Perspectives on the Ethical Evaluation
in the revised Directive 86/609/EEC

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Revision of Directive 86/609/EEC

Part I

- Why the revision?
- Starting point and the process
- Key objectives
- Main differences
- Improving enforcement
- Administrative burden and competitiveness

Part II

- The Three Rs and alternative methods
- Implementation of the Three Rs
- Ethical evaluation of projects
- Retrospective assessment of projects
- Permanent Ethical Review Body and Nat’l Animal Welfare and Ethics Cttee

- Conclusions
Why the existing Directive is not sufficient?

- No longer responds to the advancements made in experimental techniques
- There is new scientific knowledge on animal welfare
- Ethical considerations have evolved since 1980s

As a consequence, national measures result in widening gap in standards in Europe
Starting point

- Ultimate goal is 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
The process

• Proposal based on **scientific input, extensive stakeholder consultation and input** including a thorough **impact assessment** (IA)

• Technical Expert Working Group (science/academia, industry, MS, NGOs, other experts)

• **SCAHAW, AHAW, SCHER**

• IA with acceptance that quantification and monetisation is not always possible

- No similar exercise has ever been carried out anywhere before -
**IA and public expert consultation**

283 expert responses with > 12,000 comments

- Users of animals – public sector: 33%
- Users of animals – private sector: 18%
- Public authorities: 14%
- NGOs: 14%
- Others: 13%
- Breeders of animals: 2%

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 principle
Main differences I

- Authorisation of projects using animals
- Systematic ethical evaluation of projects
- Severity classification

- Ban on the use of great apes with a safeguard clause
- Gradual move towards using second or higher generation captive bred (F2) non-human primates (report, review and revise if appropriate)
- Stricter use of non-human primates
Main differences II

- 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
- Methods of humane killing
Improving enforcement

- Increased transparency to ensure self-compliance and facilitate earlier detection of non-compliance
  - Non-technical summaries
  - Retrospective assessment
  - Improved reporting
- Twice yearly inspections of which one should be unannounced and covering all establishments
- Possibility for EU controls of national inspections systems
Keeping administrative burden to a minimum

• **Flexible implementation**

• 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

• Authorisation is considered granted if no decision is made to the contrary
Boosting competitiveness

- Strict 30 and 60 day deadlines for authorisation
- Critical review of scientific justification, experimental design and the use of animals for better quality science
- Boost for the development of alternative techniques with increased resources
The Three Rs

- Explicitly spells out the principle of the Three Rs: Replacement, Reduction and Refinement
- Refinement to also cover breeding, accommodation and care of animals

Alternative methods

- The use, development and validation of alternative methods more firmly anchored
- Establishment of a network of national reference laboratories for the validation of alternative methods
Comprehensive implementation of the Three Rs through

- Ethical evaluation of all projects
- Retrospective Assessment
- Permanent Ethical Review Body (PERB) in each establishment
- National animal welfare and ethics committees
The objective of the Ethical Evaluation is to ensure the project is:

- Scientifically justified or required by law
- The purposes justify the use of animals
- The project design ensures procedures are carried out in the most humane and environmentally sensitive manner
Ethical evaluation II
- the elements

- An evaluation on the objectives, scientific and educational value
- Compliance with 3Rs?
- Assessment of classification of severity
- Harm/benefit analysis
Ethical evaluation II - the elements (cont.)

The process – compliance with the 3Rs - Annex VII:

- Justification for the animals to be used, and the procedures to be performed on the animals
- Demonstration that 3Rs have been applied
- Demonstration of competence of those involved in the project
- Details on anaesthesia, analgesia and other pain relieving methods
- Reduction, avoidance, alleviation of suffering during lifetime
- Housing and care conditions
- Use of early and humane endpoints
- Experimental or observational strategy and statistical design
- Lifetime experience of the animals
- Avoidance of unnecessary duplication of procedures

European Commission - DG Environment
Ethical evaluation II - the elements (cont.)

- An evaluation on the objectives, scientific and educational value
- Compliance with 3Rs?
- Assessment of classification of severity
- Harm/benefit analysis
Ethical evaluation should draw from experts incl.

✓ Area of science for which the animals will be used
✓ Experimental design
✓ Veterinary practice in lab animal science
✓ Animal husbandry and care in relation to animals to be used
✓ The Three Rs
✓ Applied ethics
✓ Environmental science
Retrospective assessment

✓ Ethical Evaluation to determine whether and when retrospective assessment (RA) should be carried out

✓ RA shall evaluate:
  ▪ Whether the objectives were achieved
  ▪ Actual harm inflicted on animals, actual severity, numbers/species used
  ▪ Possible further application of the Three Rs

✓ RA compulsory for projects involving non-human primates
✓ RA not necessary for ‘up-to-mild’ projects
Permanent Ethical Review Body
Bringing the Three Rs to life

- To advise staff on ethical aspects of acquisition, housing, care and use of animals
- To advise staff on application of the Three Rs and keep up-to-date with the latest scientific developments
- Establish and review operations in relation to monitoring, reporting and follow up
- To provide advice on re-homing schemes
- To perform a non-administrative, internal review of multiannual projects
National animal welfare and ethics committee

✓ To provide advice to competent authorities and PERBs on: acquisition, accommodation, care and use of animals, and exchange of best practice

✓ To exchange information on the operations of the PERBs and Ethical Evaluation

✓ To share best practice with other Member States
Conclusions

✓ Ethical evaluation and the principle of authorisation form the bedrock of the proposal

✓ Comprehensive implementation and uptake of the Three Rs through Ethical Evaluation, Retrospective Assessment, PERB

✓ National Animal Welfare and Ethics Committee – helping to ensure best practice and keep communication flowing within and between MS
Further information

DG Environment web-site at:

http://ec.europa.eu/environment/chemicals/lab_animals/revision_en.htm
Thank you for your attention!
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
The process - historical

- SCAHAW opinion on the use of non-human primates 2001
- 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 and Commission adoption 2007/2008
- Co-decision procedure with the EP and the Council (2008 - )
The process – co-decision

- EP AGRI lead committee, MEP Neil Parish as the rapporteur
- ITRE committee with enhanced co-operation
- EP First reading vote on 5 May 2009

- CZ Presidency: 2 meetings held, possibly 2 more before end of June
- SE Presidency: keen to conclude early 2nd reading political agreement