

EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment Risk assessment

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

9TH PLENARY MEETING

Held on 28 June 2010 in Brussels

Minutes

1. WELCOME AND APOLOGIES

The Chairman, Prof. J. Bridges, opened the meeting and welcomed the participants. Apologies were received from Prof. A. Auvinen, Prof. K. Dawson, Dr. W. De Jong, Dr. H. Norppa, Dr. J.-M. Pagès, Prof. K. Schulze-Osthoff, Dr. J. Schüz, Prof. D. Stahl and Dr. T. Vermeire. As less than 50% of members were present at the meeting, all decisions, and in particular approval of opinions for public consultation, would be taken by written procedure.

2. ADOPTION OF THE DRAFT AGENDA

The draft agenda was adopted as written, with a few changes in the order of points under discussion. Additional items were discussed under item 11 of the agenda.

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

The Chair of the SCENIHR Working Group (WG) on Artificial Light informed the Committee that some of the invited external experts had declared an interest in view of their affiliations.

Taking into account the nature of the declarations made, the Committee decided that it did not constitute a conflict of interest and that the external experts could participate in the discussions on this matter.

In addition, one of the experts, invited to the last WG-meeting on an ad-hoc basis had provided additional clarification on the nature of his activities.

Taking into account this explanation, the Committee decided that this expert would be asked to continue supporting the WG on an ad-hoc basis as considered necessary, e.g. by providing information on specific issues and comments on the draft opinion. The expert would not become a full member of the WG due to funding of research activities received from industry related to the scope of the mandate.

4. APPROVAL OF THE MINUTES OF THE PREVIOUS PLENARY MEETING

The draft minutes of the 8th plenary meeting were adopted with one minor modification. The minutes are available at:

http://ec.europa.eu/health/scientific committees/emerging/docs/scenihr mi 036.pdf

5. CHAIR'S/MEMBERS' REPORT

5.1. Inter-Committee Coordination Group (ICCG), 8 June 2010

The Chairman informed members about the status of activities in light of the 6th Meeting of Chairs (11-12 November 2010, Copenhagen) and the 2nd International Risk Assessment Conference (25–28 January 2011, Brussels). The ICCG had furthermore endorsed the creation of an on-line "Journal of the Scientific Committees of the EC", approved a general disclaimer on personal ethical considerations of the experts, and endorsed the idea to prepare for each opinion, as a separate document, a list of all sources of information (cited and not cited in the opinion) that the committee examined during its deliberations. It discussed tentative rules for collaboration between EU-bodies involved in RA (as a starting point towards the development of future rules on collaboration) and agreed to add an additional annex to the Rules of Procedures, describing independence of experts and various forms of contributions to the work of the Scientific Committees. It also discussed the results of the survey conducted among the members of the Scientific Committees and the revised rules on indemnities regarding participation in meetings via audio link or electronic means.

5.2. Other

None

6. ONGOING WORK

6.1. Tobacco Additives (for approval for public consultation)

The Chairperson of the WG informed the Committee about the ongoing work and presented the draft opinion to the plenary followed by a discussion. The draft was slightly modified to enhance clarity and certain areas were highlighted where additional revision was still needed. Following a final round of revision and checking by the WG and the Secretariat, the opinion would be sent for approval by written procedure to the SCENIHR. Following final editing, a public consultation on the opinion would be held until early September. It would be available at the following link:

http://ec.europa.eu/health/scientific committees/consultations/public consultations/scenihr cons 12 en.htm

6.2. Methodology / Weight of Evidence Approach (for discussion)

The Chairperson informed the Committee about the revisions carried out on the draft document and the discussion at the last WG-meeting. Members further discussed and revised the document. It was agreed to use the paper as a working paper in the context of the ongoing work before finalizing it officially.

6.3. Artificial Light (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work and the last WG-meeting where the structure of the opinion was further revised. A new external expert had joined the group and an expert invited on an ad-hoc basis made a presentation related to the health effects of artificial lights.

The call for information had been extended to 2 July as little information was provided by the original deadline.

6.4. Nanodefinitions (for approval for public consultation)

In absence of the Chairperson of the WG, a WG-member informed the Committee about the ongoing work and presented the draft opinion to the plenary followed by a discussion. The draft was modified to reflect the outcome of the discussion and to highlight areas where additional revision was still

needed. Following a final round of revision and checking by the WG and the Secretariat, the opinion would be sent for approval by written procedure to the SCENIHR. Subsequently, a public consultation on the opinion would be held until mid September. It would be available at the following link:

http://ec.europa.eu/health/scientific committees/consultations/public consultations/scenihr cons 13 en.htm

7. JOINT OPINIONS / PARTICIPATION OF MEMBERS IN ACTIVITIES OF OTHER SCIENTIFIC BODIES

7.1. Improvements in risk assessment approaches (SCHER, SCCS, SCENIHR)

A member participating in the cross-committee WG informed the Committee about the ongoing work. It was foreseen to provide the outcome of this work as input to the International Risk Assessment Conference in 2011.

