

Annex

Scientific Committee on Health and Environmental Risks

Request for a scientific opinion on the need for non-human primates in biomedical research, production and testing of products and devices

1. BACKGROUND

Directive 86/609/EEC¹ on the protection of animals used for experimental and other scientific purposes provides for controls of the use of laboratory animals, it sets minimum standards for housing and care as well as for the training of personnel handling animals and supervising the experiments.

Since 1986, important progress has been made in science and new techniques are now available requiring specific attention, which the current Directive does not provide. Nor is the use of animals with a higher degree of neurophysiological sensitivity such as non-human primates specifically regulated. Therefore, DG ENV is currently revising the Directive.

The revision addresses issues such as compulsory authorisation of all experiments, inspections, severity classification, harm-benefit analysis and compulsory ethical review. Also specific problems relating to the use, care and acquisition of non-human primates are tackled.

In 2002, the Scientific Steering Committee, SSC, highlighted the continuing need to use non-human primates in biomedical research.²

Since then, a number of publications have been made on the need to replace the use of non-human primates in biomedical research due to ethical and scientific reasons. In July 2007, Animal Defenders International, National Anti-Vivisection Society and Lord Dowding Fund for Humane Research published a response to the SSC statement.³ The most recent publications include December 2006 a report "The use of non-human primates in research" by Sir David Weatherall and a subsequent response to it by NC3Rs.^{4,5}

Animal Welfare NGOs campaign on the phasing out of all experiments on non-human primates. The arguments in support of phasing-out range from ethical and moral argumentation to more scientific ones. The essential element of the discussion is on the availability of alternative methods to replace the use of non-human primates. See e.g. British Union for the Abolition of Vivisection report "Ending Primate Experiments – Meeting the challenge" by Dr Katy Taylor and David Powell.

On 25 September 2007, the European Parliament adopted a declaration (0040/2007) urging the Commission to

¹ OJ L 358 , 18.12.1986

² The Scientific Steering Committee: "The need for non-human primates in biomedical research", statement adopted 4-5 April 2002: http://europa.eu.int/comm/food/fs/sc/ssc/out253_en.pdf

³ http://www.ad-international.org/admin/downloads/ssc_response_english.pdf

⁴ <http://www.acmedsci.ac.uk/images/project/nhpdownl.pdf>

⁵ <http://www.nc3rs.org.uk/downloadaddoc.asp?id=563>

- (1) Make end to the use of great apes and wild-caught monkeys in scientific experiments;
- (2) Establish a timetable for replacing with alternatives the use of all primates in scientific experiments.

The Commission stated in its response that with the current scientific knowledge a timetable with a fixed deadline to phase out all use of non-human primates in the area of biomedical research is not possible⁶. However, the science is evolving rapidly in this field and novel technologies, such as genomics and computer modelling, are gradually emerging.

In order to participate in this debate in a balanced manner, independent scientific information is needed on the latest status of the possibilities to replace the use of non-human primates. DG ENV would therefore like to request the Scientific Committee on Health and Environmental Risks to issue an opinion in this context.

To support the co-decisions procedure and the related discussions at the European Parliament and the Council, the scientific opinion would need to be available by the end of October 2008.

The terms of reference are detailed below.

Use of non-human primates in scientific procedures

Around 12 million animals are used on a yearly basis in scientific procedures in the EU. Of these, around 10.000 are non-human primates.⁷

Due to their genetic proximity to humans and highly developed social skills, the use of non-human primates in scientific procedures raises specific ethical questions and practical problems in terms of meeting their behavioural, environmental and social needs in a laboratory environment. The capture of non-human primates from the wild is stressful for the animals and increases the risk of injuries and suffering during capture and transport. Furthermore, the use of non-human primates for scientific purposes is of the highest concern to the citizens.

Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes was adopted to improve the controls on the use of experimental animals and to harmonise practices in the area of animal experimentation in the EU. Article 7 of the Directive provides that "*an experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.*" It is therefore in the spirit of the Directive to encourage methods, which will ultimately replace the use of animals in experiments.

Further on, Article 7 states that "*When an experiment has to be performed, the choice of species shall be carefully considered and, where necessary, explained to the authority. In a choice between experiments, those which use the minimum*

⁶ http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm

⁷ 12, 117, 625 animals in 2005 in EU25, COM(2007) 675 final and SEC(2007) 1455.

number of animals, involve animals with the lowest degree of neuro-physiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected. Experiments on animals taken from the wild may not be carried out unless experiments on other animals would not suffice for the aims of the experiment."

Already today, non-human primates are used only in exceptional circumstances where no alternative methods are available and no other species may suffice for the purposes of the research. The majority (67%) of the non-human primates used in scientific procedures are required by legislation for the testing of pharmaceutical products and devices for their safety and efficacy. The rest are used for biological studies of a fundamental nature as well as for the research and development of products and devices for human medicine, dentistry and veterinary medicine. Their use is considered essential in several research programs such as on immune based diseases (e.g. multiple sclerosis), neuro-degenerative disorders (Parkinson, Alzheimer, etc), infectious diseases (HIV, Malaria, TB, Hepatitis, SARS, etc.) and other serious diseases.

Some alternative techniques are available and have been successfully used to reduce our need to resort to non-human primates. However, it is understood that, with the current scientific knowledge, not enough alternative methods are yet available to replace the use of non-human primates in all areas of biomedical research today.

2. TERMS OF REFERENCE

In view of the above, the Commission asks the Scientific Committee on Health and Environmental Risks to issue a scientific opinion on:

- The areas of research (fundamental, translational and applied) and testing of products and devices in which non-human primates are used today;
- The currently available possibilities to replace their use either with methods not entailing the use of animals or by resorting to other species of animals including genetically altered animals by type of research or testing;
- The scientific outlook as to their replacement in short, medium and long term by type of research and areas of testing with a view to establishing a specific phasing-out time-table;
- 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 Rs⁸;
- Research areas that investments should be made to advance replacement, reduction and refinement of the use of non-human primates in scientific procedures.

⁸ The Three Rs Principle (Replace, Reduce and Refine the use of animals in experiments) were first established in a book "The Principles of Humane Experimental Technique" by W.M.S. Russell and R.L. Burch in 1959

- Possible implications in 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.

3. DEADLINE

SCHER's opinion would be appreciated by the end of October 2008 to facilitate the discussions at the EP and the Council for the first reading of the forthcoming Commission proposal.