

Final Draft Agenda
66th meeting of the Committee for Risk Assessment
(RAC-66)

11-14 September 2023

Face-to-face/Hybrid meeting*

Monday, 11 September starts at 14.00
Thursday, 14 September ends at 17.30

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/66/2023
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

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5.2 Annual update of RAC accredited stakeholders' list

The Secretariat will update you on the requests from stakeholder observers to attend RAC meetings since the last review of the RAC stakeholders. You will be invited to agree on the updated list of the accredited stakeholder organisations to RAC this year.

RAC/66/2023/01
Restricted
For agreement
Closed session

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

No new requests.

For adoption

Item 7 – Health based exposure limits at the workplace

7.1 Opinions for discussion

1. Nitrosamines (*N*-nitrosodiethylamine (diethylnitrosamine) (EC 200-226-1; CAS RN 55-18-5) - *N*-nitrosodimethylamine (dimethylnitrosamine) (EC 200-549-8; CAS RN 62-75-9) - *N*-nitroso di-*n*-propylamine (EC 210-698-0 ; CAS RN 621-64-7) - *N*-nitrosodiethanoamine (2,2'-(nitrosoimino)bisethanol) (EC 214-237-4; CAS RN 1116-54-7))
2. 2-chloro-1,3-butadiene (chloroprene) (EC 204-818-0; CAS 126-99-8)

For discussion

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the July CLH Working Group

RAC/66/2023/02
For information

2. New hazard classes under CLH

For information and discussion

8.2 CLH dossiers

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

- **Clopyralid (ISO):** *skin corrosion/irritation, STOT RE, reproductive toxicity (fertility), aquatic toxicity*
- **2-bromo-3,3,3-trifluoroprop-1-ene:** *STOT SE, reproductive toxicity*
- **2,3-epoxypropyl o-tolyl ether:** *skin sensitisation*

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- **2-methyl-2H-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride:** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aquatic toxicity, hazard to the ozone layer*
- **Methyl oct-2-ynoate:** *skin sensitisation*
- **Dinotefuran (ISO):** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, aquatic toxicity*
- **Proquinazid (ISO):** *physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, aquatic toxicity, hazard to the ozone layer*
- **3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate:** *acute inhalation toxicity, aquatic toxicity*
- **Captan (ISO):** *acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, mutagenicity, aquatic hazards*

2. Hazard classes for agreement with plenary debate

1. **Clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid** (EC: 216-935-4; CAS: 1702-17-6): *reproductive toxicity (development)*
2. **Proquinazid (ISO); 6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one** (EC: - ; CAS: 189278-12-4): *STOT RE for liver and thyroid effects*
3. **Captan (ISO); 1,2,3,6-tetrahydro-N-(trichloromethylthio)phthalimide** (EC: 205-087-0; CAS: 133-06-2): *reproductive toxicity, STOT RE, carcinogenicity*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the August Restriction Working Group

***RAC/66/2023/03
For information***

9.2 Restriction Annex XV dossiers

1. Opinion development

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1. Universal per- and polyfluoroalkyl substances (U-PFAS) – First draft opinion with focus on hazard and food contact materials and packaging

For discussion

2. Creosote, and creosote related substances – adoption of the opinion

For adoption

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the July AFA Working Group

RAC/66/2023/04

For information

2. Update on incoming/future applications and horizontal issues

For information/discussion

3. Renewal of the RAC AFA WG mandate

RAC/66/2023/05

For discussion and agreement

10.2 Authorisation applications

1. Discussion on key issues

1. 311_SD_Liebherr-Aerospace (1 use)
2. 312_CT_Metalplast (2 uses)
3. 313_CT_BWI-Poland (1 use)
4. 314_CT_Benoni (1 use)
5. 315_CT_Egal (1 use)
6. 316_CT_ASO-Cromsteel (1 use)
7. 317_CA_Micron (1 use)
8. 318_CT_Sirio_Galv (1 use)
9. 319_CT_SK-Nexillis (1 use)
10. 320_CT_Fratelli-Creola (1 use)
11. 321_CT_LMC (1 use)
12. 322_CT_ArcelorMittal_plating (1 use)
13. 323_CT_HDO-Druckguss (1 use)
14. 324_CT_Tecnofiniture (1 use)

For discussion

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10.3 Agreement on draft opinions

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

1. 297_CT_Acciaierie_Italia (1 use)
2. 298_CT_Bjerringbro_Fornikling (1 use)
3. 299_OPE_MeiraTGX (1 use)
4. 300_CT_Weber-Hydraulic (1 use)
5. 304_SD_Acciaierie (1 use)
6. 305_CT_Meoni_e_Bartoletti (1 use)
7. 306_CT_Galvanica_Pasotti (1 use)
8. 309_CT_Cromatura-Staff (1 use)
9. 310_CT_Cromotecnica_Fida (1 use)
10. 303_CT_Rubinetterie_Stella (1 use)
11. 307_CT_Vinzia (1 use)

