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Explanatory Report to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes [*]

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I. The European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, drawn up within the Council of Europe, by the *ad hoc* Committee of Experts on the Protection of Animals, and adopted by the Committee of Ministers, was opened for signature by the member states of the Council of Europe on 18 March 1986.

II. The text of the explanatory report prepared on the basis of that committee's discussions and submitted to the Committee of Ministers of the Council of Europe does not constitute an instrument providing an authoritative interpretation of the text of the Convention although it may facilitate the understanding of the Convention's provisions.

Introduction

1. The member States of the Council of Europe have already drawn up several international conventions in the sphere of animal protection following initiatives by the Consultative Assembly, which adopted a series of recommendations in this field from 1961 on. [(1)]

These texts include Recommendation 621 on the problems arising out of the use of live animals for experimental or industrial purposes, adopted on 20 January 1971; in it the Assembly particularly recommends the Committee of Ministers to give a commission terms of reference "to draft international legislation setting out the conditions under which, and the scientific grounds on which, experiments on live animals may be authorised".

(*) The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

(1) Mention should be made in particular of the following:
– Recommendation 287 (1961) on the international transit of animals;
– Recommendation 620 (1971) on the problems of animal welfare in industrial stock-breeding;
– Recommendation 621 (1971) on the problems arising out of the use of live animals for experimental or industrial purposes:
– Recommendation 641 (1971) on animal welfare in intensive rearing;
– Recommendation 709 (1973) on slaughter methods for meat animals;
– Recommendation 923 (1981) on the ill-treatment of horses during international transport.
As regards the conventions drawn up in the Council of Europe in the field of animal protection, mention may be made of the:
- European Convention for the Protection of Animals during International Transport (1968);
- European Convention for the Protection of Animals kept for Farming Purposes (1976);
- European Convention for the Protection of Animals for Slaughter (1979);
- Convention on the Conservation of European Wildlife and Natural Habitats (1979).

2. On receipt of this recommendation and after having obtained the opinion of its Committee of Experts on the Protection of Animals on what action should be taken on it, the Committee of Ministers decided to include the question in the Council of Europe's intergovernmental programme of activities. The Committee of Experts on the Protection of Animals was simultaneously instructed to draw up a convention for the protection of animals for slaughter (proposed in Assembly Recommendation 709 (1973)) and a convention on the use of live animals for experimental purposes.

3. After the draft of the first of these two conventions had been finalised by the Committee of Experts in June 1977 and forwarded to the Committee of Ministers, work was begun in January 1978 on the draft convention on the use of live animals for experimental purposes.

The committee, which in January 1977 had become the *ad hoc* Committee of Experts for the Protection of Animals (CAHPA), consists of senior civil servants and researchers who are mostly qualified in veterinary medicine and come from, or are delegated by, their national ministries responsible for the protection of animals used in experiments (mainly ministries of agriculture, health, environment and the interior).

Under the chairmanship of, successively, MM. G. Vallier (France), G. Pratt (United Kingdom) and S. Erichsen (Norway) and the vice-chairmanship of MM. J.J. Siegrist (Switzerland), C.J. Kjaersgaard (Denmark), A. Steiger (Switzerland) and H. Rozemond (Netherlands) the *ad hoc* committee has devoted ten plenary meetings to work on drawing up the draft convention as well as several meetings of small working parties.

4. For the purpose of drawing up the draft convention, the *ad hoc* committee has attempted to gather a maximum of information and get to know as many points of view as possible concerning the various aspects of the problem. For instance, it has acquainted itself not only with current and pending legislation in several European countries but also with primarily scientific studies relevant to its work. It also had the advantage of contributions from observers admitted to its meetings - from the United States of America and the Commission of the European Communities as well as from several non-governmental organisations (World Society for the Protection of Animals, Federation of Veterinarians of the EEC, European Federation of Pharmaceutical Industries' Associations, International Council for Laboratory Animal Science).

5. The draft convention was approved by the CAHPA and transmitted to the Committee of Ministers on 29 April 1983.

As decided by the Committee of Ministers, a meeting of technical experts chaired by Mr S. Erichsen (Norway) took place on 7 March 1985 to prepare the final examination of the draft convention by the Committee of Ministers.

