the Consultation.

The discussion was finalised on all hazard classes at RAC-67, except for Carcinogenicity, where the Industry committed to provide more information to RAC by the end of 2023.

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

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1.

[Carc. 2; H351, Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=1)]

Rapporteurs to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat.

Secretariat to make an editorial check of the opinion documents in consultation with the Rapporteurs.

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

8.2.2.2. **Pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether (EC 429-800-1; CAS 95737-68-1)**

The Chair welcomed the Dossier Submitter representative and an expert accompanying the CropLife Regular Stakeholder Observer. He then provided some general information on the uses

of **pyriproxyfen (ISO)**, existing harmonized classification, proposed classification by the Dossier Submitter (NL) and legal deadline.
 All relevant hazard classes, except for respiratory sensitisation and aspiration hazard, were open for comments during the Consultation.
 The DS representative provided more details on the data submitted recently.
 The CropLife Regular Stakeholder Observer commented on aquatic chronic toxicity.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1.

[Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=1000)]

The opinion will reflect the uncertainties relating to the original calculation leading to the EC10 of 8.8 ng/L and incorporate the newly provided information from the DS leading to more reliable EC10 value of 13.3 ng/L.

Rapporteurs to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat.

Secretariat to make an editorial check of the opinion documents in consultation with the Rapporteurs.

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

8.2.2.3. Calcium tetraborate (EC 234-511-7; CAS 12007-56-6)

The Chair welcomed the Dossier Submitter representative, the Occasional Stakeholder Observer from IMA-Europe (Industrial Minerals Association Europe) as well as the Occasional Stakeholder Observer from PETA Science Consortium International e.V. He explained that the 10 borates dossiers are covering the following substances:

No	Chemical name	EC number	CAS number
1	magnesium metaborate	237-235-5	13703-82-7
2	sodium metaborate, anhydrous [1]; boric acid (HBO ₂), sodium salt, tetrahydrate [2]; and any other hydrated form	231-891-6 [1]; - [2]	7775-19-1 [1]; 10555-76-7[2]
3	potassium pentaborate	234-371-7	11128-29-3
4	potassium metaborate	237-262-2	13709-94-9
5	dipotassium tetraborate	215-575-5	1332-77-0
6	dipotassium octaborate	-	12008-39-8
7	diammonium decaborate	234-521-1	12007-89-5
8	calcium tetraborate	234-511-7	12007-56-6
9	calcium metaborate (Ca(BO ₂) ₂) and calcium tetraborate (CaB ₄ O ₇), amorphous reaction products of boric acid with lime	-	-
10	pentaboron sodium octaoxide	234-522-7	12007-92-0

The Chair provided some general information on the uses of borates, existing harmonized classification, proposed classification by the Dossier Submitter (SE) and legal deadline.
 Reproductive toxicity was the only hazard class open for comments during the Consultation.

The Working Group discussed the proposed hazard classes and recommended to the plenary specific conclusions.
The Occasional Stakeholder Observer from IMA-Europe commented on fertility.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1.

[Repr. 1B; H360FD, Note 11]

RAC agreed on no classification for Lactation due to insufficient data.

Rapporteurs to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat.

Secretariat to make an editorial check of the opinion documents in consultation with the Rapporteurs and to check RAC-64 discussion with regard Lactation.

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

8.2.2.4. Calcium metaborate (Ca(BO₂)₂) and calcium tetraborate (CaB₄O₇), amorphous reaction products of boric acid with lime

See above (point 8.2.2.3).

8.2.2.5. Pentaboron sodium octaoxide (EC 234-522-7; CAS 12007-92-0):

See above (point 8.2.2.3).

8.2.2.6. Sodium metaborate, anhydrous [1]; boric acid (HBO₂), sodium salt, tetrahydrate [2]; and any other hydrated form (EC 231-891-6 [1]; - [2]; CAS 7775-19-1 [1]; 10555-76-7 [2]):

See above (point 8.2.2.3).

8.2.2.7. Diammonium decaborate (EC 234-521-1; CAS 12007-89-5)

See above (point 8.2.2.3).

8.2.2.8. Potassium metaborate (EC 237-262-2; CAS 13709-94-9)

See above (point 8.2.2.3).

8.2.2.9. Dipotassium tetraborate (EC 215-575-5; CAS 1332-77-0):

See above (point 8.2.2.3).

8.2.2.10. Magnesium metaborate (EC 237-235-5; CAS 13703-82-7)

See above (point 8.2.2.3).

8.2.2.11. Dipotassium octaborate (EC – ; CAS 12008-39-8):	
See above (point 8.2.2.3).	
8.2.2.12. Potassium pentaborate (EC 234-371-7; CAS 11128-29-3):	
See above (point 8.2.2.3).	
8.2.2.13. Undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4] (EC 206-196-6[1]; 220-881-7[2]; 244-479-6[3]; - [4] ; CAS 307-24-4[1]; 2923-26-4[2]; 21615-47-4[3]; - [4]):	
<p>The Chair welcomed the Dossier Submitter representative and an Occasional Stakeholder Observer from PETA Science Consortium International e.V. He then provided some general information on the uses of PFHxA, existing harmonized classification, proposed classification by the Dossier Submitter (DE) and legal deadline.</p> <p>Reproductive toxicity and STOT RE were the only hazard classes open for comments during the Consultation.</p>	
<p><u>RAC adopted by consensus the opinion</u> with a proposal for the harmonised classification and labelling as indicated in Table 1.</p> <p>[Repr. 1B; H360D]</p>	<p>Rapporteurs to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat.</p> <p>Secretariat to make an editorial check of the opinion documents in consultation with the Rapporteurs.</p> <p>Secretariat to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
8.2.2.14. Sodium bromide (EC 231-599-9; CAS 7647-15-6):	
<p>The Chair welcomed the Dossier Submitter representatives, an expert accompanying the Eurometaux Regular Stakeholder Observer, an Occasional Stakeholder Observer from BSEF (the International Bromine Council) with an accompanying expert as well as an Occasional Stakeholder Observer from PETA Science Consortium International e.V. He then provided some general information on the uses of sodium bromide/potassium bromide/calcium bromide, existing harmonized classification, proposed classification by the Dossier Submitter (SE) and legal deadline.</p> <p>Reproductive toxicity, STOT SE and STOT RE were the only hazard classes open for comments during the Consultation.</p> <p>The expert accompanying the Occasional Stakeholder Observer from BSEF and the expert accompanying the Eurometaux Regular Stakeholder Observer commented on STOT RE.</p>	
<p><u>RAC adopted by consensus the opinion</u> with a proposal for the harmonised classification and labelling as indicated in Table 1.</p>	<p>Rapporteurs to revise the opinion in accordance with the</p>

