COMMISSION OF THE EUROPEAN COMMUNITIES

COM(85) 637 final

Brussels, 18 December 1985

SIGNATURE BY THE COMMUNITY AND THE MEMBER STATES OF THE EUROPEAN CONVENTION FOR THE PROTECTION OF VERTEBRATE ANIMALS USED FOR EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES

(Communication from the Commission to the Council)

Proposal for a

COUNCIL DIRECTIVE

on the protection of animals used for experimental and other scientific purposes

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(submitted to the Council by the Commission)

Com 687

SIGNATURE BY THE COMMUNITY AND THE MEMBER STATES OF THE EUROPEAN CONVENTION FOR THE PROTECTION OF VERTEBRATE ANIMALS USED FOR EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES

Communication from the COMMISSION to the COUNCIL

On 23 november, 1982, the Commission forwarded to the Council a communication on Community participation in the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (COM(82)773 final). In that communication, the Commission proposed in particular that the representatives of the Member States, within the framework of their common action at the Council of Europe, should support the proposal to provide for the possibility for the European Community to become a Contracting Party to the Convention.

The principle of Community competence in this area was the subject of numerous discussions in the Council. In this connection the Commission Staff forwarded to the Council on 9 March, 1984, a working document entitled "Community legislation affected by the draft European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes" (SEC(84)405).

The draft Convention drawn up by the Ad hoc Committee of Experts for the Protection of Animals (CAHPA) meeting at the Council of Europe was examined by the Committee of Ministers of the Council of Europe in October 1984 and adopted on May 31st, 1985. The Convention, as adopted, will be open for signature by the Member States of the Council of Europe and by the European Communities as from 6 December 1985. It can therefore be seen that the objectives proposed in the Commission's communications of 23 November, 1982, and of 22 February, 1985 (COM(85)54 final) have been attained.

As already noted in the Commission's earlier Communications, the Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific purposes is not only of importance for the protection of animals; it may have consequences giving rise to administrative

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excesses for conditions of research and risk of distortion of competition, but it also has implications for other activities governed by Community rules. Reference is made therein, for instance, to the use of animals for experimental purposes :

- in the veterinary field (cf., for instance, Annex B to Council Directive 64/432/EEC of 26 June, 1964, and the second indent of Article 14(a) of Council Directive 80/217/EEC of 22 January, 1980);

- in the field of animal nutrition (cf., for instance, Council Directive 70/524/EEC of 23 November 1970)

- in the field of pesticides and pesticide residues (cf., for instance, Council Directive 76/895/EEC of 23 November 1976 and Council Directive 79/117/EEC of 21 December 1978);

- in the field of chemicals (cf., for instance, Council Directive 79/831/EEC of 18 September 1979);

- in the field of human and veterinary medecine (cf., for instance, Council Directive 75/318/EEC of 20 May 1975 and Council Directive 81/852/EEC of 28 Sepember 1981);

- in the field of food additives (cf., for instance, Commission Recommendation 80/1089/EEC of 11 November 1980);

- in the cosmetics field (cf., for instance, Council Directive 76/768/EEC of 27 July 1976);

- in the toxicology field (cf., for instance, Council Directive 67/548/EEC of 27 June 1967).

It is therefore essential that the Community be in a position to sign the Convention as soon as possible after it is open for signature. The Commission will subsequently make the appropriate proposals for the conclusion of the Convention by the Community.

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It is also essential, if the Convention is to enter into force in the near future, that States who are Members of the Council of Europe sign and ratify the Convention. In this context, it would be appropriate for the Council to recommend to the Member States, who are all also members of the Council of Europe, to sign the Convention at the earliest possible date.

A related proposal for a directive is intended to provide for common rules to give effect within the Community to the provisions of the Convention as soon as the directive enters into force.

PROPOSED DECISION

The Commission proposes that the Council :

- decides to proceed to the signature of the European Convention for the Protection of Vertebrate Animals used for Experimental or other Scientific Purposes;

- authorizes its President to designate the person empowered to sign the Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes on behalf of the European Communities;

- recommends to the Member States to sign the Convention for the Protection of Vertebrate Animals used for Experimental or other Scientific Purposes; at the earliest possible date.

DRAFT COUNCIL DIRECTIVE ON THE PROTECTION OF ANIMALS USED FOR EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES

EXPLANATORY MEMORANDUM

1. Laws on animal welfare exist in many countries of the world, including Member States of the Community. There is also, in many countries of the world, legislation relating specifically to animal experimentation. The provisions of such legislation, however, differ widely and these differences are to be noted even within the European Community. The present situation as regards legislation controlling animal experimentation in the Member States is set out as Annex 1 to this Memorandum. It can be seen that some Community countries have legislation going back a long way (e.g. the United Kingdom where animal experimentation is controlled by the Cruelty to Animals Act of 1876).

   In other countries, e.g. Belgium, Denmark and the Federal Republic of Germany, legislation is of relatively recent date; it can also be seen that the scope of such legislation varies as well as the arrangements under which the provisions of law are implemented. At the present time, some Community countries have new legislation under discussion. These include the United Kingdom, Belgium where the Senate has recently voted on Animal Protection Law which includes, amongst other things, questions of experimentation and Denmark, where new provisions are planned for 1986. In France, where animal experimentation is governed by a 1968 Order under Decree for Animal Experiments (1963), surveys are under way to find a consensus for possible legislation, while in Spain and in Portugal there appears to be no specific legislation on the subject currently in force, though in Portugal legislation is now being prepared.

2. On 31st May, 1985, the 21 Member States of the Council of Europe adopted a European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes. The new Convention, which is open for signature with effect from 6 December 1985, is aimed at two

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objectives, namely to reduce the number of animals used for experimental purposes, and to safeguard the welfare of animals used in experiments so as to avoid all unnecessary suffering. The Convention, as agreed on May 31st, 1985, provides for the possible participation not only of the member states of the Council of Europe, but also by the European Economic Community. On 22nd February, 1985, the Commission transmitted to the Council a Recommendation for a Council Decision, authorizing the Commission to negotiate Community participation in the Convention. The Commission has now proposed that the Community should sign the Convertion.

3. On 24th May, 1984, the European Parliament adopted a Resolution on the limiting of animal experiments and the protection of laboratory animals on the basis of a Report by Mrs Schleicher which in turn was based on motions for resolutions tabled by Mrs Dury and Mr Glinne on behalf of the Socialist Group and Mrs Herklotz and Mrs Seibel-Emmerling, as well as numerous questions by Members of the European Parliament to the Commission and Council. The text of the Parliament's Resolution is attached as Annex 2 to this Memorandum. As can be seen, the Resolution cites the (then) draft European Convention while recognising that "it is not enough for the European Community to accede to the proposed Council of Europe Convention but that there is a need to review present legislation in the Community and create at European level the legal bases for carrying out animal experiments". The Resolution then goes on to set out the broad framework for such Community legislation. The Parliament has repeated its request to the Commission to propose appropriate draft Community legislation on several occasions, most recently in the context of the Resolution adopted by the Parliament in May 1985 (Resolution on a Programme of Action of the European Communities on Toxicology for Health Protection) when (para. 8) it "repeated once more with force the desires which it had already expressed on this subject and invited the Commission, as soon as possible, and, in any case, before the Parliamentary Session of July 1985, to present to the Council and to Parliament the draft Directive on Animal Experimentation already requested".