6. The Committee of Ministers adopted the text of the Convention on 31 May 1985.

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Comments on certain provisions of the Convention

Preamble

7. The preamble defines the guiding principles which underlie the drafting of the different articles of the Convention. The states signatories to the Convention, while accepting the need to use animals for experimental and other scientific purposes, recognise that everything possible should be done to limit such use with the ultimate aim of replacing such experiments, in particular by alternative methods. The provisions of the Convention are designed to help the signatory states to harmonise the introduction of national schemes to guarantee that animals are treated properly and humanely and that where procedures which may possibly cause pain, suffering, distress or lasting harm to an animal are unavoidable, they are kept to a minimum.

PART I – General principles

Article 1

Paragraph 1

8. This paragraph states the broad scope of the Convention.

Paragraph 2

9. This paragraph contains the precise definition of the various key terms used in the text of the Convention.

a. Animal

10. It was considered that widening the Convention's scope to cover animal species other than vertebrates was not justified at present. It was agreed to exclude foetal forms from the Convention's scope in order to overcome the problem of using fertilised birds' eggs, since procedures on foetuses of viviparous species are carried out via the mother, which is covered by the Convention.

11. Larval forms capable of free life without any foetal or maternal appendices and/or capable of reproduction are covered by the Convention, principally to bring the tadpole and the axolotl within its scope.

b. Intended for use

12. The Convention's scope covers any animal being used or intended for use in a procedure, that is, before, during and after the procedure. However, the provisions of Article 5 and Appendix A: Guidelines for accommodation and care of animals, apply to all animals in registered breeding establishments, supplying establishments and user establishments even if some of these animals are not in fact being used in a procedure, such as, say, animals being used for controls and selected from among the animals intended for actual use in a procedure.

13. "Disposal" is designed to provide for an animal being given for use in a procedure without charge.

c. Procedure

14. The Convention lays down no absolute or arbitrary dividing lines to indicate what experimental or other scientific uses of animals cause so little pain, suffering, distress or lasting harm that they may be disregarded. It is not therefore possible to say in the Convention what minor uses would not be covered. It is up to the competent persons and responsible authorities designated by the parties to determine, on the basis of their knowledge of the animal, whether a use may cause pain, suffering, distress or lasting harm and so comes within the Convention's scope as a "procedure".

15. The breeding of animals with genetic abnormalities is not a procedure as long as the aim is only their propagation. Such animals, however, may have special requirements for their well-being. (See comments on Article 14 in this report.)

16. The use of tissues and organs taken from an animal already killed is not a procedure covered by the Convention; nor is the humane killing of an animal for that purpose.

e. Responsible authority

17. In drafting the Convention it was recognised that it would be difficult to specify how responsibility would be delegated and therefore it was left to the parties to specify at what level of competence this could be done.

f. Establishment

18. It is for the responsible authorities, as part of the registration process laid down in Articles 14 and 18, to decide which installations, buildings or group thereof or other premises constitute an establishment.

g. Breeding establishment

19. The fact that some animals, for which there is no intention that they should be used in a procedure, may be kept in a "breeding establishment" would not put an establishment outside this definition so long as there are, or are expected to be, animals bred in it which are intended for use in a procedure. An example of animals kept in such an establishment but not intended for a procedure would be the breeding parents themselves.

h. Supplying establishment

20. If an animal which is intended for use in procedures is received at an establishment where animals are bred with a view to their use in procedures, it can no longer be classed only as a breeding establishment and so comes within the above definition. It follows that animals which have been either acquired or bred on the premises may be supplied from a supplying establishment.

i. User establishment

21. An establishment is not outside the terms of this definition by virtue of the fact that it holds animals which are neither intended, nor in the event used, for procedures. The essential qualification is that it is an "establishment" where animals are used. In Article 22, it is required that in user establishments "only animals supplied from registered breeding or supplying establishments shall be used" (with provisions for exceptions as so described); but if animals are bred at the "user establishment" for the needs of persons working there, it must also be registered as a "breeding establishment". Similarly, if, in a user establishment, a practice of breeding or otherwise supplying animals for use in other user establishments is being made, it must be registered as a breeding or supplying establishment or both, as the case may be;

otherwise the person acquiring the occasional surplus animal from a user establishment must secure a special exemption as provided for in Article 22.

Article 2

22. This article sets out the permissible purposes for which procedures may be performed on animals. No procedures may be performed on an animal unless they conform to one or more of these purposes.

Paragraph a

23. Both "avoidance" and "prevention" are mentioned in order to make clear the range of activities which are covered. The steps taken to avoid disease, etc., are not necessarily the same as those taken to prevent it.

