EUROPEAN COMMISSION



HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment

C7 - Risk assessment

Scientific Committee on Health and Environmental Risks (SCHER)

Working group meeting on Risk Assessment Improvement (RAI)

Meeting date: 15 June 2010 starting at 10:00

B232 room 02/17A – Brussels

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed the participants in the two subgroups [on REACH and socio-economic analysis (SEA) and on Integrated Risk Assessment and Sustainability (IRAS)] and indicated the apologies received. Annex I contains the list of participants in the meeting.

2. MORNING MEETINGS OF THE TWO SUBGROUPS (10:00-12:00)

The two subgroups [(SEA) and (IRAS)] discussed the issues at hand.

The items below were conducted during the plenary session of the working group (WG) in the afternoon.

3. ADOPTION OF THE AGENDA

The agenda was approved after two additions:

- (i) discussion of a proposal for the setting up of a third subgroup on Methodological issues item 6.7 below;
- (ii) discussion of the structure of the opinion (number and scope of the chapters) item 6.8 below.

4. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

There were no new declarations stated.

5. ADOPTION OF THE MINUTES OF THE LAST MEETING

The minutes of the previous meeting held on 17 May were approved after some minor modifications (final version attached).

6. AFTERNOON PLENARY SESSION (13:00-16:00)

- 6.1. Feedback from the morning sessions of the two subgroups.
 - Main outcomes/conclusions of the SEA subgroup (Helmut and Stavros reporting):
 - SEA and RA need to be brought together.
 - Involve William Watts (senior economist at UK EPA) and possibly Marc Eberad (?) (not sure about the spelling). [ACTION Stavros to make informal contacts; Vladimir to follow up]
 - Low-dose uncertainties need to be properly described and made more explicit.
 - If there is no uncertainty, the absence of risk should be stated (e.g. when exposure levels are below the 10x10 level)

- Main outcomes/conclusions of the IRAS subgroup (Jim reporting):
 - There is a need to identify what is already taking place in terms of integrated RA (e.g. WGs on chemical mixtures, weight of evidence, exposure assessment, nanodefinitions, etc.)
 - There is a need to identify the existing gaps and to avoid repletion.
 - There is a need to establish a circa site [ACTION: Vladimir].
 - The goal is to draft a document by Nov/Dec 2010 and to link it with the 2nd International RA Conference to be held in late January 2011.
 - Suggested contents of three subchapters of the IRAS chapter of the opinion:
 - 1.Idenitfication of the issues;
 - 2. Integration issues (across species, across stresses, across exposure sources, and across lifecycle) each of which will need an SEA input with Roy playing the central role;
 - 3.Sustainability issues (economic, social, and natural/environmental) taking into account scarcity of resources, energy, green-house-gas emissions, non-recyclable waste, etc. and with boxes of case studies (like Hg in light bulbs, etc.) and with the precautionary principle as an interface between the cases.

6.2. Summary and main conclusions from the consultations with risk managers.

- The questionnaire is a good diagnostic tool for the issues that need to be tackled (the main results are listed in the minutes of the previous meeting).
- There is a need to involve senior-level managers including directors-general and heads of unit.
- The information received from the questionnaire may be used as a guide to approaching decision-makers including specific options to discuss and choose from.
- The European Parliament (chairs of some committees) is to be involved at some point.
- The arrangements for the contacts with senior-level managers are to be coordinated by the secretariat plan of action to be put before the September Plenary [ACTION: **Peter/Vladimir**].

6.3. Feedback from Christophe on the USEPA/NRC activity.

- The report which reviews the RA practices deals with issues that are similar to the mandate of this WG.
- In the report, the uncertainty issue is not well developed.
- A new framework is to replace the "Red Book", which aimed at separation of risk assessment from risk management. In this new framework, the close interactions between risk assessors and risk managers is emphasised, i.e risk assessors are to deal with all risk management options.
- The new framework expects the involvement of stakeholders in the RA process.

- Move away from risk characterization and from threshold estimates towards dose-response analysis with emphasis on human as opposed to environmental health.
- The whole report needs to be placed on circa by the secretariat.
- Christophe is to cross-reference the product of this WG with the NRC report.
- The discussion that followed indicated that stakeholders already participate in the RA process through consultation of the mandate and the opinions. This issue may need to be revisited further.
- 6.4. Feedback from Jose on the meeting organised by JRC and EEA in May.

Jose to report at the next meeting. [ACTION: **Jose**. Contact should be made with DG RTD to discuss any likely connections between the recommendations of the WG and the EU Research programme.]

6.5. Feedback from Peter on EFSA.

Peter informed the participants about the main conclusion: ecological risk assessment to be linked to the ecosystem services as a criterion to judge the impact in value-relevant terms. This should be taken into account by the SEA group

6.6. Feedback from Peter about the Ottawa meeting.

One aspect of RA which was discussed in Ottawa and which may be relevant to this WG is the use of the tools of behavioural science. The presentation by Dr. Fitzpatrick is to be put on the circa site by the secretariat.

6.7. The proposed new Methodological subgroup.

The participants endorsed the idea; however, those issues may need to be addressed a bit later in the work, i.e. to be integrated in the final chapter of the opinion.

6.8. Structure of the opinion.

The following 5 chapters were proposed by the Chair and endorsed by the WG:

- 1. Introduction
- 2. Dialogue with risk managers and its outcome
- 3. SEA and REACH
- 4. IRA/Sustainability
- 5. Summary (including methodological issues as proposed)

7. DISTRIBUTION OF TASKS (ACTIONS, PLAYERS, AND DEADLINES)

Initial contacts with W. Watts (Stavros) and invitation sent for the next meeting (Vladimir) by **June 25**.

Establishment of a circa site (Vladimir) by July 6.

General framework (bullet points) for each of chapters 1 (Peter), 3 (Stavros), and 4 (Jim) by **July 11**.

Discussion via e-mail of the general framework for IRA/Sustainability (Jim/Theo/Peter/Roy) and REACH/SEA (Helmut/Stavros/others) by **July 14**.

Contact to be made with DG RTD to discuss any likely connections between the recommendations of the RAI WG and the EU Research programme (Jose) by **September 23**.

Plan and organization of interviews to be conducted with senior risk managers (Peter and Vladimir) by **September 23**.

An early draft of the opinion by **December 2010**

A final draft by June 2011

- 8. Next meeting 14 July 2010
- 9. ANY OTHER BUSINESS

There was none.