

06 June 2011
RAC/A/16/2011

Final Agenda
16th meeting of the Committee for Risk Assessment

07 – 10 June 2011

Helsinki, Finland

07 June: starts at 9:00

10 June: ends at 13:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/16/2011

For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Administrative issues and information items

- a. Status report on the RAC-15 action points
- b. Outcome of written procedures
- c. Report from other ECHA bodies and activities

RAC/16/2011/13
ROOM DOCUMENT
For information

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

- Gallium arsenide

Item 6 – CLH

6.1 CLH Dossiers for opinion adoption (*substances for which opinions are adopted by written procedure before the meeting will be removed from the revised agenda*)

- a. White spirit dossiers
For adoption
- b. PHMB (poly(iminoimidocarbonyl)iminohexamethylene hydrochloride)
For adoption
- c. Chloroform
For adoption
- d. Reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene
For adoption
- e. Aluminium-magnesium-zinc-carbonate-hydroxide
For adoption
- f. Vinyl acetate
For adoption
- g. Flufenoxuron
For adoption

6.2 CLH Dossiers for first discussion (*if time allows*)

- a. Penconazole
For first discussion
- b.
- c. Di-n-hexyl phthalate
For first discussion
- d. Pitch, coal tar, high temp. (CTPHT)
For first discussion
- e. MMTC (trichloride of methyltin) and EHMA (methyltin tri(2-ethylhexyl-mercaptoacetate MMT)
For first discussion
- f. Fenamiphos
For information
- g. Anticoagulant rodenticides (brodifacoum; bromadiolone;
chlorophacinone; coumatetralyl; difenacoum; difethialone;

flocoumafen and warfarin) – outcome of accordance checks and follow-up

For information

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

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

RAC/16/2011/14

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For agreement

6.4 General CLH issues

- a. State of play of the submitted CLH dossiers

RAC/16/2011/10

For information

- Ammoniumpentadecafluorooctanoate (APFO); perfluorooctanic acid (PFOA) and its salts
- FTOH (1,1,2,2-tetrahydroperfluoror-1-decanol)

For information

- b. Outcome of the workshop on the classification and labelling of active substances in PPP taken place in April 2011

For information

- c. Framework for the accordance check

RAC/16/2011/11

For agreement

- d. Review of the process for developing CLH opinions
 - Model for the CLH opinion

RAC/16/2011/16

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For information

Item 7 – Restrictions

7.1 Restriction Annex XV dossiers

- a. Phenylmercury compounds – fourth draft opinion

For adoption

- b. Mercury in measuring devices – fourth draft opinion

For adoption

- c. Phthalates – outcome of the conformity check

For agreement

7.2 General restriction issues (if relevant)

- a. Update on intended restriction dossiers

For information

- b. Other general issues

*RAC/16/2011/17
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For information*

Item 8 – Authorisation

8.1 Formulation of RAC opinions on authorisation applications

- a. Risk assessment of non-threshold substances
- o - Carcinogenic substances
 - o - PBT substances

For discussion

- b. Format of the opinion (if time allows)

SEAC documents distributed for information
For discussion

8.2 Appointment of RAC rapporteurs for substances listed in Annex XIV

*RAC/16/2011/15
ROOM DOCUMENT
For agreement*

8.3 Preparation of structure of RAC opinions on authorisation applications (Closed Session)

- a. musk xylene
- b. MDA
- c. HBCDD
- d. DEHP
- e. BBP
- f. DBP

For information

Item 9 – Guidance issues

- a. Update on the guidance on the application of the CLP criteria
- b. Report on other guidance activities

RAC/16/2011/12

For information

Item 10 – Any other business

- a. Role of RAC STOs (Closed session)
- b. Cooperation with other Scientific Committees and Panels

For information

Item 11 – Main conclusions and Action Points of RAC-16

- Table with main conclusions and action points from RAC- 16

For adoption

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PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-16
Please note that this timeline is provisional. Changes can be made before and
during the meeting in order to accommodate the discussions.
Some discussions may require a closed session

Tuesday 07 June: Morning Session

- Item 1 Welcome & Apologies
- Item 2 Adoption of the Agenda
- Item 3 Declarations of conflicts of interest to the Agenda
- Item 4 Administrative issues and information items
- Item 6 CLH

6. 4 General CLH issues (items b.-d.)

