

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 23 March 1998

concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes

(1999/575/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a, in conjunction with Article 228(2) and (3), first subparagraph, thereof,

Having regard to the proposal from the Commission⁽¹⁾,

Having regard to the opinion of the European Parliament⁽²⁾,

Having regard to the opinion of the Economic and Social Committee⁽³⁾,

(1) Whereas on 24 November 1986 the Council adopted Directive 86/609/EEC⁽⁴⁾ on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, setting out common rules incorporating the principles, objectives and main provisions of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes;

(2) Whereas the provisions of the said Directive and Convention affect the conditions of production and placing on the market of products and substances the development of which involves the experiments referred to therein; whereas those provisions therefore contribute to the establishment and functioning of the internal market, the completion of which constitutes one of the chief objectives of the Community;

(3) Whereas the use of primates for experimental and other scientific purposes carries the risk of suffering for those animals and therefore has to be reduced;

(4) Whereas the use of primates for experimental and other scientific purposes has led to the catching of primates in the wild, and whereas, this should be avoided whenever possible in view of the suffering and losses which can arise during catching and transport;

(5) Whereas the Fifth Environmental Action Programme aims at taking some positive steps towards a reduction of 50% in the use of animals for experimentation by the year 2000; whereas this target must not, however, stand in the way of the formulation and achievement of more ambitious objectives;

(6) Whereas the Community is stepping up its efforts to develop substitute methods and computer-aided simulation models, paying particular attention to the work carried out by the European Centre for the validation of alternative methods (ECVAM), so that the goal of reducing experiments on animals may be achieved in the near future;

(7) Whereas the Community also endorses all projects that encourage a full and uncomplicated exchange of data on the use of animals in experiments and prescribe that unnecessary duplicate experiments must be avoided *inter alia* by rules for second applicants;

(8) Whereas the Community signed the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes on 10 February 1987;

⁽¹⁾ OJ C 200, 5.8.1989, p. 8.

⁽²⁾ OJ C 291, 20.11.1989, p. 43 and OJ C 269, 16.10.1995, p. 38.

⁽³⁾ OJ C 329, 30.12.1989, p. 10.

⁽⁴⁾ OJ L 358, 18.12.1986, p. 1.

(9) Whereas it is necessary for the Community to approve the said Convention,

Secretary-General of the Council of Europe, as provided for in Article 31 of the Convention.

HAS DECIDED AS FOLLOWS:

2. When depositing the instrument of approval, the designated person or persons shall, in accordance with Article 34(1) of the Convention, make the reservation set out in Annex B to this Decision.

Article 1

The Community shall approve the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, subject to a reservation in respect of Article 28(1) thereof.

Article 3

This Decision shall be published in the *Official Journal of the European Communities*.

The text of the Convention is set out in Annex A.

Done at Brussels, 23 March 1998.

The text of the reservation is set out in Annex B.

Article 2

1. The President of the Council is hereby authorised to designate the person or persons empowered to deposit the instrument of approval of the Convention with the

For the Council
The President
M. MEACHER

TRANSLATION

ANNEX A

**EUROPEAN CONVENTION FOR THE PROTECTION OF VERTEBRATE ANIMALS USED FOR
EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES****Preamble**

THE MEMBER STATES OF THE COUNCIL OF EUROPE, SIGNATORY HERETO,

Recalling that the aim of the Council of Europe is to achieve a greater unity between its members and that it wishes to cooperate with other States in the protection of live animals used for experimental and other scientific purposes;

Recognising that man has a moral obligation to respect all animals and to have due consideration for their capacity for suffering and memory;

Accepting nevertheless that man in his quest for knowledge, health and safety has a need to use animals where there is a reasonable expectation that the result will be to extend knowledge or be to the overall benefit of man or animal, just as he uses them for food, clothing and as beasts of burden;

Resolved to limit the use of animals for experimental and other scientific purposes, with the aim of replacing such use wherever practical, in particular by seeking alternative measures and encouraging the use of these alternative measures;

Desirous to adopt common provisions in order to protect animals used in those procedures which may possibly cause pain, suffering, distress or lasting harm and to ensure that where unavoidable they shall be kept to a minimum,

HAVE AGREED AS FOLLOWS:

PART I

General principles*Article 1*

1. This Convention applies to any animal used or intended for use in any experimental or other scientific procedure where that procedure may cause pain, suffering, distress or lasting harm. It does not apply to any non-experimental agricultural or clinical veterinary practice.

