

Final Agenda
48th meeting of the Committee for Risk Assessment

6 - 8 March 2019
and
12 - 15 March 2019

ECHA Conference Centre (Annankatu 18, Helsinki)

Wednesday 6 March starts at 09.00
Friday 8 March breaks at 13.00
Tuesday 12 March resumes at 14.00
Friday 15 March ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/48/2019
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

For agreement

Item 5 – Report from other ECHA bodies and activities

- a) Report on RAC 47 action points, written procedures and update on other ECHA bodies

RAC/48/2019/01
(room document)
For information

- b) RAC workplan for all processes

For information

- c) Revision of Rules of Procedure

RAC/48/2019/02
For agreement

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

Copper compounds (M-factor)

For agreement

Item 7 – Requests under Article 95 (3)

None

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

- a) Feedback from the workshop on CLH-related human health issues and information on the expert group on T25/SCLs for carcinogens

8.2 CLH dossiers

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

Prothioconazole (ISO): physical hazards (as open for the public consultation), acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, STOT RE, environmental hazards

Thiophanate-methyl (ISO): physical hazards (as open in the public consultation), acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT RE

Tolpyralate: physical hazards (as open in the public consultation), acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, respiratory / skin sensitisation, STOT SE, environmental hazards

p-cymene: physical hazard (flammable liquids), acute toxicity, skin corrosion / irritation, germ cell mutagenicity, STOT SE, STOT RE, aspiration hazard

d-limonene: physical hazard (flammable liquids), aspiration hazard

alpha-terpinene: physical hazard (flammable liquids), acute oral toxicity, germ cell mutagenicity, aspiration hazard

1,2,4-triazole: acute oral toxicity

sedaxane: physical hazards, acute toxicity, skin corrosion/ irritation, serious eye damage / eye irritation, respiratory / skin sensitisation, germ cell mutagenicity, STOT SE, STOT RE, aspiration hazard

tolclofos-methyl (ISO): physical hazards (as open in the public consultation), acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, STOT SE, environmental hazards

mancozeb (ISO): germ cell mutagenicity

benzyl salicylate: skin sensitisation

pydiflumetofen: skin sensitisation

B. Hazard classes for agreement with plenary debate

- 1) 1,4-dioxane
- 2) flumioxazin (ISO)
- 3) prothioconazole (ISO)
- 4) thiophanate-methyl (ISO)
- 5) tolpyralate
- 6) p-cymene
- 7) d-limonene
- 8) alpha-terpinene
- 9) 1,2,4-triazole
- 10) sedaxane
- 11) tolclofos-methyl (ISO)
- 12) mancozeb (ISO)
- 13) benzyl salicylate
- 14) trinickel disulfide; nickel subsulfide [1]; heazlewoodite [2]
- 15) pydiflumetofen (*HH hazards*)

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

- a) General items:
 - 1) Report from Restrictions Task Force meeting
 - 2) Update of the opinion development procedure

For information

RAC/48/2019/03

For information

- b) Conformity check and key issues discussion
 - 1) Formaldehyde
 - 2) D4/D5/D6
 - 3) Microplastics

For agreement

- c) Opinion development
 - 1) *N,N*-dimethylformamide – first draft opinion
 - 2) Cobalt salts – first draft opinion

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

- a) Update on incoming/future applications
For information
- b) Working group on application for authorisation
RAC/48/2019/04
For agreement
- c) Update on the approach of evaluation of the upcoming applications for authorisation for environmental endocrine disruptors (octyl- and nonylphenol ethoxylates)
For information/discussion

10.2. Authorisation applications

- a) Discussion on key issues
 - 1. Five applications for authorisation from the November 2018 submission window (chromium trioxide)*For discussion*

10.3. Review reports

- a) Agreement of draft opinions
 - 1. RR1_TCE_Spolana (1 use)*For discussion and agreement*

Item 11 – AOB

- a) RAC consultation on ECHA Guidance Appendix to R.8-17 'Guidance for proposing Occupational Exposure Limits'
 - b) Court cases involving RAC opinions
 - c) Training session on INTERACT project
- For information/discussion*

Item 12 – Action points and main conclusions of RAC-48

Table with Conclusions and Action points from RAC-48

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-48

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

WEEK 1

Wednesday 6 March: Morning 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 9 - Restrictions

Wednesday 6 March: Afternoon session

- Item 9 - Restrictions
- Item 11 - AOB

Thursday 7 March: Morning session

- Item 9 - Restrictions
- Item 10 - Authorisation applications

Thursday 7 March: Afternoon session

- Item 5 - Revised Rules of Procedure
- Item 10 - General AfA issues
- Item 8 - CLH dossiers

Friday 8 March: Morning session

- Item 8 - CLH dossiers

WEEK 2

Tuesday 12 March: Afternoon session

- Item 8 - CLH dossiers

Wednesday 13 March: Morning session

- Item 8 - CLH dossiers

Wednesday 13 March: Afternoon session

- Item 8 - CLH dossiers
- Item 11 - AOB

Thursday 14 March: Morning session

- Item 8 - CLH dossiers

Thursday 14 March: Morning session

- Item 8 - CLH dossiers
- Item 6 - Request under Article 77.3.c

Friday 15 March: Morning session

- Item 4 - Appointment of rapporteurs
- Item 8 - CLH dossiers
- Item 11 - AOB