

Ethics for Research Using Animals in Italy

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Summary — The purpose of this report is to describe the legislative and ethical context in Italy regarding technology and the need for innovative research versus responsibility toward the living world. Questions regarding responsible behaviour in the use of animals for research are examined, and special attention is focused on the implementation of the Three Rs concept (*reduction, refinement and replacement*) and on considerations of Catholic dogma.

Key words: animal rights, animal welfare, ethics, moral values, research.

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Introduction

With the development of new biological technologies, the conflict between animal activists and researchers has become even more heated and complex. The conflict is not only between an anthropocentric conception of life that justifies the sacrifice of animals in order to improve humankind's conditions and the opinion of those who believe that animals have inalienable natural rights, but it is now also about the ability of the researcher to use animals for experimental purpose. Probably, biomedical science should develop a greater respect for animals and recognise their responsibilities, and should also not forget that the bioethical aspects of science and technology concern not only animal well-being but also the protection of Nature.

Ethical and Legal Problems

According to Italian civil law (1), animals are personal property (*beni mobili*, art. 812 of the *Civil Code*). Wild animals are dealt with under art. 923 *Civil Code*. From the same perspective, animals are useful to humankind. These facts help to account for the perspective that lawyers have taken toward animal life, based on agrarian civil law and of the constitutional rules by which it is inspired (art. 41, 42, 44 of the *Costituzione della Repubblica Italiana*). Currently, a new principle is emerging: that animal life and health must be considered worthy of protection in itself; consequently, it must be protected in practice (2).

A "Universal Declaration of the Rights of Animals" was promulgated toward the end of the 1970s (3), while the first European directives concerning safety

in biotechnology experimentation date back to 1990. Recently, the European Union (EU) has shown a strong interest in animal well-being and has promulgated directives concerning animal protection in breeding (4), transport (5) and slaughter (6) and the ill-treatment of animals (e.g. art. 727 of the *Penal Code*). The Italian *Legislative Decree* (LD) 116/92 (7), following the specific *Directive 86/609/EEC* (8) on research animals, adds to these regulations. This Decree imposes some specific rules for protection of animals used for experimental or other scientific purposes, and considers as an offence any experimentation on higher animals or any that affects their genetic identity, in particular, if the experiment will inflict unnecessary pain and suffering.

Species listed in attachment 1 of *LD 116/92* can be used in experiments. These animals must be specially bred for use in experiments, in facilities approved by the authorities, while a specific government authorisation is required for use of dogs, cats and non-human primates (art. 3, points 2 and 3 of the *Decree*). Furthermore, this use is allowed only in the interests of the health or welfare of humans and animals (art. 3, point 1b).

According to art. 15, point 1, of *LD 116/92*, the Health Ministry must record statistical data about the research use of animals and must divulge them every three years in the *Gazzetta Ufficiale* of the Italian Republic. These statistical data are collected by using tables promulgated in Italy by Ministry Circular number 8 of April 22 1994, as laid down by the EU to standardise available information in all the EU Member States.

In the *Gazzetta Ufficiale* of 30 November 2001, number 279 (9), the Health Ministry divulged the statistical data concerning the research use of animals in Italy in the years from 1998 to 2000 (Table 1).

The numbers of animals used for experimental or other scientific purposes were 1,099,491, 959,105 and 905,603 in 1998, 1999 and 2000, respectively.

Figure 1 illustrates the gradual decrease to 905,603 in 2000. More than 90% of the animals represented in those numbers were rodents, such as mice and rats. Cats, dogs, pigs, sheep, equidae and non-human primates accounted for less than 4% of the animals used.

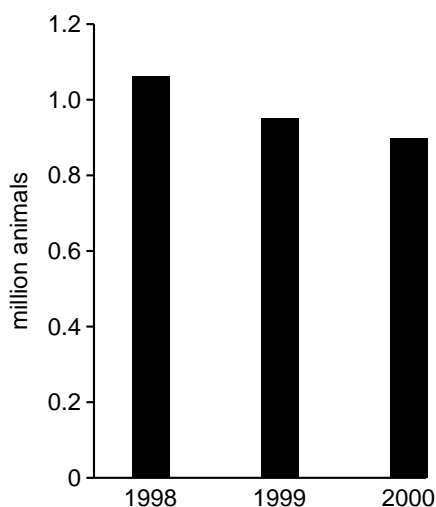
Conclusions

In most Italian universities, a Bioethical Committee has been established. These committees are controlled by the “centralised Veterinary Service for the Protection of Animals used for experimentation or other scientific purposes”. They provide reports on the research projects within each university.

Table 1: Statistical data concerning the research use of animals in Italy from 1998 to 2000

Species	Years		
	1998	1999	2000
Mice	422,454	394,310	404,602
Rats	579,479	491,966	434,664
Guinea-pigs	29,471	18,455	17,467
Mesocricetus	3955	3565	1614
Other rodents	5372	2428	2308
Rabbits	22,920	16,430	16,720
Cats	89	29	25
Dogs	876	745	766
Mustela	8	16	—
Horses	22	20	22
Pigs	1529	2045	2544
Goats	206	41	58
Sheep	345	612	552
Cattle	229	542	—
Non-human primates	103	—	—
Cebus sp.	52	50	59
Cercopithecoidea	272	450	553
Other mammals	70	25	26
Quail	107	226	—
Other birds	24,992	19,931	17,105
Reptiles	1739	1410	1046
Amphibians	3135	2164	3119
Fish	2066	3645	1924
Annual total	1,099,491	959,105	905,603

Figure 1: Numbers of animals used for experimental or other purposes in Italy from 1998 to 2000



The Bioethical Committee of Turin prepared guidelines on the regulation of animal experimentation that included fundamental principles regarding the use of animals, including the use of anaesthesia, pain-relieving drugs, and euthanasia methods, if pain and suffering could not be adequately controlled. *LD 116/92* provides clear guidelines on research practice, but it does not answer two important ethical questions: is the use of live animals for experimental purposes a morally acceptable practice, and when is it ethically valid?

The authors tried to answer the ethical questions by using the new Catechism of the Roman Catholic Church (10), which says that “. . . medical and scientific experimentation using animals are morally acceptable practices, if kept within reasonable limits, because [it] helps to treat persons and to save human lives”. The analysis of this sentence leads us to assert that the “reasonable limits” could be identified with the rules fixed by *LD 116/92*; consequently, any research use of live animals for scientific purposes is allowed if the legislation in force is respected.

But could any research use of live animals be considered “morally acceptable”? The new Catechism says research is permissible when it helps “to treat persons or to save human lives” (10). But we must consider that we cannot be sure that all research use of live animals will “treat persons and save human lives” (10). Cosmetics research, for example, is not directed toward such an aim. Therefore, we suggest changing the sentence to read “medical and scientific experimentation using animals are morally acceptable practices . . . on condition that they help to treat persons and to save human lives”.

To conclude, we hope the research world will take a scientific and cultural step forward concerning this complex matter. We are convinced that, while it is true that science must continue free of burdensome constraints, it is equally true that, in the use of animals for research, what is technically possible is not always ethically correct.

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