

EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment C7 - Risk assessment

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS 15^{TH} Plenary Meeting

Held on 24 January 2007 in Brussels

1. WELCOME AND APOLOGIES

The Chairman, Prof. J. Bridges, opened the meeting and welcomed the participants. Apologies were received from Prof. J. Hajslová, Prof. D. Stahl, and Prof. D. Williams.

2. ADOPTION OF THE DRAFT AGENDA

It was decided to discuss the ongoing requests in a slightly revised order (6.3, 6.2, 6.4, 6.5, 6.1, 6.6).

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

T. Jung declared that since autumn 2006 he had been participating in an EU research and training network (Marie Curie Programme). In addition to a large number of academic institutions, representatives of European industry are also represented in this network.

The Chair of the SCENIHR Working Group (WG) on Electromagnetic Fields (EMF) informed the Committee that one external expert had declared a new interest in view of his affiliations.

Taking into account the nature of the two declarations, the Committee decided that they did not constitute a conflict of interest and that the experts could participate in the discussions on those matters.

The rectification requested by one expert in the WG on Smokeless Tobacco Products (STP) concerning his affiliations, as presented in some journals, had still not been carried out. However, the expert had sent related e-mail correspondence to the Secretariat, supporting his efforts to seek clarification on the matter.

4. APPROVAL OF THE MINUTES OF THE PREVIOUS PLENARY MEETING

The draft minutes of the 14th plenary meeting were adopted with minor modifications. The minutes are available at:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_mi_014.pdf

5. CHAIR'S/MEMBERS' REPORT

5.1. Inter-Committee Coordination Group (ICCG) meeting on 29 November 2006

The Chairman and Secretariat informed members about a proposal to extend the terms of office of the Scientific Committees (SCs) until the end of 2008 by amending Commission Decision 2004/210/EC¹ (see minutes of the last meeting for details). At the same time the membership of the SCENIHR may be enlarged. Therefore, members were asked to consider the expertise profiles needed to complement the SCENIHR. The Chairman informed members about the new layout of scientific opinions which would require abstracts to be included in the opinion.

He also informed members that a publisher, who had been contacted, had finally decided against publicising news about the SCs. Members were asked for other suggestions for publication of such news. It was suggested that extensive abstracts or executive summaries might also be suitable for publication in journals. Another journal was mentioned as a possibility. It was suggested this issue could be raised at the next ICCG-meeting.

5.2. Other

The Chairman and Secretariat informed members about the follow up to the 2^{nd} Meeting of Chairs.

For the discussion group on Emerging Risks a first draft of a "common paper" had been prepared. It was suggested that the SCENIHR would also receive the draft at a later stage. Furthermore, it was suggested that the Chairman of the SC of the European Food Safety Authority (EFSA) should be invited to the next or another future meeting to discuss this and possibly other matters.

Regarding the earlier discussion on how to better exchange information with the European Centre for Disease Prevention and Control (ECDC), the Secretariat informed members that a videoconference could be arranged when requested well in advance. A conference call could be done as an alternative. Members suggested having a discussion with the ECDC in one of the next meetings in particular in relation to the work on emerging issues and biocides.

The Chairman informed members about the ongoing work of the Organisation for Economic Cooperation and Development (OECD) on nanomaterials.

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¹ http://eur-lex.europa.eu/pri/en/oj/dat/2004/1 066/1 06620040304en00450050.pdf

6. ONGOING REQUESTS

6.1. EMF (public consultation)

The Chairman informed members about the discussion in the WG meeting where the contributions received and the procedure for responding to the comments and for finalising the opinion was discussed. In that meeting, it was agreed to add certain sections to the opinion to respond to the contributions.

It was expected to present the revised opinion for final adoption by the SCENIHR in the next SCENIHR plenary meeting on 21 March 2007.

Members discussed various possibilities and forms to respond to the feedback received in public consultations. A discussion also took place on developing a standard document, which would explain the methodology of selecting and weighting scientific evidence in the scientific opinions, and enclosing it as an Annex. It was proposed to discuss this in the next ICCG meeting. The Secretariat informed members that a proposal for a standardized approach to public consultations would also be discussed in the next ICCG.

6.2. Nanotechnologies (for discussion)

The Vice-Chair of the WG reported on the ongoing work which was approaching its finalisation. The adoption of the Committee opinion is foreseen for the SCENIHR plenary meeting on 29 March 2007.

The forthcoming opinion will contribute to ongoing work in the Commission as well as in the OECD and in the ISO/CEN.

