

Final Agenda
53rd meeting of the Committee for Risk Assessment

1-5 June 2020
and
8-12 June 2020

Webex meeting

Monday 1 June starts at 14.00
Friday 5 June breaks at 18.00
Monday 8 June resumes at 14.00
Friday 12 June ends at 13.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/53/2020
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

- a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits

For agreement

Item 5 – Report from other ECHA bodies and activities

- a) RAC Work Plan for all processes

For information

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

- a) Classification for reproductive toxicity of DTPA-H5, DTPA-K5 and DTPA-Na5

For agreement

Item 7 – Health based exposure limits at the workplace

7.1 Health based exposure limits at the workplace

- a) Opinion development
- 1) Diisocyanates – final draft opinion
 - 2) Lead and its compounds – final draft opinion

For discussion and adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 CLH dossiers

A. Hazard classes for agreement without plenary debate (fast-track)

- Tellurium: germ cell mutagenicity
- Tellurium dioxide: germ cell mutagenicity
- Piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether: physical hazards, acute toxicity (all routes), skin sensitisation, skin corrosion/irritation, respiratory sensitisation, germ cell mutagenicity, reproductive toxicity, acute aquatic hazards, chronic aquatic hazards
- Trichlorosilane: pyrophoric liquids, substances which in contact with water emit flammable gases, acute oral toxicity, acute inhalation toxicity, eye damage/irritation
- Clofentezine (ISO); 3,6-bis(o-chlorophenyl)-1,2,4,5-tetrazine: physical hazards (explosive, flammable solid, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solid, corrosive to metals), acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, hazardous to the aquatic environment
- Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid: physical hazards (explosive, flammable solid, self-heating substances, pyrophoric solids, substances which in contact with water emit flammable gases, oxidising solid), acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment, hazardous to the ozone layer
- Fluopicolide: acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, aspiration hazard

B. Hazard classes for agreement with plenary debate

- 1) Tellurium
- 2) Tellurium dioxide
- 3) Piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether
- 4) Trichlorosilane
- 5) Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate; isobornyl acrylate
- 6) Clofentezine (ISO); 3,6-bis(o-chlorophenyl)-1,2,4,5-tetrazine
- 7) Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid
- 8) 2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol
- 9) Benzophenone
- 10) Fluopicolide
- 11) 2-Ethylhexanoic acid and its salts

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

- a) Opinion development
 - 1) Perfluorohexanoic acid – first draft opinion
 - 2) Calcium cyanamide in fertilisers – final draft opinion
 - 3) Microplastics – final draft opinion

For discussion

For discussion and adoption

Item 10 – Authorisation

10.1 General authorisation issues

- a) Update on incoming/future applications
- b) Report from RAC WG on AfAs during May 2020 meeting
- c) Renewal of the Mandate for RAC AfA WG
- d) ECHA information about the request to set DNEL for Trixylyl phosphate (TXP) for the Authorisation process

RAC/53/2020/01

For discussion and agreement

10.2 Authorisation applications

- a) Discussion on key issues
 - 1) 12 applications for authorisation and a review report from February 2020 submission window (OPE/NPE, Cr(VI), TCE)

For discussion

b) Agreement on opinions

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

- 1) 149_CTPht_Nalon (1 use)
- 2) 152_CTPht_AO_RainCarbon (1 use)
- 3) 150_CTPht_AO_Koppers (1 use)
- 4) 170_OPE_DiaSorin (1 use)
- 5) 172_OPE_DIAGAST (1 use)
- 6) 160_OPE_Merck_2 (1 use)
- 7) 165_OPE_bioMerieux_2 (1 use)
- 8) 182_NPE_Abbott (1 use)
- 9) 163_OPE_Rentschler (1 use)
- 10) 156_OPE_Hospira (1 use)
- 11) 186_OPE_NPE_Beckman (5 uses)
- 12) 185_OPE_NPE_Idexx (3 uses)
- 13) 190_OPE_TEVA (1 use)

B. Draft opinions for agreement with plenary debate

- 1) 154_OPE_Siemens_1 (1 use)
- 2) 162_OPE_LFB (1 use)
- 3) 164_OPE_Baxter (1 use)
- 4) 180_OPE_NPE_Bio-Rad (4 uses)
- 5) 184_OPE_Lilly (1 use)
- 6) 187_OPE_AGC (2 uses)
- 7) 189_OPE_Lonza (1 use)
- 8) 191_NPE_Sekisui (1 use)
- 9) 192_OPE_Pfizer_2 (1 use)

For discussion and agreement

C. Adoption of final opinions

- 1) OPE_Sebia (3 uses)
- 2) NPE_Sebia (1 use)
- 3) OPE_Stago (2 uses)
- 4) ~~OPE_bioMerieux (3 uses)~~
- 5) SC_Ariston (1 use)

For discussion and adoption

Item 11 – AOB

Item 12 – Minutes of RAC-53

- a) Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-53

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-53 – 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 1 June 2020: 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 7 – Health based exposure limits at the workplace

Tuesday 2 June 2020: Morning session

- Item 7 – Health based exposure limits at the workplace
- Item 9 – Restrictions

Tuesday 2 June 2020: Afternoon session

- Item 9 – Restrictions

Wednesday 3 June 2020: Morning session

- Item 9 – Restrictions

Wednesday 3 June 2020: Afternoon session

- Item 9 – Restrictions

Thursday 4 June 2020: Morning session

- Item 9 – Restrictions

Thursday 4 June 2020: Afternoon session

- Item 10 – Authorisation applications

Friday 5 June 2020: Morning session

- Item 10 – Authorisation applications

Friday 5 June 2020: Afternoon session

- Item 10 – Authorisation applications

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-53 – 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 8 June 2020: Afternoon session

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

Tuesday 9 June 2020: Morning session

- Item 8 – CLH dossiers

Tuesday 9 June 2020: Afternoon session

- Item 8 – CLH dossiers

Wednesday 10 June 2020: Morning session

- Item 8 – CLH dossiers

Wednesday 10 June 2020: Afternoon session

- Item 8 – CLH dossiers

Thursday 11 June 2020: Morning session

- Item 8 – CLH dossiers

Thursday 11 June 2020: Afternoon session

- Item 6 – Request under Article 77(3)(c)-
- Item 11 – AOB
- Item 4 – Appointment of rapporteurs
- Item 12 – Minutes of RAC-53

Friday 12 June 2020: Morning session

- Item 8 – CLH dossiers