The EU Directive on the Protection of Animals used for Scientific Purposes

Directive 2010/63 EU

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THE DIRECTIVE IN BRIEF

66 articles
8 annex
43 pages

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20 October 2010 (2010/63/EU)
THE AIMS OF THE DIRECTIVE

• eliminate disparities across EU in the treatment of animals used for scientific procedures

• fully incorporate the principle of the "3 Rs", including the promotion of alternative methods

• improve the welfare of the animals
• The revision of EU 86/609 has been a political process

• Some decisions were based on science

• Consultation has been good practice

• The EU institutions can ignore the views of individuals and organisations
A political agreement has been reached.

The 2010/63 EU has been published on October 20, 2010.

Member states are preparing for implementation.

There are two years allowed.
THE REVISION PROCESS

- Harmonisation
- Animal welfare
Harmonization

- The EC Treaty is concerned with functioning of the internal market (see 86-609 EU)
- Animal studies and scientific projects are not tradable goods
- Benefits of harmonization?
• Concern of EU is internal market

• Pharmaceutical companies operate in a global market

• Harmonisation can mean a high level of regulatory burden, with increased costs for the EU, and inability to carry out research (restrictions)
Implementation

• The final result is an acceptable compromise

• Interpretation is and will be a critical issue
THE 3Rs APPROACH

3Rs principle:

- Replacement
- Reduction
- Refinement
The use of animals should not pose a threat to biodiversity, therefore the use of endangered species must be allowed only under special circumstances.
• Vertebrates (including foetal forms)
• Invertebrates
  – Cephalopods
  – Cyclostomes, Myxini
Cephalopods

squad

cambrered nautilus

octopus
SPHERE OF ACTION

Would it be obligatory to use alternative methods involving human embryonic stem cells if these present themselves as alternatives to animal tests?

The directive is not designed to regulate research using human embryonic stem cells. It also does not define what an ethically acceptable alternative replacement method is. Neither of these subject matters falls within the scope of the directive.

The use of human embryonic stem cells raises a number of ethical questions on which positions between, and often within, Member States differ. Bearing in mind this ethical dimension and the principle of subsidiarity, the Commission believes these issues are best regulated at Member State level.
**DEFINITIONS**

**Procedure:**
any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purpose, which may cause the animal a level of pain, suffering distress or lasting harm equivalent to, or higher, than that caused by the introduction of a needle according to good veterinary practice

**Project:**
a programme of work having a defined scientific objective and involving one or more procedures
The revised directive will make it compulsory to carry out ethical evaluation and require that experiments where animals are used be subject to authorisation.

This is taken and communicated to the applicant **40 working days** at the latest from the receipt of the complete and correct application.

There will be an *'Animal welfare body'* in each establishment to foster a climate of care and ensure a systematic application of the 3 Rs methods and techniques as well as to ensure the uptake of the new, emerging ones.
SEVERITY CLASSIFICATION and RE-USE

- Severity classification (art 15):
  - mild
  - moderate
  - severe
  - non recovery

- Re-use of animals (art 16):
  - previous procedure: mild or moderate
  - new one: mild, moderate or of non recovery
  - in accordance with veterinary advice
Non-Human Primates

Macaca fascicularis (cynomolgus)

Macaca mulatta (rhesus)

Callithrix jacchus (marmoset)

Chlorocebus aethiops (vervet)

Saimiri sciureus

Papio

M. nemestrina

M. arctoides
Development of pharmaceuticals, in particular, safety testing

Treatment and prevention of infectious diseases and infection immunology

HIV, Tuberculosis, Malaria, Hepatitis C

Neuroscience

Stem cells, development and testing of xenotransplantation methodologies
Non-human primates shall not be used in procedures, with the exception of those procedures meeting the following conditions:

a) basic research

b) translational or applied research with any of the following aims:

   i) the procedure is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings

c) there is a scientific justification that the purpose of the procedure cannot be achieved by the use of other species

d) studies aimed at preservation of the specie

A debilitating clinical condition is a reduction of a person’s normal physical or psychological ability to function
Animals bred for use in procedures

Member States shall ensure that non-human primates may only be used in procedures where they are the offspring (F2) of non-human primates which have been bred in captivity (F1) or sourced from self-sustaining colonies.

The Commission shall, conduct a feasibility study, which shall include an animal health and welfare assessment. The study shall be ready by 2017.

only F2 colonies can be used?
Two ways of reducing reliance on capture of animals:

**F2 colonies** – means that first generation (F1) born in captivity is only used for reproduction and cannot be used for research purposes. F2 implies killing first generation surplus males which could neither be used for reproduction purposes nor can they be used for research.

