

## the time is now ending primate research in the european union

### introduction >>

Every year, over 10,000 nonhuman primates are used in experiments within the European Union (EU). The source and use of primates raises important ethical and scientific questions and is a real concern for citizens of the EU. No law specifically calls for primates to be used in research or testing in the EU and in the 21st century, we have a responsibility to do better.



There are no morally relevant differences between non-human primates and humans that would justify doing to them what we would never consider doing to human beings. Nonhuman primates share many of the important characteristics of humans. They are intelligent and highly evolved animals with complex behavioural and social needs that laboratories and breeding centres can never hope to meet adequately. Primates are often housed on their own in small, essentially barren, metal cages for many years with no meaningful environmental enrichment. With little opportunity for mental stimulation and physical exercise, these animals frequently develop abnormal and self-destructive behaviours that may include pacing, rocking, swaying, bar biting, and self-mutilation. Primates are not domesticated pets, they are essentially wild animals and do not adjust well to a captive environment. Even routine procedures such as catching and handling by humans, forced restraint, injections, or repeated blood sampling can cause great anxiety and stress for these wild animals.



In addition to ethical objections to animal experimentation, there are also strong scientific arguments against the use of primates in research. Because of biological differences between humans and other primates, as well as the unnatural conditions in which the primates must live, the results of such research cannot be safely and reliably extrapolated to humans.

### public opinion >>

A 2009 opinion poll in six EU states carried out by YouGov, a leading polling company, showed that an overwhelming majority (81%) of those people surveyed agree or strongly agree that the new law should prohibit all experiments causing pain or suffering to primates (1). In 2007, a clear majority of members of the European Parliament signed Written Declaration 40/2007 which called for a phase-out in primate experiments. And in 2006, in response to the Commission's public consultation on the future of Directive 86/609, 82% of those that responded stated that they did not believe that primate experiments were acceptable.

## the research >>

Primates are subjected to experimental procedures that can cause them pain, discomfort and suffering, much of it profound. Most will be killed at the end of the experiment. The latest available statistics (from 2005) show that EU member states used 10,449 Old and New world monkeys and prosimians for research. Disturbingly, the use of primates (Old and New world monkeys) increased by 5%. New world monkeys (i.e. marmosets) increased by 31%. The main users of primates were France (3,789), the UK (3,115) and Germany (2,086). The main fields of research in which primates are used within the EU can generally be categorized into three areas: medical research, toxicology and fundamental (curiosity driven) research (2).

According to the most recent figures available, 67% of primates are used in toxicological (poisoning) research. Such testing can last for months, during which primates are dosed daily with chemicals or drugs through injection or forced ingestion (gavage). Fundamental research accounts for around 14% of procedures and may include studies in neurological research and other human disease. Many of these primate studies involve the implantation of electrodes and/or brain lesions. Medical research which accounts for 17% of total procedures includes research, development and quality control of products and devices (2). It may be surprising to learn that less than 20% of primate experiments are done in order to see whether human medicines are likely to work.

## the source and supply chain >>

The majority of primates used are Old world monkeys (*Cercopithecidae*) which includes the macaque (*Macaca* sp), as well as baboons (*Papio* sp) and the African Green monkey (*Chlorocebus aethiops*). The remainder of the primates used are New World species such as squirrel monkeys (*Saimiri sciureus*), marmosets (*Callithrix* sp) and tamarins (*Saguinus* sp). All these primates are listed under Appendix II of CITES (the Convention on the International Trade in Endangered Species) – meaning that the species could become endangered if trade is not controlled.

Many of the primates used in European laboratories are imported from countries outside the EU. The most recent EU statistics show that the figure for Old World monkeys is 73%. Some of these primates are taken from the wild and exported to the EU from countries such as Mauritius and Barbados. Others will have either been born (known as F1 generation) or bred (known as F2 plus generation) in captivity in their country of origin, but with breeding colonies often permitted to be re-stocked from the wild. F1 generation primates are those where one or both parents have been captured from the wild.



In Europe the species of primate most widely used by the research industry are macaques, in particular, the long-tailed macaque (*Macaca fascicularis*) and the rhesus macaque (*Macaca mulatta*). According to the latest data available from CITES, long-tailed macaques have been imported into the EU from China, the Philippines, Vietnam and Mauritius and have included wild-caught, F1 generation and F2 generation monkeys. African green monkeys (*Chlorocebus aethiops*) have also been imported from Barbados and include both wild-caught and captive-bred animals (3).

The transportation of primates into the EU causes immense stress, distress and suffering. The animals are packed into small wooden crates and travel as cargo, usually on passenger airlines. Transit times to the European Union have taken up to 70 hours. The monkeys may also have to endure inadequate ventilation, noise, extreme temperature fluctuations and delays en route. Statistics for primate deaths and illnesses either during transportation or subsequently are not always made public. However, the BUAV has uncovered examples of monkeys found dead on arrival, often as a result of distress and shock due to the conditions on board.