For agreement

2. Draft opinions for agreement with plenary debate

1. 301_CT_SD_Liberty_Liege (1 use)
2. 302_CT_Thoma_Metallveredelung (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 283_CT_KYB (1 use)

Item 11 – Drinking Water Directive

1. Report from the June DWD Working Group

RAC/66/2023/06

For information

Item 12 – AOB

1. Any other business

Item 13 – Minutes of RAC-66

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-66

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PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-66

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 September 2023: Afternoon session

14:00	14:20	ADMIN	Welcome and apologies	0:20
14:20	14:30	ADMIN	Adoption of the agenda	0:10
14:30	14:40	ADMIN	Declarations of conflicts of interest to the Agenda	0:10
14:40	14:50	ADMIN	RAC Work Plan for Restriction, Authorisation C&L and OELs	0:10
14:50	16:30	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)) - first draft opinion	1:40
16:30	17:00		<i>Coffee break</i>	0:30
17:00	17:50	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)) Contd.	0:50
17:50	19:20	OEL	2-chloro-1,3-butadiene (chloroprene) - first draft opinion	1:30

ADMIN

00:50

OEL

04:00

Tuesday 12 September 2023: Morning session

09:30	09:45	ADMIN	Conclusions and action points from the previous day	0:15
09:45	09:55	RESTR	Report from the August Restriction Working Group	0:10
09:55	11:00	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS) - first draft opinion	1:05
11:00	11:30		<i>Coffee break</i>	0:30
11:30	12:25	RESTR	Universal per- and polyfluoroalkyl substances (U-PFAS) contd.	0:55
12:25	13:30		<i>Lunch</i>	1:05

Tuesday 12 September 2023: Afternoon session

13:30	15:30	RESTR	Creosote, and creosote related substances - second draft opinion	2:00
15:30	16:00		<i>Coffee break</i>	0:30
16:00	16:30	DWD	Report from the June DWD Working Group	0:30

				ADMIN	00:15
				RESTR	04:10
				DWD	00:30

Wednesday 13 September 2023: Morning session

09:30	09:45	ADMIN	Conclusions and action points from the previous day	0:15
09:45	10:45	AFA	AFA general issue: - Update on incoming/future applications and horizontal issues - Extension of the AfA Working Group mandate	1:00
10:45	10:55	AFA	Report from the July AfA Working Group	0:10
10:55	11:25		<i>Coffee break</i>	0:30
11:25	11:50	AFA	A-list agreement on AFAs	0:25
11:50	12:30		302_CT_Thoma_Metallverdelung	0:40
12:30	13:30		<i>Lunch</i>	1:00

Wednesday 13 September 2023: Afternoon session

13:30	13:50	AFA	301_CT_SD_Liberty_Liege	0:20
13:50	14:10	AFA	283_CT_KYB - Adoption of final opinion	0:20
14:10	15:00	AFA	311_SD_Liebherr-Aerospace, 312_CT_Metalplast, 313_CT_BWI-Poland, 314_CT_Benoni, 315_CT_Egal, 316_CT_ASO-Cromsteel, 317_CA_Micron, 318_CT_Sirio_Galv, 319_CT_SK-Nexillis, 320_CT_Fratelli- Creola, 321_CT_LMC, 322_CT_ArcelorMittal_plating, 323_CT_HDO-Druckguss, 324_CT_Tecnofiniture - Key issues discussion	0:50
15:00	15:30		<i>Coffee break</i>	0:30
15:30	16:45	CLH	General issues - New Hazard Classes under CLH	1:15

				ADMIN	00:15
				CLH	01:15
				AFA	03:05

Thursday 14 September 2023: Morning session

09:30	09:45	ADMIN	Conclusions and action points from the previous day	0:15
09:45	09:55	CLH	Report from the July CLH Working Group	0:10
09:55	10:15	CLH	Hazard classes for agreement without plenary debate (A-list): - Based on RAC members' comments - Based on the RAC WG CLH outcome	0:20
10:15	11:15	CLH	Captan (ISO); 1,2,3,6-tetrahydro-N-(trichloromethylthio)-phthalimide	1:00
11:15	11:45		<i>Coffee break</i>	0:30
11:45	13:15	CLH	Captan (ISO) contd.	1:30
13:15	14:15		<i>Lunch</i>	1:00

Thursday 14 September 2023: Afternoon session

14:15	15:00	CLH	Proquinazid (ISO);6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one	0:45
15:00	15:45	CLH	Clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid	0:45
15:45	16:15		<i>Coffee break</i>	0:30
16:15	16:45	AOB	Any other business	0:30
16:45	17:00	ADMIN	Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits Closed session	0:15
17:00	17:15	ADMIN	Annual update of RAC accredited stakeholders' list closed session	0:15
17:15	17:30	ADMIN	Adoption of the RAC-66 report	0:15

	ADMIN	01:00
	CLH	04:30
	AOB	00:30

END OF THE PLENARY