



Luxembourg, 23 May 2017

**SCIENTIFIC COMMITTEES ON HEALTH, ENVIRONMENTAL AND EMERGING RISKS
(SCHEER)**

5TH PLENARY MEETING

17-18 May 2017, Luxembourg

Minutes

17 May 2017

1. Welcome and apologies, approval of the agenda and declaration of interests

The Chair welcomed the participants; announced seven apologies received and asked the participants to adopt the agenda for the meeting. The agenda was adopted as presented. One member joined the meeting by audio.

The Chair invited participants to declare any conflict of interest regarding matters on the agenda. None of the participants declared any interest conflicting with the matter on the agenda.

2. List of points discussed and conclusions

Session on Uncertainty

The Head of Unit C2, Philippe Roux, welcomed the members and EFSA's experts, Dr Andy Hart and Peter Craig, and thanked them and the participants for their presence and participation. He explained that the session was intended as a moment of reflexion for all SCHEER members on how to consider uncertainties in the risk assessments they are requested to perform. The initiative was also intended to strengthen the cooperation and synergy with EFSA on methodological issues. Similarly, it could be considered as a source of inspiration for the members of the WG to update the SCHEER Memorandum on the Weight of evidence and uncertainties.

The Chair of the SCHEER presented the Committee.

The Chair recalled that the SCCS and the SCHEER contributed to the public consultation on Preliminary EFSA Guidance on uncertainties.

It was explained that the EFSA's Guidance, when finalised, would be mandatory for all EFSA's scientific assessments and that it might have an impact on the methodologies on uncertainties of other EU risk assessment bodies (including SCHEER and SCCS). This was

why a session on uncertainty with EFSA experts was organised to provide an opportunity for a mutually-beneficial exchange on this topic.

The Chair gave the floor to Speakers: Andy Hart for **Lecture 1: Why do we need to address uncertainty, and what output is required?**

During this session, the following points were discussed:

- What do we mean by uncertainty?
- Why address uncertainty?
- What output is required?
- What are the roles of the assessors & decision-makers?
- Why try to be quantitative?
- What is the role of qualitative methods?

It was pointed out that addressing the uncertainty is a requirement in risk assessment. It was also underlined that the uncertainties related to the various aspects and stages of the risk assessment shall be, as far as possible, systematically identified, analysed and documented. Uncertainties, limitations, and assumptions, as well as their relative importance and their influence on the results of the assessment, shall be treated and expressed quantitatively as far as possible. Moreover, uncertainty needs to be addressed because is essential information for decision-making and critical for transparency, credibility and trust.

The Chair gave the floor to Peter Craig for **Lecture 2, Methods for addressing uncertainty.** The points discussed were:

- Scales for expressing uncertainty
- Methods for expressing uncertainty and combining uncertainties
 - Qualitative
 - (Fully) Probabilistic
 - Deterministic
 - Partial probability statements
- Exploring uncertainty: influence and sensitivity analysis

It was mentioned that all the methods could be applied but the clarity of existent data and the availability of data for risk assessment should be taken into account before making any decision. These methods are used only when committees have no answers for risks managers.

The Chair gave the floor to Andy Hart for **Lecture 3** regarding the EFSA's draft Uncertainty Guidance. The session started with enumerating the main steps of EFSA Framework:

- Plan the assessment strategy
- Identify sources of uncertainty
- Select which uncertainties to assess individually
- Assess individual sources of uncertainty
- Quantify combined uncertainty
- Investigate influence/sensitivity
- Describe unquantified uncertainties, if any
- Decide whether to refine the assessment
- Report on & communicate about the assessment

It continued with the key aspects of the EFSA approach which are enumerated below:

- Mandatory:
 - List identified uncertainties and characterise their combined impact on the assessment outcome in a clear and unambiguous manner
- Flexibility:
 - Choice of methods & degree of refinement
- Major change:
 - More transparent, rigorous, quantitative use of expert judgement
- Main innovations:
 - Combined uncertainty assessment
 - Pragmatic approach for standardised procedures
 - Use of partial probability statements?
- Fit for purpose:
 - Scalable to time and resources available

The session continued with a presentation made by the Chair of the WG on Weight of Evidence, who presented the state of play of SCHEER Memorandum on weight of evidence and uncertainty. The discussion then focused on how the EFSA guidance could contribute to the work of SCs. The SCHEER members emphasised the fact that uncertainties represent only a small part of the SCHEER Memorandum and therefore the SCHEER should make use of the EFSA document on this topic.