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4. On many occasions, including at the time of the adoption of the Parliamentary Resolution of 24 May, 1984, the Commission has indicated its understanding of the concerns of the Parliament on the subject of animal experimentation and its wish to respond fully to those concerns.

On 4 March, 1985, Mr Jacques Delors, President of the Commission when replying to a letter on this subject from Mrs L. Seibel-Emmerling, Chairman of the European Parliament's Intergroup on Animal Welfare, wrote :

"As you know, and as already indicated in Commissioner Clinton Davis' letter to Sir Jack Stewart-Clark of 4th February and my own letter to Sir Jack of 5th February, the Commission is now in the process of preparing a draft directive on the subject of animal experimentation which we would hope to be able to send to the Council and Parliament in May or early June. It is, of course, extremely encouraging for us to know that this move has already the support of such a large number of Members of the European Parliament, from all political groups."

5. The question of animal experimentation is not, of course, a new field for the Commission or the European Community. As the Commission has already indicated in its communications to the Council of 23 November, 1982 (COM(82)773) and of 22 February, 1985 (COM(85)54), reference is made to the use of animals for experimental purposes in numerous Community instruments, including, for example :

- in the veterinary field (cf., for instance, Annex B to Council Directive 64/432/EEC of 26 June 1964 and the second indent of Article 14(a) of Council Directive 80/217/EEC of 22 January 1980);

- in the field of animal nutrition (cf., for instance, Council Directive 70/524/EEC of 23 November 1970);

- in the field of pesticides and pesticide residues (cf., for instance, Council Directive 76/895/EEC of 23 November 1976 and Council Directive 79/117/EEC of 21 December 1978);

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- in the field of chemicals (cf., for instance, Council Directive 79/831/EEC of 18 September 1979);

- in the field of human and veterinary medecine (cf., for instance, Council Directive 75/318/EEC of 20 May 1975 and Council Directive 81/852/EEC of 28 September 1981);

- in the field of food additives (cf., for instance, Commission Recommendation 80/1089/EEC of 11 November 1980);

- in the field of food contaminants (cf., for instance, Council Directive 76/893/EEC of 23 November 1976);

- in the cosmetics field (cf., for instance, Council Directive 76/768/EEC of 27 July 1976);

- in the toxicology field (cf., for instance, Council Directive 67/548/EEC of 27 June 1967).

6. Under the Commission's Proposed 4th Environment Research Programme (1986-90), provision is made for an initiative to be launched intended to lead to a reduction or replacement of animal tests specified in Community regulations; the Commission also intends, under the Biotechnology Programme (1985-1989) to promote the development of in vitro screening for the evaluation of the toxicological effects and the biological activity of molecules. It is also to be noted that the Commission's proposal for a draft Council Resolution on a Programme of Action of the European Communities on Toxicology for Health Protection (COM(84)284), submitted to the Council on 29 May, 1984, also states that "this Programme should help to avoid unnecessary testing on laboratory animals".

7. More generally, it is worth pointing out that even though this proposal does not address itself directly to moral questions, the 1974 EEC Directive on the stunning of animals before slaughter (EEC 74/577) for example states, in its preambular paragraphs, that, "the Community should also take action to avoid in general all forms of cruelty to animals ...". It is also to be noted that the European Parliament

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in its Draft Treaty establishing the European Union (under Article 59 - Environmental Policy) states "the Union shall take measures designed to provide for animal protection" and that the Commission, in its Programme for 1985, states : "an improvement in the quality of life also entails respect for animals in the Member States and in the Member States' dealings with the rest of the world".

8. Given the requirements of existing Community legislation, and given the prospect of new legislation in Member States (particularly in the light of the adoption of the Council of Europe Convention), there is a clear case for the adoption of Community rules on animal experimentation designed, inter alia, to safeguard the objectives of the treaty of Rome and in particular Articles 43 and 100.

9. The present proposal for a draft Directive on Animals used for Experimental and other Scientific Purposes seeks to embody within the framework of Community rules, the principles, objectives and main elements which are to be found in the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes. The intention is to ensure the full implementation of the Convention on a consistent and coherent basis in the Member States. The adoption of the directive is not of course to be seen as a substitute for the process of signature and ratification of the Convention by Member States of the Council of Europe (and the European Community) but rather as a means of ensuring that at least as far as the twelve Member States of the European Community are concerned, the provisions of that Convention are observed from the moment the directive enters into force. It is also to be expected that the adoption of Community rules will itself hasten, or even ensure, the signature and ratification of the Convention by all the Community Member States while serving to encourage similar action outside the Community. The Commission will subsequently make the appropriate proposals for the conclusion of the Convention by the Community. The present proposal also introduces certain elements which are specific to the European Community and which in the Commission's view will provide additional guarantees as to the protection of animals while avoiding unnecessary distortions of competition and trade.

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10. In preparing this proposal, the Commission has been inspired by the following main principles :

- Animal use in experimentation is at present necessary for the following purposes :
  . protection of human and animal health and the environment;
  . scientific research.

- The purposes for which experiments should be permitted should be clearly defined and limited.

- There is a need to reduce the number of animals used in experimentation; the minimum number of animals should be used consistent with the objective of the experiment.

- There is a need to reduce the level of suffering in animals occuring as a result of experimentation, and avoid it whenever possible.

- There is a need to eliminate experimentation for trivial purposes.

- The use of wild animals and endangered species should not be allowed.

- Whenever possible non-animal systems should be used.

- Lower order animals should be used as appropriate with the aim of the experiment.

- Animal experimentation must be carried out only by competent persons.

- Animal experimentation must be justified and authorized (as appropriate) by the authorities.

- There is a need to avoid unnecessary or duplicative testing.

- In breeding, supplying and experimenting with animals appropriate standards of care and accommodation should be observed.

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- The origin of the animals used in experimentation must be known.
- There is need to ensure that animal breeding, supplying and user facilities for establishments are monitored by the authorities.
- Adequate information on the number and purpose of animals used must be available.
- To further these objectives an exchange of information at all levels is advisable.
- There is a need to review current animal experimentation with a view to identify tests involving fewer animals and less painful procedures.
- Authorities should be able to avail themselves of a broad range of advice in discharging their responsibilities in this area.

12. The structure of the proposed Directive itself follows, to a substantial extent, that of the European Convention, though certain elements, for example Annexes 3 and 4, have been introduced with a view to producing an instrument which is responsive both to the particular demands of the Common Market and to the widespread concern on the question of animal experimentation expressed not only by the European Parliament, but by the wider public as well.

