

Final Agenda 41st meeting of the Committee for Risk Assessment

29 May - 2 June 2017 and 8-9 June 2017

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 29 May starts at 09.00 Friday 2 June breaks at 12.30 Thursday 8 June resumes at 9.00 Friday 9 June ends at 13.00

Item 1 - Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/41/2017 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

> RAC/41/2017/01 Restricted room document For agreement

Item 5 - Report from other ECHA bodies and activities

a) Report on RAC 40 action points, written procedures and update on other ECHA bodies

RAC/41/2017/02

RAC/41/2017/03 Room document

For information

b) RAC workplan for all processes

For information

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

a) MOCA

For adoption

b) Arsenic acid and its inorganic salts

For adoption

Item 7 - Requests under Article 95 (3)

a) OEL-DNEL methodology

For information/discussion

Item 8 - Harmonised classification and labelling (CLH)

8.1 General CLH issues

a) Evaluation fast track procedure

For discussion

8.2. CLH dossiers

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

- fludioxonil (ISO): no classification for the following hazards: physical hazards, acute toxicity (all routes of exposure), STOT SE, skin corrosion / irritation, serious eye damage / eye irritation, respiratory or skin sensitisation, STOT RE, germ cell mutagenicity, toxicity to reproduction
- 2. N,N-diethyl-M-toluamide, deet: acute toxicity

B. Hazard classes for agreement with plenary debate

- 1. phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide
- 2. diisohexyl phthalate
- 3. N,N-diethyl-m-toluamide; DEET
- 4. benzo[rst]pentaphene
- 5. dibenzo[b,def]chrysene, dibenzo[a,h]pyrene

- 6. 4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH4Cl), pentachlorophosphorane and phenol
- 7. titanium dioxide
- 8. Fludioxonil (ISO)
- 9. pentapotassium 2,2',2'',2'''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5)
- 10. N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5)
- 11. pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5)

For discussion and adoption

Item 9 - Restrictions

9.1 General restriction issues

a) Report from the Restriction workshop held in Helsinki 17-18 May 2017

For information

9.2 Restriction Annex XV dossiers

- a) Conformity check and key issues discussion
 - 1) Lead and lead compounds in shots

For agreement

- b) Opinion development
 - 1) Diisocyanates
 - 2) Lead and lead compounds in PVC

For discussion

Item 10 - Authorisation

10.1 General authorisation issues

- a) New applications received during the May 2017 submission window
- b) Review reports

For information

c) Review periods longer than 12 years

RAC/41/2017/04 Room document For discussion

- d) AfA DNEL/DR: Carcinogenicity dose-response relationship development of:
 - 1. Coal tar pitch, high temperature (CTPHT)
 - 2. Anthracene oil

RAC/41/2017/05
For discussion

10.2 Authorisation applications

- a) Discussion on key issues
 - 1. PC_SC_Saes (2 uses)

For discussion

- b) Agreement on draft opinions
 - Diglyme_Acton (1 use)
 - 2. EDC_Bayer (1 use)
 - 3.-EDC_Olon (2 uses)
 - 4. MOCA_Reachlaw (1 use)
 - 5. CT_ZFL (2 uses)
 - 6. SD_ZFL (1 use)
 - 7. CT_Haas (1 use)
 - 8. SD_Haas (1 use)
 - 9. PD_Haas (1 use)
 - 10. SC_Aviall (2 uses)
 - 11. SD_Colle (1 use)
 - 12. CT_Hansgrohe (2 uses)

For discussion and agreement

c) Adoption of final opinions

For discussion and adoption

Item 11 - AOB

1) Results of the First Forum Pilot Project on Authorisation

For information

Item 12 - Action points and main conclusions of RAC-40

Table with Conclusions and Action points from RAC-41

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-41 - 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 29 May: Morning session

Item 1 - Welcome and ApologiesItem 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 6 - Requests under Article 77 (3)(c)

Item 9 - Restrictions

Monday 29 May: Afternoon session

Item 9 - Restrictions

Evening: AfA Rapporteurs' workshop

Tuesday 30 May: Morning session

Item 10 - Authorisation applications

Tuesday 30 May: Afternoon session

Item 10 - Authorisation applicationsItem 7 - Request under Article 95(3)

Evening: Workshop on Interact Project with invited rapporteurs

Wednesday 31 May: Morning session

Item 10 - Authorisation applications

Wednesday 31 May: Afternoon session

Item 10 - Authorisation applications

Evening: Informal dinner cruise

Thursday 1 June: Morning session

Item 10 - Authorisation applications

Thursday 1 June: Afternoon session

Item 8 - CLH dossiers

Evening: possible ad hoc working groups

Friday 2 June: Morning session

Item 8 - CLH dossiers

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-41 - WEEK 2

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

Thursday 8 June: Morning session

Item 1 - Welcome and Apologies

Item 3 - Declarations of conflicts of interest to the Agenda

Item 8 - CLH dossiers

Evening: possible ad hoc working groups

Thursday 8 June: Afternoon session

Item 8 - CLH dossiers

Evening: possible ad hoc working groups

Friday 9 June: Morning session

Item 4 - Appointment of rapporteurs

Item 8 - CLH dossiers

END OF THE MEETING