At the end of the session the Chair summarised the main points from the day:

- The SCHEER will consider the EFSA document for the SCHEER's work. EFSA plans to finalise the compilations of comments received during the public consultation by December 2017.
- The SCHEER will look into the terminology used by EFSA
- The part on reporting should be developed in the Memorandum on WoE
- The way of expressing the final conclusions should be harmonised with the EFSA recommendations as much as possible.

3. Information from the Commission and WG members

- The Secretariat informed the SCHEER about a new template for the minutes of the meetings which is slightly different from that currently in use and should be used from 1st of June. Concerning the approval of WG minutes, the Chair of the SCHEER proposed not to wait until the following meeting, but to send the minutes to be published for approval by written procedure. The SCHEER agreed with this proposal.
- The Secretariat informed the Committee about the Decision of the European Ombudsman published after two years of work, which closed the inquiry into complaint 208/2015/PD concerning conflicts of interests in a Commission expert group on electromagnetic fields. The case concerned alleged conflicts of interests concerning members of a Commission working group tasked with reviewing the science on the effects that electromagnetic fields may have on health. The complaint to the Ombudsman alleged that the Commission had

not examined properly whether the scientists in the working group had conflicts of interests. The Ombudsman inquired into the issue. She was satisfied that the Commission had examined the matter properly and that the scientists had no conflicting interests. Thus, there was no maladministration by the Commission. However, the Ombudsman found that the Commission's procedures could be improved and made some suggestions for improvement. Link to the decision:

<https://www.ombudsman.europa.eu/en/cases/decision.faces/en/78175/html.bookmark>

- The Secretariat updated the SCHEER about the follow-up of the sunbeds opinion. The Commission is coordinating risk management action among Member States and relevant Commission services.
- The Secretariat informed the committee about the organisation of a Risk Assessment Day on 17 October 2017.
- The Secretariat informed the SCHEER about an IPCHEM - the Information Platform for Chemical Monitoring is the European Commission's reference access point for searching, accessing and retrieving chemical occurrence data collected and managed in Europe. JRC will be invited to attend the SCHEER's plenary meeting on 28 September to make a presentation on this topic.

List of participants

Members of the SCHEER

Roberto Bertollini, Teresa Borges, Wim de Jong, Rodica Mariana Ion, Renate Krätke, Demosthenes Panagiotakos, Ana Proykova, Theo Samaras, Marian Scott, Emanuela Testai, Theo Vermeire.

SCHEER secretariat

Philippe Roux
Silvia Hrubanova
Mihaela Haratau

EFSA

Andy Hart
Peter Craig

18 May 2017

1. Welcome and apologies, approval of the agenda and declaration of interests

The Chair welcomed the participants; announced three apologies received and asked the participants to adopt the agenda for the meeting. One member joined the meeting by audio. The Chair of the SCCS attended the plenary meeting in person.

The agenda was adopted as presented.

The Chair invited participants to declare any conflict of interest regarding matters on the agenda. None of the participants declared any interest conflicting with the matter on the agenda.

2. New mandates:

– Request to the SCHEER to evaluate the new fiscal marker (TAXUD)

The Chair welcomed the colleagues from DG TAXUD who joined the plenary by audio for the discussion on the new mandate.

The new mandate is asking the SCHEER to evaluate 4 selected candidate fuel markers; the work will involve evaluation of confidential information from applicants. The advice will not be published for comments/public consultation and will be published at a later stage when the marker will have been selected.

The SCHEER adopted the mandate and a Working Group was formed. The deadline for the Opinion was set for November 2017, but it will be adjusted depending on the amount of information available on the 4 selected candidates.

3. Preliminary Opinions (for adoption):

– Final Opinion on the need for non-human primates in biomedical research, safety and efficacy testing (Update 2009 opinion):

The representative of DG ENV joined the meeting by audio.

The Chair presented to the SCHEER members the results of the public consultation and the conclusion of the final Opinion. The public consultation took place between 10 February and 26 March and a public hearing on the preliminary Opinion took place on 14 March. The comments received during the public consultation of the preliminary Opinion resulted in adaptation of the Opinion on the use of NHP. Comments were included when they did not reflected policy recommendations, were specific for NHPs, and were anchored in the report. After discussion the SCHEER adopted the final Opinion.

The Secretariat informed about dissemination materials in preparation, namely a fact sheet and web-summary; members were asked to check their scientific content.

Contacts are on-going to publish the Opinion in a scientific journal.

– Preliminary Opinion on the tolerable intake of aluminium with regards to adapting the migration limits for aluminium in toys

The Chair of the WG presented the preliminary Opinion as drafted by the WG. The SCHEER provided several recommendations to improve the preliminary Opinion in different chapters.