<p>[Repr. 1B; H360FD, Lact.; H362, STOT SE 3; H336, STOT RE 1; H372 (nervous system), STOT RE 2; H373 (thyroid)]</p>	<p>discussion in RAC and to provide it to Secretariat.</p> <p>Secretariat to make an editorial check of the opinion documents in consultation with the Rapporteurs.</p> <p>Secretariat to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
<p>8.2.2.15. Potassium bromide (EC 231-830-3; CAS 7758-02-3)</p>	
<p>See above (point 8.2.2.14).</p>	
<p>8.2.2.16. Calcium bromide (EC 232-164-6; CAS 7789-41-5):</p>	
<p>See above (point 8.2.2.14).</p>	
<p>8.2.2.17. Dimethachlor (ISO); 2-chloro-N-(2,6-dimethylphenyl)-N-(2-methoxyethyl)acetamide (EC 256-625-6; CAS 50563-36-5):</p>	
<p>The Chair welcomed the Dossier Submitter representative and an expert accompanying the CropLife Europe Regular Stakeholder Observer. He provided some general information on the uses of dimethachlor (ISO), existing harmonized classification, proposed classification by the Dossier Submitter (HR) and legal deadline.</p> <p>Physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, hazards to the aquatic environment, hazards for the ozone layer, were open for comments during the Consultation.</p> <p>The expert accompanying the CropLife Regular Stakeholder Observer commented on carcinogenicity.</p>	
<p><u>RAC adopted by consensus the opinion</u> with a proposal for the harmonised classification and labelling as indicated in Table 1.</p> <p>Carc.: Considerations on strengths and weaknesses of the evidence will be provided in the opinion.</p> <p>[Carc. 2; H351, Acute Tox. 4; H302 (ATE=1600 mg/kg bw), Skin Sens. 1; H317, Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=10)]</p>	<p>Rapporteurs to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat.</p> <p>Secretariat to make an editorial check of the opinion documents in consultation with the Rapporteurs.</p> <p>Secretariat to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>

9. Restrictions	
9.1. General restriction issues	
9.1.1. Renewal of the RAC REST WG mandate	
The Secretariat presented and RAC agreed on the renewal of the RAC REST Working Group until March 2025.	Secretariat to publish the renewed mandate on the ECHA website.
9.1.2. Report from the March REST Working Group	
The Secretariat provided an oral report back from the March Working Group.	Secretariat to publish the report on the ECHA website.
9.2. Restriction Annex XV dossiers	
9.2.1. Opinion Development	
9.2.1.1. Universal per- and polyfluoroalkyl substances (UPFAS) – Overview on next plenary discussions and Draft opinion with focus on hazard, consumer mixtures, cosmetics, ski wax	
<p>The Chair welcomed the Dossier Submitter representatives from Denmark, Germany, the Netherlands, Norway and Sweden, as well as the occasional stakeholder observers together with their accompanying experts from CEWEP, COCIR, CONCAWE, CropLife Europe, EECA, EuChemS, EPEE, EuPC, EurEau, FIPRA, FEC, Orgalim, and Plastics Recyclers Europe, and the accompanying experts to the regular stakeholder observers from Cefic, CropLife Europe, Eurometaux, MedTech and PlasticsEurope. The dossier was submitted in January 2023 and proposes to restrict the manufacture, placing on the market and use of PFAS, i.e. universal PFAS (UPFAS). All uses of PFASs are covered by this restriction proposal except for the use of PFASs in fire-fighting foams.</p> <p>The observers and their accompanying experts from EuChemS, CEFIC, EEB, Eurometaux, FEC, MedTech Europe, Plastics Recyclers Europe, and PlasticsEurope commented on number of issues covering hazard assessment and risk characterisation, and on sector specific elements (related to consumer uses and to ski wax).</p>	
<p>RAC supported and provisionally agreed with the recommendations from the Restriction Working Group which met on 4 March, regarding the substance scope, hazards, and the sector specific elements on consumer mixtures, cosmetics, and ski wax.</p> <p>Furthermore, RAC had further discussions on the hazard assessment and provisionally agreed on:</p>	Rapporteurs to address the information submitted by the Dossier Submitter in the updated Background Document and based on the outcome of the discussions at RAC-68 (and RAC-68 REST WG) and RAC members written comments

- Non-polymeric PFAS are likely to become bio-available to humans. Toxicity may vary among PFAS and may be low for some. There are limited evidence on the toxicity of polymeric PFAS.
- RAC agreed with the Dossier Submitter analysis on the Global warming potential of fluorinated gases.
- Fluoropolymers are persistent but generally not mobile nor bioaccumulative. RAC noted that micro-sized and nano-sized fluoropolymer particles may become bioavailable and may result in (eco)toxicological effects. However, the data on these effects is limited. The full life-cycle of fluoropolymers needs to be considered to assess the risk with special emphasis on fluoropolymer manufacturing and waste-stage.
- Although the (eco)toxicity of fluorinated gases varies, fluorinated gases (or their degradation products) are very persistent, very mobile and have long-range transport potential. With some exceptions, they also have high global warming potential. Atmospheric degradation of fluorinated gases contributes to the increasing global trifluoroacetic acid (TFA) levels.

Furthermore, RAC supported rapporteurs' approach to risk characterisation, including:

- Considering their very high persistence, increasing environmental concentrations, ubiquity, and available (although limited) evidence on adverse effects of different PFAS, RAC concluded that uses of PFAS that result in releases to the environment are not adequately controlled and pose a potential health or environmental risk that needs to be addressed.
- RAC agreed that the main concerns related to high-molecular weight fluoropolymers (like PTFE) are emissions of non-polymeric PFAS, including fluorinated gases in the manufacturing and processing phase and end-of-life cycle. In addition, fluoropolymers may form micro- and nanoparticles in the environment. Therefore, RAC considered that their risks need to be assessed, by considering the whole life-cycle.

The rapporteurs will still consider the information provided by the Dossier Submitter in the update of the Background Document and will update the draft opinion, as appropriate.

submitted during RAC consultation.

SECR to table further discussions as follows:

- RAC-69 meeting in June 2024:
 - Metal plating and manufacture of metal products; and
 - Additional discussion on hazards and the scope (where relevant)
 - Updates from the opinion on cosmetics, consumer mixtures, and ski wax
- RAC-70 meetings in September 2024:
 - Textiles, upholstery, leather, apparel, carpets (TULAC);
 - Food contact materials and packaging; and
 - Petroleum and mining.

More information about the committees' plans will be announced as work advances. This information will be communicated in conjunction with the committee meetings.

10. Authorisation	
10.1. General authorisation issues	
10.1.1. Renewal of the RAC AFA WG mandate	
The Secretariat presented and RAC agreed on the renewal of the RAC AFA Working Group until March 2025.	SECR to publish renewed mandate on the ECHA website.
10.1.2. Report from the February RAC AFA Working Group	
The Secretariat presented the Report of the 18 th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group which took place on 6-7 February 2024. RAC took note of the Report.	
10.1.3. Update on incoming/future applications and horizontal issues	
<p>The Secretariat presented an update:</p> <ul style="list-style-type: none"> • on AfAs and Review Reports pipeline, • on a new opinion format. <p>The Commission presented the update on recent work of the Authorisation Task Force.</p> <p>The Secretariat presented a proposal to cancel AfA Working group meeting in July 2024 and RAC members actions to make this possible. RAC comments:</p> <ul style="list-style-type: none"> • key issues presentation should be presented by rapporteurs at the RAC-69 plenary in June, • the Secretariat should propose in a table distribution of DOs for commenting, • RAC discussed what is sufficient number of comments to propose a DO for agreement via the A-listing procedure without discussion at a working group meeting. <p>RAC supported the proposal to cancel the AfA Working Group meeting in July 2024 and committed to provide a sufficient level of comment to the Draft opinions consultation in June – August 2024.</p>	<p>SECR to prepare a table to distribute DOs between WG participants for commenting. Rapp to indicate in DOs key questions or discussion points. RAC members to provide comments on draft opinions during RAC consultations in June – August 2024.</p>
10.2.1. Discussion on key issues	
Presentation on AFA Key issues in six applications for authorisation from August 2023 submission window was uploaded for RAC. Members were requested to familiarise with the presentation before providing comments in during RAC consultations.	RAC members to provide comments during RAC consultations on draft opinions.

