

Final Agenda 58th meeting of the Committee for Risk Assessment

7-9 September and 13-16 September 2021

Virtual meeting

7 September starts at 14.00 16 September ends at 17.30

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/58/2021

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
- 5.2 RAC 59 and RAC 60 WG calendar and timings
- 5.3 RAC co-opted members The Secretariat will update you on the candidates recommended by the RAC co-opted members selection panel; you will then be asked to co-opt them to the Committee.

RAC/58/2021/01 (Restricted) For agreement Closed session

For information

For information

5.4 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/58/2021/02 (Restricted) For agreement Closed session

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

6.1 Classification for environmental toxicity of lead

For discussion and 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 July CLH WG

RAC/58/2021/03 (RAC WG/CLH/R/2/2021)

For information

8.2 CLH dossiers

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

- Clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2nitroguanidine (EC: 433-460-1; CAS: 210880-92-5): acute oral toxicity, STOT SE, hazardous to the aquatic environment
- Hydrogen sulphide, hydrogen sulfide (EC: 231-977-3; CAS: 7783-06-4): physical hazards, acute inhalation toxicity
- Resorcinol; 1,3-benzenediol (EC: 203-585-2; CAS: 108-46-3): acute toxicity via all routes, skin sensitisation, STOT SE, hazardous to the aquatic environment
- 1-phenylethan-1-one (1-phenylethylidene)hydrazone (EC: 211-979-0;
 CAS: 729-43-1): skin sensitisation
- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (EC: 278-355-8; CAS: 75980-60-8): skin sensitisation, reproductive toxicity
- Sulphur dioxide (EC: 231-195-2; CAS: 7446-09-5): physical hazards, acute inhalation toxicity
- Diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea (EC: 206-354-4; CAS: 330-54-1): acute toxicity via all routes, germ cell mutagenicity
- 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7 dimethylxanthylium chloride; Basic Red 1 (EC: 213-584-9; CAS: 989-38 8): acute oral toxicity, serious eye damage/eye irritation

- Picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[(a,a,a-trifluoro-m-tolyl)oxy]picolinanilide (EC: -; CAS: 137641-05-5): acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, carcinogenicity, reproductive toxicity, STOT SE
- tetrabromobisphenol-A (TBBPA); 2,2',6,6'-tetrabromo-4,4'isopropylidenediphenol; (EC: 201-236-9; CAS: 79-94-7): STOT RE, germ cell mutagenicity
- Dibutyltin maleate (EC: 201-077-5; CAS: 78-04-6): acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, germ cell mutagenicity
- Dibutyltin oxide (EC: 212-449-1; CAS: 818-08-6): acute dermal toxicity, serious eye damage/eye irritation
- Benzyl alcohol (EC: 202-859-9; CAS: 100-51-6): serious eye damage/eye irritation

2. Hazard classes for agreement [with plenary debate]

- Cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide (EC: 261-043-0; CAS: 57966-95-7)
- 2. Sulphur dioxide (EC: 231-195-2; CAS: 7446-09-5)
- Diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea (EC: 206-354-4; CAS: 330-54-1)
- 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7dimethylxanthylium chloride; Basic Red 1 (EC: 213-584-9; CAS: 989-38-8)
- Picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[(a,a,a-trifluoro-m-tolyl)oxy]picolinanilide (EC: -; CAS: 137641-05-5)
- 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A (TBBPA) (EC: 201-236-9; CAS: 79-94-7)
- 7. Dibutyltin maleate (EC: 201-077-5; CAS: 78-04-6)
- 8. Dibutyltin oxide (EC: 212-449-1; CAS: 818-08-6)
- 9. Benzyl alcohol (EC: 202-859-9; CAS: 100-51-6)
- 10. Dimethylpropylphosphonate (EC: 242-555-3; CAS: 18755-43-6): germ cell mutagenicity, reproductive toxicity *(discussed in the CLH WG)*
- 11. Clothianidin(ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3methyl-2-nitroguanidine (EC: 433-460-1; CAS: 210880-92-5): reproductive toxicity (discussed in the CLH WG)
- 12. [1] Lithium carbonate; [2] lithium chloride; [3] lithium hydroxide (EC: [1] 209-062-5; [2] 231-212-3; [3] 215-183-4; CAS: [1] 554-13-2; [2] 7447-41-8; [3] 1310-65-) (discussed in the CLH WG)
- 13. Nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof] (EC: 500-315-8; 500-024-6; 500-045-0; 500-209-1; 248-762-5; 243-816-4; 248-291-5; and others; CAS: 127087-87-0; 9016-45-9; 26027-38-3; 68412-54-4; 27986-36-3; 20427-84-3; 27176-93-8; 1119449-38-5 and others) (discussed in the CLH WG)

