20th plenary meeting of the

Scientific Committee on Emerging and Newly Identified Health Risks

SCENIHR

Meeting date: 26 November 2012

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed the participants and announced the apologies received (please see Annex I)

2. ADOPTION OF THE DRAFT AGENDA

Adopted after the addition of several items (7.2 and synthetic biology)

3. DECLARATION OF INTERESTS ON MATTERS ON THE AGENDA

No new declarations were made.

4. APPROVAL OF THE MINUTES OF THE PREVIOUS PLENARY MEETING

The minutes were approved after a small editorial correction and a clarification on point 4.

5. CHAIR'S/MEMBERS' REPORTS

Nothing for this meeting

6. OPINIONS FOR FINAL ADOPTION

Nothing for this meeting

7. ONGOING WORK

7.1. OWN WORK (THE RESPECTIVE CHAIRS TO PROVIDE AN UPDATE)

- **EMF**

A member of the working group updated the Committee on the progress of the opinion, the selection of experts, and future meetings.

- **PIP2**

Two tasks: to review the literature and to obtain responses to the questionnaire, which has gone out now. The responses are due in January. At the moment the expectation is to reach conclusions by then. The issue of how to deal with the laboratory component of the assessment is still unresolved. The literature review should be completed by BRE and distributed by Dec. 7th. There

are no consistent and homogeneous data on the incidence of ruptures of implants across different member-states. Implants for medical reasons may be better followed than those for purely aesthetic reasons. Concerns on the possibility for identification of the manufacturer were expressed if only a serial number is available.

- **Nanosilver**

This is a very broad dossier which makes it difficult to tackle. The expectation is to complete the work by March 2013 even though there is no specific deadline for the opinion. There are a lot of toxicological data. The hope is to be able to estimate the cumulative exposure and connect it to hazards. The environmental aspect is still rather vague and general. Environmental microbiologists are crucial for the assessment.

- **Nanomaterials in medical devices**

New experts have been identified based on the Call for Experts. The tasks have been distributed along the constructed Table of Contents. There are experts who are members of both working groups on nano (nanosilver and nano in medical devices) which will ensure coordination.

- **Metal-on-metal hip implants**

There were three meetings (a workshop and two WG meeting) which identified the experts needed (based on the Call for Experts) and helped with shaping the discussion. The mandate is focused on (but not limited to) hip implants. Any metal-on-metal implants may also be addressed. The WG may liaise with the member-states Task Force on risk-benefit analysis (in terms of health). This could happen at the December (preferably) or January meeting of the WG. The Task Force will complete its work by the end of January. The Vigilance Reports on MoM may be useful.

- **Dental amalgam (human-health aspects)**

Three DGs are interested in this dossier. The main question is if there is new information (after 2007) on the health effects of mercury from dental amalgam. The neurobiological aspects need to be addressed in a more thorough manner. The opinion is to be a stand-alone document with a summary of the previous opinion and an update. Alternatives are to be also evaluated vis-à-vis dental amalgam in terms of health risks. They also involve nanomaterials and endocrine-active substances.

- **Synthetic biology**

The mandate is not officially delivered yet. There will be a literature search and we need to identify some keywords. The deadline will be re-assessed after the start of the work. There will be involvement of SCHER members.

- **BPA in Medical Devices**

The main text has been progressing quite nicely. The thousands and thousands of *in vitro* studies indicate different endpoints and lack consistency. This applies to low-dose effects which have not been shown to be reproducible and consistent. Many *in vitro* studies apply doses that are not relevant to *in vivo* situation. A recent report issued by Karolinska Institutet found that none of the low-dose studies are reliable. Furthermore, the lowest dose effect is the toxicological effect on the liver, not the endocrine-related effects. Another problematic issue is the jump from *in vitro* effects to adverse effects (which by definition apply to the whole organism).

The EFSA WG focuses on the oral exposure route to BPA. There are two experts who liaise between the two WGs.

Based on the scientific literature, the general view for now is that the current levels of NOEL would not require revisions. The alternatives have not been studied properly for risk assessment purposes.

- **DEHP in Medical Devices**

The Chair updated the participants with the progress of the opinion. Experts were identified based on the call for Experts. The previous opinion will be used as a basis for the new text in view of the new data in the scientific literature.

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

- **SCCS on nano in cosmetics**

This is almost a standing committee now. The SCENIHR member in this WG reported on the deliberations: the safety of ZnO. The public consultation delivered some comments that were taken into account and the opinion will be presented to the full SCCS for adoption. For TiO, COLIPA presented 25 different dossiers to be reviewed. There was a Call for Experts which led to the finalization of the WG.

- **Definition of nanomaterials in cosmetics (Commission activity)**

The discussion is on the percentage of nanomaterials allowed in cosmetics. The major issue is the definition to be based on the number of particles, not on the mass of particles.

- **EFSA WG on endocrine-active substances**

The SCENIHR expert participating in this WG presented his report in writing.

- **EFSA meeting on BPA in food and food-contact materials**

The SCENIHR expert who took part in this meeting presented the mandate of the SCENIHR WG on BPA.

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

Nothing for this meeting.

9. EMERGING ISSUES

The document is to be kept as an internal one, which needs to be more focused. It will be always open for contributions from SCENIHR members.

10. ANY OTHER BUSINESS

There should be an opportunity for additional applications for the SCs (for VG to check).

Annex I

LIST OF PARTICIPANTS

Members of the SCENIHR:

Prof. Anssi AUVINEN

Prof. Jim BRIDGES (Chair)

Prof. Kenneth DAWSON – apologies

Dr. Wim DE JONG (Vice chair)

Prof. Philippe HARTEMANN (Vice chair)

Prof. Arne HENSTEN

Prof. Peter HOET

Dr. Thomas JUNG

Prof. Mats.-Olof. MATTSSON – apologies

Dr. Hannu. NORPPA

Dr. Jean.-Marie. PAGÈS – apologies

Prof. Klaus SCHULZE-OSTHOFF – apologies

Prof. Ana PROYKOVA

Prof. Eduardo RODRÍGUEZ-FARRÉ

Dr. Joachim SCHÜZ – apologies

Dr. Mogens THOMSEN

Dr. Theo VERMEIRE

European Commission:

Dr. Oana RADU

Mr. Pavlos MOURATIDIS

Dr. Vladimir GARKOV