24. The term "abnormality" is used to embrace all undesirable physical or mental conditions affecting men, vertebrate and invertebrate animals and physical conditions affecting plants.

25. The term "their effects" is governed by the opening words "the avoidance or prevention of"; therefore one of the approved purposes is the avoidance or prevention of the effects of disease, etc. It may be sought to deal with a side-effect of a disease or other undesirable condition without any intention to deal with the disease, etc. itself, for example the drugs produced to deal with the pain resulting from cancer without any intention that they should cure the cancer itself. Similarly the diagnosis or treatment of the effects of disease, etc. is a legitimate purpose under sub-paragraph ii.

26. Vertebrate and invertebrate animals are mentioned because, although the Convention is directed only towards vertebrate animals, this paragraph is aimed at improving the well-being not only of man but of all forms of animal life and indeed plant life as well.

27. The word "production" is included to make clear that production of a drug, biological product, etc., would on its own be a valid purpose, even though it would also be the normal outcome of successful safety testing.

Paragraph c

28. "Environment" does not necessarily mean only the natural environment; measures aimed at protecting the man-made environment could also, subject to the discretion of each party, be a legitimate purpose.

Paragraph d

29. "Scientific research" means both applied scientific research and fundamental research. It includes, for example, the study of animal behaviour.

Paragraph e

30. Education and training qualify as legitimate purposes for performing procedures subject to the provisions of Article 25.

Paragraph f

31. This provision allows the use of animals in procedures designed to assist courts of law in their duties.

32. The permissible purposes, listed in this article, also cover:

- the prolongation or saving of life of man, vertebrate or invertebrate animals or plants;
- the production and quality control of foodstuffs;
- the breeding of vertebrate or invertebrate animals.

33. The listing of purposes in Article 2 does not exempt the user or any other responsible person or authority from the responsibility to weigh the possible gains which may result from the procedure against the stress placed on the animal. If the stress is judged to be out of proportion to the expected gain, the procedure should not be carried out.

Article 3

34. The Convention does not go into detail as to how all its provisions should be enforced, as this is for the individual parties to decide in the light of their own national needs, organisation and arrangements.

35. "Control and" is inserted before "supervision" because the word "supervision" alone does not necessarily imply that action would be taken as a result of it, and clearly action must follow when appropriate.

Article 4

36. This article permits individual parties to adopt further measures for the protection of animals where it is considered necessary or desirable in their own national situations.

PART II – General care and accommodation

Article 5

Paragraph 1

37. Even under optimum conditions, using an animal in a procedure or keeping it with a view to such use, restricts the extent to which it can satisfy its physiological and ethological needs; this cannot be denied. The article does however draw attention to the duty to do everything possible to ensure animals' well-being under the conditions in which they have to be kept. Appendix A provides detailed guidelines for the accommodation and care of animals.

Paragraph 2

38. This paragraph refers to those environmental conditions which are of immediate importance for the well-being of animals. The Convention does not specify the means by which the daily checks on environmental conditions should be conducted. It does not therefore rule out the use of automatic checks, but it would require some means of ensuring that the automatic surveillance itself was functioning properly, such as a "failsafe" system.

PART III – Conduct of procedures

Article 6

39. Article 6 lays down one of the restrictions referred to in Article 2: a procedure shall not be carried out if there are other ways and means to obtain the same results. Apart from the alternative methods advocated in the second paragraph of this article, Article 29 provides for recognition of procedures carried out on the territory of another party; this could be efficiently realised through the establishment of data banks which would permit general access to information concerning the results of procedures already carried out.

40. The decision whether a procedure is indispensable shall be based in particular on the applicable state of scientific knowledge.

Article 7

41. Nothing in this article is intended to conflict with national legislation for the protection of endangered species. It lays emphasis on some essential considerations which should be taken into account to reduce the number of animals used and to reduce the pain, suffering, distress or lasting harm to a minimum.

Article 8

42. Article 8 excludes procedures without an anaesthetic, etc., except in cases where the administration of such an anaesthetic would be more painful than the procedure itself, or "incompatible with the aim of the procedure".

In the latter case, appropriate legislative or administrative measures must be taken to prevent such procedures from being carried out unnecessarily. These measures may include:

- specific authorisation by the responsible authority;

- specific declaration of such procedures to the responsible authority and judicial or administrative action by that authority if it is not satisfied that the conditions set out above have been met.

