



In this second edition, although the text remains unchanged, the Table of Regulations has been thoroughly revised and updated.

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The European Science Foundation acts as a catalyst for the development of science by bringing together leading scientists and funding agencies to debate, plan and implement pan-European initiatives.

Foreword

Over the past twenty years or so, there has been a ‘revolution’ in the life sciences, and our knowledge and capabilities have dramatically increased. At the same time, these advances have raised very important ethical concerns in both the scientific community and with the public at large. These issues require open and frank debate at all levels, including the European level and are of fundamental importance to our Member Organisations (the national research councils and their analogues and the academies of sciences). Thus, the European Science Foundation has undertaken, on their behalf, a number of studies within the general heading of ‘Biology and Society’. The first of these, on the use of animals in research, is a very emotive topic on which there are many strongly held opinions. The Foundation, through its High Level Expert Group, has now set out a series of policy recommendations which it believes are balanced and reasonable. This includes the need for an ethical approach to animal experimentation in which we strongly endorse the policy of replacement, reduction and refinement as a way forward in gaining knowledge and progress for the benefit of humankind. The Foundation encourages not only its Member Organisations but all those concerned with this issue to follow these guidelines which will be periodically reviewed and updated. The Foundation will continue to play its part in the ongoing debate including acting as an official observer in the consultations on the revision of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes.

Enric Banda
ESF Secretary General

ESF statement on the use of animals in research

The use of animals has significantly contributed to the results obtained in scientific research, as well as to the safety and efficiency of biological, chemical or other products. For example, within EU Member States, about 12 million vertebrate animals are used per year for these purposes. From countries where the registration of animal use has already some history, it is known that the number of animals used for these purposes has decreased substantially (40-50% during the last two decades). This decrease has slowed down in recent years but this trend may be reversed in the near future, mainly due to the increased use of transgenic animals^(Ref.1). In several countries, scientists have made and continue to make substantial progress in the development and implementation of animal welfare and alternative methods to animal use. Also, the scientific community grants that, where the use of animals is unavoidable, every possible effort must be taken to prevent undue suffering and to implement measurements that may improve the animals’ well being.

Several organisations have prepared guidelines for the ethical use of animals in research and, in many countries, the use of animals is subjected to strict legal regulations. At the European level, guidelines and legislative regulations on the use of animals for scientific purposes have been issued in 1986 by the Council of Europe^(Ref.2) and the European Union^(Ref.3). In several European countries, national laws on the protection of animals used for scientific purposes have been issued. For EU Member States the national laws must meet the requirements of the Council Directive 86/609^(Ref.3), which is currently being updated.

At the national level, ESF Member Organisations should be actively involved in the monitoring of the application of legislative provisions on animal experimentation. For this reason it is essential that ESF sets out its views on this issue and that the ESF Member Organisations adopt guidelines for the ethical use of animals in research¹.

- 1. ESF recognises that laboratory animals not only have an instrumental value, but also an intrinsic value in themselves, which must be respected. Animals must always be treated as sentient creatures.**
- 2. While accepting the need of animal use for the advancement of scientific knowledge and for human and animal health and well being, ESF strongly endorses the principles of the “Three Rs” (Ref.4). This means that efforts ought to be taken to replace the use of live animals by non-animal alternatives, to reduce the number of animals used in experiments to the minimum that is required for obtaining meaningful results and to refine procedures, so that the degree of suffering is minimised. Research aiming at improving the welfare of animals should be encouraged and actively supported by ESF Member Organisations.**
- 3. Prior to the performance of a programme of research, animal use should be subjected to independent expert review, for both scientific and animal welfare considerations. The assessment and weighing of the likely benefit and likely animal suffering should be an essential part of the review process.**
- 4. Investigators should assume that procedures that would cause pain in humans also cause pain in other vertebrates, unless there is evidence to the contrary. Procedures that may cause more than momentary or minimal pain or distress in animals should be performed, where appropriate, with sedation, analgesia, anaesthesia or any other suitable mean to reduce pain or distress, in accordance with accepted veterinary practice.**
- 5. The best practical living conditions should be maintained for animals kept for research purposes. The care and health monitoring of the animals should be under the supervision of veterinarians or specialists in the field of laboratory animal science.**
- 6. National regulations concerning the use of animals in experiments need the involvement of science and research ministries.**
- 7. ESF recognises that individual countries regulate animal experiments in different ways. ESF supports efforts to reach an agreed quality standard in such regulations, which will generate public confidence and may be used as a basis for the development of national regulation. ESF Member Organisations should develop policies to make sure that there are systems in place to ensure that European and national regulations are followed.**
- 8. Investigators and other personnel involved in the design and performance of animal-based experiments should be adequately educated and trained. ESF Member Organisations should encourage the development and organisation of accredited courses on laboratory animal science, including information on animal alternatives, welfare and ethics.**
- 9. ESF encourages the editorial board of journals publishing the results of animal-based research to include in “the instructions to authors” a statement on the ethical use of animals.**
- 10. ESF should encourage its Member Organisations to ensure that the regulations for the control of animal experimentation and protection of animal welfare are published and the public reassured that the regulations are regularly reviewed and updated.**

