

Final Agenda
38th meeting of the Committee for Risk Assessment

6-16 September 2016

ECHA Conference Centre (Annankatu 18, Helsinki)

6 September starts at 09.00
9 September breaks at 13.30
13 September resumes at 09.00
16 September ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/38/2016
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

- a) Report on RAC 37 action points, written procedures and update on other ECHA bodies

RAC/38/2016/01

RAC/38/2016/02
Room document

For information

- b) RAC workplan for all processes

For information

- c) Annual update of RAC accredited stakeholders' list.

RAC/38/2016/03
(restricted document)
For agreement

Item 5 – Requests under Article 77 (3)(c)

No requests.

Item 6 – Requests under Article 95 (3)

- a) 1-methyl-2-pyrrolidone (NMP)

RAC/38/2016/04

(no document)

For discussion/or agreement

- b) OEL-DNEL methodology request

RAC/38/2016/05

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)

- a) spirodiclofen (ISO)
physical hazards, acute toxicity (all routes), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT SE, germ cell mutagenicity, aspiration hazard
- b) Maleic anhydride
acute toxicity (oral), skin sensitisation
- c) Succinic anhydride
acute toxicity (oral), skin sensitisation
- d) D-trans-tetramethrin
physical hazards, acute toxicity (dermal), skin corrosion / irritation, serious eye damage / eye irritation, respiratory or skin sensitisation, STOT RE, germ cell mutagenicity, toxicity to reproduction, aspiration hazard, environmental hazards
- e) Tetramethrin (ISO)
physical hazards, acute toxicity (dermal), skin corrosion irritation, serious eye damage / eye irritation, respiratory or skin sensitisation, STOT RE, germ cell mutagenicity, toxicity to reproduction, aspiration hazard, environmental hazards
- f) Mesosulfuron-methyl
environmental hazards

- g) 1,2 dihydroxybenzene, pyrocatechol
acute toxicity (dermal)

B. Hazard classes for agreement with plenary debate

- h) Acetaldehyde, ethanal
i) Pinoxaden (ISO)
j) 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone
k) Spirodiclofen
l) Pyrocatechol
m) Mesosulfuron-methyl (Please note that no discussion is foreseen for this substance at RAC-38 – HH is going to be discussed at RAC-39)
n) Tetramethrin (ISO)
o) D-trans-tetramethrin
p) Maleic anhydride
q) Succinic anhydride

For discussion and adoption

7.3 Appointment of RAC (co-)rapporteurs for CLH dossiers

***RAC/38/2016/06
(Restricted room document)
For agreement***

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

- a) Conformity check
1. N,N-dimethylformamide; dimethyl formamide (DMF)
- For agreement***
- b) Opinion development
1. (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives (TDFAs)
 2. Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP)

For discussion

8.2 Appointment of (co-)rapporteurs for restriction dossiers

Item 9 – Authorisation

9.1 General authorisation issues

- a) Capacity building
 - 1. DNEL setting for the reprotoxic properties of 1-bromopropane
 - 2. DNEL setting for the reprotoxic properties of diisopentylphthalate (DIPP)

RAC/38/2016/08
RAC/38/2016/09
For discussion and/or agreement

- b) Communication with the Commission (two COM letters)

RAC/38/2016/11
RAC/38/2016/12
Room documents
For discussion

9.2 Authorisation applications

- a) Outcome of the conformity check and presentation of key issues

- 1. Diglyme_Merck

- b) Agreement on Draft Opinions

- 1. Chromium trioxide_SNECMA (1 use) (CT_Snecma)
 - 2. Chromium trioxide_MTU (2 uses) (CT_MTU)
 - 3. Chromium trioxide_ABLOY (1 use) (CT_Abloy)
 - 4. Chromium trioxide_HOOGOSENS Court Roll Surface Technologies (1 use) (CT_Hoogovens)
 - 5. Chromium trioxide_TOPOCROM GmbH (1 use) (CT_Topocrom)
 - 6. Chromium trioxide_FN HERSTAL S.A. (2 uses) (CT_Herstal)
 - 7. Chromium trioxide_GERARDHI KUNSTOFFTECHNIK GmbH (1 use) (CT_Gerardhi)
 - 8. Chromium trioxide; Potassium dichromate; Sodium dichromate_SOURIAU SAS (7 opinions) (CT_PD_SD_Souriau)
 - 9. Chromium trioxide_HAPOC (4 uses) (CT_HAPOC)
 - 10. Ammonium dichromate_VECO BV (1 use) (AD_Veco)
 - 11. Sodium dichromate_TOTAL RAFFINERIE MITTELDEUTSCHLAND GmbH (1 use) (SD_Total)
 - 12. Sodium dichromate_JACOBS DOUWEE EGBERTS DE GmbH (1 use) (SD_Jacobs)
 - 13. EDC_BASF SE (2 uses) (EDC_BASF_2)