The BUAV has undertaken many investigations into the international trade in primates for research. Footage obtained from countries such as Mauritius, Barbados, Tanzania, Vietnam and Cambodia has revealed the immense cruelty and suffering that is inflicted on monkeys during their capture, caging, holding and transportation to the research laboratory. The BUAV has often found appalling and unacceptable, even by current standards, conditions for primates in both holding and breeding facilities in those countries that export monkeys for research; conditions that breach the International Primatological Society's animal welfare guidelines. The most recent investigations have shown the cruelties involved in the trapping of wild macaques and their factory farming in Vietnam and Cambodia. Both countries currently supply monkeys to the EU research industry.

## scientific unreliability of primate research >>

Although it is true that the development of new treatments almost always involves animals, the key question is whether, scientifically, their use is necessary or beneficial. There are many reasons why animals are used in experiments, the conservatism of regulators being one of them. This is illustrated by the insistence of European medicine regulators to continue with acute toxicity experiments on animals when even the pharmaceutical industry agrees they are all but redundant (4). Toxicological research accounts for almost 70% of the procedures carried out on primates within the EU. Despite the general physical similarity between nonhuman primates and humans, however, this does not mean that the effect of a chemical will be the same in both species. Whilst there is little scientific evidence that animal experiments, including those on primates, are predictive of human effects (5), there are countless examples of where they have not been. Examples include significant differences in metabolism of drugs (6,7) as well as serious side effects (8,9,10). At a key international regulatory forum, the International Conference on Harmonisation, acknowledged that in terms of the way in which a drug is handled by the body, monkeys can differ from humans as much as any other species (11). The Food and Drug Administration in the US stated in a press release in January 2006, that "nine out of 10 experimental drugs fail in clinical studies because we cannot accurately predict how they will behave in people based on laboratory and animal studies" (12). The failure to find a vaccine for HIV/AIDS is an example of this. Not one of the 80 or more candidate vaccine tested successfully on primates has worked in patients (13).



## conclusion >>

The animal welfare costs of using primates in experiments cannot be justified. The continued use of wild-caught and F1 generation monkeys is particularly unacceptable. In some cases non-animal replacement techniques have already helped to reduce primate use, a ban on primate use would be an important stimulus to realise the full potential of such techniques. Furthermore, it should be possible to end other types of primate research – such as basic, exploratory research – without needing to seek off-the-shelf replacements. Just because primates are currently used in an area of research is not proof of its necessity. Primate research has been singularly unsuccessful in developing treatments for human illnesses.

Many of the barriers to eradicating primate use are not scientific, but cultural, economic and political. These must be strongly challenged and a fundamental shift in attitude encouraged. The EU must rise to the challenge of ending primate experimentation within the current revision of Directive 86/609/EC on the Protection of Animals used for Experimental and other Scientific Purposes.

## references >>

1. Prepared by YouGov on behalf of the ECEAE: Total sample size was 7139 adults. Fieldwork was Undertaken between 24th February - 4th March 2009. The survey was carried out online. The figures have been weighted and are representative of the population sizes of the countries surveyed.
2. Fifth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union.
3. CITES trade database: <http://www.unep-wcmc.org/citestrade/trade.cfm>.
4. Robinson S, Delongas JL, Donald E, Dreher D, Festag M, Kervyn S et al. A European pharmaceutical company initiative challenging the regulatory requirement for acute toxicity studies in pharmaceutical drug development. *Regulatory Toxicology and Pharmacology* 2008;50:345-52.
5. Pound P, Ebrahim S, Sandercock P, Bracken MB, Roberts I (2004). Where is the evidence that animal research benefits humans? *BMJ* 328:514-7.
6. Sludden J et al (1998). Liver dihydropyrimidine dehydrogenase activity in human, cynomolgus monkey, rhesus monkey, dog, rat and mouse. *Pharmacol.* 56:276-280.
7. Kling J (1996). In vitro models for in vivo drug profiles. *Nature Biotech.* 14:1655-1656.
8. Morton DM, *Toxicology*. Letters, 1998, 102-103:545-550.
9. Gad SC (1990). Model selection in toxicology: principles and practice. *J. Am. Coll. Toxicol.* 9:291-302. 10. Duff, G.W. (2006) Expert Group on Phase One Clinical Trials: Independent report to the Secretary of State for Health. 7 December 2006. The Stationery Office; London UK. P.65.
11. ICH Harmonised Tripartite Guidelines: Detection of toxicity to reproduction for medicinal products (1993)
12. Mike Leavitt, Food and Drug Administration, Press Release. Jan 12th 2006.
13. Bailey, J. (2008) An assessment of the role of chimpanzees in AIDS vaccine research. *Alternatives to Laboratory Animals* 36; 1-48.

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