

Final Draft Agenda 70th meeting of the Committee for Risk Assessment (RAC-70)

16-20 September 2024

Face-to-face/Hybrid meeting*

Monday, 16 September starts at 09.00 Friday, 20 September ends at 13.15

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/70/2024 For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Action points from the previous meetings. 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 – No remote connection

^{*}RAC members are expected to participate physically in the meeting. Regular RAC stakeholders may participate either physically or remotely. Occasional stakeholders, all stakeholder experts and dossier submitters are expected to participate remotely

Item 5 – Work plan and General RAC procedures

5.1 Report on RAC related activities and RAC Work Plan for all processes

For information

5.2 Update of RAC accredited stakeholders' list (closed session)

For discussion and agreement RAC/70/2024/01 Restricted document Closed session – No remote connection

5.3 Selection of RAC co-opted members (closed session)

For discussion and agreement RAC/70/2024/02 Restricted document Closed session – No remote connection

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

None.

For adoption

Item 7 –Health based exposure limits at the workplace

7.1 General OEL issues

1. OEL regulatory framework presentation by DG EMPL

7.2 Opinions for discussion

1. 4,4-Isopropylidenediphenol (Bisphenol A)

For discussion

7.3 Opinions for discussion and adoption

- 1. Silicon carbide fibres
- 2. Pyrocatechol

For adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the July CLH Working Group

For information

8.2 CLH dossiers

- 1. Hazard classes for agreement without plenary debate (A-list)
- **3,5-Dimethylpyrazole:** *acute oral toxicity, STOT RE, adverse effects on or via lactation*
- **3,4-Dimethyl-1***H***-pyrazole:** *acute toxicity via all routes, STOT RE, adverse effects on or via lactation*
- **3,4-Dimethyl-1***H***-pyrazol-1-ium dihydrogen phosphate:** acute toxicity via all routes, STOT RE, adverse effects on or via lactation
- **Borate minerals group:** *adverse effects on or via lactation*
- **Thermally treated garlic juice:** physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, respiratory sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, hazards to the aquatic environment, hazards to the Ozone layer
- **Fluazaindolizine (ISO):** *physical hazards, hazards to the aquatic environment*
- [Ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid: *mutagenicity*, STOT RE
- [Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt: *mutagenicity*, STOT RE
- [Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt: *mutagenicity*, STOT RE
- [Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt: *mutagenicity*, STOT RE
- **2-Pyrrolidone:** *reproductive toxicity fertility and effects on or via lactation*
- **Rape oil; rape seed oil:** physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, hazards to the aquatic environment
- **Tebuconazole (ISO):** acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, effects on or via lactation, aspiration hazard
- **Eugenol (dossier from the Spanish Competent Authority):** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, mutagenicity, carcinogenicity, STOT SE, STOT RE, reproductive toxicity, hazard to the aquatic environment, hazard to the Ozone layer*
- Eugenol (dossier from the Danish Competent Authority and includes only Skin Sensitisation): *skin sensitisation*
- Silver nitrate: physical hazards, hazards to the aquatic environment

