



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

**INTER-COMMITTEE CO-ORDINATION GROUP
(ICCG)**

**Meeting date: 25 November 2010, starting at 10:00
F101 room 02/169 (Rue Froissart 101, 2nd floor), Brussels**

DRAFT MINUTES

1. WELCOME AND APOLOGIES

The Chairman (TD) of the meeting welcomed the participants. There were no apologies received.

2. ADOPTION OF THE DRAFT AGENDA

The Agenda was approved without modifications.

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

No interest in the items of the agenda was declared

4. APPROVAL OF THE MINUTES OF THE PREVIOUS MEETING

The minutes of the previous meeting were approved with a small modification indicating that PH participated in the SCHER WG on lead in drinking water in his personal capacity as an expert, not as a representative of SCHER. The need to be more descriptive about the activities of SCCS was expressed.

ACTION: A proposal is to be prepared to clarify the issue of participation of a scientific-committee member as either in his/her personal capacity or as a representative of the respective committee.

5. INFORMATION EXCHANGE

5.1. Administrative, procedural, methodological and general matters, horizontal activities and issues.

- (a) The Journal of the EC Scientific Committees and its Editorial Board

The Chairman outlined the Commission's proposal for the ICCG to be the Editorial Board including one member from the Commission (BD). A second proposal emerged for the Editorial Board to consist of a smaller configuration of ICCG members, while the entire ICCG serve as a steering committee. Concerns were raised about: a) the extra workload involved; and b) the independence of the Editorial Board in the absence of external review. The Chairman further elaborated that the Editorial Board will most likely be involved in

reviewing the work performed by an external contractor and in identifying people to write editorials. Suggestions were made for the Journal to include: a) the whole opinion as is; or b) the executive summary only. The Editorial Board will have the final word on those issues. The main problem facing the Committees is risk communication (RC) for risk managers and the general public. It is unlikely that the Journal could alleviate this problem but it is worth exploring the options in that respect.

ACTION: - Future ICCG meetings need to address the RC issue

- ICCG endorses the creation of the Journal.

- (b) SCENIHR position paper: Evaluation of the scientific literature and weight of evidence.

The ICCG recognises the urgency and importance of this paper which should serve as guidelines (not a prescriptive set of rules) and should remain an evolving, "living" document to be adopted by all three SCs.

ACTION: - JB to prepare and circulate to the SCs the next version taking into account the suggestions voiced i.e. (i) further development of the eco part; (ii) introduction of historical controls; (iii) extensive overview of the already existing approaches to evaluation of evidence; (iv) concentrate on the first step – criteria for selection of the scientific sources – before moving on to the evaluation of those sources, mode of action, etc.; (v) add clinical studies; (vi) accommodate the cosmetics regulatory aspects which may prescribe a specific *in vitro* test as the sole methodology for a product; and finally, (vii) test the framework on some existing opinions.

- (c) Independence of the WG experts

The ICCG recognises the urgency and importance of this paper which should serve as guidelines (not a prescriptive set of rules) and should be adopted by all three SCs. :

ACTION: - JB to prepare and circulate to the SCs the final version after some further development of the personal-and-specific section;

- To develop two new versions of the Declaration of Interest which will use the format seen in Lancet and the BMJ (with boxes to simply tick). One annual version and a second version to be used before each WG meeting or all committee-related activities (workshops, conferences, etc.).

- JB to draft some guidelines that could be used for the selection of experts both for the SCs and for WGs. Some ideas of how to evaluate the ability of a potential candidate to work in a team are highly welcome.

- (d) Working procedures

- The issue of non-participation of some members in the work of the SCs was discussed and the Commission services explained the actions
- The issue of late contributions was discussed and it was decided that all submissions should be sent out at least a week in advance of a particular meeting.
- allowing sufficient time for discussion

(e) Replacement of the resigning members

The Commission services communicated the procedures for replacement of three members of SCCS, one of SCENIHR, and two of SCHER.

5.2. Information from/to Chairs on the Committees' activities

5.2.1. Joint activities and issues of common interest

(a) TTC

The opinion is planned for adoption on 14 Dec. by SCCS. Any additional comments from all SCs are welcome before that date.

(b) Improvements in risk assessment

The WG concluded the interviews with high-level risk managers and the next step is to get the European Parliament involved. The work with the text of the opinion (the two subgroups – on socio-economic analysis and integrated risk assessment) is going as planned. The preliminary report will be presented at the 2nd International Conference on Risk Assessment.

(c) Combination effects of chemicals

The work in the WG is progressing well expecting to have a more or less complete draft by February. The State-of-the-Art report commissioned by DG ENV is considered a seminal publication which covers the subject in an excellent manner. However, there are two issues with this report that need to be carefully addressed and re-evaluated vis-à-vis the evidence in the current literature: (i) the conclusions about low-dose effects; and (ii) the focus on endocrine disruptors.