10.3. Agreement on draft opinions

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

ECHA Secretariat presented the summary of the draft opinions for agreement without plenary debate (A-list):

346_CT_Safran_landing_systems (2 uses)

Use 1: *Industrial use of chromium trioxide for hard chrome plating to provide key functional properties such as wear resistance (...) in the manufacturing of landing and braking system parts for aeronautical applications exclusively supplied by Safran Landing Systems without technical limitations with the identified alternative.*

Use 2: *Industrial use of chromium trioxide for hard chrome plating in the manufacturing and the repairing of landing gear parts exclusively supplied by Safran Landing Systems and for which there is not yet potential alternatives identified as part of the substitution process.*

RAC concluded that the operational conditions and risk management measures described in the application are:

- not appropriate and effective in limiting the risk to the workers;
- appropriate and effective in limiting the risk to the general population via the environment at all sites (with the exception of site K).

RAC agreed

Section 7: additional conditions for the authorisation

Section 8: monitoring arrangements for the authorisation

Section 9: recommendations for the review report.

as proposed by the Rapporteurs.

RAC agreed the draft opinions by consensus.

Rapporteurs together with **SECR** to do the final editing of the draft opinions.

SECR to send the draft opinions to the applicants for commenting.

10.3.2. Draft opinions for discussion and agreement with plenary debate

ADCR Horizontal issues and Model opinions

RAC discussed horizontal issues common to all ADCR Review Reports and Applications for Authorisation.

- Fulfilment of authorisation conditions (RR)
- OCs & RMMs

RAC discussed representativeness of the data and what should be the required level of information provided by applicants and authorization holders.

Rapporteurs together with **SECR** to do the final editing of the draft opinions by adding agreed sections from model opinions to all relevant opinions.

RAC noted that for specific cases the authorisation conditions have to be adjusted according to RAC's concerns on OCs/RMMs in the application.

RAC agreed that for all uses RMMs and OCs are not appropriate and effective in limiting the risk for the workers and are appropriate and effective in limiting the risk for the general population via the environment.

RAC agreed to propose common conditions and feasibility studies (Section 7)

- Exposure assessment

RAC discussed

- Conservativeness of the exposure assessment of HvE,
- Representativeness of the data where the response rate for HvE is lower than for workers exposure,
- Concern that similar exposure groups cover sites having different OCs and RMMs,
- Granularity of the opinions.

RAC has moderate concerns about the inhalation exposure estimates for workers and the inhalation and oral exposure estimated for the general population via the environment, prompted by the uncertainty surrounding the representativeness of the used measurement data for all the DUs sites. These moderate concerns will be included in all DOs (except for formulation).

- Risk characterisation

RAC discussed:

- If the risk level for HvE is overestimated
- The use of default values in the models for HvE.

RAC is of the opinion that the RR/AfAs include all relevant tasks and routes of exposure, as well as endpoints and populations in cancer risk assessment and that there are no significant uncertainties in the characterisation of risk (final wording will reflect the discussion at the RAC plenary).

RAC considers that the estimates of excess cancer risk and the RCR for reproductive risk for workers allow a health impact assessment.

- Conditions for the authorisation

RAC discussed:

- use of examples in authorisation conditions

<p>RAC discussed and agreed which conditions and feasibility studies should be proposed to for certain uses.</p> <p>RAC agreed overall horizontal conclusions as presented by the rapporteurs and to apply them to all ADCR cases with agreed modifications.</p>	
<p>1. 325_ADCR_Anodise_sealing (1 use) Use 1: <i>Anodise sealing using chromium trioxide in aerospace and defence industry and its supply chains</i></p> <p>11. 336_ADCR_RR_Anodise_sealing (1 use) Use 1: <i>Anodise sealing using chromium trioxide, potassium dichromate, sodium chromate and/or sodium dichromate in aerospace and defence industry and its supply chains</i></p>	
<p>RAC discussed:</p> <ul style="list-style-type: none"> If the lack of an air abatement system in some of the sites covered by this application have been considered in the DO and if installation of such system should be a hard condition. The same solution should apply consistently to all relevant DOs on ADCR. <p>RAC agreed the draft opinions by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>2. 326_ADCR_Anodising (1 use) Use 1: <i>Anodising using chromium trioxide in aerospace and defence industry and its supply chains</i></p> <p>12. 335_ADCR_RR_Anodising (1 use) Use 1: <i>Anodising using chromium trioxide in aerospace and defence industry and its supply chains</i></p>	
<p>RAC discussed:</p> <ul style="list-style-type: none"> Correctness of recommendation to use general mechanical ventilation system. <p>RAC agreed the draft opinions by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>3. 327_ADCR_Chemical_conversion_coating (1 use) Use 1: <i>Chemical conversion coating using chromium trioxide, sodium dichromate and/or potassium dichromate in aerospace and defence industry and its supply chains</i></p> <p>13. 337_ADCR_RR_Chemical_conversion_coating (1 use) Use 1: <i>Chemical conversion coating using chromium trioxide, sodium dichromate, potassium dichromate and/or dichromium tris(chromate) in aerospace and defence industry and its supply chains</i></p>	
<p>RAC discussed:</p> <ul style="list-style-type: none"> wording to express concerns on representativeness of the data where limited information is available. <p>RAC agreed the draft opinions by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>

<p>4. 328_ADCR_Chromate_rinsing (1 use) Use 1: <i>Chromate rinsing after phosphating using chromium trioxide in aerospace and defence industry and its supply chains</i></p> <p>14. 338_ADCR_RR_Chromate_rinsing (1 use) Use 1: <i>Chromate rinsing after phosphating using chromium trioxide in aerospace and defence industry and its supply chains</i></p>	
RAC agreed the draft opinions by consensus.	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>5. 329_ADCR_Electroplating (1 use) Use 1: <i>Electroplating using chromium trioxide in aerospace and defence industry and its supply chains</i></p> <p>15. 339_ADCR_RR_Electroplating (1 use) Use 1: <i>Electroplating using chromium trioxide in aerospace and defence industry and its supply chains</i></p>	
RAC agreed the draft opinions by consensus.	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>6. 330_ADCR_Finish_stripping (1 use) Use 1: <i>Inorganic finish stripping using chromium trioxide in aerospace and defence industry and its supply chains</i></p> <p>16. 340_ADCR_RR_Finish_stripping (1 use) Use 1: <i>Inorganic finish stripping using chromium trioxide or sodium dichromate in aerospace and defence industry and its supply chains</i></p>	
RAC agreed the draft opinions by consensus.	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>7. 331_ADCR_Formulation (1 use) Use 1: <i>Formulation of mixtures with soluble Cr(VI) compounds for use in aerospace and defence industry and its supply chains for surface treatments</i></p> <p>17. 341_ADCR_RR_Formulation (1 use) Use 1: <i>Formulation of mixtures with soluble Cr(VI) compounds for use in aerospace and defence industry and its supply chains for surface treatments</i></p>	
<p>RAC discussed if is appropriate to be proposed that the feasibility study for the replacement of solid by liquid Cr(VI):</p> <p>"Replacement of solid Cr(VI) substances by liquid solutions, or implementation of a closed or automated system to perform the dilution of solids (e.g., glove box to transfer flakes to a mixing vessel) and any subsequent</p>	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>