43. Curare and substances having a similar effect shall not be regarded as anaesthetic or analgesic agents for the purposes of this article.

Article 9

44. Article 9 is based on the same considerations as Article 8: legislative and/or administrative measures must be taken to prevent unnecessary experiments which cause severe pain to an animal. In Article 9, however, these measures must include either compulsory declaration to, or specific authorisation by, the responsible authority. If the responsible authority is not satisfied that the painful procedure is of sufficient importance for meeting the essential needs of man or animal, including the solution of scientific problems, it must either take judicial or administrative action on the declaration, or not authorise the procedure.

Article 11

Paragraph 1

45. The requirements of this paragraph must not be understood as allowing the animal to be kept under permanent anaesthesia or analgesia. The animal must be killed by a humane method where it is likely to suffer lasting pain or distress.

Paragraph 3.a

46. The second sentence of this paragraph must be understood as dealing with the case where the procedure does not cause distress after its performance, leaves no after-effects and therefore does not necessitate particular attention or care. An animal in good health after a procedure may possibly be used for purposes other than another procedure, so that it is taken outside the Convention's scope.

Paragraph 4

47. Paragraph 4 aims at ensuring that whenever an animal is to be used in a further procedure, it will not experience any severe pain or suffering.

This paragraph was drafted in the light of the following considerations. It was agreed that further procedures are not common, since it is recognised by scientists that the reactions of an animal that has already been the subject of a procedure cannot be considered as being absolutely representative. In further procedures, usually larger-sized animals are involved, mainly for economic reasons; to prohibit such procedures would therefore probably affect smaller establishments rather than the bigger establishments. It would not lead to a decrease of procedures, but to an increase of the number of animals used, with possible repercussions for the populations of certain of these animals which are taken from the wild.

Finally, it was considered that in most cases an animal that has been used in a procedure would anyhow be killed in a humane way, i.e. under general anaesthesia, where it would lose all its sensory awareness and never be aware of any effect if a second procedure were to be carried out on that animal.

Article 12

48. This article is designed to enable experiments to be carried out on animals in the wild, whether or not they have been returned to their natural habitats, for example, by fitting sensors to monitor physiological parameters. Obligations may also result from the Convention on the conservation of European wildlife and natural habitats.

49. It is recognised that once the animal has been released into the wild, it is not possible to implement the Convention's provisions relating to care and accommodation set forth in Article 5.

PART IV – Authorisation

Article 13

50. This article leaves arrangements for the authorisation to the parties. Whatever rule is adopted, however, the scientific competence of the persons concerned remains the express condition for granting such authorisation.

PART V – Breeding or supplying establishments

Article 14

51. Establishments which breed or supply animals for purposes other than for use in procedures but which may supply occasionally and in limited numbers animals for procedures would not need to be registered unless the responsible authority should decide otherwise for the object and purpose of the Convention.

52. Special consideration should be given by the responsible authority to breeding or supplying establishments where animals with genetic abnormalities may be bred or kept, bearing in mind that many of these animals require a particular standard of care and supervision for their well-being to be ensured.

Article 17

Paragraph 1

53. This article lays down special rules for dogs and cats. Such provisions are necessary because the number of animals used is greater than the number provided by specialised breeding establishments. Sources of supply can be very varied and control of them is aimed at preventing any illegal dealings.

54. Tattooing is the commonest method of marking, but any other effective technique is allowed which causes no more than minimal discomfort.

Article 20

55. Next to the general conditions for care given to and accommodation provided for each animal which is or will be involved in a procedure, Article 20 lays down additional conditions for the supervision of animals in user establishments by adequate staff.

To this end, the article requires that in user establishments the administrative responsibilities be clearly defined (sub-paragraph *a*), that sufficient trained staff be employed (sub-paragraph *b*), that, when needed, veterinary advice and treatment be at hand (sub-paragraph *c*) and, finally, that a competent person supervise the well-being of the animals (sub-paragraph *d*).

This competent person, who should preferably be a veterinarian and who could be defined as an "animal protection officer" should, among other tasks:

- ensure that regulations, stipulations and orders pertaining to animal protection are being observed;

- provide advice to user establishments and to persons engaged in procedures and the care of the animals intended for use;

- give his opinion on each application for authorisation of a procedure;

- work within the establishment for the development and introduction of methods and ways to avoid or limit procedures.