14. EDC_ELI LILLY S.A. (1 use) (EDC_Eli_Lilly)
15. EDC_DOW ITALIA S.R.L. (1 use) (EDC_Dow)
16. EDC_LANXESS Deutschland GmbH (2 uses) (EDC_Lanxess)
17. EDC_H&R OLWERKE SCHINDLER GmbH (1 use) (EDC_Olwerke)
18. EDC_GRUPPA LOTOS S.A. (1 use) (EDC_Lotos)
19. EDC_GE HEALTHCARE Bio-Sciences (1 use) (EDC_Bio-Sciences)
20. Technical MDA_POLYNT COMPOSITES France (2 uses) (MDA_Polynt)
21. EDC_EURENCO (1 use) (EDC_Eurenko)
22. Sodium dichromate-Brenntag (3 uses) (SD_Brenntag)
23. Potassium dichromate-Brenntag (2 uses) (PD_Brenntag)
24. Dichromium tris(chromate)-Henkel (2 uses) (DtC_Henkel)
25. Strontium chromate-Akzo Nobel (2 uses) (SC_Akzo)
26. Potassium hydroxyoctaoxidizincatedichromate-PPG (2 uses)
(PH_PPG)
27. Potassium dichromate GENTROCHEMA BV (2 uses)
(PD_Gentrochema)
28. Sodium dichromate GENTROCHEMA BV (3 uses) (SD_Gentrochema)

For discussion and agreement

c) Adoption of Final Opinion

1. Chromium trioxide-Kromatek (1 use) (CT_Kromatek)
2. Chromium trioxide 1 (6 uses) (CT_Lanxess)

For discussion and adoption

9.3 Appointment of (co-)rapporteurs for authorisation applications

***RAC/38/2016/10
(Restricted room document)
For agreement***

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC-38

Table with Conclusions and Action points from RAC-38

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-38 – WEEK 1

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

Tuesday 6 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 4.b - RAC Work Plan for Restriction, Authorisation and C&L processes
- Item 9.2 - Authorisation applications

Tuesday 6 September: Afternoon session

- Item 9.2 - Authorisation applications

Evening: RAC and SEAC joint seminar on Man via the Environment exposure and impact assessment

Wednesday 7 September: Morning session

- Item 9.2 - Authorisation applications

Wednesday 7 September: Afternoon session

- Item 9.2 - Authorisation applications
- Item 6 - Requests under Article 95 (3)

Thursday 8 September: Morning session

- Item 9.2 - Authorisation applications

Thursday 8 September: Afternoon session

- Item 8.1 - Restrictions

Evening: possible ad hoc working groups

Friday 9 September: Morning session

- Item 9.1 - General authorisation issues
- Item 8.1 - Restrictions

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-38 – 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 13 September: Morning session

- Item 1 – Welcome and Apologies
- Item 3 – Declarations of conflicts of interest to the Agenda
- Item 4.c – Annual update of RAC accredited stakeholder's list
- Item 9.2 – Authorisation applications

Tuesday 13 September: Afternoon session

- Item 9.3 – Appointment of Rapporteurs authorisation applications (Closed session)
- Item 7.3 – Appointment of Rapporteurs CLH
- Item 8.2 – Appointment of Rapporteurs restrictions
- Item 9.2 – Authorisation applications

Wednesday 14 September: Morning session

- Item 9.2 – Authorisation applications

Wednesday 14 September: Afternoon session

- Item 7.2 – CLH dossiers
 - Item 7.1 – CLH general issues
- Evening: RAC-SEAC formal dinner*

Thursday 15 September: Morning session

- Item 7.2 – CLH dossiers

Thursday 15 September: Afternoon session

- Item 7.2 – CLH dossiers

Evening: possible ad hoc working groups

Friday 16 September: Morning session

- Item 7.2 – CLH dossiers
- Item 10 – AOB

END OF THE MEETING