6.3. Smokeless Tobacco Products (for discussion)

The Chair of the WG informed the Committee about the ongoing work. The previous change in membership and potential resignation of another WG member had led to a considerable delay in finalising the opinion. Following a discussion with the service in charge of the mandate and within SCENIHR it was agreed to extend the deadline for the adoption of the opinion to June 2007.

Members discussed the possibility of a minority opinion. According to the Rules of Procedure this is possible given that this opinion is supported by a member of the SCENIHR. The WG should strive for a consensus in particular as the questions require a science-based approach. Different viewpoints could, however, be expressed in the discussion chapters.

6.4. DEHP (for discussion)

The Chair of the WG reported on its ongoing work on di(2-ethylhexyl)phthalate (DEHP). Adoption of the opinion was foreseen for the SCENIHR plenary meeting on 29 March 2007. Members discussed procedures related to the confidential data and a proposal was prepared for further discussion in the ICCG meeting on 31 January 2007.

6.5. Dental Amalgam (for discussion)

The Committee had received the final request on the safety of dental amalgam and potential alternatives. The WG would include experts from SCHER to ensure a

regular exchange on the assessment carried out by the SCHER regarding the environmental risks of mercury in dental amalgam. Furthermore, additional external experts had been identified.

A representative of DG Enterprise and Industry (ENTR) confirmed that an assessment by December 2007 would be appreciated but that a realistic time-frame and the need for a call for information should be discussed by the WG.

6.6. Biocides (for discussion)

The Secretariat had received a draft request on the assessment of the antibiotic resistance effects of biocides. As this request touches on a broad range of applications, the Secretariat had asked other EC services for their views.

A representative of DG ENV provided information on the background of the request, in particular on Directive (98/8/EC) of the European Parliament and of the Council on the placing of biocidal products on the market.

According to the Directive, adopted in 1998, Member States had to transpose the rules into national law before 14 May 2000 with a transitional period of 10 years, during which all existing active substances would have to be reviewed with regard to the safety of their use for human health and the environment.

While the scope of the Directive is very wide, it neither applies to product types covered by other Community legislation nor to articles treated with biocides imported from third countries. Furthermore, cumulative risks and impacts resulting from the use of the active substance outside the scope of the Directive are not addressed in the evaluation process. Recent scientific evidence suggests that during the last decade, antibiotic resistance by various mechanisms had increased world wide leading to treatment failures in human and animal infections. However, scientific evidence on the risks of antibiotic resistance due to biocides is limited.

A report on the implementation of the Directive is foreseen in 2007, which could lead to the review of certain of its provisions. In light of the recent scientific evidence, clarification is sought as to whether cross resistance to antibiotics should be an additional criterion to consider in the common principles for the evaluation of dossiers for biocidal products as laid out in Annex VI of the Directive or whether the issue should be addressed by other means.

The Secretariat asked members of the SCENIHR to suggest additional external experts for the forthcoming work. Expertise from other Scientific Committees/Panels including those from the European Medicines Agency (EMEA), EFSA and ECDC would also be sought.

7. NEW REQUESTS

None

8. EMERGING ISSUES

The Chairman reminded participants to update the working document previously discussed. The Secretariat would send a reminder. This item would be discussed in the next meeting.

9. ANY OTHER BUSINESS

The Secretariat asked members to provide suggestions for future scientific events organized by SANCO C7.

Members proposed to use name plates in WG meetings.

The next meeting will take place on 21 March 2007.

Further meeting dates were reconfirmed as follows: 29 March, 10 May, 21 June, 27 September, and 29 November. All meetings are foreseen as one day events but in exceptional cases a subsequent second day may be scheduled. Members were asked to consider this in their planning. The tentative meeting on 22 February was cancelled.

Annex I

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS ${\bf 15}^{\rm TH}$ Plenary Meeting

Held on 24 January 2007 in Brussels

LIST OF PARTICIPANTS

MEMBERS OF THE SCENIHR:

Prof. A. AHLBOM, 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. K. RYDZYNSKI, Dr. M. THOMSEN

EUROPEAN COMMISSION:

SCENIHR Secretariat (DG SANCO):

Ms. K. BROMEN, Mr. T. DASKALEROS, Ms. N. FOUVEZ, Ms. A. KANELLOPOULOU, Ms. K. KILIAN, Ms. M. PUOLAMAA

Other Commission staff:

Mr. P. CHORAINE (DG ENV), Ms. I. DEMADE (DG ENTR), Ms. T. PEETSO (DG SANCO)