References

Ref.1 Stokstad, E. Human science finds sharper and kinder tools. *Science* 286 (5442) 1068-1071, 1999.

Ref.2 Council of Europe. European Convention for the protection of vertebrate animals used for experimental and other scientific purposes. 51 pp. Strasbourg: Council of Europe, 1986.

Ref.3 EEC. Council Directive 86/609 on the approximation of laws. Regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Official Journal of the European Communities, L 358, 1-29, 1986

Ref.4 Russell, W.M.S. and Burch, R.L. The principles of humane experimental technique. London: Methuen, 1959.

¹ This ESF position paper primarily refers to vertebrate animals, not excluding invertebrates of which the neurophysiological development has reached the level that a similar protection is justified.

Regulations on the use of animals in research in European countries*

As part of its study of the regulatory frameworks operating in Europe for the control of the use of animals in scientific research, the ESF Expert Group sent a questionnaire to those responsible for the administration of national and European licensing systems. The following table provides a synthesis of the responses. The Expert Group wishes to thank all those involved for their cooperation in this study.

Country	Legislation			Ministries in charge	Animals ethics Committees ¹			Competence of Committee members	Use of alternative methods stimulated	Communication ⁴
	Effective since (year)	In line with Council of Europe ETS 123	In line with EU Council Directive 86/608		L	R	N			
AUSTRIA	1974 Revised in 1989 & 1999	yes	yes	Education, Science and Culture ³ , Social Security and Generation ³ , Economics and Labour, & Agriculture, Forestry, Environment and Water Management	1		1 ²	Scientific and animal welfare representatives at national level & Members of Medical Faculty at local level	yes	yes
BELGIUM	1986 Decret 1993 Revised in 1998 & 2000	yes	yes	Public Health ³ & Agriculture ³ & Regional Governments ³	25			At least 6 members (4 laboratory/university staff, 1 or more non laboratory/university staff, 1 veterinary inspector)	no	yes
CYPRUS	1959-1993 Revised in 1995 & 1999	yes	yes	Agriculture, Natural Resources and Environment			1 ²	5 members (1 veterinarian, 1 physician, 1 biologist, 1 animal protection NGO's representative and 1 chairman)	yes	no
CZECH REPUBLIC	1992	yes	yes	Central Commission for Animal Welfare & Environment	50 ²			At least 4 members according to Animal Protection Act	yes	yes
DENMARK	1891 4 times revised, last in 1993	yes	yes	Justice			1 ²	11 members (5 scientists, 5 representatives from industry and animal welfare organisations, and a judge as chairman)	yes	yes
ESTONIA	1992 Under revision	no	no	Agriculture	1			At least 4 members (physicians, biologists and lay persons)	no	no

* The table is based on the responses to a questionnaire that was sent to ESF Member Organisations and to the national representatives and observers at the Fourth Multilateral Consultation of Parties to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (ETS 123). (31 August 2000).

It was updated (15 July 2001) and additional responses have been incorporated. 23 of the 25 European countries involved have responded.

