9 September 2019
RAC/A/50/2019

Final Agenda
50th meeting of the Committee for Risk Assessment

9 - 13 September 2019
and
16 – 20 September 2019

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 9 September starts at 14.00
Friday 13 September breaks at 13.00
Monday 16 September resumes at 14.00
Friday 20 September ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/50/2019
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, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests

Item 5 – Report from other ECHA bodies and activities

a) Report on RAC 49 action points, written procedures and update on other ECHA bodies

RAC/50/2019/01
Room document
For information

b) RAC workplan for all processes

For information

c) 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/50/2019/02
(restricted)
For agreement

Item 6 – Harmonised classification and labelling (CLH)

6.1 General CLH issues

a) CLP– suggested changes in the timing of the Appointment of rapporteurs

RAC/50/2019/03
For information

6.2 CLH dossiers

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

4-methylpentan-2-one: acute toxicity (all routes of exposure), serious eye damage / eye irritation, skin corrosion / irritation, skin sensitisation, STOT RE, STOT SE 3 (narcotic effects), germ cell mutagenicity, toxicity to reproduction, aspiration hazard, EUH066

trinexapac-ethyl (ISO): environmental hazards

clomazone (ISO): acute toxicity (all routes of exposure), serious eye damage /eye irritation, skin corrosion / irritation, skin or respiratory sensitisation, STOT RE, germ cell mutagenicity, carcinogenicity, aspiration hazard, environmental hazards

citric acid: physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity (all routes of exposure), serious eye damage / eye irritation, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, STOT RE, environmental hazards

desmedipham (ISO): environmental hazards

phenmedipham (ISO): environmental hazards

triticonazole: acute toxicity (dermal and inhalation routes of exposure), STOT SE, skin corrosion/irritation, serious eye damage/irritation, respiratory sensitisation and skin sensitisation, environmental hazards

trifloxystrobin (ISO): environmental hazards

esfenvalerate (ISO): acute toxicity (oral route of exposure), skin sensitisation, germ cell mutagenicity, environmental hazards

ethametsulfuron-methyl (ISO): acute toxicity (all routes of exposure), STOT SE, STOT RE , serious eye damage / eye irritation, skin corrosion /irritation, skin

sensitisation, germ cell mutagenicity, carcinogenicity, environmental hazards, hazardous to the ozone layer

emamectin benzoate (ISO): physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids), acute toxicity (all routes of exposure), serious eye damage / eye irritation, skin corrosion / irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT RE (except SCLs), environmental hazards

B. Hazard classes for agreement with plenary debate

1) Methyl salicylate
2) 4-methylpentan-2-one
3) Clomazone (ISO)
4) Citric acid
5) Desmedipham
6) Phenmedipham (ISO)
7) Triticonazole
8) Boric acid [1]; Diboron trioxide [2]; Tetraboron disodium heptaoxide, hydrate [3]; Disodium tetraborate, anhydrous [4]; Orthoboric acid sodium salt [5]; Disodium tetraborate decahydrate [6]; Disodium tetraborate pentahydrate [7]
9) Trifloxystrobin(ISO)
10) Esfenvalerate (ISO)
11) ethametsulfuron-methyl (ISO)
12) dimethomorph (ISO)
13) Emamectin benzoate (ISO)
14) 1,2-epoxy-4-epoxyethylcyclohexane
15) mecoprop-P (ISO)

For discussion and adoption

Item 7 – Restrictions

7.1 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Calcium cyanamide in fertilisers

For agreement

b) Opinion development

1) Skin sensitisers in textile – first draft opinion

2) Perfluorohexane-1-sulphhonic acid, its salts and related substances – first draft opinion
3) Siloxanes (D4, D5 and D6) – second draft opinion
4) Formaldehyde and formaldehyde releasers – second draft opinion
5) Microplastics – second draft opinion

For discussion

6) *N*,*N*-dimethylformamide- final draft opinion
7) Cobalt salts – final draft opinion

For adoption

Item 8 – Authorisation

8.1 General authorisation issues

a) Update on incoming/future applications

b) OPnEO – consideration of approaches to risk assessment

For information/discussion

8.2 Authorisation applications

a) Discussion on key issues
   1. 27 applications for authorisation from May 2019 submission window (OPE/NPE, CTPht, Cr(VI))

For discussion

b) Agreement on draft opinions

1. CT_TES (1 use)
2. ~~SC_Ariston (1 use)~~ – removed from the agenda
3. ~~SD_Bussi (1 use)~~ – removed from the agenda
4. CTPht_Ariane (1 use)
5. OPE_Boehringer (1 use)
6. OPE_Ortho (2 uses)

For discussion and agreement

Item 9 – AOB

AfA, a horizontal issue entitled "Qualification of risks to the environment for 4-ter-OP"

RAC/50/2019/04

For discussion and agreement

Item 10 – Action points and main conclusions of RAC-50

Table with Conclusions and Action points from RAC-50

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-50 – 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 9 September: 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 – Restrictions

Evening session

Tuesday 10 September: Morning session

Item 7 – Restrictions

Tuesday 10 September: Afternoon session

Item 7 – Restrictions

Item 8 – Authorisation applications

Wednesday 11 September: Morning session

Item 7 – Restrictions

Wednesday 11 September: Afternoon session

Item 7 – Restrictions

Evening session

Thursday 12 September: Morning session

Item 8 – Authorisation applications

Thursday 12 September: Afternoon session

Item 8 – Authorisation applications

Friday 13 September: Morning session

Item 8 – Authorisation applications

Item 5 – Annual update of RAC accredited stakeholders' list

Item 9 - AOB

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-50 – 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 16 September: Afternoon session

Item 1 – Welcome and Apologies

Item 3 – Declarations of conflicts of interest to the Agenda

Item 6 – CLH dossiers

Tuesday 17 September: Morning session

Item 6 – CLH dossiers

Tuesday 17 September: Afternoon session

Item 6 – CLH dossiers

Wednesday 18 September: Morning session

Item 6 – CLH dossiers

Wednesday 18 September: Afternoon session

Item 6 – CLH dossiers

Evening: Formal dinner

Thursday 19 September: Morning session

Item 6 – CLH dossiers

Thursday 19 September: Afternoon session

Item 6 – CLH dossiers

Friday 20 September: Morning session

Item 4 – Appointment of rapporteurs

Item 6 – General CLH issues

Item 6 – CLH dossiers

Item 9 – AOB

Item 10 – Action points and main conclusions of RAC-50