26 October 2010
RAC/A/13/2010_rev.1

Final Draft Agenda
13th meeting of the Committee for Risk Assessment

26 – 28 October 2010
Helsinki, Finland
26 October: starts at 9:00
28 October: ends at 16:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/13/2010
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of RAC-12

- Adoption of the draft minutes

RAC/M/12/2010 draft final
For adoption

Item 5 – Administrative issues and information items

a. Status report on the RAC - 12 action points
b. Outcome of written procedures
c. Report from other ECHA bodies and activities

RAC/13/2010/55
ROOM DOCUMENT
For information

Item 6 – Renewal of RAC Membership

- State of play on the renewal of RAC Memberships

For information

Item 7 – Stakeholder participation in the work of RAC (Closed Session)

RAC/13/2010/52_rev.1
For agreement

Item 8 – CLH

8.1 CLH Dossiers

a. HBCDD

For discussion and possible adoption

b. Fuberidazole

For discussion and possible adoption

c. Acequinocyl

For adoption

d. TNPP

For adoption

e. Lucirin

For first discussion

f. Metazachlor

For first discussion

g. Flufenoxuron

For first discussion

h. PHMB

For first discussion

i. Chloroform

For first discussion

j. Leucomalachite green

For first discussion

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

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

RAC/13/2010/53_rev1
ROOM DOCUMENT
For agreement

8.3 General CLH issues

- State of play of the submitted CLH dossiers

RAC/13/2010/56
ROOM DOCUMENT
For information

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

a. DMFu – state of play

For discussion

b. Lead and its compounds in jewellery – state of play

For discussion

c. Phenylmercury compounds – state of play

For initial discussion

d. Mercury in measuring devices – state of play

For initial discussion

9.2 Appointment of RAC (co-) rapporteurs for restriction dossiers (if relevant)

For agreement

9.3 General restriction issues

- Update on intended restriction dossiers

For information

Item 10 – Authorisation

10.1 RAC Conformity check of authorisation applications

a. Working procedure for conformity check of authorisation applications

RAC/12/2010/40

For agreement

b. Conformity check template

RAC/13/2010/54

For discussion

10.2 Formulation of RAC opinion on authorisation applications

c. Format of an opinion

d. Examples of conditions

For discussion

Item 11 – Guidance issues

a. Feedback from guidance consultations

b. Report on other guidance activities

c. Update on the ECHA Workshop for presenting the Guidance Document on the preparation of CLH dossiers

RAC/13/2010/57

ROOM DOCUMENT

For information

Item 12 – Any other business

a. Presentation on the Extended One Generation Reproductive Toxicity Studies (EOGRTS) by the OECD working group

For information

b. Update on the ECHA-EFSA cooperation on active substances in PPP and on the workshop scheduled for 2011

For information

Item 13 – Main conclusions and Action Points of RAC-13

- Table with main conclusions and action points from RAC- 13

For adoption

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PROVISIONAL TIMELINE FOR THE DISCUSSIONS

(Please note that this timeline is provisional and that can be changed before and during the meeting in order to accommodate the discussions)

Tuesday 26 October: Morning Session

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of RAC-12

Item 5 – Administrative issues and information items

Item 6 – Renewal of RAC Membership

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers State of Play

a. DMFu – state of play

b. Lead and its compounds in jewellery – state of play

c. Phenylmercury compounds – state of play

d. Mercury in measuring devices – state of play

9.2 Appointment of RAC (co-) rapporteurs for restriction dossiers (if relevant)

9.3 General restriction issues

Tuesday 26 October: Afternoon Session

Item 8 – CLH

8.1 CLH Dossiers

d. TNPP

a. HBCDD

b. Fuberidazole

j. Leucomalachite green

c. Acequinocyl

Wednesday 27 October: Morning Session

Item 8 – CLH (continued)

8.1 CLH Dossiers

e. Lucirin

f. Metazachlor

g. Flufenoxuron

i. Chloroform

h. PHMB

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

8.3 General CLH issues

Wednesday 27 October: Afternoon Session

Item 12 – Any other business

a. Presentation on the Extended One Generation Reproductive Toxicity Studies (EOGRTS) by the OECD working group

Item 8 – CLH (continued)

8.1 CLH Dossiers: Second discussion for CLH dossiers as needed

8.3 General CLH issues (continued)

Item 7 – Stakeholder participation in the work of RAC (**Closed Session**)

Thursday 28 October: Morning Session

Item 10 – Authorisation

10.1 RAC Conformity check of authorisation applications

a. Working procedure for conformity check of authorisation applications

b. Conformity check template

10.2 Formulation of RAC opinion on authorisation applications

a. Format of an opinion

b. Examples of conditions

Item 13 – Main conclusions and Action Points of RAC-13

Item 12 – Any other business

b. Update on the ECHA-EFSA cooperation on active substances in PPP and on the workshop scheduled for 2011

Thursday 28 October: Afternoon Session

Item 11 – Guidance issues

a. Feedback from guidance consultations

b. Report on other guidance activities

c. Update on the ECHA Workshop for presenting the Guidance Document on the preparation of CLH dossiers

Item 12 – Any other business

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