

Final Draft Agenda
67th meeting of the Committee for Risk Assessment
(RAC-67)

27-30 November 2023

Face-to-face/Hybrid meeting*

Monday, 27 November starts at 14.00
Thursday, 30 November ends at 16.20

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/67/2023
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 – General RAC procedures

5.1 RAC Work Plan for all processes

For information

5.2 Mandate for recruitment of RAC co-opted members (closed session)

For discussion and agreement

RAC/67/2023/01

Restricted

Closed session

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

n/a

Item 7 – Health based exposure limits at the workplace

7.1 Opinions for discussion

1. *N*-nitrosodiethylamine (diethylnitrosamine) (EC 200-226-1; CAS 55-18-5)

For discussion and adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

1. Report from the October CLH Working Group

**For information
RAC/67/2023/02**

8.2 CLH dossiers

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

- **Flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulfonyl)urea (EC -; CAS 104040-78-0):** physical hazards, acute toxicity (oral, dermal, inhalation), skin irritation, eye irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity (fertility, lactation), STOT SE, STOT RE (kidney), aspiration hazard, aquatic hazards, hazard to the ozone layer
- **Fosthiazate (ISO); S-sec-butyl O-ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate (EC -; CAS 98886-44-3):** physical hazards, acute toxicity, serious eye damage/eye irritation, STOT RE, reproductive toxicity (fertility, lactation), aquatic hazards
- **Tetra(sodium/potassium)7-[(E)-{2-acetamido-4-[(E)-(4-{[4-chloro-6-(2-[(4-fluoro-6-{[4-(vinylsulfonyl)phenyl]amino}-1,3,5-triazine-2-yl)amino]propyl} amino)-1,3,5-triazine-2-yl]amino}-5-sulfonato-1-naphthyl)diazenyl]-5-methoxyphenyl}diazenyl]-1,3,6-naphthalenetrisulfonate; [substance having a complex composition with <80% of the above constituents and other reaction side products]; Reactive Brown 51 (EC 466-490-7; CAS -):** skin sensitisation, reproductive toxicity
- **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):**

physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, reproductive toxicity, STOT SE, STOT RE, aquatic hazards, hazard to the ozone layer

- **Methacrylic acid, monoester with propane-1,2-diol; [HPMA] (EC 248-666-3; CAS 27813-02-1):** *serious eye damage/eye irritation, skin sensitisation, respiratory sensitisation, STOT SE, Note D*
- **2-hydroxyethyl methacrylate; [HEMA] (EC 212-782-2; CAS 868-77-9):** *respiratory sensitisation, STOT SE*
- **4-phenylbenzophenone (EC 218-345-2; CAS 2128-93-0):** *skin sensitisation, reproductive toxicity, aquatic hazards*
- **Melaleuca alternifolia, ext. [1] Melaleuca alternifolia, essential oil; tea tree oil [2] (EC 285-377-1 [1]; CAS 85085-48-9 [1] CAS 68647-73-4 [2]):** *physical hazards, aspiration hazard, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT RE, mutagenicity, carcinogenicity, lactation*
- **Penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1H-1,2,4-triazole (EC 266-275-6; CAS 66246-88-6):** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazard to the ozone layer*

2. Hazard classes for agreement with plenary debate

1. **Flazasulfuron (ISO)** (EC -; CAS 104040-78-0): *STOT RE (liver, thymus, skeletal muscle), reproductive toxicity (development)*
2. **Fosthiazate (ISO)** (EC -; CAS 98886-44-3): *STOT SE and STOT RE for nervous system and adrenals, developmental toxicity*
3. **Metiltetraprole (ISO)** (EC -; CAS 1472649-01-6): *carcinogenicity*
4. **Methacrylic acid, monoester with propane-1,2-diol; [HPMA] (EC 248-666-3; CAS 27813-02-1):** *SCL for STOT SE 3; H335*
5. **2-hydroxyethyl methacrylate; [HEMA] (EC 212-782-2; CAS 868-77-9):** *SCL for STOT SE 3; H335*
6. **Melaleuca alternifolia, ext. [1] Melaleuca alternifolia, essential oil; tea tree oil [2] (EC 285-377-1 [1]; (CAS 85085-48-9 [1] CAS 68647-73-4 [2]):** *STOT SE, reproductive toxicity (fertility, development), aquatic toxicity*
7. **Penconazole (ISO)** (EC 266-275-6; CAS 66246-88-6): *aquatic hazards*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Restriction dossiers in preparation

For information

9.2 Restriction Annex XV dossiers

1. Opinion development
 1. Universal per- and polyfluoroalkyl substances (U-PFAS) – Overview of third-party consultation outcome and the work plan for 2024

