

**Final Draft Agenda**  
**68<sup>th</sup> 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 (LiCO<sub>3</sub>), 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

- 1,3-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

- Renewal of the RAC CLH WG mandate
- Report from the January CLH Working Group

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

**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

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## 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(BO<sub>2</sub>)<sub>2</sub>) and calcium tetraborate (CaB<sub>4</sub>O<sub>7</sub>), 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 (HBO<sub>2</sub>), 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**

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## **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***

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## **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***

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PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-68  
Please note that timings are approximate. Changes may be made by the Chair before and during the meeting in order to accommodate the discussions.

***Times are Helsinki times***

INTERNAL

Week 1

**Monday 11 March 2024: Morning session**

10:00	10:05	ADMIN	Welcome and apologies
10:05	10:10	ADMIN	Adoption of the agenda
10:10	10:15	ADMIN	Declarations of conflicts of interest to the Agenda
10:15	10:20	ADMIN	RAC Work Plan for Restriction, Authorisation C&L and OELs
10:20	11:20	OEL	Boron and its compounds - first draft opinion
11:20	11:50		<i>Coffee break</i>
11:50	12:50	OEL	Boron and its compounds <b>contd.</b>
12:50	13:50		<i>Lunch (New RAC Members lunch in KP02)</i>

**Monday 11 March 2024: Afternoon session**

13:50	15:20	OEL	1,3-Butadiene - first draft opinion
15:20	15:50		<i>Coffee break</i>
15:50	16:00	CLH	Report from the January CLH Working Group
16:00	16:25	CLH	Hazard classes for agreement without plenary debate (A-list): - Based on RAC members' comments - Based on the RAC WG CLH outcome
16:25	17:10	Art. 77(3)(c)	Lithium carbonate (LiCO <sub>3</sub> ), lithium chloride (LiCl), lithium hydroxide (LiOH) - opinion adoption
17:10	18:10	Art. 77(3)(c)	Methyl methacrylate (MMA) - opinion adoption

**Tuesday 12 March 2024: Morning session**

09:45	10:00	ADMIN	Conclusions and action points from the previous day
10:00	10:30	CLH	Calcium tetraborate; calcium metaborate (Ca(BO <sub>2</sub> ) <sub>2</sub> ) and calcium tetraborate (CaB <sub>4</sub> O <sub>7</sub> ), amorphous reaction products of boric acid with lime; pentaboron sodium octaoxide; sodium metaborate, anhydrous [1]; boric acid (HBO <sub>2</sub> ), sodium salt, tetrahydrate [2]; and any other hydrated form; diammonium decaborate; potassium metaborate; dipotassium tetraborate; dipotassium octaborate; potassium pentaborate; magnesium metaborate

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10:30	11:15	CLH	Pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl ( <i>RS</i> )-2-(2-pyridyloxy) propyl ether
11:15	11:45		<i>Coffee break</i>
11:45	13:00	CLH	Sodium bromide; potassium bromide; calcium bromide
13:00	14:00		<i>Lunch</i>

### **Tuesday 12 March 2024: Afternoon session**

14:00	14:45	CLH	Undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4]
14:45	15:30	CLH	Dimethachlor (ISO); 2-chloro- <i>N</i> -(2,6-dimethylphenyl)- <i>N</i> -(2-methoxyethyl)acetamide
15:30	16:00		<i>Coffee break</i>
16:00	16:45	CLH	Metyltetraprole (ISO); 1-[2-({[1-(4-chlorophenyl)-1 <i>H</i> -pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5 <i>H</i> -tetrazol-5-one
16:45	17:00	ADMIN	Renewal of the RAC CLH WG mandate Renewal of the RAC REST WG mandate Renewal of the RAC AFA WG mandate Renewal of the RAC DWD WG mandate

