EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment **Risk assessment**

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

7TH PLENARY MEETING

Held on 17 March 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. K. Dawson, Prof. P. Hoet, Dr. H. Norppa, Prof. K. Schulze-Osthoff, and Prof. D. Stahl.

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 several of the invited external experts had declared an interest in view of their affiliations.

The Chair of the SCENIHR WG on Nanodefinitions informed the Committee that several of the invited external experts had declared an interest in view of their affiliations.

Taking into account the nature of this declaration, 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.

4. APPROVAL OF THE MINUTES OF THE PREVIOUS PLENARY MEETING

The draft minutes of the 6th plenary meeting were adopted with one minor modification. The minutes are available at:

http://ec.europa.eu/health/scientific committees/emerging/docs/scenihr mi 034.pdf

5. CHAIR'S/MEMBERS' REPORT

5.1. Inter-Committee Coordination Group (ICCG), 1 February 2010

The Secretariat and vice-chairs informed members about the status of the follow-up activities to the 5th meeting of Chairs (harmonization of terminology, emerging risks, exposure assessment) that will also feed into the 2nd International Risk Assessment Conference in January 2011, the statistics of attendance of Committee-members in meetings, the revised rules on indemnities for participation in meetings via audio link or electronic means, the changes in DG Health and Consumers (SANCO) under the new Commission, and the discussions between EU bodies on guidelines to prevent divergences.

5.2. Other

None

6. ONGOING WORK

6.1. Tobacco Additives (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work. Following discussions with the requesting service, the deadline for this request was extended to September 2010. About 20 documents had been submitted during the call for information (deadline: 11 January 2010) that were discussed by the WG.

6.2. Reprocessing of Single-use Medical Devices (for discussion)

The Chairperson and the rapporteurs of the WG informed the Committee about the ongoing work and presented the draft opinion to the plenary followed by a discussion. Members provided feedback to the opinion that was foreseen to be completed in the upcoming final meeting of the WG. After this meeting the opinion would be sent to members for adoption by written procedure. Following adoption and subsequent final editing it would be published at the following webpage:

http://ec.europa.eu/health/scientific committees/emerging/docs/scenihr o 027.pdf

Representatives from DG Health and Consumers (SANCO) thanked the SCENIHR and the WG for the work carried out.

6.3. Antimicrobial Resistance effects of Biocides – Research Strategy (for discussion/adoption)

The Chairperson of the WG presented the draft opinion to the plenary followed by a discussion. The draft was slightly modified to enhance clarity. The opinion was adopted. Following final editing, the opinion would be published at the following webpage:

http://ec.europa.eu/health/scientific committees/emerging/opinions/index en.htm#1

A representative from DG Environment (ENV) expressed his appreciation for the work carried out by the SCENIHR. The relevance of discussing the recommendations in the context of appropriate funding schemes was emphasized.

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

The Chairperson informed the Committee briefly about the contributions received on the draft document. It was agreed that WG-members would send additional contributions to the Chairperson who would establish a joint version before seeking input from other SCENIHR-members. The discussion on the draft was postponed to the next plenary.

6.5. Artificial Light (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work. The mandate had been slightly revised following the public consultation. The results of the consultation are described in an explanatory document that was published together with the final mandate.

Link to final mandate:

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_q_025.pdf

Link to explanatory document:

http://ec.europa.eu/health/scientific committees/emerging/docs/scenihr q 025b.pdf

The WG had prepared a first outline of the opinion. It was foreseen to identify additional experts to support the WG.

6.6. Nanodefinitions (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work and the $1^{\rm st}$ WG meeting. Several experts had already been identified and additional WG-meetings scheduled to respond to the short timeline of the request. For the same reason, it was foreseen to adopt the opinion by written procedure.

Link to Mandate:

http://ec.europa.eu/health/scientific committees/emerging/docs/scenihr g 024.pdf

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

7.1. Guidance document on antimicrobials used in food decontamination (EFSA)

A member representing the SCENIHR in the WG of the European Food Safety Authority (EFSA), which is preparing the guidance document on behalf of the EFSA-BIOHAZ panel, presented the opinion to the Committee and informed them about the last steps in finalizing the report.

The report in question had been adopted recently by the BIOHAZ Panel of EFSA. After discussion, the SCENIHR endorsed the report. Nevertheless, some remarks were formulated by SCENIHR members on the process, terminology used as well as on certain formulations in the report. On the process, members regretted that the report had been submitted to the SCENIHR for endorsement only after its adoption by the BIOHAZ Panel of EFSA. SCENIHR emphasized once more the need for rules and procedures on collaboration between different EU-bodies involved in risk assessment and stressed the importance to launch work for developing and defining clear operational procedures for future collaboration between Scientific Committees/Panels of different EU-bodies.

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

A member participating in the cross-committee WG informed the Committee about the ongoing work and the relevance for the work carried out by other bodies for the tasks at hand.

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. The WG sent questions about the dossier to industry. Industry agreed to provide the required answers, but this would take time as new data would have to be generated. Regular follow-up meetings with industry would be organized to monitor progress.

Triclosan

A member participating in the WG organized by the Scientific Committee on Consumer Safety (SCCS) informed the Committee about the ongoing work that would soon be finalized and enter public consultation subsequently.