2. In this Convention:

(a) 'animal', unless otherwise qualified, means any live non-human vertebrate including free-living and/or reproducing larval forms, but excluding other foetal or embryonic forms;

(b) 'intended for use' means bred or kept for the purpose of sale, disposal or use in any experimental or other scientific procedure;

(c) 'procedure' means any experimental or other scientific use of 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 conditions, but excluding the least painful methods accepted in modern practice (that is 'humane' methods) of killing or marking an animal. A procedure starts when an animal is first prepared for use and ends when no further observations are to be made for that procedure; 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;

(d) 'competent person' means any person who is considered by a Party to be competent in its territory to perform the relevant function described in this Convention;

(e) 'responsible authority' means, in the territory of a given Party, any authority, body or person designated for the relevant purpose;

- (f) 'establishment' means any stable or mobile facility, any building, group of buildings or other premises, including a place which is not wholly enclosed or covered;
- (g) 'breeding establishment' means any establishment where animals are bred with a view to their use in procedures;
- (h) 'supplying establishment' means any establishment, other than a breeding establishment, from which animals are supplied with a view to their use in procedures;
- (i) 'user establishment' means any establishment where animals are used in procedures;
- (j) 'humane method of killing' means the killing of an animal with a minimum of physical and mental suffering appropriate to the species.

Article 2

A procedure may be performed for one or more of the following purposes only and subject to the restrictions laid down in this Convention:

- (a) (i) 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, efficacy and safety testing of drugs, substances or products;
- (ii) diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, vertebrate or invertebrate animals or plants;
- (b) detection, assessment, regulation or modification of physiological conditions in man, vertebrate and invertebrate animals or plants;
- (c) protection of the environment;
- (d) scientific research;
- (e) education and training;
- (f) forensic inquiries.

Article 3

Each Party undertakes to take all the necessary steps to give effect to the provisions of this Convention and to ensure an effective system of control and supervision as soon as possible and in any case within a period of five years from the date of entry into force of the present Convention in respect of that Party.

Article 4

No provision in this Convention shall affect the liberty of the Parties to adopt stricter measures for the protection of animals used in procedures or for the control and restriction of the use of animals in procedures.

PART II

General care and accommodation

Article 5

1. Any animal used or intended for use in a procedure shall be provided with accommodation, an environment, at least a minimum degree of freedom of movement, food, water and care, appropriate to its health and well-being. Any restriction on the extent to which an animal can satisfy its physiological and ethological needs shall be limited as far as practicable. In the implementation of this provision, regard should be paid to the guidelines for accommodation and care of animals set out in Appendix A to this Convention.

2. The environmental conditions in which animals are bred, kept or used shall be checked daily.

3. The well-being and state of health of animals shall be observed sufficiently closely and frequently to prevent pain or avoidable suffering, distress or lasting harm.

4. Each Party shall determine arrangements to ensure that any defect or suffering discovered is corrected as quickly as possible.

PART III

Conduct of procedure

Article 6

1. A procedure shall not be performed for any of the purposes referred to in Article 2, if another scientifically satisfactory method, not entailing the use of an animal, is reasonably and practicably available.

2. Each Party should encourage scientific research into the development of methods which could provide the same information as that obtained in procedures.

Article 7

When a procedure has to be performed, the choice of species shall be carefully considered and, where required, be explained

to the responsible authority; in a choice between procedures, those should be selected 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.

