

A Vision for Europe

Using the proposed new directive to replace Directive 86/609 on animal experiments, to protect animals and advance European science

The following is a summary of our key areas of concern about the draft revision, and recommendations for moving Europe forward in science and technology, beyond the use of animals. Animal research methods date back over 100 years and represent an outdated technology, not appropriate in the 21st century.

In 2007, 433 Members (55%) of the European Parliament signed Written Declaration 40/2007, calling for an end to the use of great apes and wild-caught primates, and for a phase-out of the use of all primates. In a European Commission survey, 80% of European citizens stated that they found the use of primates in laboratories to be “not acceptable”. The proposals we have outlined for the revision of the directive would deliver on this public and political will.

Animal Defenders International has produced a Committee Digest with our commentary and suggested amendments to the proposed directive, and this is available to MEPs on request. In addition, all of the points outlined below are expanded upon in technical briefings.

Key areas of concern

Primates

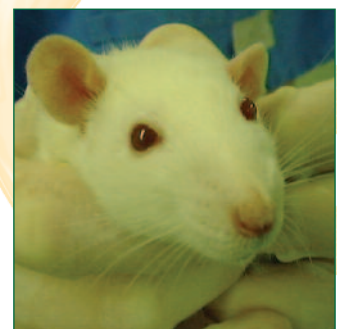
As it stands the provisions on primates fail to fully address the policy objectives of Written Declaration 40/2007, the following would do so:

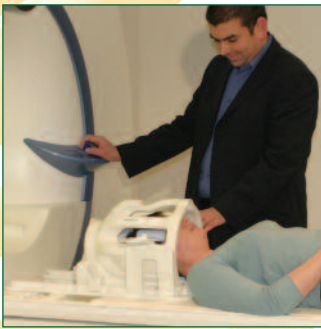
- Ban on the use of great apes (without exceptions).
- Ban on the use of wild caught monkeys (without exceptions).
- Full implementation of F1 ban (offspring of wild-caught parents); although we would favour earlier than the 7 years suggested in the draft.
- Arrangements to replace the use of primates to be established during bi-annual, thematic reviews setting timetables or objectives for replacement in specific areas.

Regular Reviews – bi-annual

• A framework and a mechanism to allow regular, thematic reviews of the use of animals in research every 2 years, which will allow the legislation to keep up-to-date with developments in science and technology and establish timetables or objectives for replacement. Such reviews to include for example:

- o Developments in science, technology, and animal welfare knowledge
- o Availability and implementation of new replacement methods
- o The use of specific species and types of experiment or fields of research
- o The species within the scope of the directive
- o This could overlap with regulatory requirement reviews geared to adoption of replacements





Legislation needs to keep pace with developments in science and technology. During the 22 years since Directive 86/609 came into effect, the world has seen these changes:

- o The digital age and the World Wide Web
- o New mobile communication technology, allowing transfers of sound, text, pictures and moving images
- o Videotape replaced film, then DVD replaced video tape, next is downloads....
- o Introduction of microsurgical techniques and keyhole surgery
- o Brain and full body imaging technology
- o Creation of the first virtual organs
- o DNA chips
- o Transgenic animals and cloning

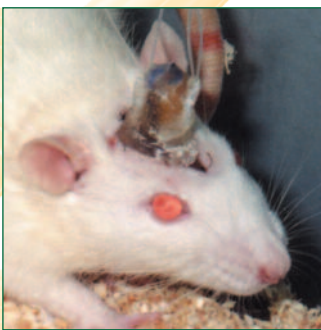


A formal periodic review (bi-annual) would enable the legislation to keep up-to-date.

Replacements and Centres of Excellence in Advanced Technology

It is vital that replacement of animal experiments be placed at the heart of the Directive. Time and again this has been shown to be what the public desire from legislation regulating animal experiments. The Directive must create incentives for the widespread adoption of modern replacement methods. This is an opportunity for European science to benefit enormously through support of modern techniques.

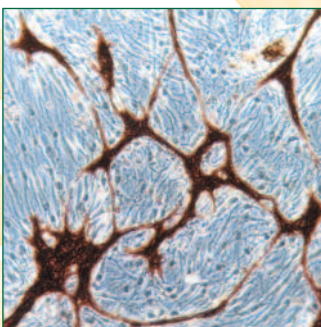
- The implementation of replacement methods needs to be part of the framework of the authorisation process.
- **A European Centre of Excellence** for the development of advanced alternative techniques (3Rs) should be established to provide funding, dissemination of information and training in replacement technology. This could be managed by the Commission and funded as a public-private partnership between the Commission, alternatives funding bodies, industry and Member States.
- We support the principle of the establishment of **national reference laboratories** (NRLs) as outlined in the draft of the new directive, but are concerned at the description in the Impact Assessment. Nevertheless, these could be developed into national centres of excellence for the development of replacement techniques, working as 'spokes' from the central European 'hub' as described above, with funding contributions from the central hub.