Country	Legislation			Ministries in charge	Animals ethics Committees ¹			Competence of Committee members	Use of alternative methods stimulated	Communication ⁴
	Effective since (year)	In line with Council of Europe ETS 123	In line with EU Council Directive 86/608		L	R	N			
FINLAND	1986 Under revision	yes	yes	Agriculture and Forestry & Social Affairs and Health ³	<or=117 ²			At least 4 members (<i>experimental animal care</i>)	yes	no
FRANCE	1987 Under revision	yes	yes	Agriculture ³	yes	yes		9 members (<i>scientists, lay persons</i>)	no	some
GERMANY	1972 Revised in 1986 & 1998	yes	yes	Food, Agriculture and Forestry & Health ³		≅35 ²		Medical and biological experts, animal welfare organisations	yes	no
HUNGARY	1998	not totally	not totally	Health & Agriculture and Regional Development ³	47 ²		1 ²	9 members (<i>1 academic, 3 scientists, 3 researchers, 1 geneticist, 1 representative of the veterinary chamber</i>)	yes	yes
IRELAND	1876 Revised in 1994 Under new revision	yes	yes	Dept of Health and Children & Dept of Environment and Local Government ³	yes				yes	yes (at level of Associations)
ITALY	1992	yes	yes	Health ³	4		1 ²	41 members at national level (National Bio-ethical Committee) & 7-10 members at local level (<i>1 veterinarian, biology researcher(s), 1 theologian and/or 1 lawyer, clinician(s)</i>)	yes	yes
NETHERLANDS	1977 Revised in 1997	yes	yes	Public Health, Welfare and Sport & Agriculture, Nature Management and Fisheries ³	29 ²		1 ²	At least 7 members (<i>biology, animal welfare, ethics and alternatives</i>)	yes	yes
NORWAY	1974 Revised in 1996	yes	yes	Agriculture	no		1 ²	7 members at national level (<i>2 doctors, 2 veterinarians, 1 biologist, 1 lawyer, 1 representative from the Norwegian Federation for Animal Protection</i>)	yes	?

¹ The animal ethics Committees are local (L) and/or regional (R) and/or national (N)

² Animal ethic Committees with a legal status

³ Ministries or governmental bodies in charge of specific regulations dealing with transgenic animals

⁴ Communication: conferences, public debates dealing with the use of animals in research, publications

Country	Legislation			Ministries in charge	Animals ethics Committees ¹			Competence of Committee members	Use of alternative methods stimulated	Communication ⁴
	Effective since (year)	In line with Council of Europe ETS 123	In line with EU Council Directive 86/608		L	R	N			
POLAND	1997 Revised in 1999	yes	yes	Agriculture & Education		17 ²	1 ²	5 members at national level & 6 to 15 members at local level (2/3 scientists and 1/3 animal welfare organisations)	yes	no
PORTUGAL	1992 Revised	yes	yes	Agriculture	some		1 ²	11 representatives from scientific institutions and 1 from animal welfare associations	no	no
SLOVAK REPUBLIC	1995	yes	yes	Agriculture	some		1 ²	Scientists, Specialists in animal care	yes	no
SLOVENIA	1985 Revised in 1999	yes	yes	Agriculture, Forestry and Food			in preparation ²	In preparation	no	yes (at level of Associations)
SPAIN	1988	yes	yes	Environmental Health & Agriculture, Fisheries and Food		yes		3 to 9 members (scientists, medical and biological experts, 1 veterinarian, biosafety experts, lay persons) and an institutional representative as chairman	yes	yes
SWEDEN	1989 Revised in 1998	yes	yes	Agriculture & Justice ³		7 ²		12 members (6 scientists and 6 lay persons) and a judge as chairman	yes	yes
SWITZERLAND	1978 Revised in 1991-1995, currently in revis.	yes	yes	Federal Dept of Public Economy & Swiss Veterinary Office		13 ²	1 ²	Scientists, specialists in animal experiments and animal protection	yes	yes (at level of Associations)
TURKEY	1996	ND	ND	Health	≡	6		A surgeon and experts in the field	no	no
UNITED KINGDOM	1987 Revised in 1993 & 1999	yes	yes	Home Office ³	265 ^x		1 ²	At least 12 members (2/3 veterinary surgeon(s), physicians, scientists, lawyer(s) and lay persons) and a chairman	yes	yes

¹ The animal ethics Committees are local (L) and/or regional (R) and/or national (N)

² Animal ethic Committees with a legal status

³ Ministries or governmental bodies in charge of specific regulations dealing with transgenic animals

⁴ Communication: conferences, public debates dealing with the use of animals in research, publications

^x Local animal ethics committees are not required by law, but the Secretary of State requires that "all designated establishments have a viable ethical review process in place"

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