13. The proposed Directive, like the Council of Europe Convention, is intended not merely to limit the numbers of animals used in experimentation, but also to safeguard their welfare to the fullest extent possible. As far as the first point is concerned, it is not possible to estimate accurately the total number of animals used annually in the Community. Not all EEC countries produce detailed official statistics and those which do produce figures do not categorise them on a stricly comparable basis. The publication "Statistics of Experiments on Living Animals" (Her Majesty's Stationary Office, London) shows that an average of 4.5 million vertebrate animals are used annually

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in the United Kingdom under the Cruelty to Animals Act (1876).[1] The total number of animals used annually in West Germany (including non-experimental purposes) under its Animal Protection Law (1972) is estimated by the Ministry of Health to be 7 million, though other sources put it as high as 15 million. For the Netherlands, the figure is 1.5 million.[2] The implementation of the provisions of this draft Directive, particularly insofar as the avoidance of duplicative testing and the mutual recognition of procedures is concerned, should over the long-term contribute to a reduction in the numbers of experimental animals used.

14. As far as the second point is concerned - the welfare of the animals, including the limitation of pain, suffering and distress - the Commission believes that the entry into force of the Directive in all Member States will help to improve the situation. In drawing up its proposal, the Commission has been inspired to a considerable extent by the forward-looking thinking of certain Member States, particularly those who have recently legislated on this matter or who are now contemplating legislation.

15. Finally, the Commission hopes that a proposal of this nature will be seen by the European Parliament and by the wider public as an example of its commitment to the goals not only of the internal market and of environmental protection in its widest sense, but also to those of the People's Europe. In this field, perhaps as much as in any other, there is a need to respond to legitimate concerns while seeking to avoid extremist positions of all kinds. This is what the Commission has attempted to do.

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(1) See Annex 3

(2) See Annex 4

COMMENTARY ON THE ARTICLES

Article 1.1 sets out the aim of the directive

Article 1.2. sets out the permissible purposes for which experiments may be performed on animals, following the list established in Article 2 of the Convention.

Article 2 generally follows the definitions in Article 1.2. of the Convention except that, for the sake of linguistic clarity in translation "experimentation" or "experiment" is used where the Convention uses "procedure". 2(a) provides for the inclusion of invertebrates of the Plytum mollusca, class cephalopoda since there is some neurophysiological evidence that species of the higher mollusca may be substantially perceptive of pain.

Article 3 aims to prohibit experiments on endangered species. This requirement is not to be found within the Convention, but is consistent with other EEC rules, e.g. the Community regulation implementing the Convention on International Trade in Endangered Species (EEC 3626/82).

Article 4 deals with conditions of general care and accommodation and follows Article 5 of the Convention.

Articles 5.1. and 5.2. follow Article 13 of the Convention and provide for Members States to designate competent authorities for the welfare of experimental animals.

Article 6 deals with the conduct of procedure and follows Articles 6 and 7 of the Convention.

Article 6.3. provides for Advisory Committees to be set up at national level to advise competent authorities.

Article 7 deals with the training of personnel handling experimental animals (see Article 20 of the Convention).

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Article 8 deals with the procedures for the notification and authorization of experiments.

Article 9 deals with reporting (see Article 27 of the Convention and Annex VI of the directive).

Article 10, on education and training, follows Article 25 of the Convention.

Articles 11, 12 and 13, follow Articles 14, 15 and 16 of the Convention, in providing for breeding or supplying establishments to be registered with the responsible authority and for records to be kept.

Article 14 deals with experiments on dogs and cats and follows Article 17 of the Convention.

Article 15 deals with user establishments and follows Articles 18 and 19 of the Convention.

Article 16 lists the species used in experiments which should originate from or be acquired directly from registered breeding establishments or registered suppliers. The list in Annex I follows Article 21 of the Convention, but includes chickens, non-human primates and frogs.

Articles 17 and 18 provide for a Committee for Adapting the Directive to Technical Progress along the normal lines.

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Article 19, on the mutual recognition of procedures, reflects Article 29 of the Convention while taking into account the special interests of the Community and in particular those relating to the completion of the internal market.

Article 20 reflects Article 4 of the Convention

Article 21 provides that Member States shall comply with the Directive within 12 months following notification.

Article 22 concerns information to the Commission and reports to be made by the Commission to the Council and European Parliament.

Annex I gives the genus and species of experimental animals covered for the purpose of Article 16 and is based on Article 17 of the Convention.

Annex II, relating to care and accommodation, etc, is at present only a skeleton and will be completed subsequently in accordance with the procedures laid down in Articles 18 and 19, taking into account progress made within the Council of Europe and elsewhere.

Annexes III and IV seek to clarify the obligations laid down in Article 5, as far as the avoidance of pain and suffering is concerned.

Annex V sets out the measures to be taken at the end of a procedure and follows Article 11 of the Convention

Annex VI lists the information to be provided in accordance with Article 9 and follows Article 27 of the convention.

COMMENTS ON PREAMBULAR PARAGRAPHS

2nd whereas	-	See COM(85)54
3rd-7th whereas	-	See Council Directive 77/489/EEC
6th whereas	-	See Council Directive 74/577/EEC

