



"Ethical justification of animal experiments in Germany"

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Central question of ethics concerning animals

Is it allowed for humans to use animals for their purposes / interests?

Is it necessary to justify actions with / against animals?





Ethical concept of our modern western (?) society Conflict of interest:

Interests of animals:

- right to live and right of integrity
- respect for individualism and uniqueness
- respect for worth and dignity

Interests of humans:

- food
- achievement and increase of knowledge, basic research
- interindividual responsibility (medicine: research for therapy)
- assurance of the own existence (predators, varmints...)





Ethical concept of our modern western (?) society Consequence for animal experiments:

Right of animals to be protected is based on the following facts:

- ability to suffer
- loss of conditions for a "good" life leads to discomfort
- an animal which suffers has interest not to suffer, but has no ability to judge about the quality of the suffering
- death of an animal counts less than pain and discomfort





Ethical concept of our modern western (?) society Solution:

Consideration of Interests → meets principles of guidelines for animal experiment

Justification of the research (clear scientific purpose – increase of knowledge – consideration of benefit for humans against distress of animals)

Personnel: familiar with the experimental methods and with care, maintenance and handling

Best care and housing of the animals according to current knowledge; acquisition of animals: authorized breeding facilities

Experimental procedures: avoidance of discomfort, stress and pain consistent with sound scientific practices





Aims of the animal welfare law based on EU 2010/63

- Animal welfare is part of the EU treaty
- Care and attention to the intrinsic value of animals and to the ethic concerns of the community
- High degree of transparency
- Harmonization of animal welfare within the European Union
- Minimum standard of laboratory animal protection
- Forcefull realisation of the 3 R's (Reduce, Refine and Replace)
- No lethal endpoints if possible
- Aiming at the end towards replacement of animal experimentation





The 'anything goes' view

If humans see value in research involving animals, then it requires no further ethical justification (no member of the Working Party took this position).

The 'on balance justification' view

Research involving animals is morally acceptable if the costs are outweighed by the benefits, but every reasonable step must be taken to reduce the harm to animals.

The 'moral dilemma' view

Most forms of research involving animals pose moral dilemmas. Animal research is morally unacceptable, but so is avoiding research that could be beneficial to humans or animals.

The 'abolitionist' view

There is no moral justification for any harmful research on animals that is not to the benefit of the individual animal. Humans experiment on animals not because it is right but because they can.





German Animal welfare law §1

Basic principle

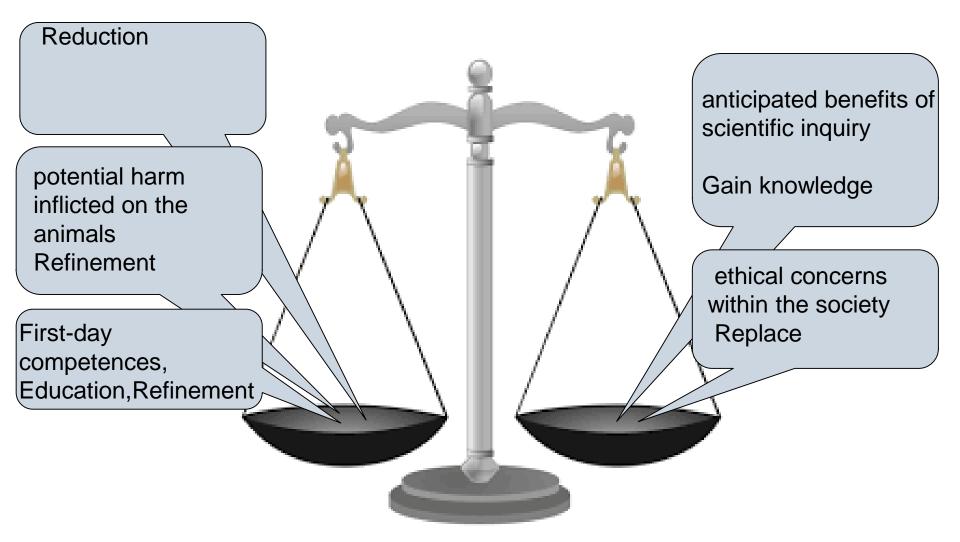
The objective of this Act is to protect the life and welfare of animals on the basis of human responsibility for them as fellow creatures.

Nobody may cause an animal pain, distress or harm without reasonable grounds.





Ethical Dilemma



Harm – Benefit – Analysis





Harm – Benefit – Analysis

A harm-benefit analysis of the project to assess whether

- "the harm likely to be caused to animals in terms of
- the suffering pain and distress is justified by the expected outcome taking into account ethical considerations,
- and may ultimately benefit human beings, animals or the environment ".





Ethical justification – Principle of Proportionality

- By the responsibel scientist within the application
- By the responsibel animal welfare officer by reviewing the application
- By the §15 animal experimentation committee (their results assists the competent authority in deciding whether to authorizes the experiment)
- By the competent authority (they decide whether the authorization is granted or not and under what terms).





