

Provisional Draft Agenda
54th meeting of the Committee for Risk Assessment

8-9 September
and
14-17 September 2020

Virtual meeting

Tuesday 8 September starts at 14.00
Wednesday 9 September breaks at 18.30
Monday 14 September resumes at 14.00
Thursday 17 September ends at 17.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/54/2020
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

- b) 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 stakeholder's. You

will be invited to agree on the updated list of the accredited stakeholder organisations to RAC for this year.

For agreement

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

- 1) DNEL development for trixylyl phosphate

For agreement

Item 7 – Health based exposure limits at the workplace

No items to discuss at this meeting.

Item 8 – Harmonised classification and labelling (CLH)

8.1 CLH dossiers

A. Hazard classes for agreement without plenary debate (fast-track) (To be added later)

B. Hazard classes for agreement with plenary debate

- 1) Trimethylolpropane triacrylate
- 2) 4,4'-oxydi(benzenesulphonohydrazide)
- 3) Toluene-4-sulphonohydrazide
- 4) N-(2-nitrophenyl)phosphoric triamide
- 5) 1,3-bis(1-isocyanato-1-methylethyl)benzene
- 6) 1,3-bis(isocyanatomethyl)benzene
- 7) 2,4,6-triisopropyl-m-phenylene diisocyanate
- 8) 1,5-naphthylene diisocyanate
- 9) Cumene
- 10) Divanadium pentaoxide; vanadium pentoxide
- 11) Theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione
- 12) Barium diboron tetraoxide
- 13) Dibutyltin bis(2-ethylhexanoate)
- 14) Dibutyltin di(acetate)
- 15) Quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

- a) Opinion development
 - 1) Perfluorohexanoic acid – second draft opinion

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

- a) New AfAs and review reports (RRs) submitted in the August 2020 submission window
- b) Upcoming AfAs, RRs and Substitution Plans
- c) Report from RAC WG on AfAs during July 2020 meeting

For information/discussion

10.2 Authorisation applications

- a) Discussion on key issues
 - 1) 6 applications for authorisation from May 2020 submission window (Cr(VI), diglyme)

For discussion

- b) Agreement on draft opinions

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

- 1) To be added

B. Draft opinions for agreement with plenary debate

- 1) 164_OPE_Baxter (1 use)
- 2) 194_OPE_Yposkesi (1 use)
- 3) 195_OPE_IL (1 use)
- 4) 200_OPE_RSI (1 use)
- 5) 201_OPE_Vetter_2 (1 use)
- 6) 204_OPE_Merck_3 (2 uses)
- 7) 205_OPE_Pfizer (2 uses)
- 8) 206_OPE_Sanquin (1 use)

For discussion and agreement

C. Adoption on opinions

- 1) 147_CTPht_Bilbaina (1 use)
- 2) 148_CTPht_DEZA (1 use)
- 3) 153_CTPht_AO_Bilbana (1 use)
- 4) 155_OPE_Siemens_2 (5 uses)

- 5) 171_OPE_Wallac (2 uses)
- 6) 173_OPE_Sobi (1 use)
- 7) 175_OPE_Rousselot (1 use)
- 8) 181_OPE_NPE_Roche (Uses 2 and 4 only)

For discussion and adoption

Item 11 – AOB

Item 12 – Minutes of RAC-54

- a) Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-54

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-54 – 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 8 September 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 – Annual update of RAC accredited stakeholders' list
- Item 5 – RAC Work Plan for Restriction, Authorisation and C&L processes
- Item 9 – Restrictions

Wednesday 9 September 2020: Morning session

- Item 10 – Authorisation applications

Wednesday 9 September 2020: Afternoon session

- Item 10 – Authorisation applications
- Item 6 – Article 77(3)(c) requests
- Item 12 – Minutes of RAC-54

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-54 – 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 14 September 2020: Afternoon session

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

Tuesday 15 September 2020: Morning session

- Item 8 – CLH dossiers

Tuesday 15 September 2020: Afternoon session

- Item 8 – CLH dossiers

Wednesday 16 September 2020: Morning session

- Item 8 – CLH dossiers

Wednesday 16 September 2020: Afternoon session

- Item 8 – CLH dossiers

Thursday 17 September 2020: Morning session

- Item 8 – CLH dossiers

Thursday 17 September 2020: Afternoon session

- Item 8 – CLH dossiers
- Item 4 – Appointment of rapporteurs
- Item 12 – Minutes of RAC-54