COUNTRY	CONTROLLING LEGISLATION	ADMINISTRATIVE AUTHORITY	MAIN CONTROLS
Belgium	Animal Protection Act (1975)	Ministry of Justice and Ministry of Agriculture	Licence from Office of Veterinary Medical Inspection to Directors of laboratories; inspection by State Veterinary Inspector; anaesthesia required unless it frustrates object of experiment; 1981 decree requires biological, medical & veterinary science students to be trained in "alternative" methods. New legislation under discussion.
Denmark	Animal Experiments (N° 220/1977)	Ministry of Justice A board appointed by the Ministry is responsible for administration, represents all interest groups including animal welfare.	Individual licence to qualified persons for experiments likely to cause pain and suffering; anaesthesia required for experiments likely to cause pain, but can be dispensed with; licences not required for procedures causing no more than minor and momentary suffering; "lower" animals to be used if possible; only vertebrates covered; animals must not be used where "alternatives" have equal relevance; records of numbers, species and purposes to be kept and presented annually to controlling board; method of euthanasia for dogs, cats and non-human primates must be declared. Order amendment to bring into line with Swedish system. New law (1986) will include strict provisions on animal supply and local ethical committees.
Ireland	Legal basis as for UK Act of 1876.	Ministry of Health	Licences, conditions and inspection by Ministry of Health; basis of control as for UK.
Federal Republic of Germany	Animal Protection Law (1972) parts 5 & 6	Ministry of Food, Agriculture and Forestry	Licences issued by local authorities to head of institutions only; orders issued by central Ministry are effected by local authorities. All painful/injurious procedures subject to licensing. Ministry team of veterinary inspectors. Anaesthesia required for all surgical procedures (can be dispensed with where it frustrates the object of the experiment); surgery restricted to suitably qualified persons.
France	1968 Order under Decree for Animal Experiments (1963), n° 68-139 (constitutes articles R24-14 to R24-31 of article 454 of the Penal Code).	Ministry of Agriculture and other ministries. (has advisory interministerial commission)	Individual authorisation from relevant government department; inspection by Ministry of Agriculture veterinarians or Ministry of Public Health pharmacists; anaesthesia or equivalent analgesia required unless it frustrates object of experiment; experiments without anaesthesia restricted to one only. Surveys underway to find a concensus for possible legislation.
Greece	Law 1197, concerning the protection of Animals (1981), Article 4	Ministry of Agriculture (aided by Consultative Committee with the Vetinary Service of the Ministry)	Licence required for experiments causing pain or suffering; anaesthesia required for surgical experiments, administered by veterinary surgeon; surgical experiments restricted to graduates in medical, veterinary or biological sciences. No inspection.
The Netherlands	Law for Animal Experiments (1977) Order in Council (1980) provisions in process of implementation	Ministry of Public Health : Veterinary Public Health's Department of Animal Experimentation	Retrospective licences to institutions (no project assessment); compulsory for all painful experiments; animals in pain must be euthanised once the experiment is satisfied; anaesthesia can be dispensed with if it frustrates the object, but required for all surgery. Alternatives must be used where available and "lower" vertebrates in place of "higher" ones where possible. No cats, dogs, equines or primates should be used if other species will suffice, source of dogs and cats recorded, strict rules on supply but exemptions allowed. Inspection and supervision by two state veterinary inspectors and a team of 35 regional inspectors. Inspectorate requires annual returns including numbers, purpose, species and estimate of degree of discomfort. Detailed statistics produced. Central advisory committee to Minister for Public Health includes animal welfare members (members appointed by Royal Academy of Sciences). Produces Annual Report New controls being phased in currently, Project leaders will be required (by 1986) to undergo training in laboratory animal science. Detailed provisions on husbandry and care under consideration A named person responsible for animal care in each institution (animals' advocate) several now appointed. These are vets, doctors and biologists who undergo training under the Chair of Laboratory Animal Science at Utrecht. Neither they nor inspectors can stop experiments, but can impose restrictions. It is likely that institutional ethical committees will be recommended.

OUNTRY	CONTROLLING LEGISLATION	ADMINISTRATIVE AUTHORITY	MAIN CONTROLS
taly	Animal Protection Law (1913) amended 1941	Ministries for Health & Culture	Experiments performed only by named, suitably qualified individuals in authorised insititutes; Director holds responsibility; inspection by medical and veterinary officers of provincial health authorities; adequate anaesthesia required unless it frustrates object of experiment; only warm-blooded vertebrates covered; annual report required by pertinent ministry. Services undermanned, no prospected change.
;rand Duchy)f Luxem-)ourg	Law for the Protection and Welfare of Animals (1983)	Ministry of Agriculture	Licences issued by Ministry of Health; inspection by Ministry of Agriculture veterinarians. Same provisions as for German & Swiss laws.
Jnited Kingdom	Cruelty to Animals Act (1876)	Home Office	Personal licences; registration of premises; special certificates required for experiments with no anaesthesia or recovery from anaesthesia, for teching and for use of dogs, cats and equines. Special permission for use of primates. Applications reviewed & premises and experiments inspected by team of medical & veterinary inspectors. Encouragement to use "alternatives". Prohibition of severe pain thought likely to endure (responsibility of licence). Annual returns of all experiments required by Home Office. Detailed statistics published annually. New legislation at drafting stage.
Portugal			Legislation in line with Council of Europe Convention in preparation.
Spain	No legislation		

RESOLUTION

on the limiting of animal experiments and the protection of laboratory animals

The European Parliament,

having regard to

— the motion for a resolution tabled by Mrs Dury and Mr Glinne, on behalf of the Socialist Group, on the regulations governing the Lethal Dose 50 % Test (Doc. 1-1096/83),

— the motion for a resolution tabled by Mrs Herklotz and Mrs Seibel-Emmerling on the limiting of animal experiments and the protection of laboratory animals (Doc. 1-1254/83),

— numerous questions by Members of the European Parliament to the Commission and Council,

— the draft European Convention of the Council of Europe on the protection of vertebrates used for experimental and other scientific purposes,

— the OECD guidelines on 'good laboratory practice' (GLP),

— the OECD guidelines for toxicity testing,

— the biotechnological research programme of the European Community,

— the preliminary draft of the Commission for an action programme on toxicology as part of health protection,

— numerous laws and regulations at national and European level which directly or indirectly result in animal experiments,

— Article 59 of the draft Treaty establishing the European Union 'The Union shall take measures designed to provide for animal protection',

— the report of the Committee on the Environment, Public Health and Consumer Protection (Doc. 1-213/84),

A. recognizing the different points of view taken by those absolutely opposed to animal experiments, those favouring animal experiments who see no reason to change the present situation and the moderate representatives of both sides who recognize the need for animal experiments in certain areas but who are concerned to reduce the number of animal experiments and improve the living conditions of laboratory animals,

B. seeking as politicians to create the necessary conditions for restricting suffering on the part of the animals and reconcile the different points of view,

C. recognizing that it is not enough for the European Community to accede to the proposed Council of Europe Convention but that there is a need to review present legislation in the Community and create at European level the legal bases for carrying out animal experiments,

D. recognizing that with present legislation and the safety needs of the population, the demand for a total ban on animal experiments is unrealistic,

E. whereas Members of the European Parliament are calling for a general ban on carrying out animal experiments and only wish to see exceptions permitted where necessary and subject to strict conditions,

F. convinced that it is possible to reduce considerably the number of animal experiments currently being carried out so as to restrict these to the absolute minimum recognized as necessary,

G. convinced that a substantial reduction in animal experiments can only be achieved if those who are constantly setting ever higher standards for product safety are prepared to reconsider,

1. Calls for a ban on animal experiments in the following areas:

(a) animal experiments should not be carried out if the same results can be achieved by other methods, for example using materials insensitive to pain,

(b) a ban on all animal experiments where the outcome is already known and which are unlikely to provide any new insights,

(c) a ban on animal experiments carried out to save labour, time or costs,

(d) a ban on all experiments involving animals threatened with extinction,

(e) a ban on animal experiments which involve serious injury to non-anaesthetized animals,

2. Calls for the restriction and reduction of animal experiments (especially in primary and secondary education) to the absolute minimum necessary and as a very last resort by means of such measures as are feasible within the framework of the European Community:

(a) avoiding duplication of experiments and unnecessary repetitions of animal experiments by:

