

Final Agenda
45th meeting of the Committee for Risk Assessment

4 – 8 June 2018

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 4 June starts at 09.00
Friday 8 June ends at 13.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/45/2018
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 44 action points, written procedures and update on other ECHA bodies

RAC/45/2018/01
Room document
For information

- b) RAC workplan for all processes

For information

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

- 1) CT_Wesco (formerly Haas): chemical conversion and slurry coating application, re-consideration of a proposed authorisation condition
- 2) Request to review a derogation request for the PFOA restriction (entry 68 of Annex XVII to REACH)

For discussion/adoption

Item 7 – Requests under Article 95(3)

None

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

8.2 CLH dossiers

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

- paclobutrazol (ISO): physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, respiratory / skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, aspiration hazard, environmental hazards
- dimethyl disulphide: physical hazards (flammable liquid), acute toxicity (dermal and inhalation routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT SE, environmental hazards
- 2,2-bis(bromomethyl)propane-1,3-diol: carcinogenicity
- pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc: physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, carcinogenicity, STOT SE
- mecetronium ethyl sulphate [MES]: physical hazards, skin sensitisation, germ cell mutagenicity, STOT SE
- glyoxylic acid ... %: skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation
- 2-methyl-1,2-benzisothiazol3(2H)-one;[MBIT]: physical hazards, respiratory sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, STOT RE, aspiration hazard
- butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime: acute toxicity (dermal and inhalation routes of exposure), serious eye damage / eye irritation, mutagenicity, toxicity to reproduction
- tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane: germ cell mutagenicity, toxicity to reproduction
- azoxystrobin (ISO); methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate: acute toxicity (inhalation route of exposure), environmental hazards

B. Hazard classes for agreement with plenary debate

- 1) paclobutrazol (ISO)
- 2) dimethyl disulphide
- 3) 2,2-bis(bromomethyl)propane-1,3-diol
- 4) pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc
- 5) bis(α,α -dimethylbenzyl) peroxide
- 6) N-(hydroxymethyl)acrylamide (NMA)
- 7) mecetronium ethyl sulphate [MES]
- 8) Glyoxylic acid ... %
- 9) 2-Methyl-1,2-benzisothiazol3(2H)-one; [MBIT]
- 10) butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime
- 11) trimethoxyvinylsilane; trimethoxy(vinyl)silane
- 12) tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane
- 13) azoxystrobin (ISO); methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}phenyl}-3-methoxyacrylate
- 14) bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme
- 15) nitric acid ...%
- 16) Granulated copper (ENV hazards only)

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

- a) Opinion development
 - 1) Substances used in tattoo inks and permanent make-up – second draft opinion

For discussion
 - 2) C9-C14 PFCAs, their salts and related substances– second draft opinion

For information

Item 10 – Authorisation

10.1 General authorisation issues

- a) Update on incoming/future applications
- b) Updated AfA opinion templates

***RAC/45/2018/02
For information***

10.2. Authorisation applications

- a) Dossiers for discussion of key issues
 - 1. None

- b) Agreement on draft opinions
 - 1. PCO_IP (2 uses)
 - 2. SD_Olwerke (1 use)
 - 3. Diglyme_Omnichem (1 use)
 - 4. DBP_AVX (1 use)

For discussion/agreement

- c) Adoption of final opinions
 - 1. None

10.3. Authorisation review reports

- a) Dossiers for discussion of key issues
 - 1. None

- b) Agreement of draft opinions
 - 1. RR1_DEHP_VINYLOOP (2 uses)
 - 2. RR1_DEHP_PP (2 uses)

For discussion/ agreement

- c) Adoption of final opinions
 - 1. None

Item 11 – AOB

- a) Efficiency in RAC consultations

For discussion

Item 12 – Action points and main conclusions of RAC-45

Table with Conclusions and Action points from RAC-45

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-45

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

Monday 4 June: 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
- Item 6 - Art.77.3 (c)

Monday 4 June: Afternoon session

- Item 10 Authorisation applications and review reports

Tuesday 5 June: Morning session

- Item 8 - CLH dossiers

Tuesday 5 June: Afternoon session

- Item 8 - CLH dossiers

Wednesday 6 June: Morning session

- Item 8 - CLH dossiers

Wednesday 6 June: Afternoon session

- Item 8 - CLH dossiers

Thursday 7 June: Morning session

- Item 8 - CLH dossiers

Thursday 7 June: Afternoon session

- Item 8 - CLH dossiers

Friday 8 June: Morning session

- Item 4 - Appointment of (co-) rapporteurs
- Item 8 - CLH dossiers
- Item 6 - Art. 77. 3 (c)
- Item 11 - AOB