

Article 8 - Limiting and replacing the use of non-human primates in research

Proposal for a Directive on the protection of animals used for scientific purposes (revising Directive 86/609/EEC): Article 8

The use of primates in experiments is a matter of extreme concern to **Eurogroup For Animals and Animal Defenders International (ADI)** as it is to the public in general. Any use of non-human primates must be strictly controlled. Their use must be scientifically and ethically justified. Opening up the use of primates would effectively remove any restrictions on primate use, which is unacceptable.

We believe that the use of primates should be reviewed every two years, as called for by the European Parliament, and that in particular the reviews should examine the impact of developments in technological, scientific and animal welfare knowledge and set targets for the implementation of alternative methods.

The reason given by the Commission to dedicate an Article to non-human primates was *'specific provisions have been incorporated to reduce the use of non-human primates to an absolute minimum. A strict case-by-case scrutiny is imposed in cases where non-human primates are still the only suitable species'*. However, as the process continues, this specific Article originally dedicated to protecting primates now widens the possibilities to use primates.

Due to their considerable capacity to suffer in captivity and during experiments, the use of non-human primates in research is subject of enormous public concern. 80% of respondents to the European Commission's public consultation on the revision of Directive 86/609/EEC on animal experiments considered the use of primates in laboratories as not acceptable. In 2007, this concern was reflected when Written Declaration 40/2007 was signed by 433 Members of the European Parliament and called for "a timetable for replacing the use of all primates in scientific experiments with alternatives." Support was clear as this is many more than the required 393 signatures. The NGO Resolution¹ on Primates (Berlin, August 2005) signed by many animal welfare supporters, calls for an immediate, internationally co-ordinated effort to define a strategy to bring all non-human primate experiments to an end.

There is a broad consensus that primates should only be used when it is absolutely necessary and for investigation of serious human conditions. During the lobby process, justification for primate experiments that is given to the public or Parliament states that they are required for conditions such as Alzheimer's disease. **However, it is important to note that the regulatory framework presently allows their use for almost any experimental procedure.**

¹ Resolution: Call to end the use of non-human primates in biomedical research and testing from animal protection organisations worldwide. Berlin, August 2005

Through the revision process, Article 8 of COM(543)2009 aims to address the permissible uses for these sensitive species and includes measures that might reduce or replace the use of non-human primates in procedures (e.g., review of Directive to identify areas for replacement specifically for non-human primates – Article 53).

Background

All primate species are intelligent, some use tools, others show self-awareness and they are good at problem-solving. Most live in family groups with complex social structures. They have proved themselves capable of learning rudimentary arithmetic, have demonstrated reasoning, where some have even learnt to speak in human sign language, and they display similar emotions to us, such as affection, anger and sorrow – even empathy.

It is acknowledged that these animals suffer in the limited, often very restrictive, facilities available in laboratories. Confining primates in the laboratory, when they would normally live in a large and complex home range, has a significant adverse effect on their welfare. At its best, laboratory primate housing represents only a small fraction of their home range. The worst, still commonly used in many countries, is a small, barren metal box in which the animals can only take a few steps in any direction. New recommendations adopted by Commission in 2007 indicate floor sizes per monkey from 0.5 m² for Marmosets to 2m² for macaques and vervet monkeys)², Most of the indicated sizes are not yet implemented, however they still allow very restrictive movement if any. Their level of awareness means that they are capable of suffering greatly during even basic experimental procedures – for example the stress of being restrained has been known to cause monkeys to suffer rectal prolapse.

Presently, about 10 000 primates are used in a very wide range of procedures in the European Union including basic fundamental research, however, the largest single area of primate use in the EU is in pharmaceutical testing. Yet there are questions as to the need for primates in a number of procedures including those used where a second species (dogs or primates) is required to follow other animal tests and also the reliability of the data. In 2006, two men almost died in the UK taking test drug TGN1412. Yet, the same drug was tested on laboratory monkeys with doses 500 times higher without adverse effects.

Despite similarities with humans, species differences still prevent results obtained with primates from being extrapolated with precision to humans. Around one third of drug candidates fail in the first human trials – we urgently need more reliable human based techniques to be adopted.

Potential replacement techniques include microdosing, cell and tissue culture, and computer modeling. Modern scanning techniques such as Functional Magnetic Resonance Imaging and magneto-encephalography (MEG) are being combined to make enormous advances in neuroscience. These modern technologies provide human data without the confusion of species differences.

Our views on the present positions indicated by the different institutions are outlined below:

Commission

Article 8

Non-human primates shall not be used in procedures, with the exception of those procedures meeting the following conditions:

² 2007/526/EC - Commission Recommendation of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes (*notified under document number C(2007) 2525*)

- (a) the procedure has one of the purposes referred to in points (1), (2)(a), (3) and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of life-threatening or debilitating clinical conditions in human beings or the purpose referred to in point (5) of Article 5;
- (b) there is a scientific justification that the purpose of the procedure cannot be achieved by the use of other species than non-human primates.

Article 53

The Commission shall review this Directive by **[10 years after the date of entry into force]** taking into account advancement in development of alternative methods not entailing the use of animals, and in particular of **non-human primates**, and propose any amendments, where appropriate.