- creating a central data bank for animal experiments at Community level in which every documented animal experiment carried out in any Member State is to be retroactively recorded,
- mutual recognition of product licensing,
- mutual recognition of the findings from animal experiments,
- introduction and standardization of the notification and approval procedures for carrying out animal experiments;

(b) reducing the number of animal experiments by:

- a review of legal requirements which compel recourse to animal experiments,
- review of certain tests such as the acute toxicity test with the aim to increase the emphasis placed on cageside and other toxicological observations while accepting approximate D_{50} values obtained from these tests as sufficient; such acute toxicity test results would form an adequate input for the specification of dangerous substances,
- applying alternative and supplementary methods such as *in vitro* techniques, in particular tissue and cell cultures, experiments on individual organs, experiments on lower forms of life, such as bacteria, amoeba, micro-fungi, experiments with chicken or sea urchin eggs and theoretical methods such as electronic data processing, epidemiological studies and mechanical models;

(c) compilation of statistics on animal experiments;

3. Calls for compulsory notification and authorization of animal experiments to restrict abuses as far as possible and improve the conditions under which experimental animals are kept:

(a) introduction of compulsory notification for all experiments on non-vertebrates and all experiments required by law;

(b) introduction of compulsory licensing for all other animal experiments;

(c) the following requirements must be met for notification and authorization:

- a demonstrable need for the animal experiment,
- proof of the qualifications of the scientists carrying out the animal experiments,
- use only of animals coming from specially licensed and supervised animal breeding stations,
- proper accommodation for laboratory animals,
- experiments carried out wherever possible under anaesthetic followed by a painless death,
- care and treatment for animals where this is still possible,
- the creation of an ethics committee or independent person responsible for animal protection in all institutions carrying out animal experiments;

4. Calls for financial and scientific assistance to be given to research into methods which can be used as an alternative to or to supplement animal experiments;

5. Calls for a comprehensive statement by the Commission on the protection of animals used for animal experiments as a basis for discussion by the Council;

6. Requests that consideration be given, in appropriate instances, to amending producers' liability in respect of new products which have been produced without the aid of experiments previously conducted on animals, provided that this fact is specifically stated on the packaging of such products;

7. Instructs its President to forward this resolution to the Council and the Commission.

NUMBER OF EXPERIMENTAL ANIMALS USED IN 1981
(4,344,843) CATEGORISED BY PURPOSE (U.K.)

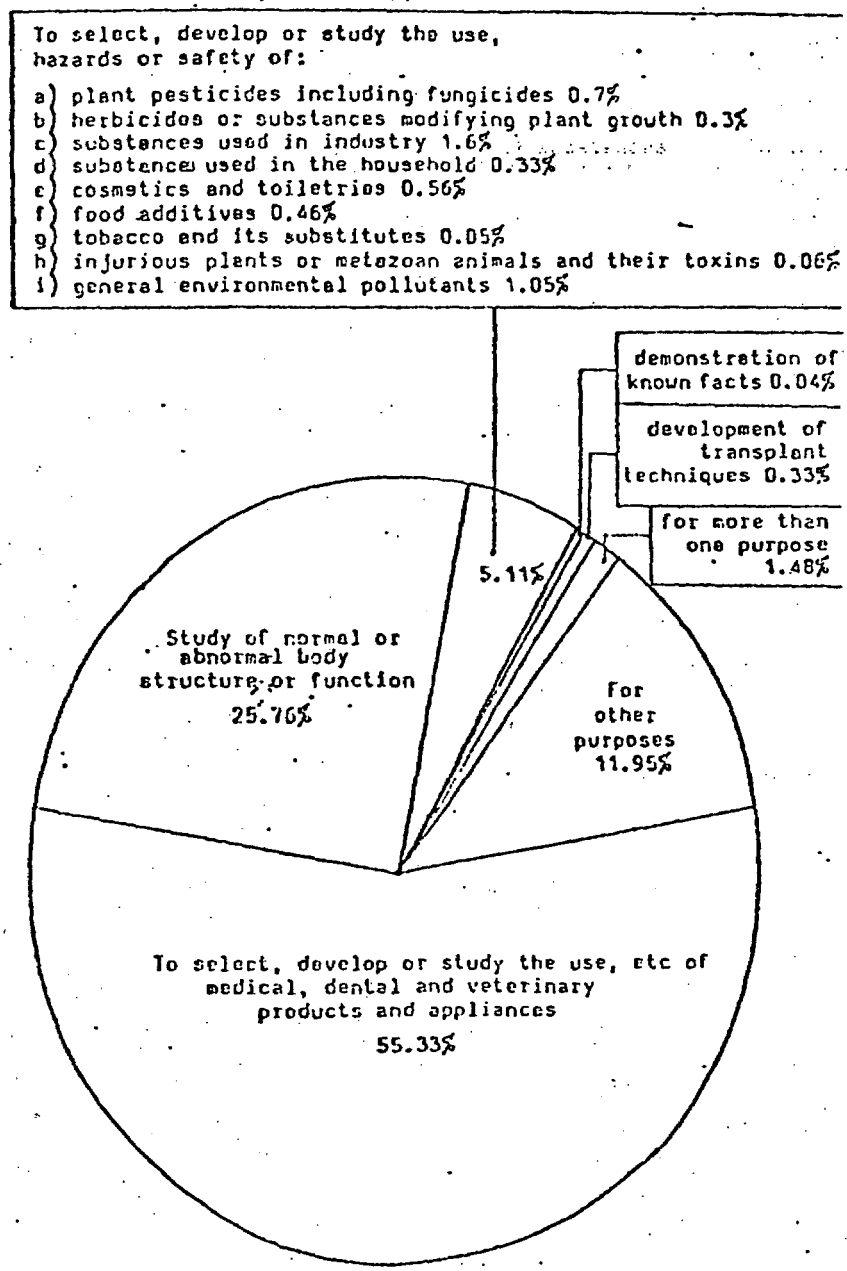

Table a

Animal species used in experiments in the Netherlands in 1978, 1980, 1981 and 1982

Animal species	1978	1980	1981	1982
Mice (Mus musculus)	61.10%	56.74%	54.86%	55.88%
Rats (Rattus norvegicus)	27.26	24.34	24.75	25.73
Syrian hamsters	0.82	1.4	1.45	0.92
Guinea pigs	2.63	2.73	2.82	2.61
Other rodents	0.09	0.21	0.19	0.28
Rabbits	1.19	1.63	1.68	1.64
Monkeys	0.13	0.14	0.08	0.15
Dogs	0.25	0.32	0.28	0.27
Cats	0.28	0.2	0.14	0.13
Other carnivores	0.02	0.01	0.01	0.02
Horses	0.01	0.01	0.01	0.01
Pigs		0.31	0.50	0.54
Ruminants	0.37	0.31	0.32	0.36
Other mammals	0.62	0.01	0.00	0.00
Birds	3.0	6.86	8.79	6.94
Reptiles	0.02	0.03	0.03	0.04
Amphibians	0.48	0.91	0.64	0.31
Fishes	1.75	3.84	3.44	4.19
total number of animals	1.572.534	1.486.639	1.448.015	1.422.094

