

EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

INTER-COMMITTEE COORDINATION GROUP

15TH MEETING

7 May 2007

MINUTES

1. WELCOME AND APOLOGIES

The Chair, Mr. Bernardo Delogu welcomed the participants. Apologies were received from Prof. B. Janssen and Prof. J. Tarazona.

2. APPROVAL OF THE DRAFT AGENDA

The draft agenda was adopted.

3. DECLARATIONS OF INTEREST

None.

4. APPROVAL OF THE MINUTES OF THE 14^H MEETING OF THE ICCG

The minutes were approved and are available at http://europa.eu.int/comm/health/ph_risk/committees/coordination/docs/coor_mi_014.pdf.

5. ECVAM WORK ON ALTERNATIVE METHODS

Dr. Thomas Hartung presented the activities and progress on the development of the alternative methods, especially in view of the objectives of the 7th amendment of the Cosmetics directive and REACH and explained the current situation. The Chairs highlighted the need for appropriate data to assess all relevant toxicological aspects especially in regard to cosmetics. Dr. Hartung explained the methodologies applied and the need to have a combination of assays in various steps of the validation. The Chairs also pointed out that there are domains of toxicology, such as neurotoxicity, endocrine disruption, metabolism etc. that can not be studied with simple alternative tests. Dr. Hartung highlighted that the aim of in vitro test is to reduce use of animal testing, not necessarily to replace them completely.

6. INFORMATION EXCHANGE

6.1. ADMINISTRATIVE AND GENERAL MATTERS

<u>The Panel of Scientific Advisors:</u> The Chair informed that the Secretariat is assessing possibilities to modify the Commission Decision establishing the SCs in order to establish a Panel of Scientific Advisors that could participate in the SC activities and ad hoc Workshops.

Training of risk assessors: The Chair informed about the proposal to organise a discussion on the training of risk assessors possibly in conjunction to the next EUROTOX conference on 6-11 October 2007. It was considered necessary to not only toxicologists but risk assessors in all relevant areas, including on issues related to physical and biological risks (which the SCHENIHR is dealing with). The Chairs considered therefore important to launch a discussion on the subject covering all relevant risk assessment fields. The item was also proposed to be added to the agenda of the Meeting of Chairs later this year.

<u>Declaration of Interest – Overview to practices in other SCs</u>: the Secretariat informed about the situation in EMEA and EFSA as well as in WHO and IARC. Both EMEA and EFSA have categorised the levels of potential conflict and recognise in the evaluation both financial and intellectual interests (of last 5 years). The practices in WHO and IARC resemble the above mentioned ones. The Chairs considered important to ensure the consistence between SCs and to facilitate also contributions from highly qualified experts of industry. The latter requires limitation of their tasks, participation etc. and ensuring the transparency of all the processes. It was decided to follow the developments and if needed, to revise the current practices in the light of new information in 2008.

Renewal of the Committees: The Secretariat provided overview of the current situation. The Secretariat will send shortly a letter to members of the Committees on the prolongation of their mandate. After that, it will be necessary to assess the need for additional expertise and decide whether to launch a Call for Experts either with a limited or extended scope. A scoping paper about role of the Scientific Committees and on the restructuring of the Committees will be provided later this year.

A procedure for rapid consultation in case of crisis will be addressed in the new Decision.

<u>EMF Policies</u>: The Chair informed the meeting about the SANCO/C7 new responsibilities on EMF policies.

6.2. INFORMATION FROM/TO CHAIRS AND VICE CHAIRS

6.2.1. SCCP

The key points of discussion were the situation in Nanocosmetics, safety evaluation of vitamin K1 in cosmetic products following MS ban and the Call for Information on Hydrogen peroxide.

6.2.2. SCHER

The main discussion points were modification of the Indoor air opinion after the public consultation, Call for Information on Mercury from dental amalgam and risk assessment on zinc.

6.2.3. SCENIHR

The main points of discussion were final opinion of EMF and its press communication, Smokeless Tobacco Products, Nanomaterials in TGDs, DEHP in medical devices and dental amalgam and the situation in the request for biocides. After the public consultation of the EMF, it has been considered useful to add methodological details to the opinion and to prepare a SCENIHR guidance document on the risk assessment of EMF. For the DEHP opinion, special arrangements will be necessary with respect to confidential data.

6.3. NEW REQUESTS TO THE SCIENTIFIC COMMITTEES

New mandates have been received or announced to be received on hair dyes, use of animal by-products for technical purposes, evaluation of Fragrance substances pre-evaluated using the QRA-approach, application of TCC for cosmetic ingredients and Tee tree oil for SCCP, on RAR under Regulation 973/93 for the SCHER and on noise of MP3 players and on risk assessment of nanomaterials for the SCENIHR.

