

Final Agenda
65th meeting of the Committee for Risk Assessment
(RAC-65)

5-8 June 2023

Face-to-face meeting*

Monday, 5 June starts at 14.00
Thursday, 8 June ends at 18.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/65/2023
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)

* Members are expected to attend in person.

- 6.1 Article 77(3)(c) request on Silanamine (SAS-HMDS): review of the acute toxicity classification of Silanamine as adopted by RAC in its opinion of 5 December 2019.

For adoption

Item 7 – Health based exposure limits at the workplace

7.1 Opinions for discussion

1. 2,3-epoxypropyl methacrylate (glycidyl methacrylate) (EC: 203-441-9; CAS: 106-91-2)

For discussion

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the April CLH Working Group

RAC/65/2023/01
For information

8.2 CLH dossiers

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

- **9-Octadecenoic acid (Z)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt:** *mutagenicity, carcinogenicity, reproductive toxicity*
- **2,3-epoxypropyl isopropyl ether:** *reproductive toxicity*
- **Tetrahydrofurfuryl methacrylate:** *skin sensitisation, reproductive toxicity, STOT RE*
- **Bixlozone (ISO):** *physical hazards, acute toxicity via all routes, skin irritation, eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, hazards to the aquatic environment*
- **Trimethyl phosphate:** *acute toxicity via oral and dermal routes, mutagenicity, carcinogenicity, reproductive toxicity, STOT RE*
- **Barium chromate:** *mutagenicity, carcinogenicity, reproductive toxicity*
- **3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate:** *acute toxicity, STOT SE, EUH071, skin irritation, eye irritation, skin sensitisation*
- **Folpet (ISO); N-(trichloromethylthio)phthalimide:** *acute toxicity, skin irritation, eye irritation, skin sensitisation, carcinogenicity, mutagenicity, reproductive toxicity, STOT SE, STOT RE, hazards to the aquatic environment*
- **2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB]:** *physical hazards, acute toxicity, skin irritation, eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazard to the aquatic environment, hazards to the ozone layer*
- **1,1-dichloroethylene; vinylidene chloride:** *acute toxicity, eye irritation, carcinogenicity, STOT RE, hazards to the aquatic environment*

- **Fluoroethylene:** *mutagenicity, note D*
- **Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]; C.I. Pigment Red 53:1:** *carcinogenicity*
- **Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide (HH) (EC: 289-699-3; CAS: 89997-63-7)/ Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents:** *STOT SE, STOT RE*

2. Hazard classes for agreement with plenary debate

1. **Fluoroethylene** (EC 200-832-6; CAS 75-02-5): *carcinogenicity*
2. **1,1-dichloroethylene; vinylidene chloride** (EC 200-864-0; CAS 75-35-4): *mutagenicity*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the May Restriction Working Group

For information

2. Updated Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers and changes in the opinion template

RAC/65/2023/02

For information and agreement

9.2 Restriction Annex XV dossiers

1. Key issues and recommendations to the DS
 1. Universal per- and polyfluoroalkyl substances (U-PFAS)– key issues and recommendations to the DS
 - stakeholder statements

For discussion

2. Opinion development

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

For discussion and adoption

2. BPA+ - ***not for discussion at RAC-65***
3. Creosote, and creosote related substances – ***not for discussion at RAC-65***

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the May AFA Working Group

***RAC/65/2023/03
For information***

2. Update on incoming/future applications and horizontal issues

For information/discussion

10.2 Authorisation applications

1. Discussion on key issues

1. 14 applications for authorisation (chromium trioxide and OPE) from Nov 2022 submission window

For discussion

10.3 Agreement on draft opinions

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

1. 285_CT_Liebherr-Aerospace_Linden (2 uses)
2. 287_CT_Bacrom (1 use)
3. 288_CT_Leonardo (1 use)
4. 289_CT_Beretta (2 uses)
5. 290_CT_Fir-Italia (1 use)
6. 291_CT_Belloni (1 use)
7. 294_CT_Kludi (2 uses)
8. 295_CT_Ugitech (1 use)

For agreement

2. Draft opinions for agreement with plenary debate

1. 286_CT_Hartchrom-Beck (4 uses)
2. 292_CT_Artech (1 use)
3. 293_CT_Talleres-Aykrom (1 use)
4. 296_CT_Mahle-2 (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 261_CT_Metalbrass (1 use)
2. 263_CT_Orelec (1 use)
3. 265_TXP_EDF (2 uses)
4. 267_CT_SPGPrints (1 use)
5. 271_CT_Villeroy (1 use)
6. 272_CT_RIGHI (1 use)

For discussion and adoption

Item 11 – Drinking Water Directive

1. Report from the June DWD Working Group

For information

Item 12 – Joint RAC and SCCS symposium

***RAC/65/2023/04
For information***

Item 13 – AOB

1. Introduction of new processes

Item 14 – Minutes of RAC-65

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-65

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-65

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

Monday 5 June 2023: 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
- Item 11 – DWD
- Item 9 – Restrictions: General RESTR issues

Tuesday 6 June 2023: Morning session

- Item 9 – Restrictions

Tuesday 6 June 2023: Afternoon session

- Item 9 – Restrictions
- Item 10 – Authorisation applications

Wednesday 7 June 2023: Morning session

- Item 12 – Joint RAC and SCCS symposium

Wednesday 7 June 2023: Afternoon session

- Item 10 – Authorisation applications

Thursday 8 June 2023: Morning session

- Item 8 – CLH dossiers

Thursday 8 June 2023: Afternoon session

- Item 6 – Art. 77(3)c
- Item 8 – CLH dossiers
- Item 13 – AOB
- Item 5 – Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits
- Item 14 – Summary records