Table b)

Animal experimentation in the Netherlands

QUESTION 1

PURPOSE OF THE EXPERIMENT

The main purpose of the experiment is:

	Percentage of all animals used			
	1978	1980	1981	1982
1. Research on biologicals:				
1. The production, control or biological standardization of sera, vaccines or other biological products	24.19	15.77	19.92	18.84
2. Other biological standardization		1.68	1.12	1.38
2. Toxicological or pharmacological research on:				
1. Pesticides, herbicides or fungicides	0.44	0.36	0.54	0.58
2. Toiletries or cosmetics	0.09	0.01	0.08	0.01
3. Other substances used in industry or in the household	0.87	1.17	0.94	0.61
4. Food additives	0.41	0.38	0.27	0.10
5. Tobacco and its substitutes	0.02	0.00	0.04	0.00
6. Medicinal drugs	20.50	30.73	24.01	25.99
7. Other substances affecting the feeding or the health of man or animal	1.10	1.72	1.43	1.51
8. More than one of these categories	10.79	0.26	0.23	0.38
9. Another category	1.12	0.82	1.04	0.15
3. The diagnosis or identification of diseases, pregnancy or other physical conditions or physical characteristics other than in the practise of veterinary medicine in the animal in question	7.85	6.88	5.80	4.30
4. Training or education				
1. In practicals and/or demonstrations in support of theoretical knowledge	0.58	0.38	0.56	0.38
2. To gain skill in the performance of interferences	0.63	0.10	0.07	0.11
3. Both categories	0.23	0.31	0.29	0.27
4. Neither of these categories	0.01	0.02	0.02	0.01
5. The solution of a scientific problem relating to:				
1. The study of neoplasms	8.81	6.80	7.22	6.22
2. The study of cardiac and vascular disease	1.13	1.35	2.00	1.09
3. The study of transplantation of organs	2.84	3.37	2.77	3.70
4. The study of other diseases or physical conditions or physical characteristics, including pregnancy in man or animals	6.01	8.57	8.78	10.43
5. Another scientific problem	10.20	12.56	19.41	15.41
6. More than one of the purposes mentioned	2.19	3.77	1.59	2.43
7. Another purpose	-	2.97	1.88	6.10
Total	100.01	99.98	100.01	100.00

Proposal for a

COUNCIL DIRECTIVE

on the protection of animals used for experimental and other scientific purposes

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas a European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes was adopted by the Committee of Ministers of the Council of Europe on 31 May 1985,

Whereas certain provisions of the Convention could affect certain common rules laid down in particular by Council Directives 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (1), 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (2), 79/831/EEC of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (3), 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols

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(1) OJ N° 121, 29.07.1964, 1977/64
(2) OJ N° L 147, 09.06.1975, p. 1
(3) OJ N° L 259, 15.10.1979, p. 10

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in respect of the testing of veterinary medicinal products (4), and 83/228/EEC of 18 April 1983 on the fixing of guidelines for the assessment of certain products used in animal nutrition (5) and Commission Directive 84/449/EEC of 25 April 1984 adapting to technical progress for the sixth time Council Directive 67/548/EEC (6);

Whereas the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes is open to signature by the Member States; whereas the Convention is also open for signature by the European Communities;

Whereas, however, Community measures on the subject should be adopted without delay;

Whereas there exist between the national laws at present in force for the protection of animals used for experimental purposes disparities affecting the functioning of the common market;

Whereas the Community should also take action to avoid in general all forms of cruelty to animals;

Whereas, in order to eliminate these disparities, the laws of the Member States should be harmonized; whereas that would accordingly enable action to be taken at Community level to protect animals used for experimental purposes from unnecessary pain and suffering;

HAS ADOPTED THIS DIRECTIVE :

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(4) OJ N° L 317, 06.11.1981, p. 16
(5) OJ N° L 126, 13.05.1983, p. 23
(6) OJ N° L 251, 19.09.1984, p. 1

Article 1

1. This Directive is concerned with the animals used for experimental and other scientific purposes. It is aimed to ensure that the number of animals used for experimentation is reduced to a minimum, that such animals are properly taken care of and that no pain or suffering is inflicted unnecessarily.

2. Experimentation using experimental animals shall be undertaken only for one or more of the following purposes and subject to the restrictions laid down in this Directive.

   a) i) the avoidance or prevention of disease, ill-health or other abnormality, or their effects, in man, vertebrate or invertebrate animals or plants, including the production and the quality, effectiveness and safety testing of drugs, substances or products;

      ii) the diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, vertebrate or invertebrate animals or plants;

   b) the assessment, detection, regulation or modification of physiological conditions in man, vertebrate and invertebrate animals or plants;

   c) the protection of the environment;

   d) scientific research;

   e) education and training;

   f) forensic inquiries.

Article 2

1. For the purpose of this Directive the following definitions shall apply :

(a) "animal" unless otherwise qualified, means any live non-human vertebrate, including foetuses and free living larval and/or reproducing larval forms; and invertebrates of the Phylum mollusca, Class cephalopoda.

(b) "experimental animals" means animals used or to be used in required or approved experimentation;

(c) "bred animals" means animals specially bred in facilities approved by the authority;

(d) "experimentation" or "experiment" means all tests, demonstrations and procedures carried out on an animal which may cause it pain, suffering, distress or lasting harm, including any course of action intended to, or liable to, result in the birth of an animal in any such condition, but excluding the least painful methods accepted in modern practice (i.e. "humane" methods) of killing or marking an animal; an experiment starts when an animal is first prepared for use and ends when no further observations are to be made for thatexperiment; the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does not place the use of an animal outside the scope of this definition.

(e) "authority"means the authority designated by each Member State as being responsible for supervising the practice of experimentation within the meaning of this Directive.

(f) "competent person" means any person who is considered by a Member State to be competent to perform the relevant function described in this Directive.

(g) "establishment" means any installation, building, group of buildings or other premises and may include a place which is not wholly enclosed or covered and mobile facilities;

(h) "breeding establishment" means an establishment where animals are bred with a view to their use in experiments;

(i) "supplying establishment" means an establishment, other than a breeding establishment, from which animals are supplied with a view to their use in experiments;

(j) "user establishemnt" means an establishment where animals are used for experiments;

Article 3

Each Member State shall ensure that experimentation using animals considered as endangered species by Council Regulation (EEC) No 3626/82 (1) or under national legislation of the Member State shall be prohibited.

Article 4

Member States shall ensure that, as far as the general care and accommodation of animals is concerned:

- all experimental animals shall be adequately housed, fed, and cared for;

- any restriction on the extent to which an experimental animal can satisfy its physiological and ethological needs shall be limited only as permitted by the provisions set out in Annex II;

- the environmental conditions in which experimental animals are bred, kept or used must be checked daily;

- the well-being and state of health of animals shall be observed by a competent person to prevent pain or avoidable suffering, distress or lasting harm;

- arrangements are made to ensure that any defect or suffering discovered is corrected as quickly as possible.