(d) New challenges for risk assessment

This project, as opposed to the improvement of risk assessment exercise concentrates on the risk-assessment methodology. The exposure assessment and the eco part are components that need to be tackled. The WG doubts the line taken by with the US National Academy of Sciences report which presents human cell lines as a panacea for risk assessment.

5.2.2. SCCS – Summary of ongoing activities

- The hair dyes opinions may be completed in 2011.
- Industry reacted positively to the reaction products opinion
- The WG on fragrances should complete its comprehensive review within a year.
- The paraben opinion was just completed and its conclusions are considered well-balanced between the different interest groups.
- The food-imitating products document has an extended deadline. Public consultation will run until mid-February and final adoption envisioned in March.

5.2.3. SCHER

The Chair of SCHER and its secretariat informed the ICCG about its current activities as follows:

(a) Chemicals and the Water Framework Directive: Technical Guidance for Deriving Environmental Quality Standards

The opinion was adopted last month.

(b) Fluoridation of Drinking Water

The WG is currently studying the contributions received as a result of the public consultation and public hearing. Adopted not expected before March.

(c) Lead standards in drinking water

Adoption expected in January 2011. Main conclusion: In the absence of a threshold for lead, there is no basis for increasing its level in drinking water due to lower exposure to lead elsewhere in the environment.

(d) Uncertainty for Risk Assessment and Risk Management (International perspective)

On-going activity in view of the upcoming 2nd International Risk Assessment Conference.

(e) Assessing Human Exposures for Risk Assessment and Risk Management (International perspective)

On-going activity in view of the upcoming 2nd International Risk Assessment Conference.

5.2.4. SCENIHR (Jim Bridges/KB/AK)

(a) Tobacco Additives

The main conclusions: Nicotine is the only addictive agent. Acetaldehyde increases its addictiveness which is a strange finding given the fact that acetaldehyde is rapidly metabolized in the organism.

(b) Artificial Light

The opinion is ready for public consultation and hearing scheduled for 2011.

(c) Nanodefinitions

There are 94 contributions to the public consultation on the nano-definition opinion which are to be discussed by the WG.

6. NEW REQUESTS

The responsible secretaries for the new opinions explained the essence of the requests as follows:

a) Nitrosamines in cosmetic products and balloons (SCCS)

Some of the nitrosamines, such as N-nitrosodiethanolamine (NDELA) and N-nitrosodimethylamine (NDMA) are classified as category 1B carcinogens. The SCCS is requested to assess the safety of NDELA in cosmetics and nitrosamines in balloons.

b) Request for a clarification of entry 411, Annex II of the Cosmetics Directive (secondary alkyl-amines) (SCCS)

The SCCS is asked to elaborate an opinion on the potential risks to human health by the presence of nitrosamines or of chemicals which contain secondary amine groups which could give rise to nitrosamines with the view to guide the Commission in revising the relevant entries of Annexes II and III of the Cosmetics Directive (76/768/EEC). The mandate is to be open for public consultation until the end of January. Only one WG will deal with both nitrosamine requests (a and b)

c) Synthetic Biology (SCENIHR)

This mandate is under consideration.

d) TCEP in Toys (SCHER)

Following the publication of the CMRs in Toys opinion, DG ENTR asks the Committee if there are risks when TCEP, *tris*(2-carboxyethyl)phosphine (or its halogenated alternatives) is used in toys or part of the toys.

e) Environmental Quality Standards under the Water Framework Directive (SCHER)

After the delivery of the opinion on the Technical Guidance Document related to the Water Framework Directive, DG Environment now seeks

the opinion of the SCHER on the draft Environmental Quality Standards (EQS) for the proposed priority substances and the revised EQS for a number of existing priority substances.

f) Aircraft Cabin Air Quality (SCHER)

This mandate is under consideration and will involve ECDC.

g) Air and water quality in swimming pools (SCHER)

This mandate is under consideration and will involve ECDC.

7. COLLABORATION WITH OTHER COMMUNITY BODIES

Information on the Chairs Meeting: Copenhagen, 11-12 November 2010 (*report of the outcomes*)

The participants in the meeting outline its main conclusions: (i) the focus on specific, cross-cutting scientific issues for discussion proved a successful one; (ii) there is a need to re-evaluate the format of the meeting in view of increasing its effectiveness; and (iii) the expectation is from its participants to supply unit C7 with their ideas for the future of this exercise.

8. THE EU AND INTERNATIONAL RISK ASSESSMENT DIALOGUES

Organisation of the 2nd International Risk Assessment Conference

The agenda was distributed and the main goals of this event explained.

9. ANY OTHER BUSINESS

Organisation of the 4th Nano Safety-for-Success Dialogue

The Nano Dialogue will be held on 29-30 March 2011. Its main focus will be the scientific aspects of nanotechnology.