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DIRECTORATE-GENERAL

SANTE

Directorate C – Public Health, Country Knowledge, Crisis Management

SANTE.C.2 – Country Knowledge and Scientific Committees

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SANTE.C.2/

SCIENTIFIC COMMITTEE ON HEALTH, ENVIRONMENTAL AND EMERGING RISKS

SCHEER

PUBLIC HEARING ON THE PRELIMINARY OPINION ON NON-HUMAN

PRIMATES TESTING - 14 MARCH 2017

SUMMARY RECORDS

European Commission:

Philippe Roux, Donata Meroni, Silvia Hrubanova (SANTE C.2)

Susanna Louhimies (ENV B.2)

SCHEER experts:

Romina Aron-Badin (WG member)

Michelle Epstein (WG member, rapporteur of the Opinion)

Jan Langermans (WG member)

Mark Prescott (WG member)

Alain Simonnard (WG member)

Registered participants:

17 organisations were represented

1. AbbVie Deutschland GmbH & Co KG, Germany
2. Biosimia, French Non-Human Primate Research Group (CNRS), National Institute of Health and Medical Research (Inserm), France
3. Charles River, France
4. Cruelty Free International/ European Coalition to End Animal Experiments (ECEAE), UK
5. Deutsches Primatenzentrum GmbH, Germany
6. Erasmus MC, The Netherlands
7. European Federation of Primatology, Italy
8. For Life On Earth (FLOE)
9. French Atomic Agency (CEA), France
10. MRC Harwell Institute, UK
11. Netherlands Institute for Neuroscience, The Netherlands

12. People for the Ethical Treatment of Animals Foundation (PETA UK), UK
13. Pierre et Marie University/ National Institute of Health and Medical Research (Inserm), France
14. The European Animal Research Association, UK
15. The University of Newcastle, UK
16. University College London, UK
17. University of Parma, Italy

1. WELCOME AND OPENING (DG SANTE)

The Chair, Philippe Roux, Head of Country Knowledge and Scientific Committees Unit from the European Commission's DG SANTE, welcomed the 20 participants representing 17 organisations from several EU countries and briefly explained the role of the SCHEER Committee as an independent advisory body on scientific matters.

The Chair passed on apologies from the Chair of the SCHEER, Theo Vermeire, who had to cancel his presence at the hearing due to an unexpected event.

The Chair introduced the agenda and explained that the purpose of the public hearing was to present the preliminary Opinion and to have a scientific discussion. The hearing provides an opportunity for various stakeholders to take part in an open scientific discussion with the scientists involved in producing the Opinion.

He reminded the participants that the public hearing was not intended to fulfil the same purpose as the on-going public consultation, which was launched on 10 February and which will remain open until 26 March, and reminded them that only the comments submitted in writing via the on-going public consultation would be taken into account by the SCHEER in the finalisation of the Opinion.

2. PRESENTATION OF THE MANDATE (DG ENV)

Susanna Louhimies from the European Commission's Directorate-General for Environment summarised the legal framework on the protection of animals used for scientific purposes.

DG ENV explained that **Directive 2010/63/EU** provides for controls of the use of live animals for scientific purposes including a systematic project evaluation and authorisation, setting binding standards for housing and care of the animals used as well as for the education, training and competence of personnel who both handle the animals and supervise the experiments.

DG ENV explained that the reason for updating the Directive 2010/63/EU is laid down in Article 58 "*the Commission shall review this Directive by 10 November 2017, taking into account **advancements in the development of alternative methods not entailing the use of animals, in particular of non-human primates, and shall propose any amendments, where appropriate***". In order to update the Directive, DG ENV requested the SCHEER to provide an **update to an earlier Opinion** by the SCHER concerning **the need for the use of non-human primates** in biomedical research, safety and efficacy testing.

3. PRESENTATION OF THE PRELIMINARY OPINION (SCENIHR)

Michelle Epstein, the rapporteur of the SCHEER WG, gave an overview of the mandate and of the composition of the experts of the SCHEER WG on non-human primates and provided a summary of SCHEER's replies to the following six issues addressed in the mandate:

- **Q1** What are the areas of research (fundamental, translational and applied) and testing of products and devices in which non-human primates continue to be used today;
- **Q2** What are the currently available possibilities by type of research or testing to replace their use either with methods not entailing the use of animals or by using other species of animals including those genetically altered;
- **Q3** What is the scientific viewpoint on when their use would no longer be necessary, considering the type of research and areas of testing with a view to the establishment of a specific phasing-out time-table where possible;
- **Q4** What are the opportunities for the reduction and refinement of their use in areas where no replacement can be foreseen in medium or long term as per the principles of the Three Rs;
- **Q5** To identify specific research areas where effort should be made to advance replacement, reduction and refinement of the use of non-human primates in scientific procedures;
- **Q6** What are potential implications for biomedical research (e.g. immune based diseases, neuro-degenerative disorders, infectious diseases and serious diseases) should the use of non-human primates be banned in the EU?

