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Community research

The Use of Animals for Experimental Purposes in the EU



European Commission
Research Directorate-General, Governance and Ethics Unit
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In 15 minutes...

1. Ethics, research and animals
2. The revision of Directive 86/609/EEC
3. Conclusion



1. Ethics, Research and Animals

- a) Ethics
- b) Ethics and research
- c) Ethics, research and animals



a) Ethics

- A major branch of philosophy
 - Ethics ≠ limited to specific acts or defined moral codes
 - Applied ethics: bioethics, medical ethics, research ethics...
- (Research) Ethics and the EU
 - Democratic fundamentals through a common European framework: “[The Charter of Fundamental Rights of the European Union](#)” (published 18 December 2000)
 - EU does already address ethical issues in regulations (patents, clinical trials, data protection) and in research programmes (FP)
 - However under existing treaties [there is no specific EU competence on ethics](#): there is guidance but subsidiarity applies in most cases → Member States and their respective national ethics bodies



b) Ethics and Research (1/3)

- 3 main activities
 - Fundamental rights review (EC's Legal Services)
 - Opinions of the European Group on Ethics in Science and Technology (EGE)
 - FP's Ethics review by DG RTD and other activities
- The European Commission
 - Not to carry out ourselves*, nor to control European research!
 - To establish the ERA as a framework for political and practical cooperation
 - To ensure that fundamental ethical principles are respected in the implementation of FPs
- Major objectives
 - Does not replace the need for ethical approval at national or local level
 - Assure citizens & decision makers that EC does not fund ethically unsound research
 - Facilitate research excellence in FP & raise awareness amongst researchers



b) Ethics and Research (2/3)

- 11% of all funded FP6 projects have undergone an ethical review
 - Biomedicine and genetics ~ 45%
 - About 10% each for IT, nanotechnology and food and green biotech
- Based on “FP ethical rules”, supporting both subsidiarity and fundamental ethical principles (National regulation, EU regulations, international agreements...)
- Recurring concerns: informed consent, developing countries, data protection, children, animals



b) Ethics and Research (3/3)

- Ethics = integral part of research (from conception to publication)
- Ethics permeates every area of research
- Ethics reviews = integral component of research's approval
- Ethics = closely linked with law, rules and regulations but \neq go against research
- "*It's only by getting the ethics right that research excellence can be achieved*" (Commissioner Janez Potočnik)



c) Ethics, Research and Animals

- EC Treaty's Protocol on Animal Welfare (1997)
- *"Should this particular animal experiment be done at all?"* (now) v *"Animal use is not a moral issue, it is a scientific necessity"* (mid-1980s)
 - Animal experimentation was rare before 19th Century
 - *"British Cruelty to Animals Act"*, 1876 (passed to control animal experimentation)
 - ~ 50 to 100 million animals used yearly, world-wide (from fruit flies to zebra fishes, mice, dogs, pigs, non-human primates...)
 - E.g. LD50 gradually banned/abolished
- *"Society does not wish to see innocent animals suffer"* v *"Society is not yet prepared to risk losing the benefit of animal research"*
 - control of pain & suffering, enriching living environments, assuring proper care...



2. The Revision of the Directive 86/609/EEC

- a) Key objectives
 - b) Driving forces
 - c) Impact assessment (IA)
 - d) Public consultation
 - e) Areas under consideration
 - f) Timeline
-
- Note:
 - DG ENV & Legal basis Article 95 of EC Treaty (harmonization of internal market)
 - Review clause included



Revision: Key Objectives & Driving Force (1/4)

■ Key objectives:

- Ensure level playing field for industry and research community + Strengthen protection of animals
- Ensure significant increase in animal welfare
- Actively promote and have the 3Rs principle implemented

■ Driving force:

- Science is evolving
- Directive dating back to 1986
- Directive's text containing inappropriate legal provisions and language (Convention formulation)
- Increasing consideration for animal welfare and ethical aspects in general
- Acceptance of the 3Rs as the basis for improved animal welfare and good science
- Recognition of the specific nature of non-human primates (NHP)
- Acknowledgement that animals (incl. NHP) are still needed today



Revision: IA & Public Consultation (2/4)

- Impact assessment (March 2007)
 - Problem dimensions with indicators, option development and their related impacts
 - Attempt to quality, quantify and monetise (where the case) benefits and costs
 - Acceptance that quantification and monetisation is not always possible – e.g. quality of life and wellbeing, ethical considerations
 - Inclusion of information about third country systems of laboratory animals protection
 - Examination of links with other Community legislations
- Public consultation
 - Citizen's consultation with >42.000 responses
 - Expert consultation with >12.000 detailed comments about impacts of options for revision
 - Expert comments served to complete the IA but also to either confirm the chosen policy options or to have them fine-tuned or abandoned



Revision: Areas Under Consideration (3/4)

Safeguards the competitiveness of industry and research in the EU, with flexible wording allowing implementation appropriate to MS

- Scope
- Promotion of the 3Rs & use of alternatives
- Authorisation of establishments + staff + projects
 - Fine-tuning in final proposal to diminish administrative burden
- Ethical evaluation of projects
 - Ethical review strategy in place for each establishment for the uptake of 3Rs
 - Ethical evaluation of projects
- Housing and care standards (Annex)
- Inspections, transparency and public access to information (improvement of enforcement)
- Severity classification and re-use
- Acquisition, housing and use of non-human primates (NHP)



Revision: Estimated Timeline (4/4)

- 6 June 2007: Draft finalised
- Mid-November 2007 till mid-January 2008: Inter-Service Consultation (→ comments)
- ~ Mid-March 2008 (tbc): Finalisation of the proposal + legal revision (DG ENV)
- ~ April 2008 (tbc): Translations / Adoption (?)
- ~ May 2008 onwards (tbc): start of Co-decision with EP/Council (Publication & 1st readings)



3. Get the Balance Right

- Public debate
 - All actors
 - Public accountability can be enhanced
- Coherent approach
 - MS to establish national ethical committees? (when not already existing)
 - Network of national ethical committees / exchange of best practice at EU level
 - DG RTD Expert Group “Animals for experimental purposes” (ethical dimension of revised Directive, legal and regulatory aspects, practical impact...)
- New ethical challenges, more moral issues
 - Genetically modified animals
 - Chimeric embryos
 - Better control of chronic pain & suffering
 - Use of animals in non-medical research; etc.



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Thank you

DG RTD *Science, Economy and Society*

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