

ETHICAL AND LEGAL REQUIREMENTS FOR USING ANIMALS IN RESEARCH

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This paper reviews the most significant ethical and moral concepts surrounding the use of non-human living beings in scientific experimentation. The principle: "Animals as living beings are capable of suffering and that human beings should respect them and afford them due protection and care" is embodied in Directive 86/609/EEC and the relevant Polish legislation. The essence of Directive 86/609/EEC is exemplified by two rules: (1) animals may only be used when the results of the research will provide additional knowledge or be generally advantageous to humans or animals; (2) man has a moral duty to respect all animals and should bear this in mind to avoid any unnecessary suffering. Experiments on animals should therefore be carried out only when absolutely necessary, and in compliance with national regulations laid down in response to the Directive. One of the overriding conditions in the use of animals for scientific purposes is adherence to the 3R rule devised by Russel and Burch [1959], *i.e.* consideration of the possibility of replacing *in vivo* method with *in vitro* technique (replacement), reduction in the number of animals to the necessary minimum (reduction), and refinement of experimental methods to limit invasiveness (refinement).

The classification of individual procedures used in animal experimentation is discussed, and the numbers of animals used in scientific experiments and teaching in Germany and Poland are presented.

ETHICAL PREMISE OF LEGAL PROTECTION OF ANIMALS

European Union and national legislation specifying conditions for the use of animals in scientific experimentation within Europe, reflects an evolution of views and moral concepts that has been developing gradually in Western civilisations. The list of precursors of legal protection of animals in Europe originates from Michel de Montaigne, a French writer and philosopher. Montaigne opposed numerous incidences of cruelty to animals which are the children of the same Mother Nature (Table 1). Almost two centuries later in defence of animals raised Jan Jacques Rousseau, the most outstanding philosopher of the French Enlightenment. For Rousseau, crucial in moral assessment is the fact that animals are capable of feeling. Since animals also show capability of feeling, they have the right not to be hurt by humans. This problem was even more clearly expressed by an English barrister Jeremy Bentham: "...animals can't think and speak but they can suffer" [1789]. For this reason, humans have moral obligation to animals. One hundred years later Bentham's views were culminating in the 1876 British Cruelty to Animal Act regulating animal protection, including animal experimentation.

Over the past 30 years, the question of man's moral responsibility towards animals has gained importance, mainly as a result of changes caused by industrialisation and its impact on environment and agriculture. Such changes have substantially decreased the numbers of wild animal

species, introduced intensive farming practices for livestock breeding and production, and have substantially increased the use of animals in scientific research or product testing, *e.g.* pharmaceuticals and cosmetics. Vivid descriptions of suffering of animals kept under "factory farming" conditions, hunted for sport or subjected to radical cosmetic tests [Ryder, 1974, 1975, 1980; Singer, 1975, 1980; Regan, 1976, 1980], have stimulated discussions in many societies and affected public opinion particularly in the European countries. The popularity and activity of ecological trends and followers of the alternative methods of nutrition (*e.g.* vegetarians) increased significantly. It was the main reason that the ideologies expounded by M. De Montaigne, J.J. Rousseau and J. Bentham in the second half of the XXth century for limiting animal suffering have been reflected in radical ethical concepts. It is not the intention of this paper to elaborate on this discussion but to concisely present the moral and ethical considerations surrounding human attitudes to animals which have formed the premise for current European Union legislation.

To Richard Ryder [1974], ignoring the interest of an animal just because it is not a human is "speciesism". The concept of "speciesism" as a sin akin to racism was established by Australian philosopher Peter Singer in famous and accusatory book "*Animal Liberation*" [Singer, 1975]. According to Singer [1980], equal respect for the interests of humans and animals means that if a procedure is not acceptable for human experiments, then it should not be applied to animals. Equal uncompromising principles assumed also Tom Regan, a philosopher from North

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TABLE 1. Precursors and ethical premise of legal protection of animals in Europe¹.