<p>refilling of the vessels with liquid solutions (e.g., fix-piping from the containers to the vessels).”</p> <p>RAC agreed to delete the request to perform the feasibility study to replace solid Cr(VI) substances by liquid solutions as the use as such is the formulation of mixtures for other uses.</p> <p>RAC pointed that the outcome of the discussion on the conservativeness of the exposure assessment of HvE should be considered in all opinions on the ADCR cases.</p> <p>RAC request rapporteurs to improve clarity of text concerning request for feasibility study to install a continuous LEV control system triggering automatically an alarm and measures to reduce exposure in case of an LEV malfunction in all DOs on the ADCR cases.</p> <p>RAC agreed the draft opinions by consensus.</p>	
<p>8. 332_ADCR_Passivation_metallic_coatings (1 use) Use 1: <i>Passivation of (non-Al) metallic coatings using chromium trioxide or sodium dichromate or potassium dichromate in aerospace and defence industry and its supply chains</i></p> <p>18. 342_ADCR_RR_Passivation_metallic_coatings Use 1: <i>Passivation of (non-Al) metallic coatings using chromium trioxide or sodium dichromate or potassium dichromate in aerospace and defence industry and its supply chains (1 use)</i></p>	
<p>RAC agreed the draft opinions by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>9. 333_ADCR_Pre-treatments (1 use) Use 1: <i>Pre-treatments: Deoxidising, pickling, etching and/or desmutting using chromium trioxide in aerospace and defence industry and its supply chains</i></p> <p>19. 343_ADCR_RR_Pre-treatments (1 use) Use 1: <i>Pre-treatments: Deoxidising, pickling, etching and/or desmutting using chromium trioxide or sodium dichromate in aerospace and defence industry and its supply chains</i></p>	
<p>RAC agreed the draft opinions by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>10. 334_ADCR_Stainless_steel_passivation (1 use) Use 1: <i>Passivation of stainless steel using chromium trioxide or sodium dichromate in aerospace and defence industry and its supply chains</i></p> <p>20. 345_ADCR_RR_Stainless_steel_passivation (1 use) Use 1: <i>Passivation of stainless steel using chromium trioxide or sodium dichromate in aerospace and defence industry and its supply chains</i></p>	

<p>RAC requested the rapporteurs to consider unclear information on physical segregation between work areas as the major concern as in other DOs on the ADCR cases.</p> <p>RAC agreed the draft opinions by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>21. 344_ADCR_RR_Slurry_coating (1 use) Use 1: <i>Slurry coatings using chromium trioxide in aerospace and defence industry and its supply chains</i></p>	
<p>RAC discussed the request to add installation of a robotic arm to the list of examples of the technics to automatise spraying process.</p> <p>RAC agreed the draft opinions by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>22. 347_CT_Safran_Aircraft_Engines (1 use)</p>	
<p>Use1: <i>Industrial use of slurry mixtures containing chromium trioxide for the surface treatment of aircraft engines parts including turbines and compressors.</i></p> <p>RAC concluded that the operational conditions and risk management measures described in the application <u>are not appropriate and effective</u> in limiting the risk for workers. RAC concluded that the operational conditions and risk management measures described in the application for authorisation are appropriate and effective in limiting the risk for humans via the environment.</p> <p>RAC agreed</p> <ul style="list-style-type: none"> • Section 7: additional conditions for the authorisation • Section 8: monitoring arrangements for the authorisation • Section 9: recommendations for the review report. <p>as proposed by the Rapporteurs.</p> <p>RAC agreed the draft opinion by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the draft opinions.</p> <p>SECR to send the draft opinions to the applicants for commenting.</p>
<p>10.4. Adoption of opinions</p>	
<p>10.4.1. 305_CT_Meoni_e_Bartoletti (1 use)</p>	
<p>Use 1: <i>Use of Chromium Trioxide for the hard-chrome plating of hydraulic and pneumatic cylinders for various applications, and inner tubes of motorbike front suspension for the automotive industry.</i></p> <p>The rapporteur presented applicants comments on the draft opinion and informed RAC that those comments</p>	<p>SECR to send the final opinion to the applicant, the European Commission and MS CAs.</p>

<p>addressed only the SEAC sections of the draft opinion. Therefore, the rapporteur recommended RAC to adopt the final option without changes in RAC sections.</p> <p>RAC adopted the final opinion by consensus.</p>	
<p>10.4.2 310_CT_Cromotecnica_Fida (1 use)</p>	
<p>Use 1: <i>Functional chrome plating of hydraulic cylinders, stems, pistons and rollers using chromium trioxide.</i></p> <p>The rapporteur presented applicants comments on the draft opinion and informed RAC that those comments addressed only the SEAC sections of the draft opinion. Therefore, the rapporteur recommended RAC to adopt the final option without changes in RAC sections.</p> <p>RAC adopted the final opinion by consensus.</p>	<p>SECR to send the final opinion to the applicant, the European Commission and MS CAs.</p>
<p>11. Drinking Water Directive</p>	
<p>11.1. Renewal of the RAC DWD WG mandate</p>	
<p>The Secretariat presented and RAC agreed on the renewal of the RAC DWD Working Group until March 2025.</p>	<p>Secretariat to publish the renewed mandate on the ECHA website.</p>
<p>11.2. Update on the adoption of the DWD implementing legislation</p>	
<p>The Secretariat orally presented the progress made since October 2023. The implementing acts were voted favourably by the DWD Committee on 15 December 2023 and the Commission adopted all six implementing and delegated acts on 23 January 2024. The Commission shall publish all 6 acts at the same time. Publication in the EU Official Journal is expected by the end of March 2024.</p> <p>The link to the legal acts is: https://environment.ec.europa.eu/publications/delegated-acts-drinking-water-directive_en</p>	<p>RAC members and DWD WG members: to familiarise themselves with the legal acts.</p>
<p>11.3. Case Study 1: Starting substance: Introduction</p>	
<p>Two members of the RAC DWD WG presented an introduction to the first case study, the application submitted to the German National Authority for the starting substance AATMP.</p> <p>Helping applicants: It was questioned how much ECHA can help applicants to prepare the dossiers in addition to issuing guidance. SECR explained that there will be additional collective activities to support the applicants, but</p>	<p>SECR to consider and propose a consistent way of using information not included in a DWD application.</p> <p>SECR to further develop the working relationship between the WG and RAC to manage the considerable workload.</p>

