



Outline for the revision of Dir 86/609/EEC



- Driving forces for the revision
- The process
- The objectives
- Key changes concerning the Three Rs
- The Three Rs in the proposal
- The development and validation of alternative approaches



Driving forces for the revision



- Directive dating back to 1986
- Directive's text contains inappropriate legal provisions and language (Convention formulation)
- Increasing consideration for animal welfare and ethical aspects in general
- The Three Rs as basis for improved animal welfare and good science (Replacement, Reduction and Refinement of the use of animals in procedures)



Driving forces for the revision



- Amended Cosmetics Directive
- Adoption of the Protocol for Animal Welfare - 1997
- New EU Chemicals Policy, REACH
- Increased standards at the Council of Europe
- Community Animal Welfare Action Plan - Jan 2006



Starting point



- Ultimate goal to replace the use of animals
- Acknowledgment that animals, including non-human primates, are still needed today
- The principles of the Three Rs to govern all breeding, use and care of animals for scientific purposes



Impact assessment



- Qualification, quantification, monetisation of impacts
- Acceptance that quantification and monetisation is not always possible – e.g. quality of life and wellbeing, ethical considerations
 - No similar exercise has ever been carried out anywhere before -



Public consultation



Two separate consultations in parallel:

- Citizen's consultation with > 42.000 responses
- Expert consultation with >12.000 detailed comments about impacts of options for revision
 - Refining options - further pursued, revised or replaced



Key objectives of the revision



- ☐ Significant increase in animal welfare
- ☐ Level playing field for industry and academia
- ☐ Active promotion and implementation of the Three Rs principles



Key changes concerning the Three Rs



- Explicitly spelled out and anchored both in the preamble and in the enacting terms
- Ensuring that Refinement is not limited to scientific procedures but also relevant in relation to accommodation, care and breeding
- Emphasis on a hierarchy between Replacement, Reduction and Refinement
- Practical implementation through a number of measures



The Three Rs in the Commission proposal



Comprehensive implementation of the Three Rs through

- Ethical evaluation of projects covering issues such as
 - ✓ Demonstration of the use of all available alternatives
 - ✓ The use of early and humane end-points
 - ✓ Experimental or observational strategy and statistical design
- Ethical review body in each establishment to ensure timely uptake of new developments in the field of the Three Rs



The Three Rs in the Commission proposal



In addition, a number of specific provisions such as on

- More clarity on the requirement to use an alternative method to remove legal ambiguity
- Re-use as a means to reduce the numbers of animals
- Requirements on sharing of organs and tissues
- Minimum housing standards and a requirement to provide enrichment appropriate to species
- Education, training and obtaining and maintaining competence



The development and validation of alternative approaches



- The Commission and Member States to contribute to the development and validation of alternative approaches
- Member States to *designate* a national reference laboratory to participate in validation studies
- Co-ordination of the pre-validation and validation work through the Commission, ECVAM



Further information



DG Environment web-site at:

http://ec.europa.eu/environment/chemicals/lab_animals/revision_en.htm



Thank you for your attention!



The process



- SCAHAW opinion on the use of non-human primates 2001
- EP Own Initiative report on Directive 86/609/EEC 2002
- Technical Expert Working Group (TEWG) 2003
- EFSA (AHAW) opinion on 4 specific questions 2005
- Impact assessment on different options 2006/2007
 - Public internet consultation in summer 2006
- Finalisation of the drafting 2007
- Commission adoption (2008)
- Co-decision procedure with the EP and the Council (2008 -)



Main differences



- Compulsory ethical evaluation
- Authorisation of projects using animals
- Introduction of non-technical summaries
- Introduction of retrospective assessment

- Ban on the use of great apes (chimpanzees, bonobos, gorillas and orangutans)
- Gradual move towards using second or higher generation captive bred non-human primates



Main differences



- Enlarged scope to include
 - certain species of invertebrate animals
 - foetuses from the last third of the development
 - animals used for the purposes of basic research, education and training
 - animals bred for their organs and tissue
- Minimum housing and care requirements



Main differences



- Explicitly spells out the principle of the Three Rs: Replacement, Reduction and Refinement of the use of animals in experiments and incorporates them into the provisions of the proposal
- Refinement to also cover breeding, accommodation and care of animals
- The use, development and validation of alternatives methods more firmly anchored
- Establishment of a network of national reference laboratories for the validation of alternative methods



Keeping administrative burden to minimum



A number of specific measures to boost the competitiveness of the EU industry and research

- Flexible implementation
- Critical review of scientific justification, experimental design and the use of animals for better quality science
- Boost for the development of alternative techniques



Keeping administrative burden to minimum



- Strict 30 and 60 day deadlines for authorisation
- Possibility for group project authorisation for testing required by legislation
- Possibility for lighter authorisation of projects consisting only of ‘up-to-mild’ procedures and not using non-human primates



Improving enforcement



- Increased transparency to re-enforce self-compliance and facilitate earlier detection of non-compliance
 - Publication of non-technical summaries
 - Updating of non-technical summaries with the results of retrospective assessment
 - Improved statistical reporting
- Twice yearly inspections of which one should be unannounced and covering all establishments
- Possibility for EU controls of national inspections systems