(1) OJ No L 384, 31.12.1982, p. 1.

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Article 5

1. Each Member State shall designate an authority responsible for supervising the practice of experimentation within the meaning of this Directive.

2. The designated authority shall have responsibility for authorising competent persons to undertake or to supervise the practice of experimentation in registered or approved establishments.

3. The designated authority should, in discharging its functions under this Directive, have access to the advice of interested parties, including scientific, industrial and animal welfare interests.

Article 6

1. An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.

2. When an experiment has to be performed, the choice of species shall be carefully considered and, where required, shall be explained to the responsible authority. In a choice between experiments, those which use the minimum number of animals, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected.

3. All experiments shall be designed to avoid distress and unnecessary pain to the experimental animals, using whenever appropriate general or local anaesthesia. They should be subject to the "Anaesthesia Condition" laid down in Annex III and to the "Pain Condition" laid down in Annex IV. The measures set out in Annex V shall be taken in all cases.

Article 7

Member States shall ensure that all personnel handling experimental animals have received training or instruction in animal welfare appropriate to his/her function.

Article 8

1. Details of experiments must be notified 30 days in advance to the authority, which shall have the possibility of disallowing the experiment, or of requiring changes thereto, within the said 30 days.

2. All decisions disallowing an experiment, requiring changes to an experiment or refusing authorization to conduct an experiment should indicate the reasons on which they are based and should provide for the possibility of an appeal.

3. Each experiment shall be performed in all respects in accordance with any directions given under paragraph 1, and in conformity with the animal wellbeing aspects of good laboratory practice and in conformity with all provisions of this Directive.

4. All experiments on non-human primates shall be subject to prior authorization. Such experiments shall be authorized only where there is a justification and where they are essential to solve a serious medical problem or where they are necessary to comply with Community measures for the protection of public health.

5. Notifications made pursuant to this Article may also cover a programme of work involving experiments of a similar nature, using standard testing procedures, where the experiment is not expected to cause pain, distress or equivalent suffering of more than trivial severity.

6. The provisions of this Article shall not preclude the performing of experiments required by existing Community directives or recommendations.

Article 9

1. On the basis of requests for authorization and notifications received, and on the basis of the reports made, the authority in each Member State shall :

   - ensure that unnecessary duplication of experimentation is avoided as far as possible;

   - collect, and as far as possible make publicly available, the statistical information on the use of animals in experiments set out in Annex VI.

2. Member States shall take all necessary steps to ensure that the confidentiality of commercially sensitive information communicated pursuant to this Directive is protected.

Article 10

1. Member States shall ensure that experimentation for teaching purposes is carried out as far as possible on bred animals and following authorization by the authority. Whenever possible audio-visual or other suitable methods should be used instead of carrying out experiments.
2. Experiments shall not be permitted in secondary schools or other institutions of education and training of equivalent or lower level, except where the course of education or training concerned is specifically directed to preparing for a career involving the performance of experiments or the treatment or care of animals and the experiments entail no severe or enduring pain or severe or enduring suffering.

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Article 11

Breeding and supplying establishments shall be registered with the authority and shall comply with the requirements of Articles 4 and 7. A supplying establishment shall not obtain any animal from any source other than a breeding establishment unless the supplier can demonstrate that the animal has been obtained from another supplying establishment and is not a feral or stray animal, or has been lawfully imported.

Article 12

The registration provided for in Article 11 shall specify the competent person in charge of the establishment who shall administer or arrange for suitable care of the animals of the species bred or kept in the establishment.

Article 13

1. Breeding and supplying establishments shall record the number and the species of animals sold or supplied, the dates on which they are sold or supplied, and the name and address of the recipient and the number and species of animals dying while in the breeding or supplying establishment in question.

2. Each authority shall prescribe the records which are to be kept and made available to it by the person in charge of the establishments mentioned in paragraph 1; such records shall be kept for a minimum of three years from the date of the last entry and shall be subject to periodic inspection by officers of the authority.

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Article 14

1. Each dog and cat in any breeding or supplying establishment shall be permanently marked with a unique individual identification in the least painful manner before it is weaned, except for cases provided for under paragraph 3.

2. Where an unmarked dog or cat is taken into an establishment as referred to in paragraph 1 for the first time after it has been weaned it shall be marked as soon as possible.

3. Where a dog or cat is transferred from one establishment as referred to in paragraph 1 to another before it is weaned and it is not practicable to mark it beforehand, a full documentary record, specifying in particular its mother, must be maintained by the receiving establishment until it can be so marked.

4. Particulars of the identity and source of each dog or cat shall be entered in the records of all establishments as referred to in paragraph 1.

5. In no case shall feral or stray cats and dogs be used for experiments.

Article 15

1. User establishments shall be registered with or otherwise approved by the authority. Provisions should be made at user establishments for installations and equipment appropriate to the species of animals used and the performance of the experiments conducted there, the design, construction and functioning of which shall be such as to ensure that the experiments are performed as effectively as practicable, with the object of obtaining consistent results with the minimum number of animals and the minimum degree of pain, suffering, distress or lasting harm.

2. In each user establishment :

   (a) a competent person working full-time in the establishment who is responsible for the care of the animals and the functioning of the equipment used in the experiment shall be identified and shall have the authority to terminate experiments , if he is reasonably convinced that the experiment is not being properly conducted;

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(b) sufficient trained persons shall be provided ;

(c) adequate arrangements shall be made for the provision of veterinary advice and treatment and the names of veterinarians responsible for the welfare of animals shall be specified;

(d) only competent persons shall undertake experimentation, or supervise the undertaking of experimentation. Such persons shall have received instruction in a scientific discipline relevant to the experimental work being undertaken, and in the requisite skills of laboratory animal handling and care and shall have satified the responsible authority that they have attained a satisfactory standard in relation to those matters.

3. In user establishments only animals supplied from breeding or supplying establishments shall be used. Bred animals should be used whenever possible.

4. User establishments shall maintain records of all animals used and make them available as required by the responsible authority. In particular, these records shall show the number of species of all animals acquired, from whom they were acquired and their date of arrival. Such records shall be made available as required by the responsible authority. User establishments shall be subject to periodic inspection by officers of the authority.

Article 16

1. Animals of the species listed in Annex I which are used in experiments shall be acquired only from a breeding establishment or a supplying establishment.

2. The list set out in the Annex may be modified in accordance with the procedure set out in Article 18.

Article 17

1. A Committee responsible for adapting the Annexes of this Directive to technical progress (hereinafter referred to as "the Committee") is hereby set up. It shall consist of representatives of the Member States and be chaired by a representative of the Commission.

