NORECOPA

Directive 2010/63/EU

Is EU legislation on animals used for scientific purposes sufficiently geared towards research using farm animal species?

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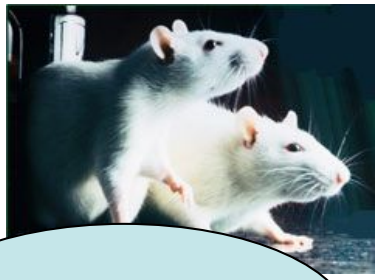
Directive 2010/63/EU

- *The Directive and the revision*
- *The principle of the Three Rs*
- *The Directive and farm animal species*
- *Conclusions and questions*



RTD
Framework programs
Horizon 2020

Pharmaceuticals

Pesticides

DIRECTIVE 2010/63/EU

Agriculture

International activities

Biocides

Cosmetics

REACH

Chemicals

Food safety

Commission, RTD
Alternative Methods

Objectives of the revision

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

Acknowledging that…

- *Animals, including non-human primates, are still needed today for research and testing*
- *The ultimate goal is to replace the use of animals*
- *Animals have intrinsic value in themselves which must be respected*
- *The principle of the Three Rs is the key to more humane and better science*

Key elements

- *Authorisation of establishments and projects*
- *Systematic project (ethical) evaluation*
- *Binding standards for housing and care*
- *Active implementation of the principle of the Three Rs and promotion of alternative approaches*
- *Increased transparency and better enforcement*
- *New structures for the validation and regulatory acceptance of alternative methods*

Key dates

- *Entry into force on 10 November 2010*
- *Transposition to be completed by 10 November 2012*
- *The Directive takes full effect on 1 Jan 2013*
- *Minimum enclosure sizes in Annex III 1 Jan 2017*

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Main differences and the 3Rs

- *Explicitly spells out the Three Rs: (e.g. Recitals 10-13; Articles 1, 4, 13)*
- *Ensuring that Refinement is not limited to scientific procedures but also relevant in relation to care, accommodation and breeding of animals*
- *The development, validation and use of alternative approaches more firmly anchored* ***– as a clear legal requirement***

Article 1

“Subject matter and scope”

1. This Directive establishes measures for the protection of animals used for scientific or educational purposes
To that end, it lays down rules on the following:

(a) the **replacement** and **reduction** of the use of animals in procedures and the **refinement** of the breeding, accommodation, care and use of animals in procedures;
…”

Article 4

"Principle of Replacement, Reduction and Refinement"

1. Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure *[= a method using animals]*.

2. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.

Article 4

3. Member States shall ensure **refinement** of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.

4. This Article shall, in the choice of methods, be implemented in accordance with Article 13.”

Article 13

"Choice of methods

1. Without prejudice to national legislation prohibiting certain types of methods, Member States **shall ensure** that a **procedure** [= *a method using animals]* **is not carried out** if another method or testing strategy for obtaining the result sought, **not entailing the use of a live animal**, is **recognised** under the **legislation of the Union**.

Article 13

2. In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected:

(a) use the minimum number of animals;

(b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;

(c) cause the least pain, suffering, distress or lasting harm;

and are most likely to provide satisfactory results.

…"

Systematic project (ethical) evaluation (Art 38)

To assess contents for:

- **The aims and objectives of the project**
- **Application of the Three Rs – Annex VI**
- Severity classification of the procedures – Annex VIII
- Harm-benefit analysis of the project

resulting in more humane treatment of animals and improved science.

Systematic project (ethical) evaluation (Art 38)

Application of the Three Rs – Annex VI (1/3)

1. Relevance and justification of the following:
   - (a) use of animals including their origin, estimated numbers, species and life stages;
   - (b) procedures.

2. Application of methods to replace, reduce and refine the use of animals in procedures.

3. The planned use of anaesthesia, analgesia and other pain relieving methods.

Systematic project (ethical) evaluation (Art 38)

Application of the Three Rs – Annex VI (2/3)

4. Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate.

5. Use of humane end-points.

6. Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate.

7. Reuse of animals and the accumulative effect thereof on the animals.

Systematic project (ethical) evaluation (Art 38)

Application of the Three Rs – Annex VI (3/3)

8. The proposed severity classification of procedures.
9. Avoidance of unjustified duplication of procedures where appropriate.
10. Housing, husbandry and care conditions for the animals.
11. Methods of killing.
12. Competence of persons involved in the project.

Systematic project (ethical) evaluation (Art 38)

To assess contents for:

- The aims and objectives of the project
- Application of the Three Rs – Annex VI
- **Severity classification of the procedures – Annex VIII**
- Harm-benefit analysis of the project

and to determine the need for a retrospective assessment resulting in more humane treatment of animals and improved science.