7. COLLABORATION WITH OTHER COMMUNITY BODIES

7.1. EFSA

The Secretariat informed about the EFSA Scientific Committee plenary meeting in April 2007. The current mandates of interest of SCs refer to Animal cloning, Benchmark dose, Animal welfare and animal testing and Emerging risks.

7.2. MEETING OF CHAIRS OF SCS IN THE COMMUNITY RISK ASSESSMENT

<u>RA Terminology</u>: Pilot study ongoing, mid-term report foreseen on the searchable database of 100 SC opinions and final report in August 2007.

<u>Emerging risks</u>: Draft definition exists, Common framework for the next meeting. EFSA is developing MoU with international bodies.

ECHA impacts: C7 inventory of borderline issues on EFSA and ECHA exists.

Diverging opinions: Further comments received.

<u>Confidentiality</u>: Common guidelines needed. MoU between EMEA and the Commission, position of EFSA to be investigated. Exchange of scientific data to made possible with appropriate confidentiality measures.

<u>US/EU RA approaches</u>: The 1st conference in June 2008, programme out in December 2007. <u>SCENIHR</u>: Nanotechnology Workshop on 25-26 October, the Road Map needs engagement of EMEA and EFSA.

Alternative methods: SCCP Memorandum on Alternative methods coming in June.

7.3. OTHER

7.3.1. RISK ASSESSMENT DAYS 2007

The Chair informed about the contacts with the Parliament. A presentation of the SCCP is foreseen in IMCO; for other EP committees the Secretariat will organise presentations of the SCs in informal meetings and distribute information packages to MEPs and the parliament secretariats. On major issues (like EMF, nanotech etc), workshops involving scientists,

decision makers and stakeholders aimed to discuss the outcome of a consultation might be organised in collaboration with the Parliament.

For stakeholders, it is planned to define a procedure, tentatively in June 2007, in order to introduce the possibility to submit comments and suggestions on the preliminary versions of mandates. The procedure might also define a framework for hearings of stakeholders at an early stage on the formulation of a mandate, initiated by the Scientific Committees and/or Commission services. This procedure will not apply in case of urgent consultations, confidential matters or subjects with a very narrow scope and interest. Also invitations to submit data and information would be published at the beginning of the preparatory process, each time that the subject justifies such an approach.

7.3.2. PROGRESS WITH THE IMPLEMENTATION OF THE ACTION PLAN

The Secretariat presented proposals for the longer term work programme (incl. TTC (Threshold of Toxicological Concern), QRA (Quantitative Risk Assessment), RA of carcinogens, Benchmark Dose concept) striving for harmonisation/development of common approaches, setting up the stage for discussions, thematic conferences (the 1st one in 2008) and identification of fundamental support work. It was considered necessary to prepare a mandate for a test case.

The Chair informed briefly about the 1st SC Newsletter as well as about advancements made with regard to video, publication of opinions, logo and the brochure and posters of SCs.

8. COLLABORATION WITH JRC + RTD

The Secretariat informed about the new calls in the 3rd pillar issue of the theme Health of FP7 as well as Sanco's actions with RTD on issues related to EMF research projects and alternative methods etc.

The Chair reminded the Chairs about the forthcoming free capacities in JRC/IHCP and encouraged chairs to suggest proposal for further technical assistance to SCs and for the follow-up of opinions.

9. ANY OTHER BUSINESS

The next ICCG meeting will take place on 20 June 2007.

Annex I: List of participants

Annex I

INTER COMMITTEE COORDINATION GROUP

15TH MEETING

7th May 2007 in Brussels

LIST OF PARTICIPANTS

Chairs and vice-Chairs of the Scientific Committees

Prof. J. BRIDGES, Prof. H GREIM, Prof. P. HARTEMANN, Prof. B. JANSSON, Dr. W. de JONG, Prof. V. ROGIERS, Prof. T. SANNER, and Dr. I. WHITE.

Apologies: Dr. J. TARAZONA.

European Commission

JRC 12 'VALIDATION OF BIOMEDICAL TESTING METHODS'

Dr. T. HARTUNG (morning)

SANCO C7 'RISK ASSESSMENT'

Mr. B. DELOGU (Chair), Ms. M. PUOLAMAA (ICCG Secretariat), Ms. Marina MARINI, Mr. T. DASKALEROS, Ms. Katja BROMEN (SCENIHR Secretariat), Ms. G. FONTANESI (SCHER Secretariat), Ms. K. KILIAN and Mr. A. VAN ELST (SCCP Secretariat).