

Final Agenda 40th meeting of the Committee for Risk Assessment

6- 10 March 2017 and 14 - 15 March 2017

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 6 March starts at 14.00 Friday 10 March breaks at 13.30 Tuesday 14 March resumes at 9.00 Wednesday 15 March ends at 13.30

Item 1 - Welcome and Apologies

Item 2 - Adoption of the Agenda

RAC/A/40/2017 For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

For information

Item 4 - Report from other ECHA bodies and activities

a) Report on RAC 39 action points, written procedures and update on other ECHA bodies

RAC/40/2017/01

RAC/40/2017/02 Room document For information

b) RAC workplan for all processes

For information

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

No requests.

Item 6 - Requests under Article 95 (3)

a) OEL-DNEL methodology

RAC/40/2017/03 For agreement

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)

<u>Mandestrobin (ISO)</u>: no classification for the following hazards: physical hazards, acute toxicity (all routes of exposure), STOT SE, skin /eye irritation, skin sensitisation, STOT RE, germ cell mutagenicity

Methylmercuric chloride: Acute Tox. 2 (H330), Acute Tox. 2 (H300), STOT RE 1 (H372) (central nervous system, kidneys)

<u>Pentapotassium 2,2',2'',2'''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5)</u>: Acute Tox. 4 (H332)

<u>Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5):</u> Acute Tox. 4 (H332)

N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5): Acute Tox. 4 (H332)

Thiabendazole (ISO): Aquatic Acute 1 (H400), M=1. Aquatic Chronic 1 (H410), M=1

For agreement/adoption

B. Hazard classes for agreement with plenary debate

- a) Glyphosate (ISO)
- b) 2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone
- c) Mandestrobin (ISO)
- d) Methylmercuric chloride
- e) pentapotassium 2,2',2'',2'''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5)
- f) N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5)
- g) Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5)

For discussion and adoption

C. Dossiers for key issues debate

h) Titanium dioxide

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

RAC/40/2017/04 Restricted room document For agreement

Item 8 - Restrictions

8.1 Restriction Annex XV dossiers

- a) Conformity
 - 1. Diisocyanates conformity and key issues discussion
 - 2. Lead in PVC conformity and key issues discussion

For agreement

- b) Opinion development
 - 1. TDFAs third draft opinion
 - 2. 4 phthalates- third draft opinion

For adoption

8.2 Appointment of (co-)rapporteurs for restriction dossiers

RAC/40/2017/05
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For agreement

Item 9 – Authorisation

9.1 General authorisation issues

a) Updated working procedure for the authorisation process

RAC/40/2017/06 RAC/40/2017/07

- b) New applications received during the February 2017 submission window
- c) Report from the AfA Task Force
- d) Feedback from seminar 'Man via the Environment'

For information

- e) RAC Reference values
 - 1. Carcinogenicity dose-response relationship development and DNEL setting for the reprotoxic properties for coal tar pitch high temperature (CTPHT)
 - 2. Carcinogenicity dose-response relationship development for anthracene oil

For discussion

9.2 Authorisation applications

- a) Discussion on key issues
 - 1. SD_Colle (1 use)

- 2. CT_Hansgrohe (2 uses)
- 3. SD_Hapoc (1 use)

For discussion

- b) Agreement on draft opinions
 - 1. CT_Reachlaw (4 uses)
 - 2. CT_Clariant (1 use)
 - 3. CT_Cryospace (1 use)
 - 4. SD_Borealis (1 use)
 - 5. SD_Ormezzano (2 uses)
 - 6. AD_BAE (2 uses)
 - 7. EDC_Biotech (1 use)
 - 8. EDC_ORGAPHARM (2 uses)
 - 9. EDC_Akzo (1 use)
 - 10. Diglyme_Roche (1 use)
 - 11. Diglyme_LifeTech (1 use)
 - 12. Diglyme_Acton (2 uses)

For discussion and agreement

- c) Discussion on draft opinions
 - 1. MOCA_Reachlaw (1 use)
 - 2. CT_Haas (1 use)
 - 3. SD_Haas (1 use)
 - 4. PD_Haas (1 use)
 - 5. SC_Aviall (2 uses)
 - 6. CT_Hapoc (4 uses)
 - 7. CT_Hapoc_2 (1 use)
 - 8. CT_Hapoc_3 (1 use)

For discussion

- d) Adoption of final opinions
 - 1. AsA_Circuit (1 use)
 - 2. CT Circuit (1 use)
 - 3. EDC_Eli Lilly (1 use)
 - 4. CT_Gerhardi (1 use)

For discussion and adoption

9.3 Appointment of (co-)rapporteurs for authorisation applications

RAC/40/2017/08
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Item 10 - AOB

Item 11 - Action points and main conclusions of RAC-40

Table with Conclusions and Action points from RAC-40

For adoption