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: 17 May 2010 starting at 10:00

B232 room 02/17A – Brussels

Minutes

1. WELCOME AND APOLOGIES

Apologies were received from Roy Brouwer, Tomas Oberg (EFSA), and Karin Nienstedt (EFSA)

2. ADOPTION OF THE AGENDA

The agenda was approved.

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

There were no declarations stated.

4. TOUR DE TABLE (BRIEF INTRODUCTIONS BY EACH PARTICIPANT)

Each participant introduced herself/herself in a tour de table.

5. DISCUSSION

5.1. Review of the mandate and the overall goals of the exercise

The Chairman reviewed the mandate and clarified the steps taken so far.

5.2. Discussion of the responses to the questionnaire

Question 1: Do you think that you clearly understand the process of risk assessment including its underlying data, assumptions, hypotheses, uncertainties, expert judgement and limitations?

- Even though experienced risk managers feel that they clearly understand the process of risk assessment (RA), there is a need to create a guidance document about this process for less experienced colleagues (especially distinguishing between hazard and risk).
- How do committees draw their conclusions? Even though this is done on a case-by-case basis, there are some general principles. Weighing the evidence and the level of uncertainty sit at the core of this process. These two aspects of the RA process are like two sides of the same coin.
- The RA process needs to be spelled out in concrete terms and published.
- Minority opinions are not particularly helpful.
- The general conclusion is that the RA process is generally well understood.

Question 2: Do you think that outputs from risk assessment (the scientific opinions) are clear?

- The expression "more research is needed" is not helpful. Concrete suggestions about what is needed "now" would be more helpful.
- The opinions are like a "gold standard" which puts a lot of burden on the experts to deliver something that is based on solid data. Sometimes the available data may not be conclusive and the answers still have to be provided. Therefore, the expert judgement is essential here. The opinions are never questioned for their validity by the risk manager.
- Cost-benefit analysis means to get away from the opinion *per se*, however, this analysis may be quite helpful to the risk manager.
- The language used in the opinions needs to be precise and quantifiable (as much black-and-white as possible).
- There are 5 steps in the RA process: (i) nature of risk; (ii) magnitude of risk; (iii) uncertainty level; (iv) comparison with other risks; and (v) expression of risk (as a specific figure in terms of probability or qualitatively using consistent language).
- It may be better to say "this level of risk requires action".
- The general conclusion is that opinions need more clarity and consistency in the expression of risk.

Question 3: Do you think that risk assessment should be coordinated with the cost-benefit analysis?

- The short answer is "no" because the Commission performs Impact Assessments which include cost-benefit analysis. Therefore, this analysis does not need to be part of the opinions.
- However, risks should be expressed in a way that facilitates impact assessment.

Question 4: Do you think changes are needed in the way risk is communicated to risk managers?

- Yes, in terms of expression of risk.
- The mandates should be as clear as possible, and the opinions should as much as possible give a clear answer to the questions asked
- The opinions should be reviewed from legal and regulatory perspectives, in particular in order to ensure consistency in the terminology used and avoid diverging interpretation afterwards

Question 5: What are your suggestions for changes, if any, in the risk assessment and/or its communication that may be helpful to risk managers?

- Clarity
- Precision
- Summary after each section
- Overall summary (Sometimes the opinions end abruptly and it is necessary to search back through the text to extract the key statements)
- Holistic approach
- It would be useful if the opinions clearly expressed when doubts are present and, for instance what meaning is attached to missing data.

Question 6: What are the elements (background information, requests, guidance) that risk managers can/should offer to the risk assessors so that they can deliver optimal/usable results?

- More formalized discussion of the mandates between risk assessors and risk managers. The best way to ensure that the opinion fulfils the expectations of the risk manager is for the risk manager to sit in on the committee's discussions to clarify the mandate where necessary.
- Clarity of the mandate: What we want to protect? What are the expectations?
- What is being done on the issue under discussion in elsewhere (the US, Japan, etc.)
- Few risk assessors have a good grasp of the legislative constraints within which risk managers are operating. It could be useful if for each Committee one member or one person from the secretariat was identified as being the resource relating to a specific piece of legislation. That member could then take contact with the DGs and Agencies concerned in order to develop a better knowledge of the legislation and the way it is applied.

Question 7: Are you of the opinion that societal / ethical aspects ought to be included in some way or another into the RA process? If so, in what way/form would you like to see this happening?

- The short answer is "no" because ethical issues change over time and cultures. Risk analysis is objective and this is the main strength of the committee's opinions. They are the Commission's gold standard for evidence-based decision making.
- However, ethical issues should be mentioned.
- Ethical issues are usually considered by the European Parliament.

Question 8: While the application of the precautionary principle is strictly a risk management issue, if you agree with the notion that "the precautionary principle should be considered within a structured approach to the analysis of risk", how is this to be achieved?

- The precautionary principle is totally in the hands of risk managers given that the level of uncertainty is clearly defined and communicated in the opinions (only when there is lack of suitable data to perform proper risk assessment).
- High level of uncertainty is not useful. It renders the opinion meaningless.

- Transparency is essential. Expressing uncertainty is always a matter of expert judgement which needs to be transparent and stated clearly.
- There is no need to involve the European Parliament unless it is absolutely necessary.
- This issue could be dealt with in a more systematic way through the development of guidelines that could be used by risk assessors and risk managers but I am not sure that you could impose a standardized approach. (1: 10,000 chance of cancer vs. 95 percent chance of PEC/NEC < 1- How do you compare?)

Question 9: What are your overall expectations and needs from risk assessment and communication? How exactly are the opinions being used in practice (e.g. in drafting legislation)?

- Expect clear and fully objective view on whether a risk exists or not, and if it exists on the magnitude of the risk i.e. how many additional deaths in the EU
- The opinions are used as a basis for legislative proposals in the field of cosmetics and medical devices.
- Varies for the different pieces of legislation and in particular is dependent upon whether consultation of the risk assessor group is compulsory or not.
- The opinions are used to show that there is a risk that needs to be managed. They are therefore the justification for legislative restrictions and bans e.g. those in Annex XVII of REACH. The opinions allow the Commission to defend its proposals against amendments in Council and Parliament, for example to introduce additional measures to "protect" the environment when the risk is only to human health. In the absence of clear scientific committee conclusions, the Precautionary Principle is all too readily evoked to justify concerns, however unrealistic.
- The risk management measures adopted on the basis of scientific committee opinions in the past often seem to lack consistency. In fact, they were influenced by the public perception of the risk at that time i.e. benzene in petrol is tolerated, but PAHs in tyres are not. Asbestos is banned in all manufactured articles, but asbestos containing rock is still used for construction e.g. ballast for railways in Italy, the construction of dams in Greece. This should be less noticeable in the future now that the Commission has introduced a requirement for a formal impact assessment for all legislative procedures. The REACH RA and SEAC procedures are regarded as equivalent to the formal impact assessment.

6. NEXT MEETING – 15 JUNE 2010

7. ANY OTHER BUSINESS

There was none.