4. QUESTION AND ANSWER SESSION

Twelve representatives from 17 organisations asked questions and made comments or presentations during the "Question and Answer" session. The Chair asked that issues raised during this session, in addition to supporting evidence, be submitted through the public consultation process to ensure that the SCHEER will examine them in more detail for the finalisation of the Opinion. A summary of the main points raised orally is provided below.

A majority of representatives from the participating organisations welcomed the SCHEER's preliminary Opinion, although the representatives of the animal protection organisations expressed major disagreement with the conclusions of the preliminary Opinion and stressed that NHP models should not be used at all.

Representatives of animal protection organisations criticised that the Opinion is not a sufficiently comprehensive review of this issue. However, the SCHEER secretariat clarified that task of the SCHEER is to focus on the questions asked in the mandate and not to provide a comprehensive review of the field.

There was an issue about the lack of information about the methodology used for the Opinion and the SCHEER secretariat clarified that the SCHEER's working method was a

meta-analysis of scientific literature published in peer-reviewed journals and an application of a weight of evidence approach as per the Memorandum on the use of the scientific literature for human health risk assessment purposes – weighing of evidence and expression of uncertainty¹. Furthermore, it was pointed out that this information would be added in the final Opinion.

Representatives of animal protection organisations criticised the fact that animal protection organisations were not invited and represented in the SCHEER WG. The SCHEER's Secretariat (provided by the European Commission, DG SANTE) stressed the scientific nature of the Opinion, and that the selection of experts for the SCHEER WG is not based on individual invitations of interested parties, but strictly follows the rules of the EU Commission and the Rules of Procedure of the Scientific Committees to ensure that all areas of the mandate given to the SCHEER are covered by appropriate expertise. Experts were first selected among SCHEER members, then among experts on the reserve list and finally through a specific open call. In a second phase, the Commission checked the declarations of interests of the selected experts to exclude any conflict of interest.

Many representatives stressed the importance of non-human primate research, especially for the study of brain and its diseases and for research on infectious and emerging diseases. These representatives also pointed out that non-invasive human neuroimaging techniques, such as functional magnetic resonance imaging (fMRI), were proposed as potential alternatives to research with NHPs; however, these approaches do not offer simple alternatives to invasive experiments with NHPs.

Many organisations pointed out that the definition of replacement is not used correctly in the preliminary Opinion. In response to this issue, the SCHEER representatives agreed to ensure that the definition in the final Opinion would be used correctly.

Several organisations emphasised the need to apply positive training techniques, to refine some of the procedures used in neurophysiological and to promote a positive interaction between study subjects and personnel (care-takers and researchers), which was well received by the SCHEER.

Several representatives pointed out that the report focuses too much on the UK experience and UK initiatives. The SCHEER clarified that although many UK-based initiatives are cited in the Opinion, these initiatives are based on international cooperation, e.g., NC3Rs. This issue, however, would be reconsidered in the final Opinion and more attention would be paid to the situation in the EU.

Several organisations criticised a lack of clarity with respect to the statistics on NHP use included in the Opinion. However, the representative from DG ENV explained that the reporting template for 2014 statistics was different from the previous template and therefore the data are not comparable.

Several organisations commented on the severity classification of neuroscience procedures. The representative from DG ENV responded by pointing out that according

¹ https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_s_001.pdf

to Directive 2010/63/EU, prospective severity classification should be made on a case-by-case basis and be in line with the highest severity that may be experienced.

A few organisations did not agree with the conclusions of the Bateson report. The SCHEER replied that the Bateson review is the most evidence-based and systematic review to date of the outputs and impacts of NHP research.

5. CLOSING (DG SANTE)

The Chair thanked participants for their contributions and reiterated that the deadline for the submission of written contributions and supporting evidence through the public consultation process would be on 26 March 2017.

The Chair explained that according to the Rules of procedures, contributions to the consultation process shall not be about policy or risk management issues but should aim at improving the scientific basis of the Opinion.

The Chair clarified that only submissions directly referring to the content of the preliminary Opinion and relating to the issues that the report addresses would be considered.

The Chair reiterated the invitation to submit any relevant scientific evidence that might have been omitted in the preliminary Opinion. However, only studies and data which are published or accepted for publication in peer-reviewed scientific reports or journals would be taken into consideration.

The SCHEER will consider all the relevant submissions related to the scope of the public consultation and will decide if and to what extent each of the contributions should be taken into account in the formulation of the final Opinion.

The Chair concluded by thanking the members of the SCHEER for their work and expressing his wishes for their continued support going forward.



Scientific Committee on Health, Environmental and Emerging Risks

SCHEER

Public Hearing on the preliminary Opinion on non-human primates testing

Meeting date: 14 March 2017

10:00 – 17:00

DRAFT Programme

- 1. WELCOME AND OPENING (DG SANTE)**
- 2. PRESENTATION OF THE MANDATE - EU POLICY CONTEXT**
- 3. PRESENTATION OF THE PRELIMINARY OPINION (SCHEER)**
- 4. QUESTION AND ANSWER SESSION**
- 5. CLOSING (DG SANTE)**