**Self-sustaining colonies** – are closed colonies, where retired breeders (F0 or F1) are replaced by animals bred in the colonies. There is no replenishment from the wild. All purpose-bred animals, including F1, can be used for research. Requires exchange of breeders between colonies from time to time to maintain genetic diversity. This approach does not create the problem of surplus males and achieves the objective of limiting capture of wild primates for reproduction.
Great Apes
The use of Great Apes should only be allowed in research:

• aimed at the preservation of those species

• in relation to condition endangering human life (malaria, hepatitis C, respiratory syncitial infection)

• in the case of an unexpected outbreak of a life-threatening or debilitating disease in human beings

• no other species or alternative method could suffice for the aims of the procedure
A retrospective assessment shall be carried out on

- Projects involving the use of NHPs
- Projects involving procedures classified as “severe”

The aims are to evaluate:

- whether the goals of the project have been achieved
- the harm inflicted to animals
- the number and species of animals used
- any elements contributing to the further implementation of the 3Rs
The use of NHPs and Great Apes (with regard to human diseases), as well as that of procedures involving severe pain, suffering or distress that is likely to be long-lasting can be authorized through provisional measures and by informing the Commission that will authorize or revoke the provisional measure.

The Member State claiming such a need should provide the necessary information for the Commission to take a decision

(Article 55, Safeguard clauses)
Article 8

- Applied research or testing on NHPs must be... undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings.

- ... shall mean a reduction of a person’s normal physical or psychological ability to function.

- What does this mean? How is it translated?
Article 15

- Subject to the use of the **safeguard clause** (art. 55) member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

- *What is meant by long-lasting?*

- *Why do we need the safeguard clause?*
• The directive limits the freedom of research.

• The directive makes an arbitrary distinction between basic and applied research and between species that receive more protection than other species.

• There are many special rules for research on NHPs.

• The directive claims to emphasize but fails to apply the 3R-principle (replacement, reduction, refinement).

• The directive will further bloat the bureaucracy involved.
IMPACT ON NEUROSCIENCE

• re-use of animals
• severity classification
• ban on procedures that involve severe pain
• retrospective assessment
• ban on research on great apes
The use of animals in research remains controversial in many European countries.

The EU now determines national laws.

Difference in the national laws across EU will limit scientists’ circulation in Europe.

The new Directive will increase the cost of research.
• Coordinate actions to vigilate on the national implementation laws across Europe
• Explain to the public and to the politicians how and why we use animals
In the meantime in the USA...

The rise of animal law

- A new area of study that examines how the law treats animals.

- As recently as 2000, only a few Law Schools offered courses on this subject.

- To date they are about 200 and include:

Conferring legal rights to animals

The rise of animal law

- Erode the notion of animals as property
- Confer personhood to animals
- Establish fundamental rights for animals, at least for those with higher cognitive capacities
- Include the interest of the animals themselves to stay alive and avoid pain
- Use science, in particular cognitive ethology, as a theoretical frame to justify such claims.
Conferring legal rights to animals

The rise of animal law

- The Animal Legal Defence Fund (ALDF) has students chapters at 155/200 Schools of Law accredited by the American Bar Association (ABA).
- ABA created a committee on animal law to educate practising lawyers on this issue.
- The Association of the American Law schools in 2008 opened a section on animal law.
- The Non Human Rights Project (NHRP) is ready to file the first suits in 2012, by carefully choosing the jurisdictions they will consider more likely to be sympathetic with their arguments.
THANKS FOR YOUR ATTENTION
THE EU NUMBERS (2007)

Percentages of animals used by classes by the reporting Member States

- Mice 53%
- Rats 19%
- Guinea-Pigs 2,1%
- Other rodents 0,8%
- Cold-blooded animals 15%
- Birds 5,4%
- Artio+perissodactyla 1,1%
- Carnivores 0,33%
- Other mammals 0,08%
- Prosimians+Monkeys+Apes 0,09%
### Changes in NHP use in the EU

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<th>2002</th>
<th>2005</th>
<th>change</th>
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<tbody>
<tr>
<td>Prosimians (Prosimia)</td>
<td>1095</td>
<td>677</td>
<td>- 418 (38.2%)</td>
</tr>
<tr>
<td>NW Primates (Ceboidea)</td>
<td>1192</td>
<td>1564</td>
<td>+372 (31.2%)</td>
</tr>
<tr>
<td>OW Primates (Cercopithecoidae)</td>
<td>8075</td>
<td>8208</td>
<td>+76 (0.9%)</td>
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67%: toxicological and other safety evaluations, including safety evaluation of products - mainly OW primates.

Type of products tested in the safety evaluation: 82% are products / substances / devices for human medicine and dentistry.