The SCHEER concluded that the preliminary Opinion should be revised, taking into account the comments of the SCHEER, and then sent for adoption by written procedure.

- **Preliminary Opinion on potential risks to human health of Light Emitting Diodes (LEDs)**

The Chair of the WG presented the preliminary Opinion as drafted by the WG. During the discussion, the SCHEER provided several recommendations for improving the preliminary Opinion. The Opinion was not adopted and the WG was asked to address the comments submitted by members in several chapters and to rephrase some paragraphs from the abstract and Opinion. The SCHEER concluded that the preliminary Opinion should be revised, taking into account the comments of the SCHEER, and then sent for adoption by written procedure.

- **Scientific Advice on proposed EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge**

The rapporteur of the WG presented the latest version of the scientific advice. The comments of the SCHEER were mainly related to AMR issues. The SCHEER concluded that the preliminary Opinion should be revised, taking into account the comments of the SCHEER, and then sent for adoption by written procedure.

The secretariat informed that the Advice will not undergo public consultation because it is an advice on JRC methodology. However, it will be published on the website and it will contribute to DG ENV stakeholders' consultation scheduled on 23 June.

4. Ongoing Opinions

- **Revision of the 'Memorandum on weight of evidence and uncertainties'**

The Chair of the WG updated the SCHEER members on the progress of the WG. There are two additional meetings scheduled before the summer break, in May and June. The advanced draft of the Memorandum should be ready to be discussed by the SCHEER during the plenary meeting on 28 September.

The Chair reminded the committee about the contribution sent by the SCHEER to EFSA's public consultations on guidance documents on the use of the weight of evidence approach in scientific assessments and on the identification of biological relevance of adverse/positive health effects from experimental animal and human studies.

- **Scientific Advice on "Guidance document n°27: technical guidance for deriving environmental quality standards"**

The chair of the WG updated the SCHEER members on the progress of the WG and informed that the WG held one audio and one physical meeting. One additional physical meeting is planned for 1 June and a specific Plenary audio meeting end of June 2017 to adopt the Advice.

- **Draft Opinion on public health impacts and risks resulting from onshore hydrocarbon exploration and production in the European Union**

The rapporteur of the WG updated the SCHEER members on the progress of the WG. The working group had 3 meetings so far. A call for experts was open until 7 May. 2 external experts were selected by the WG. A literature search was organised by the Secretariat with the support of the EC Library and a call for information was published with the deadline of 18 June. The next meeting will be a audioconference with the newly appointed external experts at the beginning of June. The preliminary Opinion should be sent for adoption during the plenary meeting on 28 September.

– **Rapid Risk assessment**

The Chair of the WG updated the SCHEER about the activity of this WG. She informed that the WG and the pool of experts (including currently 46 experts) participated in the EDREX exercise organised by DG ECHO on 14 -16 March.

The WG hold a meeting on 29 March where it discussed the exercise and lessons learned. The WG agreed to organise small exercises for the WG members and for the pool of experts; as not all were involved in EDREX exercise.

5. Information from the Commission and WG members

- ECHA invited SCCS/SCHEER to review its report on the regulatory applicability of alternative and non-animal approaches in the course of July-September 2017.

The SCCS will discuss possible contribution at next plenary meeting on 6 June and a template for replying should be provided by ECHA. The SCHEER agreed to contribute to common answer.

6. Next steps

- The Preliminary Opinion on the tolerable intake of aluminium with regards to adapting the migration limits for aluminium in toys, the preliminary Opinion on potential risks to human health of Light Emitting Diodes (LEDs) and the Scientific Advice on proposed EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge will be submitted to the SCHEER for adoption by written procedure once the WGs are finished with the revision of these reports, taking into account all comments received during the plenary meeting.
- The Advices on PIP Silicone Breast Implants (SBI) and the possible relation SBI and ALCL are now open for comments until 15 June. Then the WG will meet to consider comments and papers submitted, if any, in view of finalising these Advices.

7. Next plenary meeting(s)

28 September 2017 and 22 January 2018

List of participants

Members of the SCHEER

Roberto Bertollini, Teresa Borges, Raquel Duarte-Davidson, Wim de Jong, Rodica Mariana Ion, Renate Krätke, Demosthenes Panagiotakos, Ana Proykova, Theo Samaras, Marian Scott, Remy Slama, Emanuela Testai, Theo Vermeire, Marco Vighi

Members of the SCCS

Qasim Chaudhry

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Other Commission departments

DG ENV

Susanna Louhimies