Threshold of Toxicological Concern (TTC) Approach for Safety Assessment of Chemical Substances

A member informed the Committee that the non-food Scientific Committees had provided comments on the opinion that had been revised after the public consultation and the subsequent hearing. To account for the suggestions made, an additional WG-meeting would be held. Upon completion it would be circulated to the Committees for adoption.

Depleted uranium

A member participating in the WG organized by the Scientific Committee on Health and Environmental Risks (SCHER) informed the Committee about the opinion that had been approved by SCHER for public consultation on 1 March. A Public consultation on the pre-consultation opinion was launched on 5 March (deadline: 12 April 2010). More information was available at the following link:

http://ec.europa.eu/health/scientific committees/consultations/public consultations/scher_cons_04_en.htm)

An additional WG-meeting would be held following the public consultation.

Mercury in light bulbs

A member participating in the WG organized by the SCHER informed the Committee about the ongoing work which is expected to be concluded shortly.

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

Personal Music Players

A representative from DG SANCO provided a short update on further follow-up to the earlier opinion on personal music players¹.

A mandate for the development of new safety standards was sent to the European standardisation bodies in September 2009. The standards should ensure that exposure to high sound levels is limited and that users are provided with adequate warnings and information on health risks. They are based on the safety requirements as defined in the Commission decision 2009/490/EC² adopted on 23 June 2009, which refers to the SCENIHR-opinion. The standards will be developed by CENELEC within a 2-year period.

Additional information can be found at the following webpage: http://ec.europa.eu/consumers/safety/projects/index en.htm#mp3

Mercury Sphygmomanometers

A representative from DG Enterprise and Industry (ENTR) informed that the European Chemical Agency (ECHA) was currently preparing an Annex XV dossier under the provisions of the REACH Regulation to restrict the marketing of mercury sphygmomanometers with some exemptions, as recommended in the SCHENIR opinion.

9. New requests

none

¹ See http://ec.europa.eu/health/archive/ph risk/committees/04 scenihr/docs/scenihr o 018.pdf

² See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:161:0038:0039:EN:PDF

10. EMERGING ISSUES

Several members had provided feedback on this issue since the last plenary meeting. Due to time constraints it was decided to postpone the discussion on this issue to the next meeting. In the meantime, the Chairman would further revise the presentation of the working documents.

11. ANY OTHER BUSINESS

Definition of independence, categorization of interests, and experts' involvement in WGs

Members briefly discussed the draft document describing different potential mechanisms for involving external experts in WGs and the meaning of independent advice. Following internal discussion and a brief discussion at the last meeting of the Inter-Committee Coordination Group (ICCG), where the SCENIHR Vice-Chairs and the Secretariat had described the background of the draft proposal, it had been sent to the three non-food Scientific Committees for comments. Subsequently, it would be further discussed at the next meeting of the ICCG.

The future of risk assessment - meeting new challenges

Members briefly discussed a proposal on new challenges for risk assessment that will become a new mandate for the non-food Scientific Committees and should provide an occasion for dialogue with experts from other bodies. The draft mandate will be discussed at the next ICCG-meeting

Satisfaction Survey among members of the Scientific Committees

The Secretariat briefly informed about the results on a satisfaction survey carried out anonymously with the 51 members of the non-food Scientific Committees.

Overall, most members were satisfied with the content and the scientific level of the work carried out by the Committees, the organisation of meetings, the conduct of Chairs and the assistance provided by the Secretariat. Nevertheless, certain areas for improvement were identified.

Synthetic Biology Workshop, Brussels, 18-19 March

The Secretariat provided an overview about the final programme of the workshop that would start on the following day. More information was available at the following webpage:

http://ec.europa.eu/health/dialogue collaboration/events/ev 20100318 en.htm

Other

The Secretariat informed the Committee that one member would resign from the Committee due to a change in the professional position. The Pool of Scientific Advisers would be examined to identify a possible replacement.

Publication of opinions in dedicated journal

The Secretariat informed members that SANCO would shortly launch the "Journal of the Scientific Committees of the European Commission", to publish on a semi-annual basis, *inter alia*, the opinions of the non-food Scientific Committees. The first issue would appear in the summer of 2010.

Annex I: List of Participants.

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

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LIST OF PARTICIPANTS

MEMBERS OF THE SCENIHR:

Prof. A. AUVINEN, Prof. J. BRIDGES (Chair), Dr. W. DE JONG (Vice chair), Prof. P. HARTEMANN (Vice chair), Dr. T. JUNG, Prof. M.-O. MATTSSON, Dr. J.-M. PAGÈS, Prof. A. PROYKOVA, Prof. E. RODRÍGUEZ-FARRÉ, Dr. J. SCHÜZ, Dr. M. THOMSEN, Dr. T. VERMEIRE

EUROPEAN COMMISSION:

SCENIHR Secretariat (DG SANCO):

Mr. L. BONTOUX, Ms. K. BROMEN, Ms. A. KANELLOPOULOU, Mr. P. MARTIN, Ms. O. ZIANE

Other Commission staff:

Mr. P. CHORAINE (DG ENV), Mr. T. FAIRLEY (DG SANCO), Ms. J. HOUINS-ROULET (SANCO), Ms. S. LECRENIER (DG SANCO), Ms. S. OSAER (DG SANCO), Ms. T. PEETSO (DG SANCO), Mr. A. PEREZ (DG SANCO), Mr. S. PICKERING (DG ENTR)