Systematic project (ethical) evaluation (Art 38)

Prospective severity classification assisted by Annex VIII

Section 1: Definitions of the four severity categories

Section 2: Assignment criteria

- always on a case-by-case basis
- two types of factors to take into account:
  a) procedure related
  b) other related factors

Section 3: Examples of the types of procedures to assist in assessing procedure related severity

Systematic project (ethical) evaluation (Art 38)

To assess contents for:

- The aims and objectives of the project
- Application of the Three Rs – Annex VI
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- **Harm-benefit analysis of the project**

and to determine the need for a retrospective assessment

resulting in more humane treatment of animals and improved science.

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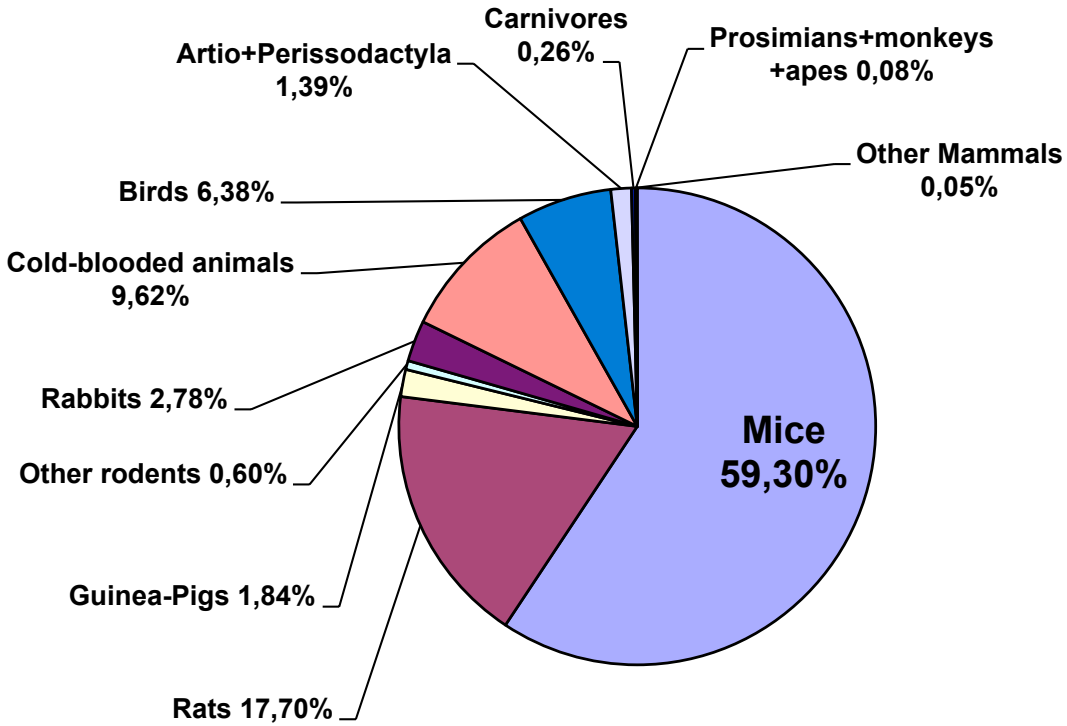
Figure 1.1
Percentages of animals used by classes in the Member States



EU Stats 2008

Article 1 'Subject matter & scope' within scope:

- *live non-human vertebrates;*
- *Fœtal forms of mammals from last third of development.*

Article 3 'Definitions' procedure

- use, invasive or non-invasive, with known or unknown outcome, or educational purposes, which may cause a level of pain, suffering, distress or lasting harm equivalent to, or higher than, ***that caused by the introduction of a needle in accordance with good veterinary practice.***

Article 1 'Subject matter & scope'

not within scope:

- non-experimental agricultural practices;
- non-experimental clinical veterinary practices;
- veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;
- practices undertaken for the purposes of recognised animal husbandry;
- practices undertaken for the primary purpose of identification of an animal;
- practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

Key elements - farm animals

- *Authorisation of establishment / registered breeder – not always necessary (Art 3)*
- *Methods of killing – (Art 6 / Annex IV)*
- *Binding standards for housing & care (Annex III) see exemptions*
- *Severity classification – upper limit of severity – 'severity assessment framework' (Art 15 / Ann VIII)*
- *Re-use (Art 16)*

Key elements - farm animals

- *Returning of the animal to a suitable husbandry system following a project (Art 19)*
- *Competent personnel, E&T guidelines (to be developed for farm animals (Art 23))*
- *Animal Welfare Body – in each establishment to foster a climate of care and ensure uptake of the Three Rs can help determine the need for authorisation (Art 27)*

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Conclusions I

- *Directive 2010/63/EU covers all animals used for scientific purposes*
- *The new Directive provides a unique opportunity to advance animal welfare whilst ensuring the continuity and competitiveness of EU research.*
- *The Three Rs will embrace all care and use of animals facilitating establishment of a climate of care through all levels.*

Conclusions II

- *Legislation sets the general framework and is fully adaptable for all species and types of use*
- *New measures aim to improve science and animal welfare in agricultural research*

More information on Directive 2010/63/EU

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

Thank you for your attention !

Any questions?

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