To the attention of:

Commissioner Janez Potocnik
EU Commissioner Science & Research

Commissioner Guenter Verheugen
EU Commissioner Enterprise & Industry

Commissioner Stavros Dimas
EU Commissioner Environment

10 April 2008

Subject: **Revision of the European Directive 86/609 on the protection of animals used for experimental and other scientific purposes**

The European Brain Council (EBC) is a co-ordinating council formed by European organisations in neurology, psychiatry, neurosurgery, and basic neuroscience as well as patient organisations and industry. Its mission is to realise better understanding of the unmet health needs associated with brain disorders across Europe, to improve the quality of life of those affected by such diseases, and to promote relevant brain research to tackle these problems.

The EBC has followed closely the revision of the Directive 86/609 and, in particular, the European Parliament's Written Declaration requesting an immediate ban on the use of great apes and wild caught monkeys as well as a timetable for the phasing out of all use of non-human primates.

The EBC approves of well considered efforts to implement the reduction, refinement and replacement (3Rs) of animals in biomedical research in general, and to develop scientifically-based alternatives that have the potential to provide alternative or superior information to that obtained from animals. Specifically, the EBC recognises the importance of the debate on use of non-human primates (NHPs). Their genetic and social similarities to man make them attractive as models for the study of human disease, but these also place scientists with a burden of responsibility to ensure that their use is minimised, and associated with the least possible suffering. European biomedical scientists are leading the world in considering this dilemma.

The EBC shares the view of the EC that much greater justification should be demanded of the use of great apes and wild caught NHPs in research. We see no justification for the use of great apes in brain research, nor the use of wild caught animals when NHPs bred in captivity are available. Any justification in other spheres of research should be revised regularly in the light of scientific discoveries and the development of alternatives.

However, the Parliament's declaration for the phasing out of all use of NHPs is problematic. In keeping with a recent major report on the scientific benefits that have accrued from the use of NHPs (1), the EBC does not agree with the declaration that more efficient and reliable alternatives yet exist. If they did, they would already be used, and this statement undervalues both the serious research work going on across Europe to develop such alternatives and validate them, and the careful use of primates in selected biomedical projects (e.g. vaccine development for HIV). The large size of the brain compared to mice and the very similarity of the brain circuits in NHPs to what is believed to exist in the human brain, makes their use important in a

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number of different biomedical research programmes, both in vitro and in vivo. These involve diverse techniques ranging from cell-culture, computer modelling, in vitro physiology and biochemistry, to the development of new tracers for radio-imaging and new forms of deep brain stimulation. Small but key aspects of these are the conduct of a limited but critical number of experiments using NHPs.

The EBC wishes to point out that in many areas of research (for example, functional imaging, deep brain recording and drug development) the use of human subjects for experimentation and validation is clearly superior to the use of animals including NHPs. However, it is society that demands assessment of the safety of such interventions through prior use of animals, and the EBC supports current efforts such as those being led by the UK's National Centre for the 3Rs to examine critically the use of NHPs for safety and toxicology testing and eliminate such use that is not based on good science and does not protect the patient.

A ban of the use of non-human primates based on a timetable rather than on scientific research will merely lead to research moving abroad. Moving research elsewhere is likely to be to the detriment of animal welfare and certainly detrimental to the public and private research base of the EU. Instead, the EBC asks the EC to develop a strategy to support reduction and ultimately replacement of primate use based on advances in scientific knowledge. It is essential that proper investment is provided to facilitate this, and that there is clear framework in place for validation and for acceptance of alternatives by regulatory bodies where issues of human safety are involved.

In summary, the EBC believes that the EC should challenge and encourage biomedical researchers to find and use alternatives to NHPs in order that the legitimate concerns of European citizens about animal welfare can be addressed. However, the EC should also recognise that brain research in Europe must continue to prosper to the benefit of those living with brain diseases.

For the EBC Board

Professor Jes Olesen
President EBC

Reference

1. Weatherall Report (2006) "The use of non-human primates in research", Academy of Medical Sciences, UK (Email: apollo@acmedsci.ac.uk
Web: www.acmedsci.ac.uk).

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