Author	Treatise (book, article) and its premise
Michel de Montaigne	<i>Essais (1580)</i> ² : If we condemn cruelty to people, than we should also condemn it with respect to other creatures, since we are somehow one family, children of the same Mother Nature.
J. Jacub Rousseau	<i>Discours sur l'origine de l'inegalite' (1755)</i> ³ : We should not hurt others, not because they are capable of thinking, but because they are capable of feeling. Since animals also show capability of feeling, they have the right not be hurt by humans.
Jeremy Bentham	<i>An introduction of the Principles of Moral and Legislation (1789)</i> ⁴ : It is not the ability to think or speak, but the ability to feel pain and suffering that is decisive with respect to beings towards which we have moral duties.
Richard Ryder	<i>Speciesism: the Ethic of Vivisection (1974)</i> : The higher intelligence of humans is not connected with greater rights but with a higher responsibility. He who says that one species has the right to tread down another species makes a moral mistake called speciesism. Similarly he who claims that one race has the right to distain another race makes a mistake called racism.
Peter Singer	<i>Animal Liberation (1975)</i> : Improper behaviour toward non-human creatures is wrong to the same extent as racism or sexism. By analogy, humans causing suffering to others is only justified when it prevents more suffering.
Tom Regan	<i>Animal Right and Human Obligations (1976)</i> : Our duties to animals can be fully expressed by affording them some rights. Respect for the values and rights of animals, as for human beings, cannot be satisfied by anything less.
R.W. Burch	<i>Animals, Right and Claims (1977)</i> : Animals do not have rights, as they are not capable of moral thought or moral self-defense; these qualities are necessary for beings to have rights.
Paul W. Taylor	<i>Respect for nature. A Theory of Environmental (1986)</i> : Each being capable of living within the capacity of its own species (irrespective of humans) has its inner value and deserves to be protected and favoured as an object itself.

¹Compiled from the opinions expressed in articles by other authors [Piątek, 1998; Ryder, 1974, 1980; Singer, 1980; Regan, 1980].

²Polish edition: PIW, Warszawa 1985; ³Polish edition: UKF, Warszawa, 1956; ⁴Polish edition: BKF Warszawa, 1958.

Carolina State University. According to Regan [1980], respect for the value and rights of animals, as for human beings, cannot be satisfied by anything less. The concept of animal-right has numerous opponents. Their arguments were formulated by Burch [1977]: "Animals do not have rights, as they are not capable of moral thought or moral self-defense; these qualities are necessary for beings to have rights". Compromising conception described as "biocentral behaviour" was proposed by Paul Warren Taylor, a retired Professor of the University of New York City. Biocentral behaviour postulated by Taylor [1986] assumed that life is central to all other values both for people and animals. The resulting rule of species neutrality places animals in the sphere of values and moral judgements as humans, and means that we should treat them accordingly. Man, with his special place in nature, has full moral responsibly for his deeds, and this applies to the use of animals. This rule is to a large extent incorporated into the legislation of the European Union and Member States, which specifies the conditions of authorised experimentation and requires the limitation of animal suffering.

LEGAL REQUIREMENTS FOR USING ANIMALS IN RESEARCH

Member States of the Council of Europe have adopted two documents. The first produced by the European convention for the protection of vertebrate animals used for experimental and other scientific purposes on 24 March 1986 [ETS 123]. Secondly the Council Directive of 24 November 1986 on the approximation of law, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes [Directive 86/609/EEC], adopted and supplemented in Directive of the European Parliament and of the Council [COM (2001) 703]. The preamble to the European Convention [ETS 123] included five very important

principles: (i) the aim of the Council of Europe is to protect live animals used for experimental and other scientific purposes; (ii) man has a moral obligation to respect all animals and have due consideration for their capacity for suffering and memory; (iii) man in his quest for knowledge, health and safety has a need to use animals where there is a reasonable expectation that the results will be to extend knowledge or be to the overall benefit of man or animal, just as he uses them for food, clothing and as beasts of burden; (iv) use of animals for experimental and other scientific purposes should be limited, with the aim of replacing such use wherever practical, in particular by seeking alternative measures and encouraging the use of these alternative measures; (v) man is obliged to protect animals used in those procedures which may possibly cause pain, suffering, distress or lasting harm and to ensure that where unavoidable they shall be kept to a minimum.