<p>due to the workload it will not be possible to support them individually.</p> <p>Drinking water and food contact materials: Legislation for the two is different, but where possible alignment and harmonisation should be considered. ECHA and EFSA collaborate in the preparation of DWD guidance.</p> <p>How RAC could use additional information: It was clarified that RAC may use any information, even if not in the application, that is available for drafting its opinion. However, further information cannot be used for filling in information gaps in the application submitted by the applicant.</p>	<p>SECR to continue the close cooperation with EFSA.</p>
<p>11.4. Case Study 2: Metallic composition: Introduction</p>	
<p>A member of the RAC DWD WG presented an introduction to the second case study, the application submitted to the German National Authority for the metallic composition (alloy) CW727R.</p> <p>Some differences in approaches in assessment between metallic compositions and organic materials were highlighted the German National Authority.</p> <p>There is a good alignment in relation to the required migration data needed for national application and EU application, but stricter MTC_{tap} values may apply under the EU legislation.</p> <p>For many metallic compositions, no toxicological information will be required, but in some special cases (e.g., bismuth), toxicological information will be needed for the creation of a MTC_{tap} value.</p> <p>For assessing metallic compositions, specific expertise in corrosion may be needed for the assessment of the worst case test piece. Important for a worst-case testing is the length of migration testing, the choice of test water(s) and the test piece composition.</p>	
<p>11.5. Proposal for a support group on toxicokinetics for DWD guidance</p>	
<p>The Secretariat announced the setting up of a small informal group that will work in the period April-September 2024 towards supporting ECHA experts with the drafting of the toxicokinetics parts of Volumes I and II of the DWD Guidance. Three members have already been invited and the invitation to participate is extended to all Committee and Working Group members.</p> <p>The Secretariat presented the scope and timelines for the support group on toxicokinetics for DWD Guidance and</p>	<p>RAC members and DWD WG members to express their interest to join the group by 25 March 2024.</p> <p>SECR to provide written description of the task to those with an interest.</p>

invited the participants to express interest to participate in this work by 25 March.	
12. AOB	
There was no other item discussed.	
13. Minutes of RAC-68	
13.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-68	
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-68 to the ECHA Website.

CLH opinions at RAC-68

1. <u>benzobicyclon (ISO); 3-[2-chloro-4- (methylsulfonyl)ben zoyl]-4- (phenylthio)bicyclo [3.2.1]oct-3-en-2- one</u>	25
2. <u>1-amino-4-hydroxy-2-phenoxyanthraquinone</u>	26
3. <u>metyltetraprole (ISO); 1-[2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5H-tetrazol-5-one</u>	27
4. <u>pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether</u>	28
5. <u>magnesium metaborate</u>	29
6. <u>undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]</u>	30
7. <u>sodium bromide</u>	31
8. <u>dimethachlor (ISO); 2-chloro-N-(2,6-dimethylphenyl)-N-(2-methoxyethyl)acetamide</u>	32

1. benzobicyclon (ISO); 3-[2-chloro-4- (methylsulfonyl)ben zoyl]-4- (phenylthio)bicyclo [3.2.1]oct-3-en-2- one

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	benzobicyclon (ISO); 3-[2-chloro-4-(methylsulfonyl)benzoyl]-4-(phenylthio)bicyclo [3.2.1]oct-3-en-2-one	605-078-5	156963-66-5	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 100 M = 100	
RAC opinion	TBD	benzobicyclon (ISO); 3-[2-chloro-4-(methylsulfonyl)benzoyl]-4-(phenylthio)bicyclo [3.2.1]oct-3-en-2-one	605-078-5	156963-66-5	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 100 M = 100	
Resulting Annex VI entry if agreed by COM	TBD	benzobicyclon (ISO); 3-[2-chloro-4-(methylsulfonyl)benzoyl]-4-(phenylthio)bicyclo [3.2.1]oct-3-en-2-one	605-078-5	156963-66-5	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 100 M = 100	

2. 1-amino-4-hydroxy-2-phenoxyanthraquinone

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-amino-4-hydroxy-2-phenoxyanthraquinone	241-442-6	17418-58-5	Skin Sens. 1A	H317	GHS07 Wng	H317			
RAC opinion	TBD	1-amino-4-hydroxy-2-phenoxyanthraquinone	241-442-6	17418-58-5	Skin Sens. 1A	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	1-amino-4-hydroxy-2-phenoxyanthraquinone	241-442-6	17418-58-5	Skin Sens. 1A	H317	GHS07 Wng	H317			

3. metyltetraprole (ISO); 1-[2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5H-tetrazol-5-one

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	metyltetraprole (ISO); 1-[2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5H-tetrazol-5-one	-	1472649-01-6	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=10 M=1	
RAC opinion	TBD	metyltetraprole (ISO); 1-[2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5H-tetrazol-5-one	-	1472649-01-6	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=10 M=1	
Resulting Annex VI entry if agreed by COM	TBD	metyltetraprole (ISO); 1-[2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5H-tetrazol-5-one	-	1472649-01-6	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=10 M=1	

4. pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-303-00-3	pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether	429-800-1	95737-68-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitters proposal	613-303-00-3	pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether	429-800-1	95737-68-1	Retain Aquatic Acute 1 Aquatic Chronic 1	Retain H400 H410	Retain GHS09 Wng	Retain H410		Add M=10 M=1000	
RAC opinion	613-303-00-3	pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether	429-800-1	95737-68-1	Retain Aquatic Acute 1 Aquatic Chronic 1	Retain H400 H410	Retain GHS09 Wng	Retain H410		Add M=10 M=1000	
Resulting Annex VI entry if agreed by COM	613-303-00-3	pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether	429-800-1	95737-68-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=10 M=1000	

5. magnesium metaborate

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	magnesium metaborate	237-235-5	13703-82-7	Repr. 1B	H360FD	GHS08 Dgr	H360FD			Note 11
RAC opinion	TBD	magnesium metaborate	237-235-5	13703-82-7	Repr. 1B	H360FD	GHS08 Dgr	H360FD			Note 11
Resulting Annex VI entry if agreed by COM	TBD	magnesium metaborate	237-235-5	13703-82-7	Repr. 1B	H360FD	GHS08 Dgr	H360FD			Note 11

The same table applies to all the borates on RAC-68 Agenda.

6. undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]

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	undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]	206-196-6[1]; 220-881-7[2]; 244-479-6[3]; - [4]	307-24-4[1]; 2923-26-4[2]; 21615-47-4[3]; - [4]	Repr. 1B	H360D	GHS08 Dgr	H360D			
RAC opinion	TBD	undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]	206-196-6[1]; 220-881-7[2]; 244-479-6[3]; - [4]	307-24-4[1]; 2923-26-4[2]; 21615-47-4[3]; - [4]	Repr. 1B	H360D	GHS08 Dgr	H360D			
Resulting Annex VI entry if agreed by COM	TBD	undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]	206-196-6[1]; 220-881-7[2]; 244-479-6[3]; - [4]	307-24-4[1]; 2923-26-4[2]; 21615-47-4[3]; - [4]	Repr. 1B	H360D	GHS08 Dgr	H360D			

7. sodium bromide

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 bromide	231-599-9	7647-15-6	Repr. 1B Lact. STOT SE 3 STOT RE 1	H360FD H362 H336 H372 (nervous system)	GHS08 GHS07 Dgr	H360FD H362 H336 H372 (nervous system)			Note on additive effects ^[1]
RAC opinion	TBD	Sodium bromide	231-599-9	7647-15-6	Repr. 1B Lact. STOT SE 3 STOT RE 1	H360FD H362 H336 H372 (nervous system, thyroid)	GHS08 GHS07 Dgr	H360FD H362 H336 H372 (nervous system, thyroid)			Note on additive effects ^[1]
Resulting Annex VI entry if agreed by COM	TBD	Sodium bromide	231-599-9	7647-15-6	Repr. 1B Lact. STOT SE 3 STOT RE 1	H360FD H362 H336 H372 (nervous system, thyroid)	GHS08 GHS07 Dgr	H360FD H362 H336 H372 (nervous system, thyroid)			Note on additive effects ^[1]

The same table applies also to calcium bromide and potassium bromide on RAC-68 Agenda.

^[1] "The classification of mixtures as category 1 reproductive toxicant is necessary if the sum of the concentrations of individual bromide salts that are classified as category 1 reproductive toxicant in the mixture as placed on the market $\geq 0.3\%$ "

8. dimethachlor (ISO); 2-chloro-*N*-(2,6-dimethylphenyl)-*N*-(2-methoxyethyl)acetamide

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	616-031-00-3	dimethachlor (ISO); 2-chloro- <i>N</i> -(2,6-dimethylphenyl)- <i>N</i> -(2-methoxyethyl)acetamide	256-625-6	50563-36-5	Acute Tox. 4* Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H317 H400 H410	GHS07 GHS09 Wng	H302 H317 H410			
Dossier submitters proposal	616-031-00-3	dimethachlor (ISO); 2-chloro- <i>N</i> -(2,6-dimethylphenyl)- <i>N</i> -(2-methoxyethyl)acetamide	256-625-6	50563-36-5	Retain Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1 Add Carc. 2 Modify Acute Tox. 4	Retain H302 H317 H400 H410 Add H351	Retain GHS07 GHS09 Wng Add GHS08	Retain H302 H317 H410 Add H351		Add M = 10 M = 10	
RAC opinion	616-031-00-3	dimethachlor (ISO); 2-chloro- <i>N</i> -(2,6-dimethylphenyl)- <i>N</i> -(2-methoxyethyl)acetamide	256-625-6	50563-36-5	Retain Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1 Add Carc. 2 Modify Acute Tox. 4	Retain H302 H317 H400 H410 Add H351	Retain GHS07 GHS09 Wng Add GHS08	Retain H302 H317 H410 Add H351		Add oral: ATE = 1600 mg/kg bw M = 10 M = 10	
Resulting Annex VI entry if agreed by COM	616-031-00-3	dimethachlor (ISO); 2-chloro- <i>N</i> -(2,6-dimethylphenyl)- <i>N</i> -(2-methoxyethyl)acetamide	256-625-6	50563-36-5	Carc. 2 Acute Tox. 4 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H317 H410		oral: ATE = 1600 mg/kg bw M = 10 M = 10	

Part III. List of Attendees of the RAC-68 meeting

RAC members	
Angeli	Karine
Aquilina	Gabriele
Barański	Bogusław
Biró	Anna
Brovkina	Julija
Chiurtu	Elena-Ruxandra
Christodoulou	Sotirios
Deviller	Genevieve
Docea	Anca Oana
Esposito	Dania
Facchin	Manuel
Fernández	Mariana
Geoffroy	Laure
Hakkert	Betty
Hartwig	Andrea
Hoffmann	Frauke
Kadikis	Normunds
Karadjova	Irina
Kloslova	Zuzana
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Manusadzianas	Levonas
Martinek	Michal
Menard Srpčič	Anja
Mendas Starcevic	Gordana
Mohammed	Ifthekhar Ali
Murray	Brendan
Neumann	Michael
Piña	Benjamin
Pribu	Mihaela
Rakkestad	Kirsten Eline
Rodriguez	Wendy
Santonen	Tiina
Schlüter	Urs
Schuur	Gerlienke
Sørensen	Peter Hammer
Spetseris	Nikolaos
Stalter	Daniel
Tekpli	Nina
Tobiassen	Lea Stine
Užomeckas	Žilvinas
van der Haar	Rudolf
Varnai	Veda Marija
Viegas	Susana

Wildemann	Tanja
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RAC DWD members	
Almeida	Cristina
Antoniou	Maria
BARON	Jean
Berger	Sabrina
Bergkvist	Charlotte
Georgieva	Tzveta
Junek	Ralf
Kontou	Stella
Lampi	Evgenia
Liadakis	Georgios
Novelli	Anne
Pavlova	Vera
Rapp	Thomas
Sanchis Sandoval	Josep Angel
Spiteri	David
Uurasjärvi	Emilia
van de Ven	Bianca
Vogel	Lisa

Members' advisers		Nominated by
Beestra	Renske	Hakkert Betty and Schuur Gerlienke
Bil	Wieneke	Betty Hakkert
Bjørge	Christine	Kirsten Eline Rakkestad
Broderick	Mike	Brendan Murray
Capolupo	Marco	Dania Esposito
Catone	Tiziana	Aquilina Gabriele
Geraets	Liesbeth	Gerlienke Schuur
Granum	Berit	Kirsten Eline Rakkestad
Houlihan	Margarete	Brendan Murray
Jankowska	Agnieszka	Peczowska Beata
Kovačić	Jelena	Veda Varnai
Kristensen	Mette Albæk	Lea Stine Tobiassen
Marinkovic	Marino	Schuur Gerlienke
Moilanen	Marianne	Riitta Leinonen
Moeller	Ruth	Annemarie Losert
Rehl	Anna-Lena	Manuel Facchin
Russo	Maria Teresa	Aquilina Gabriele
Smith	Jenny	Murray Brendan
Suutari	Tiina	Leinonen Riitta
Van Herwijnen	Rene	Betty Hakkert

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

Invited experts		Role/Substance
Saksa	Jana	AFA A-list :CT Safran
Levy	Patrick	Working Party on Chemicals (WPC)
Saarikoski	Sirkku	Working Party on Chemicals (WPC)

