EUROGROUP FOR ANIMALS

8th annual *ecopa* workshop
24th and 25th November 2007
Brussels, Sheraton-Airport Hotel

Wish-list of Animal Welfare

Kirsty Reid
Policy Officer for Research Animals
EWLA/Eurogroup for Animals

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EU legislation

and the

Promotion of Alternative Methods

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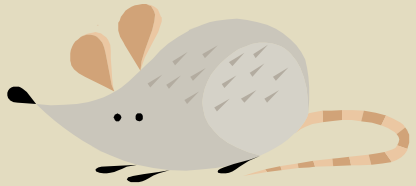
EU legislation under Revision

Directive 86/609/EEC



Directive 86/609/EEC has a requirement to use alternatives where they are available and states that EU Member States should encourage the development of new alternatives.

However, the impact of these provisions has been limited…

WHY?

- The Directive only covered applied research such as safety testing.
- It failed to ensure that all EU Member States put in place a system of control of animal experiments which would ensure that alternative methods were in fact used.

Revision of Directive 86/609/EEC

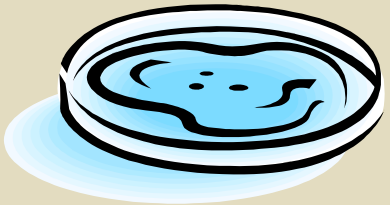
- The Directive must maintain the legal obligation to use existing alternatives to animals.

- It must also contain an article explicitly stating the importance of implementing each of the 3Rs.

- It must strongly emphasise the need to replace animals, and/or apply approaches that avoid their use.

Revision of Directive 86/609/EEC

- It must emphasise the importance of minimising suffering and improving welfare through refinement (life time experience).
- The Commission and Member States must actively promote research into the development and validation of complete replacements for animal experiments, not just ‘encourage’ as currently stated.
- To ensure that new alternative methods are developed rapidly and efficiently, the Directive must make explicit demands for additional support for alternatives research from all EU Member States.



Plant Protection Products
Revision of Directive 91/414

Avoiding Duplication of Animal Testing: Obligatory data sharing

- There should be a central database to all relevant information on active substances, safeners, synergists and plant protection products in order to ensure that all relevant data is shared and duplicate animal testing does not take place.

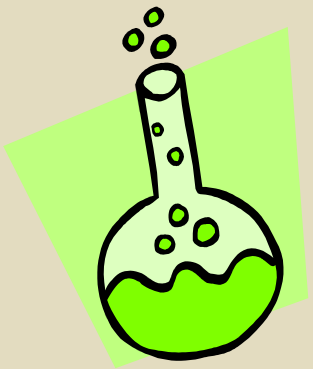
Data Requirements: Inclusion of non-animal test methods and 'Intelligent/integrated' testing strategies

- Testing requirements must be in line with actual requirements for each product and not follow a general 'tick-box' approach

- The Regulation should include a provision which ensures that the data requirements are defined with an obligation to minimise animal testing and ensure the application of non-animal test methods and intelligent testing strategies.

Recently adopted EU legislation

REACH



…will result in the use of millions of animals for safety testing.

However, to keep this to a minimum…

1) Mandatory sharing of animal test data

2) Alternatives are strongly promoted throughout the REACH text

- One of the objectives of REACH is the 'promotion of alternative methods for assessment of hazards of substances''.
- The Chemicals Agency is obliged to submit a report to the Commission every 3 years on the implementation of non-animal test methods.
- The Commission must publish a report every 5 years on the funding of Alternative test methods.

ECVAM has coordinated the development of testing strategies for REACH.

This process has involved 200 experts from regulatory agencies, industry and other stakeholders. Testing strategies have been developed based on existing data *in silico*, *in vitro* and *in vivo* methods.

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Cosmetics 7th amendment

- The marketing ban will be introduced 2009, for all human health effects
- Exception of repeated-dose toxicity, reproductive toxicity and toxicokinetics. For these specific health effects, a deadline 2013, irrespective of the availability of alternative non-animal tests.

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Cosmetics

For the 2013 deadline the replacement of animal test methods by alternative methods remains '*scientifically difficult*'

However…

Example - **Repeated dose toxicity study**

Alternative methods possibly proposed as replacements for repeated-dose toxicity

- *in vitro* cultures of various organ tissues.
  Human cell cultures have been established for kidney, nervous, immune, reproductive and other essential organ systems.

- Computer-based modelling approaches have shown promising results as an alternative.

Biotechnology

Modern biotechnologies have had, and will continue to have, a serious adverse impact on animals, particularly with regard to their use in scientific research and agriculture.

- This adverse impact relates to the numbers of animals used and the nature of the harms caused to them.
- technology is progressing at a rate that is outstripping public understanding and ethical and public debate.

Biotechnology

- There needs to be greater transparency with regard to the use of animals in biotechnology throughout Europe.
- Restrictions should be placed on the species of animal that it is permissible to genetically modify.

Biotechnology

- There should be far greater effort devoted to developing and validating alternatives to animal use in all fields.

- There should be greater commitment to, and endorsement of, the principles of the 3Rs in animal experiments. Examples especially relevant to modern biotechnology are:

  - the development of GM germ cells for *in vitro* testing;
  - the production of drugs, proteins, or material by bacteria rather than 'bioreactor' animals;
  - generating cells, tissues and organs for treatment or transplantation using a patients own cells, e.g. human bladders.

Nanotechnologies

- Identifying the hazards of the nanoparticle form of a well known chemical requires a testing method that can determine if this nanoparticle form will cause significantly different adverse effects compared to the same chemical at larger scale.

- There is insufficient data available to identify any generic rules governing the likely toxicology and ecotoxicology of nanoparticles in general.

Nanotechnology

The application of nanotechnology is currently revolutionizing.

nanotechnology could also play a role in improving or refining the development of alternatives to animal testing whilst maintaining safety.

- human cell-based *in vitro* models
- novel computer models and bioreactor systems for screening, toxicology and targeting studies
- surface modification at the nanoscale to improve biosensors and *in vitro* test systems
- potential new strategies for applying nanotechnology to alternatives