The above-mentioned principles have been precisely described in Directive 86/609/EEC, which embodies three issues: (1) the use of animals for experimental or other scientific purposes, (2) the type of animal - any live non-human vertebrate, and (3) any procedures which may cause pain, suffering, distress or lasting harm to them (Table 2). The regulations in this Directive do not apply to non-experimental agricultural and clinical veterinary procedures on foetal or embryonic forms and exclude the least painful (*i.e.* humane) methods of killing or marking an animal which are accepted in modern practice. The directive applies to the use of animals in experiments which are undertaken for one

TABLE 2. The scope of the Directive 86/609/EEC.

Issue	Included	Excluded
Purpose	Any experimental use of animals	Non-experimental agriculture, veterinary
Animal	Live non-human vertebrate	Foetal, embryonic forms
Procedure	May cause pain, suffering, distress, lasting harm	Human killing, human marking, other scientific (non-painful)

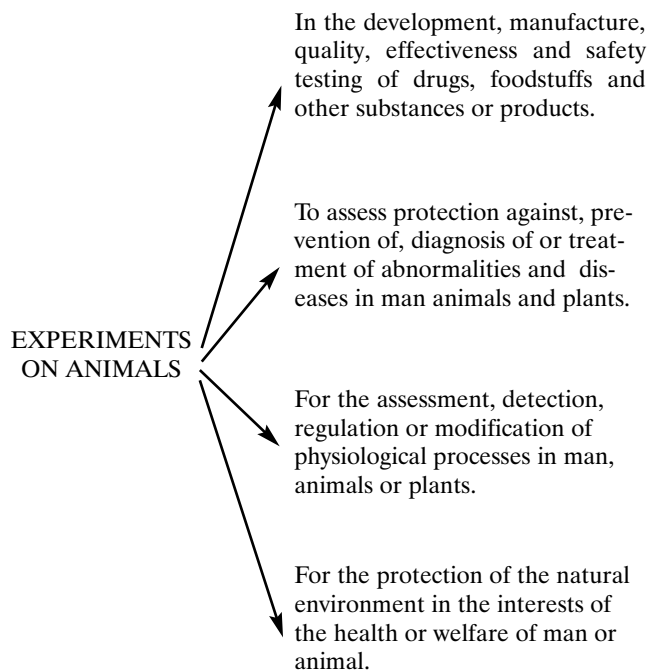


FIGURE 1. Purposes of experiments on animals permitted within Directive 86/609/EEC.

of the purposes mentioned in Figure 1. It states that experiments shall be performed solely by competent authorised persons (employees in registered establishments), provided that the experimental or other scientific project concerned is authorised in accordance with the provisions of national legislation.

In Poland each use of animals for experimentation must be authorised by the Local Ethical Committee consisting of authorities designated by the National Ethical Committee for Experiment on Animals. The Local Ethical Committee is responsible for verifying and supervising the experiment within the meaning of the Polish Act concerning animal protection, which is compatible with Directive 86/609/EEC. The authorising body, with the help of experts, licences establishments and ensures that the housing and care of animals, the qualifications of persons who carry out experiments and the justification, aims and experimental procedures

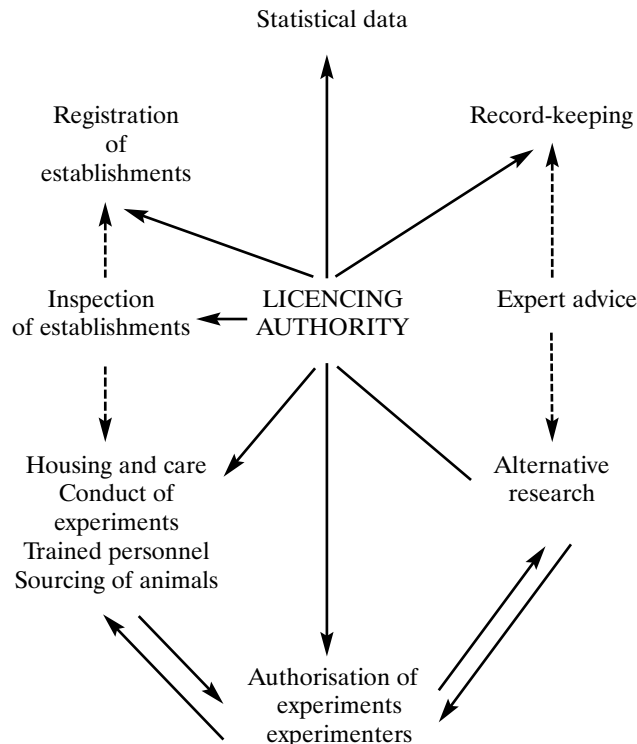


FIGURE 2. An overview of Directive 86/609/EEC.