Dossier submitters		Substance
Baumbusch	Angelika	(NO) - UPFAS
de Blaeij	Arianne	(NL) - UPFAS
Borg	Daniel	(SE) - UPFAS
Dannenberg	Carl	(DE) - UPFAS
De Kort	Thijs	(NL) - UPFAS
Detjens	Marc	(DE) - UPFAS
Drost	Wiebke	(DE) - UPFAS
Carlsson-Feng	Mattias	(SE) - UPFAS
Heggelund	Audun	(NO) - UPFAS
Ivarsson	Jenny	(SE) - UPFAS
Johansson	Tommy	(SE) - UPFAS, 3 x bromides
Kühnert	Agnes	(DE) - Undecafluorohexanoic acid, PFHxA [1]
Kupprat	Franziska	(DE) - UPFAS
Larsson	Kristin	(SE) - UPFAS, 3 x bromides
Mrnjavčić Vojvoda	Ana	(HR) - Dimethachlor
Nielsen	Peter Juhl	(DK) - UPFAS
Posner	Stefan	(SE) - UPFAS
Sanders	Marion	(NL) - UPFAS
Simpson	Peter	(NL) - UPFAS
Witasp Henriksson	Erika	(SE) - 10 x Borates

Regular stakeholder observers		
Barry	Frank	ETUC
De Backer	Liisi	Cefic
Duguy	Hélène	ClientEarth
Hermann	Christine	EEB
Santos	Roumiana	MedTech Europe
Robin	Nicolas	Plastics Europe
Robinson	Jan	AISE
Ruelens	Paul	CropLife Europe
Verougstraete	Violaine	Eurometaux
Van de Merckt (DWD)	Lara	Eurometaux

Occasional stakeholders		Substance
Belarmino	Paradela (ASD-Europe)	AFA general issues
Corridori	Ricardo (COCIR)	UPFAS
Dainelli	Dario (FEC)	UPFAS
De Badereau	Vincent (EPEE)	UPFAS
De Bruycker	Leen (WECEP)	UPFAS

De Kort	Patrick (PRE)	UPFAS
Di Caprio	Elisabetta (Concawe)	UPFAS
Doome	Roger (IMA-Europe)	CLH: 10 x Borates/OEL: Boron and its compounds
Engelbrecht	Vera (PSCI)	CLH: 10 x Borates / 3 x Bromides
Glüge	Juliane (EuChemS)	UPFAS
Loebel	Oliver (EurEau)	UPFAS, DWD
Mateos	Julio (Orgalim)	UPFAS
Rothenbacher	Klaus (BSEF)	CLH: 3 x bromides
Tillieux	Geoffroy (EuPC)	UPFAS, AfA general issues/OEL/Art. 77(3)(c)

Stakeholder experts		Substance
Barber	David (CropLife Europe)	UPFAS
Bock	Ronald (Plastics Europe)	UPFAS
Consoli	Elisa (Eurometaux)	UPFAS
Danzeisen	Ruth (Eurometaux)	Art 77: Lithium
Fritz	Stéphanie (CropLife Europe)	Pyriproxyfen
Fukunaga	Satoki (CropLife Europe)	Metyltetrapole
Hedfors	Cecilia (EEB)	UPFAS
Henry	Barbara (Cefic)	UPFAS
Jacobi	Sylvia (Eurometaux)	3 x Bromides
Kirman	Chris (Cefic)	OEL: 1,3-Butadiene
Koehl	Werner (Cefic)	Art 77: Lithium
Müller	Viktoria (EEB)	UPFAS
Mutter	Corinna (MedTech Europe)	UPFAS
Nödler	Karsten (EurEau)	UPFAS
Pemberton	Mark (Cefic)	HEMA/HPMA
Soufi	Maria (CropLife Europe)	Dimethachlor
Speziale	Lighea (CEWEP)	UPFAS
Stings	Annette (EPEE)	UPFAS
Van Wely	Eric (CEFIC)	UPFAS
Werner	Michael (BSEF)	3 x Bromides

European Commission		DG
André	Vivienne	DG ENV
Beekman	Martijn	DG GROW
Bertato	Valentina	DG ENV
Ceridono	Mara	DG ENV
Dunauskiene	Lina	DG GROW
Faraulo	Fabio	DG EMPL (OELs)
Jamers	An	DG ENV
Roebben	Gert	DG GROW
Schutte	Katrin	DG ENV
EU Agency Observers		
Barthélémy	Eric	EFSA

ECHA staff
Scazzola Roberto (Chair)
Sosnowski Piotr (Deputy Chair)
Arnaudova Ralica
Atanasova Marina
Barnewitz Greta
Basmatzi Theodora
Bin Essi
Blainey Mark
Bohumila Bichlmaier
de la Flor Tejero Ignacio
Demattio Silvia
Etholen Anita
Fabjan Evelin
Galetska Feindt Athina E.
Gmeinder Michael
Hellsten Kati
Hellsten Niko
Henrichson Sanna
Herbatschek Nicolas
Hirmann Doris
Husa Stine
Karjalainen Antti
Kokkola Leila
Konstantinos Kiakos
Lapenna Silvia
Lefevre Sandrine
Lehto Hürlimann Mikko
Lisboa Patricia
Logtmeijer Christiaan
Loukou Christina
Ludborzs Arnis
Mäkelä Petteri
Marchetto Flavio
Martinelli Erika
Mattiuzzo Marco
Mercedes Marquez-Camacho
Mesquita Rochelly
Mushtaq Fesil
Myohanen Kirsi
Nicot Thierry
Niemela Helena
Nogueroles Marta
Nygren Jonas
Orispää Katja
O'Rourke Regina
Parikka Petra
Perazzolo Chiara
Pillet Monique
Portugal Laura
Regil Pablo
Ricardo Simoes
Richarz Andrea
Ruoss Jurgan
Ryan Paul
Sadam Diana

Sihvola Virve
Sokolova Maia
Spjuth Linda
Stoyanova Evgenia
Tai Kaihsu
Thierry-Mieg Morgane
Tiina Multasuo
Väänänen Virpi
van Galen Joost
Vitcheva Vessela
Wilk Mateusz
Xydaki Elena
Zarogiannis Panos
Zeiger Bastian

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-68 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-68 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-68 meeting

Final Agenda
68th meeting of the Committee for Risk Assessment
(RAC-68)
11-14 March 2024

Face-to-face/Hybrid meeting

Monday, 11 March starts at 10.00
Thursday, 14 March ends at 18.20

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/68/2024

For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

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

For agreement

Closed session

Item 5 – Work plan

- 5.1 RAC Work Plan for all processes

For information

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

- 6.3 Request to review the CLH Opinion on Lithium carbonate (LiCO₃), lithium chloride (LiCl), lithium hydroxide (LiOH)

- 6.4 Request to review the CLH Opinion on Methyl methacrylate (MMA)

For adoption

Item 7 – Health based exposure limits at the workplace

7.1 Opinions for discussion

1. 1,3-Butadiene (EC number: 203-450-8; CAS RN: 106-99-0)
2. Boron and its compounds (EC numbers: 233-139-2, 215-575-5, 215-540-4, 215-125-8 and CAS RN: 10043-35-3, 1332-77-0, 1330-43-4, 1303-86-2 respectively)

