

22 November 2021 RAC/A/59/2021

Registration deadline 4 November 2021 rac@echa.europa.eu

Final Agenda

59th meeting of the Committee for Risk Assessment

22-26 November 2021

Virtual meeting

22 November starts at 14.00 26 November ends at 13.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/59/2021

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

5.2 Annual Declaration of Interests exercise – New declaration tool to be presented to the RAC members

For information

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

6.1 Reference DNEL/PNEC values or dose-response curves considering updated properties of DEHP, BBP, DIBP and DBP

For discussion/adoption

Item 7 –Health based exposure limits at the workplace

No agenda items.

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the October CLH WG

RAC/59/2021/01 For information

8.2 CLH dossiers

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

- 1. Sulfur dioxide (EC: 231-195-2; CAS: 7446-09-5): skin sensitisation, carcinogenicity, STOT SE
- Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC 255-894-7; CAS 42576-02-3): physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, germ cell mutagenicity, carcinogenicity, developmental toxicity, lactation, hazardous to the aquatic environment, hazardous to the ozone layer
- Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate (EC 275-728-7; CAS 71626-11-4): physical hazards, acute oral toxicity, STOT SE, hazardous to the aquatic environment
- 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC 220-120-9; CAS 2634-33-5): acute toxicity via all routes, skin corrosion/irritation, skin sensitisation, hazardous to the aquatic environment
- 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs.; Reaction mass of N-phenyl,N'-o-tolyl-phenylene diamine, N,N'-diphenylp-phenylene diamine and N,N'-di-o-tolyl-phenylene diamine (EC 273-227-8; CAS 68953-84-4): skin sensitisation, fertility, lactation
- 6. Tetramethylene dimethacrylate (EC 218-218-1; CAS 2082-81-7): skin sensitisation
- 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12diazahexadecane-1,16-diyl bismethacrylate (EC 276-957-5; CAS 72869-86-4): skin sensitisation
- 8. 2,2'-ethylenedioxydiethyl dimethacrylate (EC 203-652-6; CAS 109-16-0): skin sensitisation
- 9. 2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol (EC 221-665-5; CAS 3179-89-3): skin sensitisation
- 10. 4-methylimidazole (EC 212-497-3; CAS 822-36-6): carcinogenicity, reproductive toxicity, germ cell mutagenicity
- 11. 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol (EC 211-477-1; CAS 647-42-7): STOT RE, hazardous to the aquatic environment

2. Hazard classes for agreement [with plenary debate]

- 1. Sulfur dioxide (EC: 231-195-2; CAS: 7446-09-5): germ cell mutagenicity
- 2. Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC 255-894-7; CAS 42576-02-3): STOT RE, fertility
- Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate (EC 275-728-7; CAS 71626-11-4): carcinogenicity
- 4. 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC 220-120-9; CAS 2634-33-5): SCL for skin sensitisation
- 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs.; Reaction mass of N-phenyl,N'-o-tolyl-phenylene diamine, N,N'-diphenylp-phenylene diamine and N,N'-di-o-tolyl-phenylene diamine (EC 273-227-8; CAS 68953-84-4): developmental toxicity
- Silver (EC 231-131-3; CAS 7440-22-4): physical hazards, acute toxicity, STOT SE, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, hazardous to the aquatic environment

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the November restriction WG

RAC/59/2021/02 For information

9.2 Restriction Annex XV dossiers

- 1. Conformity check and key issues discussion
 - 1. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting

For discussion and agreement

- 2. Opinion development
 - Lead in outdoor shooting and fishing third draft opinion
 For discussion/agreement (appropriate sections)
 - 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo-[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene ("Dechlorane Plus") – second draft opinion

For agreement (appropriate sections)

2,4-dinitrotoluene – first draft opinion
 For agreement (appropriate sections)

Item 10 – Authorisation

10.1 General authorisation issues

- 1. Update on incoming/future applications
- 2. Revision of A-listing criteria

RAC/59/2021/03 For discussion and agreement

3. Report from the October AFA Working Group and the Capacity Building Seminar on Assessment of human biomonitoring data

> RAC/59/2021/04 For information/discussion

10.2 Authorisation applications

1. Discussion on key issues

1. 3 applications for authorisation (chromium trioxide, MOCA) and 2 review reports (TCE) from August 2021 submission window

For discussion

10.3 Agreement on draft opinions

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

- 1. 231_CT_Kesseboehmer (1 use)
- 2. 232_DtC_Monroe (1 use)
- 3. 233_CT_Betz-Chrom (1 use)
- 4. 234_CT_Kwalter (use 1 only)
- 5. 235_CA_Neoperl (1 use)

For agreement

- 2. Draft opinions for agreement with plenary debate
 - 1. 234_CT_Kwalter (use 2 only)

For discussion and agreement

10.4 Adoption of opinions

1. 221_CT_SD_USSK (1 use)

For discussion and adoption

Item 11 – AOB

Item 12 – Minutes of RAC-59

12.1 Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-59

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-59

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

Monday 22 November 2021: 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 5 New Declaration of Interest tool demo
- Item 9 Restrictions

Tuesday 23 November 2021: Morning session

Item 9 – Restrictions

Tuesday 23 November 2021: Afternoon session

Item 6 – Article 77(3)c

Wednesday 24 November 2021: Morning session

Item 10 – Authorisation applications

Wednesday 24 November 2021: Afternoon session

- Item 10 Authorisation applications
- Item 9 Restrictions
- Item 8 CLH dossiers

Thursday 25 November 2021: Morning session

Item 8 – CLH dossiers

Thursday 25 November 2021: Afternoon session

Item 8 – CLH dossiers

Friday 26 November 2021: Morning session

- Item 8 CLH dossiers
- Item 11 AOB
- Item 12 Summary records