2. Hazard classes for agreement with plenary debate

- 8.2.1 **3,5-Dimethylpyrazole** (EC 200-657-5, CAS 67-51-6): *reproductive toxicity fertility and development*
- 8.2.2 **Borate minerals group:** *reproductive toxicity fertility and development*
- 8.2.2.1 Ulexite $(CaNaH_{12}(BO_3)_5 \times 2H_2O)$ [1] ulexite $(CaNaH_{12}(BO_3)_5 \times 2H_2O)$, calcined [2] (EC - [1] 296-662-5 [2], CAS 1319-33-1 [1] 92908-33-3 [2])
- 8.2.2.2 Colemanite $(CaH(BO_2)_3 \times 2H_2O)$ [1] boron calcium oxide $(B_6Ca_2O_{11})$, hydrate (1:5) [2] colemanite, calcined [3] (EC - [1] - [2] 296-640-5 [3], CAS 1318-33-8 [1] 854267-07-5 [2] 92908-12-8 [3])
- 8.2.2.3 Tincalconite (B₄Na₂O₇ × 5H₂O) (EC -, CAS 12045-88-4)
- 8.2.3 [Ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid (EC 215-851-5, CAS 1429-50-1): *carcinogenicity*
- 8.2.4 [Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt (EC 287-370-9, CAS 85480-89-3): carcinogenicity
- 8.2.5 [Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt (EC 251-910-1, CAS 234274-30-1): carcinogenicity
- 8.2.6 [Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt (EC 244-742-5, CAS 22036-77-7): *carcinogenicity*
- 8.2.7 **2-Pyrrolidone; pyrrolidin-2-one** (EC 210-483-1, CAS 616-45-5): *reproductive toxicity development*
- 8.2.8 **Tebuconazole (ISO);** 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol (EC 403-640-2; CAS 107534-96-3): *reproductive toxicity fertility and development*
- 8.2.9 **Talc** (Mg₃H₂(SiO₃)₄) (EC 238-877-9; CAS 14807-96-6): *carcinogenicity*
- 8.2.10 Burgeonal group: all relevant hazard classes
- 8.2.10.1 2-(4-*tert*-butylbenzyl) propionaldehyde (EC 201-289-8, CAS 80-54-6)
- 8.2.10.2 4-*tert*-butylbenzoic acid (EC 202-696-3, CAS 98-73-7)
- 8.2.10.3 3-(4-*tert*-butylphenyl)propionaldehyde [1] 4-*tert*-butyltoluene [2] 4-*tert*-butylbenzaldehyde [3] methyl 4-*tert*-butylbenzoate [4] (EC 242-016-2 [1] 202-675-9 [2] 213-367-9 [3] 247-768-5 [4], CAS 18127-01-0 [1] 98-51-1 [2] 939-97-9 [3] 26537-19-9 [4])
- 8.2.11 Cyclamal group: all relevant hazard classes
- 8.2.11.1 *p*-cymene; 1-isopropyl-4-methylbenzene and 3-*p*-cumenyl-2methylpropionaldehyde (EC 202-796-7, CAS 99-87-6) and
- 8.2.11.2 2-methyl-3-(4-isopropylphenyl)propanal [1]; 3-(*p*-cumenyl)propionaldehyde; 3-(4-isopropylphenyl)propanal [2]; 4-isopropylbenzaldehyde; cuminic aldehyde [3]; 4-isopropylbenzoic acid; cuminic acid [4] (EC 203-161-7 [1]; 231-885-3 [2]; 204-516-9 [3]; 208-642-5 [4], CAS 103-95-7 [1]; 7775-00-0 [2]; 122-03-2 [3]; 536-66-3 [4])
- 8.2.12 Silver nitrate (EC 231-853-9, CAS 7761-88-8): part of HH hazard classes

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

- Review of the Conformity Check procedure

For discussion

9.2 Restriction Annex XV dossiers

a) Opinion development on Universal per- and polyfluoroalkyl substances (UPFAS) restriction proposal -state of play and next steps

For information

- b) Evaluation of sector-/use-specific aspects of UPFAS restriction proposal:
 - i. Waste emissions (cont.)
 - ii. Textiles, upholstery, leather, apparel, carpets (TULAC)
 - iii. Food contact materials and packaging
 - iv. Petroleum and mining

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

1. Update on incoming/future applications and horizontal issues

For information/discussion

10.2 Authorisation applications

No content under this agenda item.

10.3 Agreement on draft opinions

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

- 1. 354_RR1_CT_Airbus (2 uses)
- 2. 355_RR1_SD_Airbus (1 use)
- 3. 356_RR1_SD_AD-International (1 use)
- 4. 359_RR1_CT_Circuit (1 use)
- 5. 361_TEL_Trafigura (1 use)
- 6. 362_TEL_Warter-Fuels (1 use)
- 7. 363_CT_Indestructible_Paint_Turbines (1 use)

For agreement

2. Draft opinions for agreement with plenary debate

1. 352_DEHP_Baxter (3 uses)

- 2. 357_RR1_PD_Lynred (1 use)
- 3. 358_RR1_AsA_Circuit (1 use)

For discussion and agreement

10.4 Adoption of opinions

- 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)
- 22.346_CT_Safran_landing_systems (2 uses)
- 23.347_CT_Safran_Aircraft_Engines (1 use)

For discussion and adoption

Item 11 – Drinking Water Directive

1. Update on Drinking Water Directive (DWD)

For information

Item 12 – AOB

Item 13 – Minutes of RAC-70

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-70

For adoption

Times are Helsinki times

Monday 16 September 2024: Morning session

09:00	09:20	ADMIN	Welcome and apologies
09:20	09:25	ADMIN	Adoption of the agenda
09:25	09:30	ADMIN	Declarations of conflicts of interest to the Agenda
09:30	09:40	ADMIN	Report on RAC-69 action points, written procedures and update on other ECHA bodies
09:40	10:30	AFA	11 ADCR RRs, 10 ADCR AfAs, 346_CT_Safran_landing_systems, 347_CT_Safran_Aircraft_Engines - adoption of opinions
10:30	11:00		Coffee break
11:00	12:30	OEL	4,4-Isopropylidenediphenol (Bisphenol A) - first discussion
12:30	13:30		Lunch

Monday 16 September 2024: Afternoon session

13:30	14:30	OEL	4,4-Isopropylidenediphenol (Bisphenol A) contd.
14:30	15:30	OEL	Silicon carbide fibres - for discussion and adoption
15:30	16:00		Coffee break
16:00	16:30	OEL	Silicon carbide fibres <i>contd.</i>
16:30	18:00	OEL	Pyrocatechol - for discussion and adoption
18:00	18:15	OEL	OEL regulatory framework by DG EMPL