Article 8

A procedure shall be performed under general or local anaesthesia or analgesia or by other methods designed to eliminate as far as practicable pain, suffering, distress or lasting harm, applied throughout the procedure unless:

- (a) the pain caused by the procedure is less than the impairment of the animal's well-being caused by the use of anaesthesia or analgesia; or
- (b) the use of anaesthesia or analgesia is compatible with the aim of the procedure. In such cases, appropriate legislative and/or administrative measures shall be taken to ensure that no such procedure is carried out unnecessarily.

Article 9

1. Where it is planned to subject an animal to a procedure in which it will or may experience severe pain which is likely to endure, that procedure must be specifically declared and justified to, or specifically authorised by, the responsible authority.

2. Appropriate legislative and/or administrative measures shall be taken to ensure that no such procedure is carried out unnecessarily.

Such measures shall include:

- either specific authorisation by the responsible authority,
- or specific declaration of such procedure to the responsible authority and judicial or administrative action by that authority if it is not satisfied that the procedure is of sufficient importance for meeting the essential needs of man or animal, including the solution of scientific problems.

Article 10

During a procedure, an animal used shall remain subject to the provisions of Article 5 except where those provisions are incompatible with the objective of the procedure.

Article 11

1. At the end of a procedure it shall be decided whether the animal shall be kept alive or killed by a humane method. An animal 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 this Article shall be taken by a competent person, in particular a veterinarian, or the person who, in accordance with Article 13, is responsible for, or has performed, the procedure.

3. Where, at the end of a procedure:

- (a) an animal is to be kept alive, it shall receive the care appropriate to its state of health, be placed under the supervision of a veterinarian or other competent person and kept under conditions conforming to the requirements of Article 5. The conditions laid down in this subparagraph 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 5 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 procedure entailing severe or enduring pain or suffering, irrespective of whether anaesthesia or analgesia was employed, shall be used in a further procedure unless it has returned to good health and well-being, and either:

- (a) the further procedure is one in which the animal is subject throughout to general anaesthesia which is to be maintained until the animal is killed; or
- (b) the further procedure will involve minor interventions only.

Article 12

Notwithstanding the other provisions of this Convention, where it is necessary for the legitimate purposes of the procedure, the responsible authority may allow the animal concerned to be set free provided that it is satisfied that the maximum practicable care has been taken to safeguard the animal's well-being. Procedures that involve setting the animal free shall not be permitted solely for educational or training purposes.

PART IV

Authorisation

Article 13

A procedure for the purposes referred to in Article 2 may be carried out only by persons authorised, or under the direct

responsibility of a person authorised, or if the experimental or other scientific project concerned is authorised in accordance with the provisions of national legislation. Authorisation shall be granted only to persons deemed to be competent by the responsible authority.

PART V

Breeding or supplying establishments

Article 14

Breeding and supplying establishments shall be registered with the responsible authority subject to the grant of an exemption under Article 21 or Article 22. Such registered establishments shall comply with the requirements of Article 5.

Article 15

The registration provided for in Article 14 shall specify the person in charge of the establishment, who shall be competent to administer or arrange for suitable care for animals of the species bred or kept in the establishment.

Article 16

1. Arrangements shall be made at registered breeding establishments to record, in respect of the animals bred there, the number and species of such animals leaving, the dates they leave and the name and address of the recipient.

2. Arrangements shall be made at registered supplying establishments to record the number and species of such animals entering and leaving, the dates of these movements, from whom the animals concerned were acquired and the name and address of the recipient.

3. The responsible 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 paragraphs 1 and 2 of this Article; such records shall be kept for a minimum of three years from the date of the last entry.

Article 17

1. Each dog and cat in an establishment shall be individually and permanently marked in the least painful manner possible before it is weaned.

2. Where an unmarked dog or cat is taken into an establishment 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 to another before it is weaned and it is not practical to mark it beforehand, a full documentary record, specifying in particular its mother, shall be kept until it can be marked.

4. Particulars of the identity and origin of each dog or cat shall be entered in the records of the establishment.

PART VI

User establishments

Article 18

User establishments shall be registered with or otherwise approved by the responsible authority and shall comply with the conditions laid down in Article 5.

