EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Risk assessment

17th plenary meeting of the Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR

Meeting date: 19 March 2012

Meeting minutes

1. WELCOME AND APOLOGIES

The Chairman, Prof. J. Bridges, opened the meeting and welcomed the participants. Apologies were received from Prof. K. Dawson and Prof. K. Schulze-Osthoff.

2. ADOPTION OF THE DRAFT AGENDA

The order of points under discussion in the draft agenda was slightly modified to accommodate the availability of participants in the meeting.

3. DECLARATION OF INTERESTS ON MATTERS ON THE AGENDA

No new declarations of interest were made. T. Jung declared that he is starting a new project funded by Roche, but unrelated to the topics dealt with by the Committee. The Committee reiterated the need to keep the names of the experts in Working Groups confidential until adoption of the opinions.

4. APPROVAL OF THE MINUTES OF THE PREVIOUS PLENARY MEETING

The minutes of the previous plenary meeting were adopted after a brief discussion.

5. CHAIR'S/MEMBERS' REPORTS

5.1. Information on the fast-track PIP implants opinion

The members discussed what happened with this fast-track opinion. This was a successful exercise but created a challenge for the SCENIHR in terms of access to the best expertise, reduced number of Working Group meetings, the massive work pressure on the rapporteurs and the need to respect the SCENIHR process within a very short time frame. This first experience for a fast-track opinion showed that teleconferencing can be used for WG meetings, that the external contractor could perform a good quality literature search at very short notice, and that quality of the expert advice could be maintained in spite of the very strong time pressure. The main limitation was created by the difficulty to find data. The high quality input from the American experts was greatly appreciated. The fact that this was a very specific and relatively easy topic made it possible to achieve such a short deadline.

5.2. Dental amalgam

A discussion was held following criticisms concerning the dental amalgam opinion. The members remarked that this issue is not new, that it was discussed at length previously, that the scientific opinion was produced in full respect of the SCENIHR procedures and standards of scientific quality, and that the experts all fulfilled the requirement of competence, independence and transparency. It is up to the Commission to provide a general response to the criticisms.

5.3. Nanomaterials in cosmetics

A member reported on the work with the SCCS WG on nanomaterials in cosmetics. Work on the specific ingredients is continuing, with significant progress on ZnO. The guidance document on how to assess the risk of nanomaterials in cosmetics is nearing completion.

6. OPINIONS FOR FINAL ADOPTION

6.1. Artificial Light

The issue raised at the previous plenary meeting about the calculation of the worst case scenario was addressed and the opinion was adopted.

6.2. Security scanners

An almost final draft of the opinion was discussed. There is a high political sensitivity on this topic as this could be a case of the application of ionising radiation to a non medical use. Few questions were raised but some final pieces of information still need to be added before the opinion can be adopted. In view of the time pressure, it was agreed that the opinion would be adopted by written procedure as soon as these small gaps are filled. The EURATOM Article 31 Committee was consulted and provided some comments.

7. OPINION FOR ADOPTION IN VIEW OF PUBLIC CONSULTATION

Nothing for this meeting

8. ONGOING WORK

8.1. OWN WORK

- **EMF**

As always, this issue witnesses the release of strong forces in the public debate. This requires setting up an expert group. A discussion among all involved members about the required expertise is planned shortly after the plenary meeting.

- **BPA in medical devices**

A first Working Group meeting took place and the structure of the opinion is becoming clear. The WG will be completed with 1 more expert.

- **Nanosilver**

A first Working Group meeting took place. At that occasion the needs for expertise were discussed and gaps were identified. A first proposal for the structure of the work was also made. As a result, the Working Group is still being completed, in particular with expertise on the environmental side.

- **Methodology / Weight of Evidence Approach**

A final draft of the memorandum was discussed and adopted. It will be published after minor editing.

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

- **New Challenges for Risk Assessment (SCENIHR, SCHER, SCCS)**

Work on this opinion is continuing. After a few major revisions to the structure on the human health part, the group has reached a common understanding and an adoption can be envisaged in the foreseeable future. Many new contributions were made over the last few WG meetings but a number of gaps remain. In particular, more text is needed on studies in man, modes of action and the use of morphological information for risk assessment.

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

The SCENIHR proposed some comments relating to the general scientific merits of the approach and adopted the opinion. In particular, the SCENIHR proposes to adopt a Class 3 classification by default and to only put substances in Class 1 if sufficiently justified by data. Research is still needed on low dose effects. Adoption of the opinion by the SCHER and the SCCS is planned after the SCENIHR plenary.

- **Improvement of Risk Assessment (SCENIHR, SCHER, SCCS)**

The public consultation attracted 80 contributions that will be taken into account. The main point of discussion was on how to translate risk assessment endpoints in terms that economists and sociologists can understand and use?

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

Nothing to report at this stage.

10. NEW REQUESTS

10.1. Nanomaterials in medical devices

A new request to assess the safety of nanomaterials used in medical devices was made to the SCENIHR. The purpose of this request is to provide input for the preparation of a new regulation on this topic to reduce the risk from nanomaterials as much as possible and maximise benefits. Issues of classification and terminology were raised, especially in relation to the distinction between medicines and medical devices. This request was accepted after a short discussion.

10.2. PIP implants

The SCENIHR also received a request for a follow-up to the opinion on PIP implants. The new request asks essentially to:

- help elaborate a questionnaire;
- provide guidance for analyses;
- analyse the data collected by the Member States;
- make a general update the previous opinion.

This request was accepted after discussion. Important points were raised on the availability of data from all countries concerned and on the need to make an effort to generate and collect as much information as possible (e.g. characteristics of explants, epidemiological data, etc). Members also insisted on the importance of the quality and consistency of the data to be able to prepare a good scientific opinion.

11. PLANNED REQUESTS

11.1. Metal on metal implants

DG SANCO announced that it is planning to send a new request to the SCENIHR to assess the safety of metal on metal implants.

11.2. Research on artificial light

The opinion on artificial light identified some research needs to address gaps in knowledge, but did not develop them. DG ENER plans to send a new request to the SCENIHR to develop them.

12. EMERGING ISSUES

12.1. Synthetic biology

The recent publication of a report on this issue by Friends of the Earth was discussed. This report is mostly critical of the US government. No mandate to the SCENIHR on this issue is foreseen for the time being.

12.2. Other

None

13. ANY OTHER BUSINESS

In view of the forthcoming change to the structure of the Scientific Committees, the mandates of the three SCs are being extended. New plenary meetings must be planned under the current configuration until the end of 2012.

Annex I

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

17TH PLENARY MEETING

Held on 19 March 2012
in Brussels

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), Prof. A. HENSTEN, Prof. Peter HOET, Dr. T. JUNG, Prof. M.-O. MATTSSON, Dr. H. NORPPA, 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):

Dr. L. BONTOUX, Dr. V. GARKOV, Dr. P. MARTIN, Dr T. DASKALEROS

Other Commission staff:

Ms. I. DEMADE (SANCO), Mr. M. KOHLER (SANCO)