

Final Agenda 57th meeting of the Committee for Risk Assessment

31 May-3 June and 8-10 June 2021

Virtual meeting

31 May starts at 14.00 10 June ends at 17:30

Times are Helsinki times

Item 1 - Welcome and Apologies

Item 2 - Adoption of the Agenda

RAC/A/57/2021 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. CLH: Procedure for agreement seeking

For agreement RAC/57/2021/01

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

7.1 Adoption of opinions: Asbestos – final draft opinion

For discussion and adoption

Item 8 - Harmonised classification and labelling (CLH)

8.1. Report from the 27/28 April 2021 RAC CLH WG

For information/discussion RAC/57/2021/02

(RAC WG/CLH/R/1/2021)

8.2. CLH dossiers

8.2.1 Hazard classes for agreement without plenary debate

- Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC: -; CAS: -): germ cell mutagenicity, reproductive toxicity (discussed in the CLH WG)
- Sodium chlorate (EC: 231-887-4; CAS: 7775-09-9): acute oral toxicity, hazardous to the aquatic environment (discussed in the CLH WG)
- Potassium chlorate (EC: 223-289-7; CAS: 3811-04-9): acute oral and inhalation toxicity, hazardous to the aquatic environment (discussed in the CLH WG)
- Triethylamine (EC: 204-469-4; CAS: 121-44-8): acute inhalation and dermal toxicity, serious eye damage/eye irritation (discussed in the CLH WG)
- Di-n-butylamine (EC: 203-921-8; CAS: 111-92-2): acute oral, dermal and inhalation toxicity, skin corrosion/irritation, serious eye damage/eye irritation, STOT SE (discussed in the CLH WG)
- Difenoconazole (ISO): physical hazards, acute dermal and inhalation toxicity, skin sensitisation, skin corrosion/irritation, serious eye damage/eye irritation, germ cell mutagenicity, STOT SE, hazardous to the aquatic environment
- 4-Nitrosomorpholine: carcinogenicity
- N,N-dimethyl-p-toluidine: acute toxicity via all routes, germ cell mutagenicity

- Metribuzin (ISO): acute toxicity via all routes, skin irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE
- Lithium carbonate; lithium chloride; lithium hydroxide: germ cell mutagenicity, carcinogenicity

8.2.2 Hazard classes for agreement with plenary debate

- 8.2.2.1 Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC: -; CAS: -) developmental toxicity
- 8.2.2.2 Triethylamine (EC: 204-469-4; CAS: 121-44-8) acute oral toxicity
- 8.2.2.3. Difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1*H*-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether (EC 601-613-1; CAS 119446-68-3)
- 8.2.2.4. 4-Nitrosomorpholine (EC: 627-564-6; CAS: 59-89-2)
- 8.2.2.5. N,N-dimethyl-*p*-toluidine (EC: 202-805-4; CAS: 99-97-8)
- 8.2.2.6. Metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4*H*)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one (EC: 244-209-7; CAS: 21087-64-9)
- 8.2.2.7. [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-)
- 8.2.2.8. 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)
- 8.2.2.9. 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)
- 8.2.2.10. 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)

For discussion and adoption

Item 9 - Restrictions

9.1 General restriction issues

9.1.1. Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals

For information/discussion

9.1.2. Update on the Restrictions Task Force meeting (29/4)

For information/discussion

9.1.3. Report from the 11/12 May 2021 RAC REST WG

RAC/57/2021/03

(RAC WG/REST/R/1/2021)

For information/discussion

9.2 Restriction Annex XV dossiers

- 9.2.1 Conformity check and key issues discussion
 - 9.2.1.1 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" $^{\text{TM}}$)

For discussion and agreement

- 9.2.2 Opinion development
 - 9.2.2.1 Undecafluorohexanoic acid (PFHxA), its salts and related substances fourth draft opinion

For discussion and adoption

9.2.2.2 Substances in single-use baby diapers – second draft opinion

For discussion/agreement

9.2.2.3 Lead and its compounds in ammunition and fishing tackles – first draft opinion

For discussion/agreement

Item 10 - Authorisation

10.1 General authorisation issues

10.1.1. Update on incoming/future applications

For information/discussion

10.1.2. Report from RAC WG on AfAs during May 2021 meeting

For information/discussion RAC/57/2021/04

For information/discussion

10.1.4. Evaluation of review reports

For information/discussion RAC/57/2021/05

10.2 Authorisation applications

10.2.1. Discussion on key issues

10.2.1.1. 5 applications for authorisation (chromium trioxide, chromic acid, dichromium tris(chromate))) from February 2021 submission window

For discussion

10.3 Agreement on draft opinions

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

- 10.3.1.1 218_CT_DOURECA (2 uses)
- 10.3.1.2 219_CT_HusqvarnaAB (1 use)
- 10.3.1.3 220_CT_SRG Global (2 uses)
- 10.3.1.4 225_MOCA_Luc (2 uses)
- 10.3.1.5 226_OPE_LETI (1 use)

10.3.2. Draft opinions for agreement with plenary debate

- 10.3.2.1. 221_CT_SD_USSK (1 use)
- 10.3.2.2. 222_RR1_SD_Colle (1 use)
- 10.3.2.3. 223_RR1_EDC_Lanxess (1 use)
- 10.3.2.4. 224_RR1_EDC_Eurenco (1 use)

For discussion and agreement

10.4 Adoption of opinions

- 10.4.1. 196_OPE_Becton (1 use)
- 10.4.2. 198_OPE_Zoetis (4 uses; comments on Use 4 only)
- 10.4.3. 199_OPE_Biokit (2 uses; comments on Use 2 only)
- 10.4.4. 203_OPE_NPE_Qiagen (4 uses)

For discussion and adoption

Item 11 - AOB

11.1. Update form the ECHA legal services on the current legal cases

For information

Item 12 - Minutes of RAC-57

12.1 Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-57

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-57 - WEEK 1

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

Monday 31 May 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 11	- AOB
Item 7	- OEL

Tuesday 1 June 2021: Morning session

Item 9 - Restrictions

Tuesday 1 June 2021: Afternoon session

Item 7 – OEL
Item 9 – Restrictions

Wednesday 2 June 2021: Morning session

Item 9 - Restrictions

Wednesday 2 June 2021: Afternoon session

Item 9 – Restrictions

Item 10 - Authorisation applications

Thursday 3 June 2021: Morning session

Item 10 - Authorisation applications

Thursday 3 June 2021: Afternoon session

Item 10 - Authorisation applications

Item 12 - RAC-57A Summary Record adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-57 - WEEK 2

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

Tuesday 8 June 2021: Morning session

Item 1	 Welcome 	and	Apol	logies
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Item 3 - Declarations of conflicts of interest to the Agenda

Item 8 - CLH dossiers Item 6 - Art. 77(3)c

Tuesday 8 June 2021: Afternoon session

Item 8 - CLH dossiers

Wednesday 9 June 2021: Morning session

Item 8 - CLH dossiers

Wednesday 9 June 2021: Afternoon session

Item 8 - CLH dossiers

Thursday 10 June 2021: Morning session

Item 8 - CLH dossiers

Thursday 10 June 2021: Afternoon session

Item 8 - CLH dossiers Item 6 - Art. 77(3)c

Item 11 - AOB

Item 12 - RAC-57A Summary Record adoption

Item 4 - Appointment of rapporteurs

Social event (optional)