- 14. Nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC: 230-770-5; 248-743-1; 247-555-7; 248-293-6 and others; CAS: 127087-87-0; 9016-45-9; 7311-27-5; 27942-27-4; 26264-02-8; 27177-05-5; 14409-72-4 and others) (discussed in the CLH WG)
- 15. Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC: -; CAS: 127087-87-0; 9016-45-9 and others) (discussed in the CLH WG)

For discussion and adoption

Item 9 – Restrictions

9.1 **General restriction issues** 1.—The role of the opinion for the decision-making phase For discussion 2. Report from the August restriction WG RAC/58/2021/04 (RAC WG/REST/R/2/2021) For information 9.2 **Restriction Annex XV dossiers** 1. Conformity check and key issues discussion 1. 2,4-dinitrotoluene [to be confirmed] For discussion and agreement 2. Opinion development 1. Substances in single-use baby diapers – third draft opinion

- For discussion and adoption
- Lead in outdoor shooting and fishing second draft opinion
 For discussion

Item 10 – Authorisation

10.1 General authorisation issues

- 1. Update on incoming/future applications
- 2. Renewal of the Mandate for RAC Working Group on AfA

RAC/58/2021/05 For information/discussion

3. Assessing representativeness of downstream users information (this item will be discussed in a joint session with SEAC)

For discussion

10.2 Authorisation applications

1. Discussion on key issues

1. 6 applications for authorisation (chromium trioxide, sodium dichromate, 4-tert-OPnEO, 4-NPnEO) from May 2021 submission window

For discussion

10.3 Agreement on draft opinions

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

(no A-list opinions in this meeting)

2. Draft opinions for agreement with plenary debate

- 1. 227_RR1_TCE_ROQUETTE (1 use)
- 2. 228_CT_Eaton (1 use)
- 3. 229_RR1_CT_Volta (1 use)

For discussion and agreement

10.4 Adoption on opinions

No opinions to adopt.

For discussion and adoption

Item 11 – AOB

Item 12 – Minutes of RAC-58

12.1 Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-58

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-58 – WEEK 1

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

Tuesday 7 September 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 9 Restrictions

Wednesday 8 September 2021: Morning session

Item 9 – Restrictions

Wednesday 8 September 2021: Afternoon session

- Item 6 Article 77(3)c
- Item 5 Administrative agenda points (closed session)
- Item 10 Optional social event: Joint AfA RAC-58 plenary session with SEAC

Thursday 9 September 2021: Morning session

Item 10 – Authorisation applications

Thursday 9 September 2021: Afternoon session

- Item 10 Authorisation applications
- Item 5 Administrative agenda points (closed session)

Friday 10 September 2021: Morning session

- Item 10 Authorisation applications
- Item 5 Administrative agenda points
- Item 11 AOB
- Item 12 Summary records

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-58 – WEEK 2

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

Monday 13 September 2021: Morning session

- Item 1 Welcome and Apologies
- Item 3 Declarations of conflicts of interest to the Agenda
- Item 8 CLH dossiers

Tuesday 14 September 2021: Morning session

Item 8 - CLH dossiers

Tuesday 14 September 2021: Afternoon session

Item 8 – CLH dossiers

Wednesday 15 September 2021: Morning session

Item 8 – CLH dossiers

Wednesday 15 September 2021: Afternoon session

Item 8 – CLH dossiers

Thursday 16 September 2021: Morning session

Item 8 – CLH dossiers

Thursday 16 September 2021: Afternoon session

- Item 8 CLH dossiers
- Item 11 AOB Remaining issues
- Item 12 Summary records
- Item 4 Appointment of rapporteurs (closed session)

Social event (optional)
