Final Draft Agenda
14th meeting of the Committee for Risk Assessment

07 – 10 December 2010
Helsinki, Finland
07 December: starts at 9:00
10 December: ends at 13:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/14/2010
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of RAC-13

- Adoption of the draft minutes

RAC/M/13/2010 final draft
For adoption

Item 5 – Administrative issues and information items

a. Status report on the RAC - 13 action points
b. Outcome of written procedures
c. Report from other ECHA bodies and activities

RAC/14/2010/58
For information

For information
Item 6 – Renewal of RAC Membership

- State of play on the renewal of RAC Memberships
  
  RAC/14/2010/66
  ROOM DOCUMENT
  For information

Item 7 – CLH

7.1 CLH Dossiers

a. HBCDD
   For adoption

b. White spirit dossiers
   For discussion and possible adoption

c. Metazachlor
   For discussion and possible adoption

d. Flufenoxuron
   For discussion and possible adoption

e. PHMB
   For discussion and possible adoption

f. Chloroform
   For discussion and possible adoption

g. 4-tert-butylbenzoic acid
   For first discussion

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

- Appointment of RAC (co-) rapporteurs for CLH dossiers
  
  RAC/14/2010/67
  ROOM DOCUMENT
  For agreement

7.3 General CLH issues

a. State of play of the submitted CLH dossiers
  
  RAC/14/2010/68
  ROOM DOCUMENT
  For information

b. Analysis of adopted CLH opinions and preparation of the workshop for presenting the guidance document on the preparation of CLH dossiers
   For information

c. Preparation of the workshop on the classification and labelling of active substances in PPP scheduled for April 2011
   For information
d. Discussion of the application of the CLP criteria for reproductive toxicity

RAC/14/2010/69
ROOM DOCUMENT
For discussion

e. Discussion of the application of the CLP criteria for germ cell mutagenicity

For discussion

**Item 8 – Restrictions**

8.1 Restriction Annex XV dossiers
a. DMFu – second draft opinion

For discussion

b. Lead and its compounds – second draft opinion

For discussion

c. Phenylmercury compounds – first draft opinion

For discussion

d. Mercury in measuring devices – first draft opinion

For discussion

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

RAC/14/2010/70
ROOM DOCUMENT
For agreement

8.3 General restriction issues
a. Update on intended restriction dossiers

For information

b. Revision of the working procedure on conformity check

RAC/14/2010/59
RAC/14/2010/60
RAC/14/2010/61
RAC/14/2010/62
For discussion

8.4 Joint RAC&SEAC session
a. Role and scope of conformity checks of restriction dossiers

For discussion

b. Panel discussion on co-operation between RAC and SEAC – restriction dossiers for DMFu and lead and its compounds

For discussion
Item 9 – Authorisation

9.1 Conformity check
- Revised draft conformity check template
  RAC/14/2010/63
  For information
  RAC/14/2010/64_rev1
  For agreement

9.2 Formulation of RAC opinions for authorisation applications

a. RAC working procedure for developing opinions for authorisation applications
  RAC/14/2010/65
  For agreement

b. Format of an opinion
  RAC/14/2010/71
  ROOM DOCUMENT
  For discussion

Item 10 – Guidance issues

a. Feedback from guidance consultations
b. Report on other guidance activities
  For information

Item 11 – Any other business

a. Inclusion of experts nominated by RAC members into the ECHA expert database.
b. Feedback from the PBT workshop
  For information

Item 12 – Main conclusions and Action Points of RAC-14

- Table with main conclusions and action points from RAC-14
  For adoption

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PROVISIONAL TIMELINE FOR THE DISCUSSIONS
(Please note that this timeline is provisional. Changes can be made before and during the meeting in order to accommodate the discussions)

**Tuesday 07 December: 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-13
- Item 5 – Administrative issues and information items
- Item 6 – Renewal of RAC Membership
- Item 8 – Restrictions
  8.1 Restriction Annex XV dossiers
  - c. Phenylmercury compounds – first draft opinion
  - d. Mercury in measuring devices – first draft opinion

**Tuesday 07 December: Afternoon Session**
- Item 8 – Restrictions continued
  8.1 Restriction Annex XV dossiers
  - a. DMFu – second draft opinion
  - b. Lead and its compounds – second draft opinion
  8.2 Appointment of RAC (co-) rapporteurs for restriction dossiers
  8.3 General restriction issues
  - a. Update on intended restriction dossiers
  - b. Revision of the working procedure on conformity check

**Wednesday 08 December: Morning Session**
- Item 8 – Restrictions (continued)
  8.1 Restriction Annex XV dossiers
  - a. DMFu – second draft opinion (2\textsuperscript{nd} discussion, if needed)
  - b. Lead and its compounds – second draft opinion (2\textsuperscript{nd} discussion, if needed)

- Item 7 – CLH
  7.3 General CLH issues
  - d. Discussion of the application of the CLP criteria for reproductive toxicity
  - e. Discussion of the application of the CLP criteria for germ cell mutagenicity

  7.1 CLH Dossiers
  - a. HBCDD
b. White spirit dossiers

c. Metazachlor

**Wednesday 8 December: Afternoon Session**

Item 7 – CLH (continued)

7.1 CLH Dossiers

d. Flufenoxuron

e. PHMB

f. Chloroform

**Thursday 9 December: Morning Session**

Item 7 – CLH (continued)

7.1 CLH Dossiers

g. 4-tert-butylbenzoic acid

7.1 CLH Dossiers (2\textsuperscript{nd} discussions, if needed)

7.3 General CLH issues

a. State of play of the submitted CLH dossiers

b. Analysis of adopted CLH opinions and preparation of the workshop for presenting the guidance document on the preparation of CLH dossiers

c. Preparation of the workshop on the classification and labelling of active substances in PPP scheduled for April 2011

**Thursday 9 December: Afternoon Session**

Item 7 – CLH (continued)

7.1 CLH Dossiers (3\textsuperscript{rd} discussions, if needed)

Item 8 – Restrictions (continued)

8.1 Restriction Annex XV dossiers

a. DMFu – second draft opinion (3\textsuperscript{rd} discussion, if necessary)

b. Lead and its compounds – second draft opinion (3\textsuperscript{rd} discussion, if necessary)

8.4 Joint RAC&SEAC session

a. Role and scope of conformity checks of restriction dossiers

b. Panel discussion on co-operation between RAC and SEAC – restriction dossiers for DMFu and lead and its compounds
**Friday 10 December: Morning Session**

Item 12 – Main conclusions and Action Points of RAC-14

Item 10 – Guidance issues
   a. Feedback from guidance consultations
   b. Report on other guidance activities

Item 9 – Authorisation
   9.1 Revised draft conformity check template
   9.2 Formulation of RAC opinions for authorisation applications

Item 12 – Main conclusions and Action Points for authorisation (if needed)

Item 11 – Any other business

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