comply with regulations (Figure 2). An experiment shall not be performed if another satisfactory method of obtaining the information, not entailing the use of animals, is reasonably and practically available. One of the conditions of using animals for scientific purposes is respecting the 3R rule [Russel & Burch, 1959], *i.e.* consideration of the possibility of replacing *in vivo* methods with *in vitro* techniques (replacement), reduction of the number of animals to a necessary minimum (reduction), and refinement of the experimental protocol to limit invasiveness (refinement). For this reason, the use of animals in experiments has to be highly justified when the risk of pain, suffering, distress or lasting harm is increased (Table 3). Examples of invasive experimental methods are presented in Table 3, and have been classified according to international standards [Fraser, 1990; Orlans, 1993; Menor & Reid, 1994]. Where it is planned to subject an animal to a procedure during which it will, or

TABLE 3. Category, effects, examples and conditions of experimental procedures acceptable according to the Polish Act concerning animal protection.

Degree	Effects	Examples	Conditions of acceptance
1	Non-invasive	Behavioural observations of captive small animals; behavioural tests on animals not subjected to any procedures.	Good husbandry and humane endpoint of experiments.
2	Light, short pain, stress or long-lasting discomfort	Temporary immobilization in order to make observations or conduct simple procedures: blood sampling, intravenous, subcutaneous, intramuscular or intraperitoneal injection of non toxic substances as well as humane euthanasia.	As for item 1, plus personnel performing experiments require appropriate qualifications and technical expertise.
3	Procedures causing mild pain/stress	Small surgery procedures under anaesthesia, immobilization for 15-60 min without sedative agents or anaesthesia; exposure to harmful, stressing stimuli but with the possibility of curtailment.	As for items 1 and 2, plus justification of research.
4	Intense pain/stress and irreversible damage to the body and physiological functions	Restitution of consciousness and the keeping alive of wounded animals, or those having had extensive surgery; toxicological tests and induction of lethal diseases with humane endpoint.	As for items 1, 2 and 3, plus justification of procedures to be performed.
X	Unacceptable procedures causing severe suffering	Infliction of wounds and burns without anaesthesia; infliction of death through intoxication, dehydration, starvation or altered temperature or humidity.	In specific cases, permission is given by the National Ethical Committee.

TABLE 4. The number of animals used in scientific experiments, testing and teaching in Poland¹ and Germany².

Species	Poland		Germany	
	Number	%	Number	%
Mouse	105708	27.0	1024413	48.1
Rat	85617	21.9	512393	24.1
Rabbit	48446	12.4	117890	5.5
Other rodents	7795	2.0	60412	2.8
Cat	143	0.04	648	0.03
Dog	449	0.1	4430	0.2
Other carnivorous	2021	0.5	290	0.01
Pig	6221	1.6	11661	0.5
Horse, donkey	-	-	1144	0.05
Goat	1803	0.5	223	0.01
Sheep	6938	1.8	2308	0.1
Cattle	2414	0.6	2402	0.1
Other mammals	598	0.1	2115	0.1
Quail	7736	2.0	2594	0.1
Other birds	941	0.2	-	-
Poultry	65956	16.9	63665	3.0
Amphibian	4598	1.2	15102	0.7
Fish	43558	11.1	303590	14.3
Total	391193	100	2126561	100

¹ National Ethical Committee for Experiments on Animals [2002]

² Tierschutzbericht der Bundesregierung [1997, 2002]

may, experience prolonged, severe pain, that experiment must be specifically declared and justified to, or specially authorised by, the licencing body (Directive 86/609/EEC, article 12.2.)

At the end of any experiment, it shall be decided whether an animal shall be kept alive or killed by a humane method. This is subject to the condition that it shall not be kept alive if, even though it has been restored to normal health in all other respects, it is likely to remain in lasting pain or distress. A special working party [Close *et al.*, 1996] prepared a recommendation for the euthanasia of experimental animals which refers especially to Article 2(1) published by the European Commission in October 1995. It defines "humane methods of killing" as "the killing of an animal with a minimum of physical and mental suffering, depending on the species" [Close *et al.*, 1996].