7.2. Threshold of Toxicological Concern (TTC) Approach for Safety Assessment of Chemical Substances (SCCS, SCHER, SCENIHR)

A member informed the Committee about a recent WG-meeting. Due to the need for further revision an additional meeting of the WG was scheduled for the end of September. Upon completion, the joint opinion would be circulated to the Scientific Committees for a final check before being scheduled for final adoption at the subsequent plenary sessions of the three Committees. For SCENIHR, adoption was expected for the plenary session in November.

7.3. Other

Nanomaterials in Cosmetics

A member participating in the WG organized by the Scientific Committee on Consumer Safety (SCCS) informed the Committee about the ongoing work. Additional data from industry was still awaited for the assessment.

Triclosan

A member participating in the WG organized by the SCCS informed the Committee about the public consultation that resulted in 10 contributions. The opinion had been revised to reflect all relevant comments and the list of references was updated with relevant publications. The scientific rationale and the opinion were clarified and strengthened in certain respects. The overall opinion, however, remained unchanged.

The final opinion was available at the following link:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_023.pdf

Guidance on Risk Assessment - applications of nanoscience and nanotechnologies to food, feed, and pesticides (EFSA)

The Secretariat informed members about an upcoming meeting of the WG.

8. FEEDBACK BY COMMISSION SERVICES ON FOLLOW-UP TO OPINIONS

None

9. **N**EW REQUESTS

The Secretariat and the Chairman informed members about a new request in relation to new challenges for risk assessment. This mandate had been developed as a follow-up to the discussions at the last Meeting of Chairs and Secretariats of the Scientific Committees and Panels of Community bodies involved in risk assessment.

It had been noted that despite a growing data base that supports risk assessments and several challenges encountered (e.g. access to data, exposure assessment and the explanation/expression of findings), the general procedures have not changed significantly in the last two decades. Furthermore, changes concerning both the nature and interpretation of data available for risk assessment are expected in the near future. These include e.g. the increasing restrictions on the use of animals for testing purposes in the EU and the need for alternative testing strategies and models, the availability and usability of data from new/rapidly advancing methodologies as well as developments in mode of action research.

With this request the three non-food Scientific Committees are asked to carry out a joint comprehensive review of risk assessment procedures and new challenges for RA and to provide a scientific opinion on the issue. The WG, to be chaired by a SCENIHR-member, would involve members from the three Committees plus appropriate external experts representing the different sectors and key disciplines, as well as specialists in relevant new methodologies. An expert meeting/workshop on the issue may be held throughout the process of developing the opinion.

The final version of the mandate is available at the following webpage:

http://ec.europa.eu/health/scientific committees/docs/challenges mandate en.pdf

Several members indicated an interest in participating in the WG. A first WG-meeting was scheduled.

10. EMERGING ISSUES

None

11. ANY OTHER BUSINESS

Stakeholder Meeting on Nanomaterials

The Secretariat informed about a recent meeting with stakeholders on the use of nanomaterials in textiles that was well attended by relevant stakeholders. A follow-up meeting of the same group was planned for September.

Resignation of Prof. Dorothea Stahl

Prof. Dorothea Stahl had resigned from the Committee due to a change in her professional position. The Chairman expressed his gratitude for her contribution to the work of the SCENIHR and would send her a letter. The Secretariat had launched the procedure to recruit a replacement from the Pool of Scientific Advisers.

Annex I: List of Participants.

Annex I

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

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LIST OF PARTICIPANTS

MEMBERS OF THE SCENIHR:

Prof. J. BRIDGES (Chair), Prof. P. HARTEMANN (Vice chair), Prof. P. HOET, Dr. T. JUNG, Prof. M.-O. MATTSSON, Prof. A. PROYKOVA, Prof. E. RODRÍGUEZ-FARRÉ, Dr. M. THOMSEN

EUROPEAN COMMISSION:

SCENIHR Secretariat (DG SANCO):

Mr. L. BONTOUX, Ms. K. BROMEN, Ms. N. FOUVEZ, Ms. A. KANELLOPOULOU, Mr. P. MARTIN.

Other Commission staff:

Mr. H. LAURSEN (ENV), Mr. O. LINHER (ENTR), Mr. G. LÖVESTAM (JRC-Geel), Ms. T. PEETSO (DG SANCO), Mr. S. PICKERING (ENTR), Ms. M. PUOLAMAA (ENTR).