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the October AFA Working Group

***For information
RAC/67/2023/03***
2. Update on incoming/future applications and horizontal issues

For information/discussion
3. New Opinion format

For information

10.2 Authorisation applications

1. Discussion on key issues

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

10.3 Agreement on draft opinions

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

1. 311_SD_Liebherr-Aerospace (1 use)
2. 313_CT_BWI-Poland (1 use)
3. 314_CT_Benoni (1 use)
4. 315_CT_Egal (1 use)
5. 316_CT_ASO-Cromsteel (1 use)
6. 317_CA_Micron (1 use)
7. 318_CT_Sirio_Galv (1 use)
8. 320_CT_Fratelli-Creola (1 use)
9. 321_CT_LMC (1 use)
10. 322_CT_ArcelorMittal_plating (1 use)
11. 323_CT_HDO-Druckguss (1 use)
12. 324_CT_Tecnofiniture (1 use)

For agreement

2. Draft opinions for agreement with plenary debate

1. 312_CT_Metalplast (2 uses)
2. 319_CT_SK-Nexillis (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 286_CT_Hartchrom-Beck (4 uses)
2. 288_CT_Leonardo (1 use)
3. 289_CT_Beretta (2 uses)

For discussion and adoption

Item 11 – Drinking Water Directive

1. Report from the October DWD Working Group

***For information
RAC/67/2023/04***

Item 12 – AOB

1. Operations of RAC (Caracal)
2. Update on recent upgrades to IT tools
3. Presentation by European Environmental Bureau (EEB)

Item 13 – Minutes of RAC-67

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-67

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-67

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 27 November 2023: Afternoon session

14:00	14:10	ADMIN	Welcome and apologies	0:10
14:10	14:20	ADMIN	Adoption of the agenda	0:10
14:20	14:30	ADMIN	Declarations of conflicts of interest to the Agenda	0:10
14:30	14:40	ADMIN	RAC Work Plan for Restriction, Authorisation C&L and OELs	0:10
14:40	15:10	AFA	AFA general issue: - Update on incoming/future applications and horizontal issues - New opinion format	0:30
15:10	15:20	AFA	Report from the October AFA Working Group	0:10
15:20	15:45	AFA	A-list agreement on AFAs	0:25
15:45	16:00	AFA	286_CT_Hartchrom-Beck, 288_CT_Leonardo, 289_CT_Beretta - adoption of opinions	0:15
16:00	16:30		<i>Coffee break</i>	0:30
16:30	17:50	AFA	325_ADCR_Anodise_sealing, 326_ADCR_Anodising, 327_ADCR_Chemical_conversion_coating, 328_ADCR_Chromate_rinsing, 329_ADCR_Electroplating, 330_ADCR_Finish_stripping, 331_ADCR_Formulation, 332_ADCR_Passivation_metallic_coatings, 333_ADCR_Pre- treatments, 334_ADCR_Stainless_steel_passivation, 335_ADCR_RR_Anodising, 336_ADCR_RR_Anodise_sealing, 337_ADCR_RR_Chemical_conversion_coating, 338_ADCR_RR_Chromate_rinsing, 339_ADCR_RR_Electroplating, 340_ADCR_RR_Finish_stripping, 341_ADCR_RR_Formulation, 342_ADCR_RR_Passivation_metallic_coatings, 343_ADCR_RR_Pre-treatments, 344_ADCR_RR_Slurry_coating, 345_ADCR_RR_Stainless_steel_passivation, 346_CT_Safran_landing_systems, 347_CT_Safran_Aircraft_Engines - Key issues discussion	1:20

ADMIN	00:40
AFA	02:40

Tuesday 28 November 2023: Morning session

09:45	10:00	ADMIN	Conclusions and action points from the previous day	0:15
10:00	11:30	AFA	312_CT_Metalplast (2 uses), 319_CT_SK-Nexillis (1 use) - agreement on draft opinions	1:30
11:30	12:00		<i>Coffee break</i>	0:30
12:00	13:00	DWD	Report from the October DWD Working Group	1:00
13:00	14:00		<i>Lunch</i>	1:00

Tuesday 28 November 2023: Afternoon session

14:00	15:30	OEL	Nitrosamines (<i>N</i> -nitrosodiethylamine (diethylnitrosamine) (EC 200-226-1; CAS 55- 18-5) - <i>N</i> -nitrosodimethylamine (dimethylnitrosamine) (EC 200-549-8; CAS 62-75-9) - <i>N</i> -nitroso di- <i>n</i> -propylamine (EC 210-698-0 ; CAS 621-64-7) - <i>N</i> -nitrosodiethanoamine (2,2'-(nitrosoimino)bisethanol) (EC 214-237-4; CAS 1116-54-7)) - adoption of opinion	1:30
15:30	16:00		<i>Coffee break</i>	0:30
16:00	16:20	RESTR	General restriction issues: - Restriction dossiers in preparation	0:20
16:20	16:35	AOB	Presentation by European Environmental Bureau (EEB)	0:15
16:35	17:35	ADMIN	General RAC procedures (closed session): - Mandate for recruitment of RAC co-opted members ~17:45-19:00 Christmas drink	1:00