For discussion

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

1. Renewal of the RAC CLH WG mandate

For agreement
RAC/68/2024/01

2. Report from the January CLH Working Group

For information
RAC/68/2024/02

8.2 CLH dossiers

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

- **Pyriproxyfen (ISO):** *all hazard classes, except for aquatic chronic toxicity*
- **Undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]:** *STOT RE, reproductive toxicity (fertility and lactation)*
- **Benzobicyclon (ISO):** *all hazard classes*
- **Sodium bromide:** *STOT SE, STOT RE (nervous system and adrenals)*
- **Potassium bromide:** *STOT SE, STOT RE (nervous system and adrenals)*
- **Calcium bromide:** *STOT SE, STOT RE (nervous system and adrenals)*
- **1-amino-4-hydroxy-2-phenoxyanthraquinone:** *skin sensitisation*
- **Dimethachlor (ISO):** *all hazard classes, except for carcinogenicity*

2. Hazard classes for agreement with plenary debate

1. **Metyltetraprole (ISO); 1-[2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5H-tetrazol-5-one (EC - ; CAS 1472649-01-6)** (EC - ; CAS 1472649-01-6): *carcinogenicity*
2. **Pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether (EC 429-800-1; CAS 95737-68-1)**: *aquatic chronic toxicity*
3. **Calcium tetraborate** (EC 234-511-7; CAS 12007-56-6): *reproductive toxicity*
4. **Calcium metaborate (Ca(BO₂)₂) and calcium tetraborate (CaB₄O₇), amorphous reaction products of boric acid with lime (EC - ; CAS -)**: *reproductive toxicity*
5. **Pentaboron sodium octaoxide** (EC 234-522-7; CAS 12007-92-0): *reproductive toxicity*
6. **Sodium metaborate, anhydrous [1]; boric acid (HBO₂), sodium salt, tetrahydrate [2]; and any other hydrated form (EC 231-891-6 [1]; - [2]; CAS 7775-19-1 [1]; 10555-76-7 [2])**: *reproductive toxicity*
7. **Diammonium decaborate** (EC 234-521-1; CAS 12007-89-5) : *reproductive toxicity*
8. **Potassium metaborate** (EC 237-262-2; CAS 13709-94-9): *reproductive toxicity*
9. **Dipotassium tetraborate** (EC 215-575-5; CAS 1332-77-0): *reproductive toxicity*
10. **Magnesium metaborate** (EC 237-235-5; CAS 13703-82-7): *reproductive toxicity*
11. **Dipotassium octaborate** (EC - ; CAS 12008-39-8): *reproductive toxicity*
12. **Potassium pentaborate** (EC 234-371-7; CAS 11128-29-3): *reproductive toxicity*
13. **Undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]** (EC 206-196-6[1]; 220-881-7[2]; 244-479-6[3]; - [4] ; CAS 307-24-4[1]; 2923-26-4[2]; 21615-47-4[3]; - [4]): *reproductive toxicity (development)*
14. **Sodium bromide** (EC 231-599-9; CAS 7647-15-6): *reproductive toxicity, STOT RE (thyroid)*
15. **Potassium bromide** (EC 231-830-3; CAS 7758-02-3): *reproductive toxicity, STOT RE (thyroid)*
16. **Calcium bromide** (EC 232-164-6; CAS 7789-41-5): *reproductive toxicity, STOT RE (thyroid)*
17. **Dimethachlor (ISO); 2-chloro-N-(2,6-dimethylphenyl)-N-(2-methoxyethyl)acetamide (EC 256-625-6; CAS 50563-36-5)**: *carcinogenicity*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Renewal of the RAC REST WG mandate

***For agreement
RAC/68/2024/01***

2. Report from the March REST Working Group

For information

9.2 Restriction Annex XV dossiers

1. Opinion development

- a. Universal per- and polyfluoroalkyl substances (UPFAS) – Overview on next plenary discussions and Draft opinion with focus on hazard, consumer mixtures, cosmetics, ski wax

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

1. Renewal of the RAC AFA WG mandate

***For agreement
RAC/68/2024/01***

2. Report from the February AFA Working Group

***For information
RAC/68/2024/03***

3. Update on incoming/future applications and horizontal issues

***For discussion/agreement
RAC/68/2024/04***

10.2 Authorisation applications

1. Discussion on key issues

1. 348_RR1_NPE_Chemetall (2 uses)
2. 349_RR1_OPE_Biomerieux (1 use)
3. 350_RR1_OPE_PPG (2 uses)
4. 351_PD_Turdus (1 use)
5. 352_DEHP_Baxter (3 uses)
6. 353_TEL_Shell (1 use)

For information

10.3 Agreement on draft opinions

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

1. 346_CT_Safran_landing_systems (2 uses)

For agreement

2. Draft opinions for agreement with plenary debate

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

For discussion and agreement

10.4 Adoption of opinions

1. 305_CT_Meoni_e_Bartoletti (1 use)
2. 310_CT_Cromotecnica_Fida (1 use)

For discussion and adoption

Item 11 – Drinking Water Directive

11.1 Renewal of the RAC DWD WG mandate

***For agreement
RAC/68/2024/01***

11.2 Final Draft Agenda for the 3rd Meeting of the Committee for Risk Assessment DWD Working Group reporting to RAC-68 (RAC WG/A/3/2024) - Common Session with RAC-68 and RAC-68 DWD WG on Thursday 14 March PM

***For adoption
RAC/68/2024/05***

11.3 Update on the adoption of the DWD implementing legislation

11.4 Case Study 1: Starting substance: Introduction

11.5 Case Study 2: Metallic composition: Introduction

11.6 Proposal for a support group on toxicokinetics for DWD guidance

For information/discussion

Item 12 – AOB

Item 13 – Minutes of RAC-68

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-68

For adoption

Annex II

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-68 meeting.

<i>RAC/A/68/2024</i>	RAC-68 final Draft Agenda
<i>RAC/68/2024/01</i>	Renewal of the RAC CHL/REST/AFA/DWD WG mandates
<i>RAC/68/2024/02</i>	General CHL issues: Report from the January CLH Working Group
<i>RAC/68/2024/03</i>	General authorisation issues: Report from the February AFA Working Group
<i>RAC/68/2024/04</i>	General authorisation issues: Update on incoming/future applications and horizontal issues
<i>RAC/68/2024/05</i>	Drinking Water Directive: DWD WG meeting Agenda

ANNEX III (RAC-68)

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 SCHLUETER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Restrictions		
Universal PFAS DE	Michael NEUMANN Urs SCHLUETER Frauke HOFFMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
DE	Daniel STALTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
DK	Peter Hammer SOERENSEN Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
NL	Betty HAKKERT Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NO	Kirsten Eline RAKKESTAD Nina TEKPLI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
SE	Bert-Ove LUND Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Harmonised classification & labelling		
FR Metyltetraprole (ISO)	Karine ANGELI	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Laure GEOFFROY	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Harmonised classification & labelling		
NL Pyriproxyfen (ISO)	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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		substance - no other mitigation measures applied. No personal involvement.
<p>Dimethachlor (ISO)</p> <p>HR</p>	Veda VARNAI	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Gordana MENDAS	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.
<p>1) 10 borates dossiers; 2) 3 bromides dossiers; 3) 1-amino-4-hydroxy-2-phenoxyanthraquinone</p> <p>SE</p>	Bert-Ove LUND	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
<p>Undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]</p> <p>DE</p>	Frauke HOFFMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	Urs SCHLUETER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Daniel STALTER	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.