Lisencibel Purposes TierSchG § 7a

- 1. Basic research,
- 2. Other research with one of the following objectives:
- The prevention, diagnosis or treatment of illnesses, pain, physical injury or physical conditions in humans or animals,
- Diagnosis or treatment of physiological conditions or functions in humans or animals, Promotion of the welfare of animals or the improvement of the holding conditions of animals reared for agricultural purposes,
- 3. The protection of the environment in the interests of the health or welfare of humans or animals,
- 4. The development and manufacture as well as the assessment of the quality, effectiveness or safety of drugs, foodstuffs and feed-stuffs or other substances or products with one of the objectives set out in number 2 letters a to c or number 3,
- 5. Assessment of the effectiveness of substances or products against animal pests,
- 6. Research aimed at the preservation of the species,
- 7. Higher education, professional development or training,
- 8. Forensic inquiries.



(3) Animal experimentation for the development or testing of weapons, munitions or associated equipment is prohibited.

(4) Animal experimentation for the development of tobacco products, washing agents and cosmetics is prohibited in principle.

The Federal Ministry shall be empowered by means of ordinance ratified by the Bundesrat to determine exceptions where this is necessary in order to

 avoid specific health risks and the new knowledge required could not be obtained in another way or
to implement acts of the European Community or the European Union.

Berlin

German Animal Welfare Act § 7a



(2) The following principles shall be adhered to when deciding whether animal experimentation is essential and on the performance of animal experimentation:

- 1. The respective current level of scientific knowledge shall be taken as a basis.
- 2. It should be verified whether the objective pursued could be achieved by means of other methods or procedures.
- 3. Experimentation on vertebrates or cephalopods may only be carried out if the anticipated pain, distress or harm to the animals is ethically acceptable in relation to the purpose of the experimentation.

4. Pain, distress or harm may only be caused to the animals to the extent that is necessary for the objective pursued; in particular it may not be caused for reasons of savings on labour, time or costs.

5. Experimentation on animals whose species-specific capacity to suffer the impact of experimentation is more strongly developed may only be carried out provided animals whose capacity is less strongly developed are not sufficient for the objective pursued.

Ethical evaluation procedure



- No alternative method availabel to conduct the experiment without animals
- Lisensabel purpose
- Scientific necessary and a "good reason" (vernünftiger Grund) or "moral obligation"
- The intended procedure is in fact fit to promote the stated purpose and indispensabel to achieve the stated purpose (right model, species, sex, age, study design, endpoints etc.)
- This includes a culture of care and quality of life of the involved animals by checking compliance to the 3 R's and taking responsibility for the animals
- Proportionality principle, harm benefit analysis: weight the costs like

severe pain, harm, disstress



the hoped benefit gain knowledge, contribution to future reduction of pain





Severity assessment and Welfare indicators

- Conclusion by analogy
- Animal based indicators
- Scientific validated indicators





Severity classification of repeated isoflurane anesthesia in C57BL/6JRj mice—Assessing the degree of distress

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Central ethical question concerning animals

Is it allowed for humans to use animals for their purposes / interests

→ YES – but not without ethical consideration of interests

Is it necessary to justify actions with / against animals

\rightarrow YES – based on approval of competent authority

CAVE: Agreement of interests may change: Ethical concepts can change according to current/dynamic agreements within the society





Wider function of Ethical Review

- A study of ethical review across Europe emphasises that ethical review bodies "should not be 'merely committees for review of particular projects' but should aim to permeate and influence the ethos of every institution in which animals are used –
- creating an appropriate 'culture of care', and providing advice and resources to ensure proper consideration
- of ethical aspects and application of the 3Rs in all scientific work involving animals" (Smith et al. [FELASA] 2007).

Animal science need a high degree of transparency (animaltestinfo, website, white paper, news paper, TV, discussions with the public etc.) to get an agreement from the society.







ANIMAL PROTECTION LAW

EU-RL 2012/63/EU

GUIDELINES FOR IMPLEMENTATION OF THE LAW ON ANIMAL WELFARE

WORKSHOP REPORT ON GUIDANCE ON DETERMING INDISPENSABILITY AND BALANCING POTENTIAL BENEFIT OF ANIMAL EXPERIMENTS WITH COSTS TO THE ANIMALS WITH SPECIFIC CONSIDARATION OF EU DIREKTIVE 2012/63/EU

RSPCA AND LASA, 2015, GUIDING PRINCIPLES ON GOOD PRACTICE FOR ANIMAL WELFARE AND ETHICAL REVIEW BODIES. A REPORT BY THE RSPCA RESEARCH ANIMALS DEPARTMENT AND LASA EDUCATION, TRAINING AND ETHICS SECTION. (M. JENNINGS ED.)

NUFFIELD COUNCIL, THE ETHICS OF RESEARCH INVOLVING ANIMALS, 2005

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Thank you for your attention!