	ADMIN	01:15
	AFA	01:30
	RESTR	00:20
	OEL	01:30
	DWD	01:00

Wednesday 29 November 2023: Morning session

09:30	09:45	ADMIN	Conclusions and action points from the previous day	0:15
09:45	11:15	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS) – Overview of third-party consultation outcome and the work plan for 2024	1:30
11:15	11:45		<i>Coffee break</i>	0:30
11:45	11:55	CLH	Report from the October CLH Working Group	0:10
11:55	12:15	CLH	Hazard classes for agreement without plenary debate (A-list): - Based on RAC members' comments - Based on the RAC WG CLH outcome	0:20
12:15	12:45	CLH	Penconazole (ISO) - opinion adoption	0:30
12:45	13:45		<i>Lunch</i>	1:00

Wednesday 29 November 2023: Afternoon session

13:45	14:45	CLH	Fosthiazate (ISO); <i>S</i> -sec-butyl <i>O</i> -ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate - opinion adoption	1:00
14:45	15:45	CLH	Flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulfonyl)urea - opinion adoption	1:00
15:45	16:15		<i>Coffee break</i>	0:30
16:15	17:45	CLH	<i>Melaleuca alternifolia</i> , ext. [1] <i>Melaleuca alternifolia</i> , essential oil; tea tree oil [2] - opinion adoption	1:30

	ADMIN	00:15
	CLH	04:30
	AFA	00:00

Thursday 30 November 2023: Morning session

10:00	10:15	ADMIN	Conclusions and action points from the previous day	0:15
10:15	11:15	CLH	Methacrylic acid, monoester with propane-1,2-diol; [HPMA] and 2-hydroxyethyl methacrylate; [HEMA] - opinion adoption	1:00
11:15	11:45		<i>Coffee break</i>	0:30
11:45	12:30	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 - discussion	0:45
12:30	14:00		<i>Lunch</i>	1:30

Thursday 30 November 2023: Afternoon session

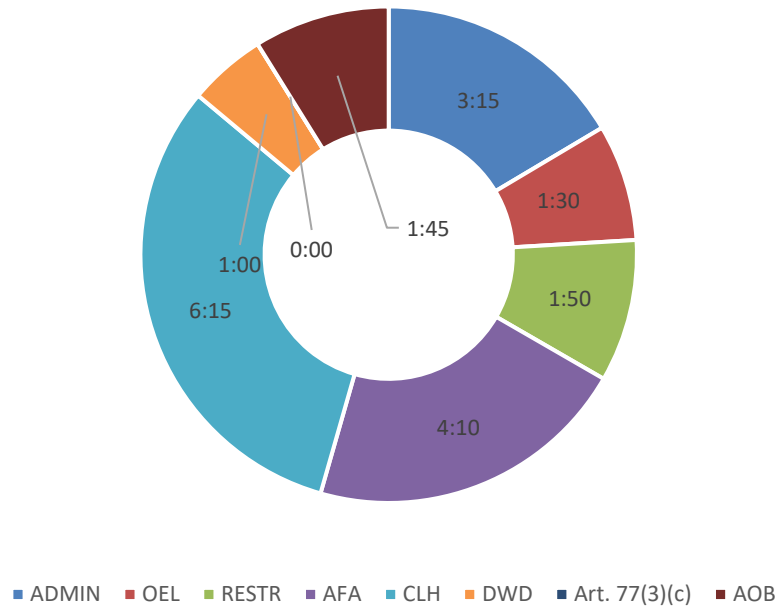
14:00	15:00	AOB	- Operations of RAC (CARACAL) - Update on recent upgrades to IT tools	1:00
15:00	15:30	AOB	Any other business	0:30
15:30	15:55	ADMIN	Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits Closed session	0:25
15:55	16:20	ADMIN	Adoption of the RAC-67 report and closure of the meeting	0:25

	ADMIN	01:05
	CLH	01:45
	AOB	01:30

END OF THE PLENARY

	ADMIN	3:15
	OEL	1:30
	RESTR	1:50
	AFA	4:10
	CLH	6:15
	DWD	1:00
	Art. 77(3)(c)	0:00
	AOB	1:45
	Total:	19:45

RAC-67 meeting structure



*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