

Final 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 –	We	Icome	and	Apo	logies
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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.

RAC/54/2020/01 Restricted For agreement

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

1) DNEL development for trixylyl phosphate

For discussion

2) Revision of derogations from proposed restrictions on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances; C9-C14 perfluorocarboxylic acids (C9-C14 PFCA), their salts and C9-C14 PFCA-related substances

For information

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)

- Trimethylolpropane triacrylate: germ cell mutagenicity, acute aquatic hazards, chronic aquatic hazards
- 4,4'-oxydi(benzenesulphonohydrazide): explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides, acute aquatic hazards, chronic aquatic hazards
- Toluene-4-sulphonohydrazide: explosives, flammable solids, selfreactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides
- N-(2-nitrophenyl)phosphoric triamide: STOT RE
- 1,3-bis(1-isocyanato-1-methylethyl)benzene: respiratory sensitisation, skin sensitisation
- 1,3-bis(isocyanatomethyl)benzene: respiratory sensitisation, skir sensitisation
- 2,4,6-triisopropyl-m-phenylene diisocyanate: respiratory sensitisation, skin sensitisation
- 1,5-naphthylene diisocyanate: skin sensitisation
- Cumene: reproductive toxicity
- Divanadium pentaoxide; vanadium pentoxide: acute oral toxicity, respiratory sensitisation, STOT RE
- Barium diboron tetraoxide: acute dermal toxicity

 Quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone: physical hazards, acute toxicity (via all routes), STOT SE, skin corrosion/irritation, serious eye damage/irritation, skin sensitisation, germ cell mutagenicity

B. Hazard classes for agreement with plenary debate

- 1) Trimethylolpropane triacrylate (EC: 239-701-3; CAS: 15625-89-5)
- 2) N-(2-nitrophenyl)phosphoric triamide (EC: 477-690-9; CAS: 874819-71-3)
- 3) 1,5-naphthylene diisocyanate (EC: 221-641-4; CAS: 3173-72-6)
- 4) Cumene (EC: 202-704-5; CAS: 98-82-8)
- 5) Divanadium pentaoxide; vanadium pentoxide (EC: 215-239-8; CAS: 58-55-9)
- 6) Theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione (EC: 200-385-7; CAS: 58-55-9)
- 7) Barium diboron tetraoxide (EC: 237-222-4; CAS: 13701-59-2)
- 8) Dibutyltin bis(2-ethylhexanoate) (EC: 220-481-2; CAS: 2781-10-4)
- 9) Dibutyltin di(acetate) (EC: 213-928-8; CAS: 1067-33-0)
- 10) Quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone (EC: 220-529-2; CAS: 2797-51-5)

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

RAC/53/2020/02 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)

- b) Agreement on draft opinions
- A. Draft opinions for agreement without plenary debate (A-list)
 - 1) 164_OPE_Baxter (1 use)
 - 2) 194_OPE_Yposkesi (1 use)
 - 3) 195_OPE_IL (1 use)
 - 4) 201 OPE Vetter 2 (1 use)
 - 5) 204_OPE_Merck_3 (use 1)
 - 6) 205_OPE_Pfizer (2 uses)
 - 7) 206_OPE_Sanquin (1 use)

For agreement

- B. Draft opinions for agreement with plenary debate
 - 8) 200_OPE_RSI (1 use)
 - 9) 204_OPE_Merck_3 (use 2)

For discussion and agreement

- C. Adoption on opinions
 - 1) 155_OPE_Siemens_2 (Uses 4 and 5)
 - 2) 171_OPE_Wallac (2 uses)
 - 3) 173 OPE Sobi (1 use)
 - 4) 175_OPE_Rousselot (1 use)
 - 5) 181_OPE_NPE_Roche (Uses 2 and 4 only)

For discussion and adoption

Item 11 - AOB

- 1) COM request for RAC's view on a proposal by DE in Caracal to add a new note to the 17th ATP regarding the inclusion of all members of a group for the purpose of mixture calculations
- 2) Presentation/video by Industry on metal processing

Item 12 - Minutes of RAC-54

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

For adoption