

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

- d. Annual satisfaction survey

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 8 December: Morning Session

- Item 8 – Restrictions (continued)
 - 8.1 Restriction Annex XV dossiers
 - a. DMFu – second draft opinion (2nd discussion, if needed)
 - b. Lead and its compounds – second draft opinion (2nd 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 (2nd 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 (3rd discussions, if needed)

Item 8 – Restrictions (continued)

8.1 Restriction Annex XV dossiers

- a. DMFu – second draft opinion (3rd discussion, if necessary)
- b. Lead and its compounds – second draft opinion (3rd 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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