Directive 86/609/EEC specifies legal provisions; it does not however exclude experiments on animals. The number of animals used in experiments in Poland and Germany is relatively high and amounts to 391 193 and 2 126 561 animals,

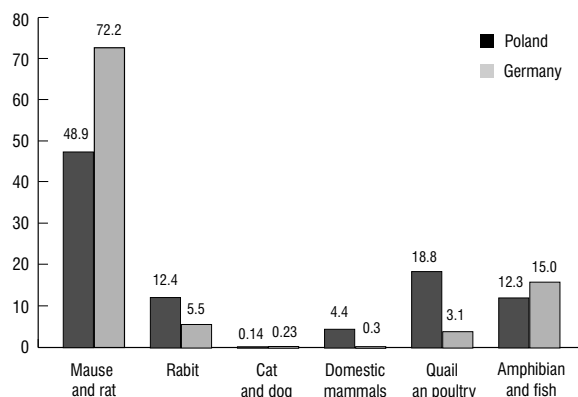


FIGURE 3. The share of different species in total number of animals used in experiments in Poland and Germany in 2001.

respectively (Table 4). The highest proportion from the species point of view are mice and rats; in Poland 48.9%, in Germany 72.2% of the total number of experimental animals (Figure 3). Relatively few experiments are conducted on cats and dogs (0.14% and 0.23%), domestic mammals (4.4% and 0.3%), and slightly more on amphibians and fish (12.3 and 15% in Poland and Germany, respectively). It is very likely that similar trends in scientific research in Poland and Germany account for the distribution data presented in Figure 3. In Germany, in the first decade after accepting Directive 86/609/EEC, the number of animals used in experiments declined progressively, and then increased again (Figure 4). Over this period, there has been a substantial decrease in the proportion of mice and rats used, from 83.9% in 1989 to 72.3% in 2001. A downward tendency has also been observed in the case of domestic mammals and poultry, whilst the reverse has been the case

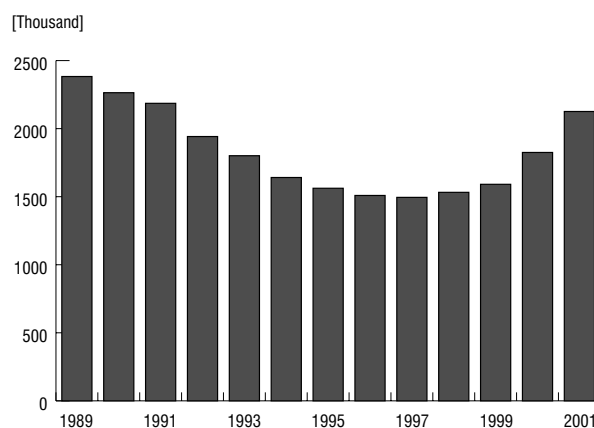


FIGURE 4. The number of animals used in experiments in Germany in 1989-2001.

for amphibians and fish. Numbers of cats and dogs used in experimentation has historically been very low, and is continuing to decline. Experiments on these species raise highly emotive issues in society.

The compromises accepted within Directive 86/609/EEC do not however satisfy those who strongly support increasing of the legal protection of animals. The Environment Committee of the European Biomedical Research Association [EBRA, 2002] are highly critical of Directive 86/609/EEC. Their concerns regard experiments on non-human primates, weapons and cosmetics testing, the killing of animals for the exclusive purpose of education and GM animals. In addition, they believe that: (1) transgenic animals should be included in the Directive and be fully recorded and traceable throughout their lives, (2) licensing procedures should be stricter than in Directive 86/609/EEC, and (3) a central EU inspectorate should be established, to guide inspectors within the Member States, with the power to visit facilities where animal experiments are being undertaken. According to EBRA [2002], Member States should be obliged to set up an ethical review procedure as a part of the authorisation system for approving animal experimentation. Such experiments should be recognised as exceptional and highly problematical procedures from the ethical point of view, and not to be generally sanctioned as normal scientific methods. Similar ideas from other organisations are believed to be influencing the increased legal protection for animals in Europe. An example of this is

the decision of the Upper House of the Bundesrat in Germany, on June 2002, making Germany the first country in Europe to include animal welfare in its constitution [EBRA, 2002].

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