

Final Draft Agenda
51st meeting of the Committee for Risk Assessment

25-28 November 2019
and
3 December – 5 December 2019

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 25 November starts at 14.00
Thursday 28 November breaks at 13.00
Tuesday 3 December resumes at 09.00
Thursday 5 December ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/51/2019
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, evaluation of occupational exposure limits

For agreement

Item 5 – Report from other ECHA bodies and activities

- a) Report on RAC 50 action points, written procedures and update on other ECHA bodies

RAC/51/2019/01
Room document
For information

- b) RAC workplan for all processes

For information

- c) Revised rules of procedure

RAC/51/2019/02
For agreement

Item 6 – Health based exposure limits at the workplace

- a) Discussion on key issues
1) Lead and its compounds
2) Diisocyanates

For discussion

Item 7 – Harmonised classification and labelling (CLH)

7.1 General CLH issues

7.2 CLH dossiers

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

- 24-epibrassinolide: physical hazards (explosives, flammable solids, pyrophoric solids, self-heating substances, oxidising solids), human health hazards
- carbendazim (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), skin sensitisation, hazards to the aquatic environment
- silanamine: physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid, substance or mixture corrosive to metals), acute toxicity (dermal and inhalation routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, hazards to the aquatic environment
- trinexapac-ethyl (ISO): physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising liquid, oxidising solid), acute toxicity, STOT SE, skin corrosion/irritation, serious eye damage/irritation, germ cell mutagenicity, carcinogenicity
- 1,4-dimethylamine: physical hazards (explosive, flammable gas, flammable liquid, self-reactive substance or mixture, pyrophoric liquid, substance or

mixture which in contact with water emits flammable gas, oxidising liquid), acute toxicity (dermal and inhalation routes of exposure), skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, STOT SE, STOT RE, hazards to the aquatic environment

- imazamox (ISO): hazards to the aquatic environment
- 3-methylpyrazole: acute oral toxicity, skin corrosion / irritation, serious eye damage / eye irritation

B. Hazard classes for agreement with plenary debate

- 1) 24-epibrassinolide
- 2) acetamiprid (ISO)
- 3) cypermethrin (ISO)
- 4) tetrafluoroethylene
- 5) thiamethoxam (ISO)
- 6) silanamine
- 7) trinexapac-ethyl (ISO) (human health hazards only)
- 8) 1,4-dimethylnaphthalene
- 9) imazamox (ISO)
- 10) 3-methylpyrazole

For discussion and adoption

Item 8 – Restrictions

8.1 General restriction issues

- a) Report from the Restrictions Efficiency Task Force

For information

8.2 Restriction Annex XV dossiers

- a) Opinion development
 - 1) Calcium cyanamide in fertilisers – first draft opinion
 - 2) Skin sensitisers in textile – second draft opinion
 - 3) Perfluorohexane-1-sulphonic acid, its salts and related substances – Update from public consultation comments
 - 4) Microplastics – fourth draft opinion
 - 5) Formaldehyde and formaldehyde releasers – third draft opinion
- 6) Cobalt salts – final draft opinion
- 7) Siloxanes (D4, D5, and D6) – final draft opinion

For discussion

For discussion and adoption

Item 9 – Authorisation

9.1 General authorisation issues

- a) Update on incoming/future applications
- b) Report from RAC WG on AfAs received during October 2019

For information/discussion

9.2 Authorisation applications

- a) Discussion on key issues
 - 1) 19 applications for authorisation from August 2019 submission window (OPE/NPE)

For discussion

- b) Agreement on draft opinions

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

- 1) SC_Ariston (1 use)
- 2) SD_Bussi (1 use)

B. Hazard classes for agreement with plenary debate

- 1) OPE_Sebia (3 uses)
- 2) NPE_Sebia (1 use)
- 3) OPE_bioMerieux (3 uses)
- 4) OPE_Stago (2 uses)
- 5) OPE_BioMarin (2 uses)
- 6) OPE_Janssen (1 use)

For discussion and agreement

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC-51

Table with Conclusions and Action points from RAC-51

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-51 – 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 25 November: 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 5 – Revised Rules of Procedure
- Item 6 – Occupational exposure limits
- Item 8 – Restrictions

Tuesday 26 November: Morning session

- Item 8 – Restrictions

Tuesday 26 November: Afternoon session

- Item 8 – Restrictions

Wednesday 27 November: Morning session

- Item 8 – Restrictions

Wednesday 27 November: Afternoon session

- Item 8 – Restrictions
- Item 9 – Authorisation applications

Thursday 28 November: Morning session

- Item 9 – Authorisation applications

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-51 – WEEK 2

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

Tuesday 3 December: Morning session

- Item 1 - Welcome and Apologies
- Item 3 - Declarations of conflicts of interest to the Agenda
- Item 7 - CLH dossiers

Tuesday 3 December: Afternoon session

- Item 7 - CLH dossiers

Wednesday 4 December: Morning session

- Item 7 - CLH dossiers

Wednesday 4 December: Afternoon session

- Item 7 - CLH dossiers

Thursday 5 December: Morning session

- Item 4 - Appointment of rapporteurs
- Item 7 - CLH dossiers
- Item 10 - AOB