PART VI – User establishments

Article 21

Paragraph 1

56. Most of the species listed in this article are nowadays bred commonly and extensively for use in procedures, so that researchers have a sufficient number of those species available in breeding establishments. Dogs and cats are included to give these specially regarded animals additional protection.

Paragraph 3

57. For the purposes of paragraph 3 a stray animal is defined as an animal of a domesticated species which is found wandering and whose owner has not yet been identified or is unidentifiable, or is non-existent, whether or not the animal has been impounded.

Article 22

58. This article recognises the need to use animals of known origin. The reasons are to reduce the number of animals required, to avoid illegal acquisition and to preserve rare and endangered species; it is also the surest way of obtaining healthy animals which are already adapted to life in laboratory conditions and will therefore be less distressed. However, it is not always possible to use purpose-bred animals; hence the possibilities of acquiring animals from registered supplying establishments and of allowing exceptions, which should however be as few as possible.

59. Each party may make its own arrangements for granting exceptions.

Article 23

60. Sometimes it may be necessary to carry out procedures on an animal which is not kept in a user establishment, for example for field studies. Such circumstances are however rare and must be subject to special authorisation.

PART VII – Education and training

Article 25

Paragraph 1

61. Article 25 allows, under certain conditions, procedures to be carried out in education programmes and curricula and training programmes which are directed to preparing for professional activities involving the performance of procedures or the treatment or care of animals.

62. The phrase "including the care of animals being used or intended for use in procedures" is made only for the avoidance of doubt: it makes clear that this article deals with the special measures for the protection of animals in all courses of training, whereas Article 26 is designed to persuade the parties to provide suitable training in the care of animals.

63. The obligation to notify the procedures only to the responsible authority (as defined in Article 1.2.*e*) is designed to meet the different national policies towards controlling the content of curricula. Some states exercise a direct central control over curricula; others leave the content of courses to the academic institutions themselves. Either practice will satisfy the requirements of this article. Separate authorisation of each procedure is not required.

Paragraph 2

64. No procedures may be carried out in education and training for careers which do not involve the performance of procedures, or the treatment or care of animals.

Paragraph 3

65. This paragraph emphasises the importance of justifying the need to perform procedures on live animals as an essential and unavoidable part of the education or training concerned, before they shall be allowed. This special test of need is necessary in the context of activities not themselves directly aimed at one of the other justifying purposes of Article 2. As part of the test of absolute need, the scope for using alternative teaching methods must always be fully explored and considered. The ultimate decision whether or not to accept the procedure rests with the responsible authority, but in practice the judgement is likely to have to be made by the teacher or instructor concerned.

Article 26

66. The phrase "adequate education and training" is to be interpreted as meaning education and training appropriate for the task at hand.

PART VIII – Statistical information

Articles 27 and 28

67. Reference is made to Appendix B to the Convention.

PART IX – Recognition of procedures carried out in the territory of another Party

Article 29

Paragraph 1

68. This paragraph sets out the purpose and aim of the article and recognises that practicability is the keystone of achieving the aim.

Paragraph 2

69. This paragraph acknowledges that national legislation may debar the exchange of some information.

70. It was not considered useful at this stage to provide in the Convention for the setting up of a central data bank on the use of live animals in research and testing and on the use of *in vitro* and other alternative methods.

It was found, on the one hand, that there is no dearth of data banks and data bases covering the bio-medical field, many of which are accessible to individuals, institutions and organisations directly through new terminals or libraries or institutions which can offer such services. On the other hand, most of these data banks are privately owned and cannot be centralised through simple regulations.

PART X – Multilateral consultations

Article 30

71. It was recognised that the aims of the Convention would be more easily achieved if the representatives of the parties had the possibility of meeting regularly, either to monitor the implementation of the provisions, to adapt the Convention to changing circumstances and new scientific evidence, or to develop common and co-ordinated programmes in the field covered by the Convention.

To avoid the setting up of yet another new intergovernmental body for the purpose, it was preferred to provide for the possibility of the parties being convened at regular intervals to hold multilateral consultations within the existing structures of the Council of Europe.

PART XI – Final provisions

Articles 31 – 37

72. In general, these provisions follow the model final clauses adopted by the Committee of Ministers of the Council of Europe for Conventions and Agreements drawn up within the Organisation.

Article 34 – Reservations

73. This article sets out the conditions under which reservations can be made. It is provided that no reservation may be made in respect of Articles 1-14 or Articles 18-20.