Purposes: Animals in Higher Education/ household/forensic/preservation of species

There are a number of areas where replacements have successfully eradicated the use of animals but these are not yet universally adopted across Europe. It is disappointing that these uses of animals remain under the *Purposes of Procedure* in Article 5. For example:

- **Research aimed at preservation of the species (5):** We do not believe that this is a credible area of animal use, and is therefore an unnecessary loophole.
- **Higher education (6):** Computer simulations have successfully replaced the use of animals in universities worldwide. A periodic, thematic review could promulgate the use of computer programmes in education. A co-ordinated programme could aim for full implementation, Europe-wide, in a few years.



- **Forensic inquiries (7)** using live animals, as this is a tiny area of research, and is not scientifically justified.
- **Household product testing.** This would be a logical follow-up to the replacement of the use of animals in cosmetics tests.

Other areas of animal use can clearly be identified by thematic reviews under a biannual review clause.

Harmonisation and raising standards of science and good laboratory practice

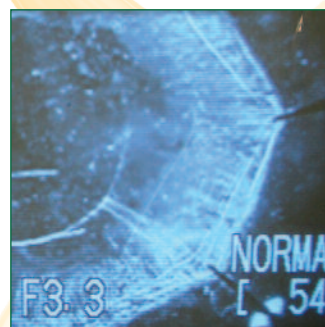
- The harmonisation aims are a very good step forward, but it is disappointing that the controls are undermined by the loopholes and derogations later in the text. It is important that the Directive uniformly raises animal welfare standards.
- Loopholes that should be removed include:
 - o permission to use killing methods other than those authorised
 - o use of endangered species
 - o derogation on purpose breeding, allowing Member States to opt out.

Review process to be independent

- We are pleased that the proposed directive describes an outline for the local ethical and scientific review process but we are concerned to note the contradictory policies in Preamble 29 and Article 25.
- It is essential that this process is seen to be independent, and therefore these committees should be modelled along the lines of the human research ethics committees:
 - o The committee should be independent of the establishment and the researcher applying for the licence
 - o At least one third lay members, bringing a range of expertise
 - o Members with expertise in alternatives and non-animal research techniques
- However, it is important that the national level of review, as part of the authorisation process, includes consideration of replacements:
- National review of project licence applications should include a wider scientific scrutiny of proposals to use animals, including input from experts in non-animal techniques and those who may be able to suggest other sources of the information required. This could be in the form of a time-limited internet consultation of anonymised applications with proprietary and confidential information removed.

Duplication / Data Sharing

- A mechanism to end duplication and ensure sharing of data can be devised along the lines of the arrangements within REACH.
- Separate arrangements (a different framework) can be implemented for regulatory and academic/fundamental research; fundamental to be based upon the licensing system. Companies to pay if necessary to access data (as in REACH). A Europe-wide strategy to avoid duplication and increase data sharing in fundamental research is urgently needed and could have considerable benefits for advancing European science.





Transparency and project authorisation

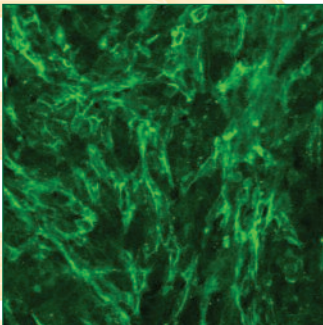
- Greater transparency is needed on this issue, which causes widespread public concern.
- It is essential that all project licence applications are put open to wider scientific scrutiny – before the licence is granted. Such scrutiny can be time-limited, in line with other public information access legislation.
- We support the introduction of 'project summaries' but these should not take the place of true transparency and public accountability.
- Publication of retrospective reviews of animal use, especially of unexpected levels of suffering, is vital to inform future cost-benefit assessments and decision-making.



Good Points in the Directive

Provided the loopholes are closed – there are some positive aspects to the draft of the new directive. It is important that these remain in place and are strengthened.

- The ban on use of stray cats and dogs is a positive move – although it does appear somewhat illogical to direct that stray domesticated species should receive more protection than endangered species and wild-caught animals.
- Primates – the moves on great apes, wild caught, and restrictions to captive bred F1 animals (offspring of captive parents) are a move in the right direction, sadly such positive aspects are undermined by loopholes and derogations.
- NRLs – These are a good concept currently undermined by the report in the Impact Assessment but in principle have some merits; they could be a good basis for a strategy for National Centres of Excellence/ECVAM/Europe-wide strategy for bringing replacements to the forefront for funding, promotion and training.
- Extension of the scope to cover invertebrates and foetal life forms is a positive move. However, it will be important to review the scope on a regular basis, to keep pace with increasing knowledge about other species.



This is a unique opportunity to make real progress in the process of eliminating animal experiments and protecting animal welfare. For the sake of animals and science it is vital that the moment is seized.