Item 6.

- 6.1 CLH Dossiers for adoption
 - a. White spirit dossiers
 - c. Chloroform
 - e. Aluminium-magnesium-zinc-carbonate-hydroxide
 - g. Flufenoxuron

Tuesday 07 June: Afternoon Session

Item 6. (cont)

- 6.2 CLH Dossiers for first discussion (if time allows)
 - g. Anticoagulant rodenticides (brodifacoum; bromadiolone; chlorophacinone; coumatetralyl; difenacoum; difethialone; flocoumafen and warfarin) – outcome of accordance checks and follow-up
 - c. Di-n-hexyl phthalate
 - d. Pitch, coal tar, high temp. (CTPHT)
 - e. MMTC (trichloride of methyltin) and EHMA (methyltin tri(2-ethylhexyl-mercaptoacetate MMT)

- 6.1 CLH Dossiers for adoption
 - f. Vinyl acetate
 - d. Reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene

Item 10. AOB. A Close Session on STOs related issues may be required.

Tuesday 07 June: Ad-hoc groups after the plenary session if needed

Maximum 3 ad-hoc groups in parallel, to be decided depending on the discussions at the meeting.

Wednesday 07 June: Morning Session

Item 6. CLH

- 6.1 CLH Dossiers for adoption (cont)
 - b. PHMB (poly(iminoimidocarbonyl)iminohexamethylene hydrochloride)

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

- Gallium arsenide

Item 6 CLH

- 6.4 General CLH issues
 - a. State of play of the submitted CLH dossiers
 - Ammoniumpentadecafluorooctanoate (APFO); perfluorooctanic acid (PFOA) and its salts
 - FTOH (1,1,2,2-tetrahydroperfluoror-1-decanol)

Item 6.1 CLH

Optional - 6.1 CLH Dossiers for adoption: second discussion on CLH dossiers for adoption as needed.

- 6.2 CLH Dossiers for first discussion (if time allows) (cont)
 - a. Penconazole
 - b. Nitrobenzene
 - f. Fenamiphos

Wednesday 08 June: Afternoon Session

Item 7 Restrictions

- 7.1 Restriction Annex XV dossiers
 - a. Phenylmercury compounds –fourth draft opinion
 - b. Mercury in measuring devices – fourth draft opinion
 - c. Phthalates – outcome of the conformity check
- 7.2 General restriction issues (if relevant)

Wednesday 08 June: Ad-hoc groups after the plenary session if needed

Maximum 3 ad-hoc groups in parallel, to be decided depending on the discussions at the meeting.

Thursday 09 June: Morning Session

Optional - Item 6 CLH (as needed)

- 6.1 CLH dossiers for adoption (cont.)
- 6.2 CLH dossiers for first discussion (cont.)

Optional - Item 7 Restrictions (as needed)

- 7.1 Restriction Annex XV dossiers

Item 9 Guidance issues

Thursday 09 June: Afternoon Session

Item 8 Authorisation

- 8.1 Formulation of RAC opinions on authorisation applications
 - o Risk assessment of non-threshold substances
- 8.2 Appointment of RAC rapporteurs for substances listed in Annex XIV
- 8.3 Closed Session: Preparation of structure of RAC opinions on authorisation applications

Optional - Item 6 CLH (as needed)

- 6.1 CLH dossiers for adoption (cont.)
- 6.2 CLH dossiers for first discussion (cont.)

Optional - Item 7 Restrictions (if needed)

- 7.1 Restriction Annex XV dossiers

Thursday 09 June: Ad-hoc groups after the plenary session (if needed)

Maximum 3 ad-hoc groups in parallel, to be decided depending on the discussions at the meeting

Friday 10 June: Morning Session

Optional - Item 6 CLH (as needed)

6.1 CLH dossiers for adoption (cont.)

6.2 CLH dossiers for first discussion (cont.)

Optional - Item 7 Restrictions (if needed)

7.1 Restriction Annex XV dossiers

Item 6 CLH

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

Item 11 Main conclusions and Action Points of RAC-16

Item 8.1 Authorisation

Format of the opinion (if time allows)

Item 10 Any other business

Cooperation with other Scientific Committees and Panels

Other AOB.