

**Final Agenda**  
**63<sup>rd</sup> meeting of the Committee for Risk Assessment**  
**(RAC-63)**

**28 November-1 December 2022**

**Face-to-face meeting\***

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

***Times are Helsinki times***

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

***RAC/A/63/2022***

***For adoption***

**Item 3 – Declarations of conflicts of interest to the Agenda**

**Item 4 – Appointment of (co-)rapporteurs**

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

***For agreement***

***Closed session***

**Item 5 – Report from other ECHA bodies and activities**

5.1 RAC Work Plan for all processes

***For information***

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\* Members are expected to attend in person.

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

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

***For discussion and adoption***

## Item 7 – Health based exposure limits at the workplace

### 7.1 Opinions for discussion

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

***For discussion and adoption***

## Item 8 – Harmonised classification and labelling (CLH)

### 8.1 General CHL issues

1. Report from the October CLH Working Group

***RAC/63/2022/01  
For information***

### 8.2 CLH dossiers

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

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

*respiratory sensitisation, skin sensitisation, mutagenicity, reproductive toxicity (fertility and lactation)*

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

## **2. Hazard classes for agreement with plenary debate**

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

***For discussion and adoption***

### **Item 9 – Restrictions**

#### **9.1 General restriction issues**

1. Report from the November Restriction Working Group

***RAC/63/2022/02***  
***For information***

#### **9.2 Restriction Annex XV dossiers**

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

***For discussion and agreement***

2. Opinion development

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

***For discussion and agreement***

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

## **Item 10 – Authorisation**

### **10.1 General authorisation issues**

1. Report from the October AFA Working Group

***RAC/63/2022/03***  
***For information***

2. Update on incoming/future applications

***For information/discussion***

### **10.2 Authorisation applications**

#### **1. Key issues**

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

***For discussion***

### **10.3 Agreement on draft opinions**

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

1. 260\_CT\_SARREL (1 use)
2. 261\_CT\_Metalbrass (1 use)
3. 262\_CT\_Cromoplastica (2 uses)
4. 263\_CT\_Orelec (1 use)
5. 264\_CT\_Cristina (1 use)
6. 265\_TXP\_EDF (2 uses)
7. 266\_CT\_Olivari (1 use)
8. 267\_CT\_SPGPrints (1 use)
9. 268\_CT\_Paffoni (1 use)
10. 269\_CT\_Rubinetterie3M (1 use)
11. 270\_CT\_Maier (2 uses)
12. 271\_CT\_Villeroy (1 use)
13. 272\_CT\_RIGHI (1 use)

***For discussion and agreement***

### **10.4 Adoption of opinions**

1. 242\_RR1\_TCE\_Microporous (1 use)
2. 243\_RR1\_TCE\_DOMO (1 use)
3. 249\_CT\_Tenneco\_CZ (1 use)
4. 250\_CT\_Tenneco\_ES (1 use)
5. 251\_CT\_Tenneco\_BE (1 use)
6. 252\_CT\_Tenneco\_PL (1 use)

***For discussion and adoption***

**Item 11 – AOB**

**Item 12 – Minutes of RAC-63**

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

***For adoption***

## **PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-63**

Please note that this timeline is provisional. Changes can be made before and during the meeting in order to accommodate the discussions.

### **Monday 28 November 2022: Afternoon session**

- Item 1 – Welcome and Apologies
- Item 2 – Adoption of the Agenda
- Item 3 – Declarations of conflicts of interest to the Agenda
- Item 5 – RAC Work Plan for Restriction, Authorisation and C&L processes
- Item 7 – OELs

### **Tuesday 29 November 2022: Morning session**

- Item 6 – Art. 77(3)c
- Item 9 – Restrictions

### **Tuesday 29 November 2022: Afternoon session**

- Item 9 – Restrictions

### **Wednesday 30 November 2022: Morning session**

- Item 10 – Authorisation applications

### **Wednesday 30 November 2022: Afternoon session**

- Item 8 – CLH general
- Item 8 – CLH dossiers

### **Thursday 1 December 2022: Morning session**

- Item 8 – CLH dossiers

### **Thursday 1 December 2022: Afternoon session**

- Item 8 – CLH dossiers
- Item 5 – Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits
- Item 12 – Summary records

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