### **Wednesday 13 March 2024: Morning session**

09:00	09:15	ADMIN	Conclusions and action points from the previous day
09:15	09:30	RESTR	Report from the March RESTR Working Group
09:30	11:00	RESTR	Universal per- and polyfluoroalkyl substances (UPFAS) – <b>Slot I: Overview on next plenary discussions and Hazard assessment</b>
11:00	11:30		<i>Coffee break</i>
11:30	13:00	RESTR	Universal per- and polyfluoroalkyl substances (UPFAS) – <b>Slot II: Cosmetics</b>
13:00	14:00		<i>Lunch</i>

### **Wednesday 13 March 2024: Afternoon session**

14:00	15:30	RESTR	Universal per- and polyfluoroalkyl substances (UPFAS) – <b>Slot III: Consumer Mixtures</b>
15:30	16:00	RESTR	Universal per- and polyfluoroalkyl substances (UPFAS) – <b>Slot IV: Ski wax</b>
16:00	16:30		<i>Coffee break</i>
16:30	17:00	AFA	AFA general issue: - Update on incoming/future applications and horizontal issues - New opinion format - Cancellation of AfA Working group meeting in July 2024
17:00	17:10	AFA	Report from the February 2024 AfA Working Group
17:10	17:20	AFA	A-list agreement on AFAs

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17:20	17:25	AFA	305_CT_Meoni_e_Bartoletti, 310_CT_Cromotecnica_Fida - adoption of opinions
17:25	18:05	AFA	347_CT_Safran_Aircraft_Engines - adreement on draft opinion

#### **Thursday 14 March 2024: Morning session**

09:00	09:15	ADMIN	Conclusions and action points from the previous day
09:15	11:00	AFA	ADCR Horizontal issues and Model opinion - Discussion
11:00	11:30		<i>Coffee break</i>
11:30	12:30	AFA	ADCR Horizontal issues and Model Opinion <b>contd.</b>
12:30	13:30	AFA	341_ADCR_RR_Formulation, 331_ADCR_Formulation, 345_ADCR_RR_Stainless_steel_passivation, 334_ADCR_Stainless_steel_passivation, 338_ADCR_RR_Chromate_rinsing, 328_ADCR_Chromate_rinsing, 344_ADCR_RR_Slurry_coating, 343_ADCR_RR_Pre-treatments, 333_ADCR_Pre-treatments, 335_ADCR_RR_Anodising, 326_ADCR_Anodising, 336_ADCR_RR_Anodise_sealing, 325_ADCR_Anodise_sealing, 337_ADCR_RR_Chemical_conversion_coating, 327_ADCR_Chemical_conversion_coating, 339_ADCR_RR_Electroplating, 329_ADCR_Electroplating, 342_ADCR_RR_Passivation_metallic_coatings, 332_ADCR_Passivation_metallic_coatings, 340_ADCR_RR_Finish_stripping, 330_ADCR_Finish_stripping - Agreement on draft opinions

13:30 14:30 Lunch

#### **Thursday 14 March 2024: Afternoon session**

14:30	14:34	DWD	Welcome and apologies - RAC Drinking Water Directive Working Group
14:34	14:37	DWD	Adoption of the Agenda
14:37	14:40	DWD	Declarations of conflicts of interest to the Agenda by RAC Drinking Water Directive Working Group
14:40	14:45	DWD	Action points from last RAC DWD WG meeting on 04/10/2023
14:45	14:50	DWD	Update on the adoption of the DWD implementing legislation
14:50	15:00	DWD	Proposal for a support group on toxicokinetics for DWD guidance
15:00	15:30	DWD	Introduction to Case Study 1: Starting substance (presentation by UBA)
15:30	16:10	DWD	Case Study 1: Introductory discussion
16:10	16:30		<i>Coffee break</i>
16:30	17:00	DWD	Introduction to Case Study 2: Metallic composition (presentation by UBA)
17:00	17:40	DWD	Case Study 2: Introductory discussion
17:40	17:45	DWD	Summary of Day 1 RAC DWD WG discussion
17:45	18:00	AOB	Any other business

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18:00	18:10	ADMIN	Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits <b>Closed session</b>
18:10	18:20	ADMIN	Adoption of the RAC-68 report and closure of the meeting

*END OF PLENARY*

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