

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)

- 6.1 Request to review the CLH Opinion on Lithium carbonate (LiCO₃), lithium chloride (LiCl), lithium hydroxide (LiOH)
- 6.2 Request to review the CLH Opinion on Methyl methacrylate (MMA)

For adoption

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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)
- 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
- Metyltetraprole (ISO);1-[2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5*H*-tetrazol-5-one (EC - ; CAS 1472649-01-6) (EC - ; CAS 1472649-01-6): carcinogenicity
- 2. Pyriproxyfen (ISO); 2-(1-methyl-2-(4phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (*RS*)-2-(2pyridyloxy) 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*
- 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-(2methoxyethyl)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
 - 1. 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

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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