EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

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

10TH PLENARY MEETING

Held on 20 September 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, Prof. E. Rodríguez-Farré and Dr. J. Schüz.

The Chairman welcomed Ms. J. Marescaux, who expressed her interest in attending as an observer a plenary meeting of the SCENIHR in the framework of her responsibilities for the Committee on Internal Market and Consumer Protection (IMCO) of the European Parliament.

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

No new declaration was made.

4. APPROVAL OF THE MINUTES OF THE PREVIOUS PLENARY MEETING

The draft minutes of the 9th plenary meeting were adopted without modifications. The minutes are available at:

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_mi_037.pdf

5. CHAIR'S/MEMBERS' REPORT

The Chairman reported about his future involvement in an advisory group at the Joint Research Centres (JRC) of the European Commission. The focus of this work would be on alternative testing.

6. ONGOING WORK

6.1. Tobacco Additives (follow-up to public consultation)

The Chairperson of the WG informed the Committee about the ongoing work and the results of the public consultation, held from 9 July to 5 September. A total of 31 contributions including 250 attachments were received. Nine comments came from individuals and 22 from organizations (9 industry, 2 academia, 4 public authority, 4 NGO, 3 other).

For all public consultations, an explanatory note would be published explaining how the Scientific Committee has taken the comments into account. This note will be published on the website of the consultation. In addition, a short section on the consultation will be presented as part of the final opinion.

The WG discussed and assessed the contributions received in a recent WG-meeting and two additional meetings were scheduled to finalize the opinion.

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

Following the discussion at the last plenary meeting, additional suggestions for revision of the document had been made by members. To discuss and further develop the draft position paper, an additional meeting was foreseen. In light of this, members briefly discussed the draft and provided feedback. The Chairman reminded members that the purpose of this document was to improve transparency and consistency of the work carried out by SCENIHR. However, in light of the common principles and standards for scientific advice on risks of the three non-food Scientific Committees (see Annex V to the Rules of Procedures[1]), feedback from the Scientific Committee for Consumer Safety (SCCS) and the Scientific Committee on Health and Environmental Risks (SCHER) on the document would be sought.

6.3. Artificial Light (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work.

The call for experts in ophthalmology had resulted in 12 applications. After assessing the applications, an expert was identified who would be invited to join the WG. In addition, a scientist specialised in chronobiology would be contacted by the Secretariat. As the information received during the call for information (deadline: 2 July) did not fully respond to the specifications of the call, the WG had decided to reconsider and possibly revise the text of the call and to resend the information request to suitable stakeholders

6.4. Nanodefinitions (follow-up to public consultation)

The Chairperson of the WG informed the Committee about the ongoing work and the results of the public consultation, held from 12 July to 15 September. A total of 94 contributions (including a few duplicates) had been received that would be assessed at an upcoming WG-meeting. In light of the number of comments received, an additional WG-meeting had already been scheduled in October.

A member informed about a recent consultation on a related definition proposed by Health Canada.

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

7.1. New Challenges for Risk Assessment (SCENIHR, SCHER, SCCS)

The Chairperson of the cross-committee WG informed members about the first WG-meeting. The outline of the opinion was briefly discussed and several members agreed to provide input to the document. In this context, the Secretariat mentioned an upcoming meeting on computational toxicology, jointly organized by the Risk Assessment Unit of DG SANCO in collaboration with DG JRC, EFSA and ECHA, involving model developers, users and risk assessors.

[1] http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_en.pdf

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 an upcoming WG-meeting.

7.3. Toxicity and Assessment of Mixtures of Chemicals (SCHER, SCCS, SCENIHR)

A member participating in the cross-committee WG informed the Committee about the first meeting of the WG in which the scope of the mandate and the outline of the opinion had been discussed.

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

A member participating in the cross-committee WG informed the Committee about an upcoming meeting in which the opinion is expected to be finalized.

7.5. Other

The standards of lead in drinking water

A member participating in the WG organized by the Scientific Committee on Health and Environmental Risks (SCHER) informed the Committee about the ongoing work that is expected to be finalized shortly.

Exposure assessment and expression of uncertainties

The SCHER had recently received two mandates in relation to human exposure assessment and expressing uncertainties for risk assessment and risk management. Both mandates are related to ongoing activities in the frame of the international dialogue on risk assessment in which SCENIHR members participate. The SCENIHR had started to discuss the issue of uncertainties in the context of their work on weight of evidence. They would feed their thoughts into the discussions in the related WG.

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 to continue the assessment.

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

A member participating in the WG organized by the European Food Safety Authority (EFSA) informed members about the ongoing work. The draft document would soon be discussed by the Scientific Committee and was expected to enter public consultation before the end of 2010.

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

Representatives from the unit on Cosmetics and Medical Devices in DG SANCO provided a short update on the follow-up to the opinion on reprocessing of medical devices. A report from the Commission to the Council and the European Parliament on the reprocessing of medical devices, which is based on this opinion, has been adopted and transmitted to the European Parliament and the Council. It is available at the following webpage:

http://ec.europa.eu/consumers/sectors/medical-devices/files/pdfdocs/reprocessing_report_en.pdf

A proposal to recast the Medical Devices Directives is planned to be adopted by the Commission in early 2012.

9. NEW REQUESTS

There are no new requests for the SCENIHR. However, members will participate in two new mandates for SCHER in relation to expression of uncertainties and exposure assessment.

More information is available at the following webpages:

http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_096.pdf

http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_095.pdf

10. EMERGING ISSUES

Members discussed the working documents in relation to this topic and agreed on additional updates to be done following the meeting. The Chairman, supported by the Secretariat would combine the relevant documents and revise the structure before additional revision by members. The aim is to establish a list of emerging issues which could be used as a basis for discussion with other Commission services.

11. ANY OTHER BUSINESS

Nanotechnology

The Secretariat informed members about various events in relation to this subject area, including the follow-up to the meeting with stakeholders on the use of nanomaterials in textiles, a meeting organized by the European Medicines Agency (EMA) on nanomedicine, an expert meeting with the Commissioner for Health and an upcoming meeting organized during the Belgian EU-presidency in relation to food. Various new applications, e.g. in pharmaceuticals and medical devices were mentioned.

EU Health Newsletter for DG SANCO

The Secretariat informed members about this newsletter that is published by DG SANCO twice per month and distributed to a broad range of stakeholders. Future topics to be presented in its welcome-section should address Nanotechnology and Risk Assessment. Two members agreed to write these sections. More information on the Newsletter can be found at the following weblink:

http://ec.europa.eu/health-eu/newsletter_en.htm

Meeting dates

The first plenary meeting in 2011 was scheduled for 20 January. Further dates would be scheduled at the next meeting.

Synthetic Biology

The Secretariat informed members about an interservice meeting and about future calls in the Framework Programme on Research in relation to this subject area.

Annex I: List of Participants.

Annex I

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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. H. NORPPA, Dr. J.-M. PAGÈS, Prof. A. PROYKOVA, Prof. K. SCHULZE-OSTHOFF, Dr. M. THOMSEN, Dr. T. VERMEIRE

EUROPEAN COMMISSION:

SCENIHR Secretariat (DG SANCO):

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

Other Commission staff:

Ms. C. BOURGUIGNON (SANCO), Mr. P. GALIAY (RTD), Ms. S. LECRENIER (SANCO), Ms. T. PEETSO (DG SANCO), Mr. A. PEREZ (SANCO)

EUROPEAN PARLIAMENT:

Ms. J. MARESCAUX, Secretariat of the Committee on Internal Market and Consumer Protection (IMCO)