European Parliament

Amendment 56: **Given their particularly high level of neurophysiological sensitivity and cognitive development**, non-human primates shall not be used in procedures, with the exception of those procedures meeting the following conditions:

Amendment 57: paragraph 1(a) the procedure has one of the purposes referred to in points (1), (2)(a), (3) **or** (5) of Article 5;

Amendment 58: paragraph 1 (b) **the applicant provides** a scientific **and ethical** justification that the purpose of the procedure cannot be achieved by the use of other species than non-human primates.

Amendment 59: paragraph 2 a (new) 2a. **Every two years, and for the first time two years after the entry into force of this Directive, the Commission shall, in consultation with Member States, conduct a review of the use of non-human primates in procedures and publish the results thereof. The review shall examine the impact of developments in technological, scientific and animal-welfare knowledge, and set targets for the implementation of validated replacement methods.**

Council

1. Non-human primates, not listed in Annex A to Council Regulation (EC) No 338/97, shall not be used in procedures, with the exception of those procedures meeting the following conditions:

- (a) there is a scientific justification that the purpose of the procedure cannot be achieved by the use of other species than non-human primates; and
- (b) the procedure has one of the purposes referred to in (i) points [...] (2)(a) **or** (3) of **Article 5** and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening [...] clinical conditions in human beings [...]; or (ii) **points (1) or (5)** of Article 5.

A debilitating clinical condition in the context of this Directive shall mean a reduction of a person's normal physical or psychological ability to function. Such a condition can be caused by illness, injury, substance abuse or be congenital, and result in a temporary or life-long impairment.

1A Non-human primates, listed in Annex A to Council Regulation (EC) No 338/97, shall not be used in procedures, with the exception of those procedures meeting the following conditions:

- (a) **there is a scientific justification that the purpose of the procedure cannot be achieved by the use of other species than non-human primates and by the use of species not listed in that Annex, and**
- (b) **the procedure has one of the purposes referred to in:**
- (i) **points (2)(a) or (3) of Article 5 and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or**
- (ii) **point (5) of Article 5.**

Recital (16)

*With current scientific knowledge the use of non-human primates in scientific procedures is still necessary in biomedical research. Due to their genetic proximity to human beings and to their highly developed social skills, the use of non-human primates in scientific procedures raises specific ethical and practical problems in terms of meeting their behavioural, environmental and social needs in a laboratory environment. Furthermore, the use of non-human primates is of the highest concern to the public. Therefore the use of non-human primates should only be allowed in those essential biomedical areas for the benefit of human beings for which no other replacement alternative methods are yet available. **Their use should only be allowed for the preservation of the respective non-human primate species, or when the work, including xenotransplantation, is carried out in relation to life-threatening conditions in humans or in relation to [...] cases [...] having a substantial impact on [...] person's day-to-day functioning i.e. debilitating [...] conditions such as infectious deceases, diabetes, allergy, asthma, dementia, hearing or visual disorder, dyslexia, addiction, obesity or infertility. [...]***

The position of ADI and Eurogroup during the trialogue discussions

We urge you to support an approach which includes specific restrictions on the use of primates, only allowing their use in exceptional circumstances. Further to this there must be an EU commitment to end the use of primates in experiments.

The attempt by the Commission to limit procedures on primates to study of “life threatening or debilitating clinical conditions in humans” was welcomed. However, the term “debilitating” has the potential for far too wide an interpretation and could be used to justify research into any human condition.

Furthermore regarding the amendments of the European Parliament, whilst Am 60 acknowledges the reasons for special consideration for primates, **Am 57** simultaneously removes any restriction on primate use and is therefore **strongly opposed**.

Additionally, the Council text is supported over European Parliament amendment 58 in that it attempts to limit primate research to what the public would consider serious ailments. Unfortunately, whilst debilitating needs definition, the one given by the Council is too broad. **We strongly recommend that the definition of “debilitating” be: ‘a permanent and substantial reduction in a person’s normal physical and psychological ability to function.’** This would ensure that the latter part of the definition could not be used to seek, for example, cures for hangovers. “Substantial” reflects the terminology considered for Council recommended Recital 16. **Without clarification of “debilitating” the Council text may fail to exclude anything.**

Council Recital 16: We believe that the use of the word debilitating was to allow for research into fields such as Alzheimer’s, Parkinson’s, or Multiple Sclerosis and NOT used to allow hangovers and obesity to be studied on primates – the Directive needs to ensure this. In this context, we are therefore concerned about the breadth of conditions the changed wording now includes. Many allergies, for example, have a day-to-day impact on humans however this is generally manageable and could not be considered “substantial”. Similarly, dyslexia should not be included here without far greater explanation. Whilst infertility is a significant issue it would be inappropriate to include it here. This effectively expands the definition of “debilitating” to almost anything that might have a psychological impact. Similarly, the inclusion of impacts of lifestyle allows primates to be used in almost any field of research. For obesity and addiction, allergies, and even dyslexia, whilst these could all be considered debilitating in certain contexts, they are areas which need not be permanently and significantly debilitating and are areas which definitely should not be considered when contemplating the use of primates.

It should be suggested that an Annex be included which lists the procedures for which primate use would be proscribed. This would be beneficial.

European Parliament amendment 59 is very important to ensure specific consideration is given to the replacement of procedures on non-human primates. It has not been covered by the Council text and it is important the Parliament continues to indicate their support. This is a practical and proportionate approach to the replacement of primates in experiments. It ensures a special focus on primates which was the ultimate aim of the Commission proposal, an area of special concern, in tandem with the broader remit of the review under Article 53.

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Position during trialogue discussions, November 2009