Tuesday 17 September 2024: Morning session

09:00	09:30	RESTR	General Restrictions issues: - Report from the September REST Working Group - Review of the Conformity Check procedure
09:30	10:05	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS): UPFAS restriction proposal: State of play and next steps
10:05	11:05	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS): Draft opinion with focus on Waste emissions (cont.)
11:05	11:35		Coffee break
11:35	13:00	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS): Textiles, upholstery, leather, apparel, carpets (TULAC)
13:00	14:00		Lunch

Tuesday 17 September 2024: Afternoon session

14:00	14:35	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS): Textiles, upholstery, leather, apparel, carpets (TULAC) <i>(cont.)</i>
14:35	16:00	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS): Food contact materials and packaging
16:00	16:30		Coffee break

16:30	17:05	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS): Food contact materials and packaging <i>(cont.)</i>
17:05	18:35	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS): Petroleum and mining

Wednesday 18 September 2024: Morning session

09:30	09:40	CLH	Report from the July CLH Working Group
09:40	10:00	CLH	Hazard classes for agreement without plenary debate (A-list): - Based on RAC members' comments - Based on the RAC WG CLH outcome
10:00	11:00	CLH	Talc (Mg₃H₂(SiO₃)₄)
11:00	11:30		Coffee break
11:30	12:30	CLH	Talc (Mg₃H₂(SiO₃)₄) <i>contd.</i>
12:30	13:30		Lunch - New RAC Member lunch in KP02

Wednesday 18 September 2024: Afternoon session

13:30	14:00	CLH	3,5-dimethylpyrazole
14:00	15:30	CLH	Silver nitrate
15:30	16:00		Coffee break
16:00	16:30	CLH	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid;
			[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt;
			[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt;
			[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt
16:30	17:00	CLH	2-pyrrolidone; pyrrolidin-2-one

Thursday 19 September 2024: Morning session

09:00	09:15	AFA	AFA general issue: - Update on incoming/future applications and horizontal issues
09:15	09:40	AFA	A-list agreement on AFAs1. 354_RR1_CT_Airbus (2 uses) 2. 355_RR1_SD_Airbus (1 use)3. 356_RR1_SD_AD-International (1 use)4. 359_RR1_CT_Circuit (1 use)5. 361_TEL_Trafigura (1 use)6. 362_TEL_Warter-Fuels (1 use) 7. 363_CT_Indestructible_Paint_Turbines (1 use)
09:40	11:00	AFA	352_DEHP_Baxter (3 uses)
11:00	11:30		Coffee break
11:30	12:10	AFA	358_RR1_AsA_Circuit (1 use)
12:10	12:40	AFA	357_RR1_PD_Lynred (1 use)
12:40	13:40		Lunch

Thursday 19 September 2024: Afternoon session

13:40 14:15	14:15 14:20	ADMIN ADMIN	Update of RAC stakeholders list <i>Closed session</i> Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits <i>Closed session</i>
14:20 <i>15:00</i> 15:30	15:00 <i>15:30</i> 16:30	ADMIN AFA	Selection of RAC co-opted members <i>Closed session</i> <i>Coffee break</i>
16:30 17:00	17:00 17:45	CLH DWD	Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4- triazol-1-ylmethyl)pentan-3-ol Update on Drinking Water Directive (DWD)

Friday 20 September 2024: Morning session

09:30	11:00	CLH	Burgeonal group: 2-(4-tert-butylbenzyl) propionaldehyde; 4-tert-butylbenzoic acid; 3-(4- <i>tert</i> -butylphenyl)propionaldehyde [1] 4- <i>tert</i> -butyltoluene [2] 4- <i>tert</i> -butylbenzaldehyde [3] methyl 4- <i>tert</i> -butylbenzoate [4] Cyclamal group: <i>p</i> -cymene; 1-isopropyl-4-methylbenzene and 3- <i>p</i> -cumenyl-2- methylpropionaldehyde and 2-methyl-3-(4-isopropylphenyl)propanal [1]; 3-(<i>p</i> - cumenyl)propionaldehyde; 3-(4-isopropylphenyl)propanal [2]; 4-isopropylbenzaldehyde; cuminic aldehyde [3]; 4- isopropylbenzoic acid; cuminic acid [4]
11:00	11:30		Coffee break
11:30	12:30	CLH	Burgeonal group <i>contd.</i>
12:30	13:00	CLH	Borate minerals group:ulexite (CaNaH ₁₂ (BO ₃) ₅ × 2H ₂ O) [1] ulexite (CaNaH ₁₂ (BO ₃) ₅ × 2H ₂ O), calcined [2]colemanite (CaH(BO ₂) ₃ × 2H ₂ O) [1] boron calcium oxide (B ₆ Ca ₂ O ₁₁), hydrate (1:5) [2] colemanite, calcined [3]tincalconite (B ₄ Na ₂ O ₇ × 5H ₂ O)
13:00	13:15	ADMIN	Adoption of the RAC-70 report and closure of the meeting

END OF THE PLENARY