2. The Committee shall draw up its own rules of procedure.

Article 18

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the Chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time-limit which may be determined by the Chairman according to the urgency of the matter. It shall decide by a majority of (54) votes, the votes of the Member States being weighted as provided for in Article 148(2) of the Treaty. The Chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where these are in accordance with the opinion of the Committee.

   (b) Where the measures envisaged are not in accordance with the opinion of the Committee, or in the absence of an opinion, the Commission shall forthwith submit a proposal to the Council on the measures to be adopted. The Council shall act by a qualified majority.

   (c) If the Council does not act within three months of the proposal being submitted to it, the measures proposed shall be adopted by the Commission.

Article 19

1. In order to avoid unnecessary duplication of experiments for the purposes of satisfying national or Community legislation on health and safety, Member States shall recognise the results of experiments carried out in the territory of another Member State unless further testing is necessary in order to protect public health and safety and the Member State concerned gives detailed reasons justifying its decision to require further testing to the person seeking to market the product concerned and to the Commission.

2. Member States shall, without prejudice to the requirements of existing Community directives, furnish information to the Commission on their legislation and administrative practice relating to experimentation including requirements to be satisfied prior to the marketing of products, as well as factual information on all experiments carried out in their territory and on authorization or any other administrative particulars pertaining to these experiments.

Article 20

This Directive shall not restrict the right of the Member States to apply or adopt stricter measures for the protection of animals used in experiments or for the control and restriction of the use of animals for experiments.

Article 21

1. Member States shall take the measures necessary to comply with this Directive within 12 months following notification. They shall inform the Commission thereof.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

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Article 22

Member States shall inform the Commission every three years of the measures taken in this area and provide a suitable summary of the information collected under the provisions of Article 9, second indent, and the Commission shall prepare a report to the Council and the European Parliament.

Article 23

This Directive is addressed to the Member States.

Annex I

Genus and species of experimental animals covered for the purposes of Article 16.

-	Mouse	Mus musculus
-	Rat	Rattus norvegicus
-	Guinea Pig	Cavia porcellus
-	Golden hamster	Mesocricetus auratus
-	Rabbit	Oryctolagus cuniculus
-	Chicken	Gallus gallus
-	Non-human primates	
-	Dog	Canis familiaris
-	Cat	Felis catus
-	Quail	Coturnix coturnix
-	Frog	Anura

Annex II

Housing, feeding and care of experimental animals; the conduct of experiments, training of persons, etc.

1. The physical facility

1.1 Functions and general design
1.2 Holding rooms
1.3 Laboratories and special purpose rooms
1.4 Service rooms

2. The environment in the holding rooms and its control

2.1 Ventilation
2.2 Temperature
2.3 Humidity
2.4 Lighting
2.5 Noise
2.6 Alarm systems

3. Care

3.1 Health
3.2 Trapping
3.3 Packing and transport
3.4 Reception and unpacking
3.5 Quarantine, isolation and acclimatization
3.6 Caging
3.7 Feeding
3.8 Water
3.9 Bedding
3.10 Exercising and handling
3.11 Cleaning
3.12 Humane killing of animals

4. Conduct of experiments

5. Training of persons

6. Other

Annex III

The anaesthesia condition

1. Where the performance of an experiment may be expected to cause an animal pain or suffering unless the animal is properly anaesthetised, the person or persons authorized to conduct the experiment shall ensure that :

   (i) the animal is properly anaesthetised before the experiment begun, and remains so until it is concluded;

   (ii) the animal is relieved from any post-operative pain or suffering by the administration of analgesics or other appropriate treatment; and

   (iii) if it is not practicable to provide that relief, the animal is immediately and humanely killed.

2. This condition shall be dispensed with in cases where application of anaesthesia is considered, by a veterinarian, to be more distressing for the animal than the experiment.

3. In cases where the animal is to be subjected to pain, suffering, distress or lasting harm which cannot practicably be relieved by the use of anaesthetics, analgesia or other pain relieving techniques shall be applied to alleviate all suffering, in compliance with the provisions of Annex II.

4. The animal shall be properly anaesthetised throughout the whole experiment, except in the case of trivial surgical experiments of less severity than superficial venesection, as set out in Annex II.

5. Special authorization may be given for dispensation with the Anaesthesia Condition where the application of anaesthesia would frustrate the object of the experiment. No such dispensation shall be given in the case of a surgical experiment. Where dispensation is granted, the experiment shall remain subject to the Pain Condition (Article 5).

6. "Properly anaesthetised" means deprived of sensation by methods of anaesthesia (whether local or general) at least as effective as those used in good veterinary practice.

7. "Humanely killed" means the killing of an animal with a minimum of physical and mental suffering appropriate to the species.

Annex IV

The "Pain Condition"

1. Where in accordance with the provisions of this Directive an animal is not properly anaesthetised, it shall not be subjected to pain; distress or equivalent suffering which is of more than momentary duration.

2. Exemptions from the Pain Condition may be granted by the responsible authority in the case of :

   (i) any emergency presenting an imminent threat to public health;

   (ii) tests and investigations necessary for compliance with requirements of regulatories bodies; and

   (iii) specific research projects where the responsible authority, having taken advice in accordance with Article 5(3), deems the research to be of sufficient value and importance to justify the exemption.

3. Where such an exemption has been granted, an experiment shall be conducted only under constant veterinary surveillance and if the veterinarian exercising constant surveillance considers that an animal is suffering severely (whether or not in consequence of the experiment, he and the person or persons authorized to conduct the experiment shall ensure that

   (i) the animal is given immediate relief by the administration of analgesics or other appropriate and effective treatment; or

   (ii) it is immediately killed by a humane method.

Annex V

Measures to be taken at the end of an experiment

1. At the end of any experiment, it shall be decided whether the animal shall be kept alive or killed by a humane method, 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.

2. The decisions referred to in paragraph 1 of Annex III shall be taken by a veterinarian.

3. Where at the end of an experiment :

   (a) an animal is to be kept alive, it shall receive the care appropriate to its state of health and be placed under the supervision of a veterinarian or other competent person and shall be kept under conditions conforming to the requirements of Article 4. The conditions laid down in this sub-paragraph may, however, be waived where, in the opinion of a veterinarian, the animal would not suffer as a consequence of such exemption;

   (b) an animal is not to be kept alive or cannot benefit from the provisions of Article 4 for its well-being, it shall be killed by a humane method as soon as possible.

4. No animal which has been used in a experiment entailing severe or enduring pain or suffering, irrespective of whether an anaesthetic or an analgesic was employed, shall be used in a further experiment.

Annex VI

Information (Article 9)

Information shall be collected in respect of :

a) the number and kinds of animals used in experiments;

b) the number of animals by category, used in experiments directly concerned with medicine and in teaching and learning;

c) the number of animals by category, used in experiments for the protection of man and his environment;

d) the number of animals by category, used in experiments required by legislation.