

Final Agenda
46th meeting of the Committee for Risk Assessment

10 – 14 September 2018

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 10 September starts at 09.00
Friday 14 September ends at 13.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/46/2018
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 45 action points, written procedures and update on other ECHA bodies

RAC/46/2018/01
(room document)
For information

- b) RAC workplan for all processes

For information

- c) Annual update of RAC accredited stakeholders' list

RAC/46/2018/02
(restricted)
For agreement

- d) General RAC-procedures

RAC/46/2018/03
(restricted room document)
For agreement

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

- 1) Request to review a derogation request for the PFOA restriction (entry 68 of Annex XVII to REACH)

For 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)

flupyradifurone: physical hazards, acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, STOT SE, germ cell mutagenicity, carcinogenicity, environmental hazards

tribenuron-methyl (ISO): physical hazards (flammable solids, pyrophoric solids, emission of flammable gases), acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT SE, germ cell mutagenicity, toxicity to reproduction, environmental hazards

dichlorodioctylstannane: acute toxicity (inhalation route of exposure)

sodium N-(hydroxymethyl)glycinate; [formaldehyde released from sodium N-(hydroxymethyl)glycinate]: acute toxicity (dermal route of exposure), STOT RE, toxicity to reproduction, environmental hazards

hymexazol (ISO): acute toxicity (oral route of exposure), skin sensitisation, environmental hazards

5-fluoro-1,3-dimethyl-N-[2-(4-methylpentan-2-yl)phenyl]-1H-pyrazole-4-carboxamide; penflufen: physical hazards, acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, STOT SE, germ cell mutagenicity, environmental hazards

2-butoxyethanol; ethylene glycol monobutyl ether: skin corrosion / irritation

mesotrione (ISO): germ cell mutagenicity, carcinogenicity, environmental hazards

B. Hazard classes for agreement with plenary debate

- 1) tribenuron-methyl (ISO); methyl 2-[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-N-methylcarbamoylsulfamoyl]benzoate
- 2) dichlorodioctylstannane
- 3) lead

- 4) trimethoxy(methyl)silane
- 5) sodium N-(hydroxymethyl)glycinate; [formaldehyde released from sodium N-(hydroxymethyl)glycinate]
- 6) 4-{[(6-chloropyridin-3-yl)methyl](2,2-difluoroethyl)amino}furan-2(5H)-one; flupyradifurone
- 7) hymexazol (ISO); 3-hydroxy-5-methylisoxazole
- 8) 5-fluoro-1,3-dimethyl-N-[2-(4-methylpentan-2-yl)phenyl]-1H-pyrazole-4-carboxamide; penflufen
- 9) 2-butoxyethanol; ethylene glycol monobutyl ether
- 10) geraniol; (2E)-3,7-dimethylocta-2,6-dien-1-ol
- 11) dioctyltin dilaurate; [1] stannane, dioctyl-, bis(coco acyloxy) derivs. [2]
- 12) citral
- 13) mesotrione (ISO); 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
- 14) mecetronium etilsulfate; N-ethyl-N,N-dimethylhexadecan-1-aminium ethyl sulfate; [MES] – *ENV only*
- 15) pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc –
- 16) butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

- a) Conformity check and key issues discussion
 - 1) Plastic and rubber granulates containing PAHs

For agreement

- b) Opinion development
 - 1) Substances used in tattoo inks and permanent make-up – final draft opinion
 - 2) C9-C14 PFCAs, their salts and related substances– final draft opinion

For discussion/adoption

Item 10 – Authorisation

10.1 General authorisation issues

- a) Update on incoming/future applications

For information

- b) Committee Procedure for fast track agreement opinions on application for authorisation

RAC/46/2018/04
For discussion and agreement

10.2. Authorisation applications

- a) Discussion on key issues
1. CT_Mahle (1 use)
 2. CT_Doosan (1 use)

For discussion

- b) Adoption of final opinions
1. DtC_Wesco (1 use)
 2. SC_Wesco (1 use)
 3. PCO_Aviall (2 uses)
 4. CT_Hapoc (2 uses)

For discussion and adoption

Item 11 – AOB

Item 12 – Action points and main conclusions of RAC-46

Table with Conclusions and Action points from RAC-46

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-46

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

Monday 10 September: 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

Monday 10 September: Afternoon session

- Item 9 - Restrictions
- Item 6 - Art. 77.3.c
- Item 10 - Authorisation applications

Evening session

Tuesday 11 September: Morning session

- Item 10 - Authorisation applications
- Item 9 - Restrictions

Tuesday 11 September: Afternoon session

- Item 8 - CLH dossiers

Evening session

Wednesday 12 September: Morning session

- Item 8 - CLH dossiers

Wednesday 12 September: Afternoon session

- Item 8 - CLH dossiers

Evening: Formal dinner

Thursday 13 September: Morning session

- Item 8 - CLH dossiers

Thursday 13 September: Afternoon session

- Item 8 - CLH dossiers

Evening session

Friday 14 September: Morning session

- Item 8 - CLH dossiers
- Item 4 - Appointment of rapporteurs
- Item 5 - Annual update of RAC accredited stakeholders' lists
 - General RAC procedures