Article 19

Provisions shall be made at user establishments for installations and equipment appropriate for the species of animals used and the performance of the procedures conducted there. The design, construction and functioning of such installations and equipment shall be such as to ensure that the procedures are performed as effectively as possible, with the object of obtaining consistent results with the minimum number of animals and the minimum degree of pain, suffering, distress or lasting harm.

Article 20

In user establishments:

- (a) the person or persons who are administratively responsible for the care of the animals and the functioning of the equipment shall be identified;
- (b) sufficient trained staff shall be provided;
- (c) adequate arrangements shall be made for the provision of veterinary advice and treatment;
- (d) a veterinarian or other competent person should be charged with advisory duties in relation to the well-being of the animals.

Article 21

1. Animals of the species listed below which are for use in procedures shall be acquired directly from or originate from registered breeding establishments, unless a general or special

exemption has been obtained under arrangements to be determined by the Party:

mouse:	mus musculus
rat:	rattus norvegicus
guinea pig:	cavia porcellus
golden hamster:	mesocricetus auratus
rabbit:	oryctolagus cuniculus
dog:	canis familiaris
cat:	felis catus
quail:	coturnix coturnix.

2. Each Party undertakes to extend the provisions of paragraph 1 of this Article to other species, in particular of the order of primates, as soon as there is a reasonable prospect of a sufficient supply of purpose-bred animals of the species concerned.

3. Straying animals of a domesticated species shall not be used in procedures. A general exemption made under the conditions of paragraph 1 of this Article may not extend to stray dogs and cats.

Article 22

In user establishments, only animals supplied from registered breeding or supplying establishments shall be used, unless a general or special exemption has been obtained under arrangements to be determined by the Party.

Article 23

Procedures may, where authorised by the responsible authority, be conducted outside user establishments.

Article 24

Arrangements shall be made at user establishments to maintain records and make them available as required by the responsible authority. In particular, these records shall be sufficient to meet the requirements of Article 27 and, in addition, show the number and species of all animals acquired, from whom they were acquired and their date of arrival.

PART VII

Education and training

Article 25

1. Procedures carried out for the purpose of education, training or further training for professions or other occupations, including the care of animals being used or

intended for use in procedures, must be notified to the responsible authority and shall be carried out by or under the supervision of a competent person, who will be responsible for ensuring that the procedures comply with national legislation under the terms of this Convention.

2. Procedures within the scope of education, training, or further training for purposes other than those referred to in paragraph 1 above shall not be permitted.

3. Procedures referred to in paragraph 1 of this Article shall be restricted to those absolutely necessary for the purpose of the education or training concerned and be permitted only if their objective cannot be achieved by comparably effective audio-visual or any other suitable methods.

Article 26

Persons who carry out procedures, or take part in procedures, or take care of animals used in procedures, including supervision, shall have had appropriate education and training.

PART VIII

Statistical information

Article 27

1. Each Party shall collect statistical information on the use of animals in procedures and this information shall where lawful be made available to the public.

2. Information shall be collected in respect of:

- (a) the numbers and kinds of animals used in procedures;
- (b) the numbers of animals in selected categories used in procedures directly concerned with medicine and in education and training;
- (c) the numbers of animals in selected categories used in procedures for the protection of man and the environment;
- (d) the numbers of animals in selected categories used in procedures required by law.

Article 28

1. Subject to requirements of national legislation relating to secrecy and confidentiality, each Party shall communicate every year to the Secretary-General of the Council of Europe information in respect of the items mentioned in paragraph 2 of Article 27, presented in the form set out in Appendix B to this Convention.

2. The Secretary-General of the Council of Europe shall publish the statistical information received from the Parties in respect of the items mentioned in paragraph 2 of Article 27.

3. Each Party is invited to communicate to the Secretary-General of the Council of Europe the address of its national authority from which information about more comprehensive national statistics may be obtained on request. Such addresses will be contained in the publications of statistics made by the Secretary-General of the Council of Europe.

PART IX

Recognition of procedures carried out in the territory of another Party

Article 29

1. In order to avoid unnecessary repetition of procedures required by law on health and safety, each Party shall, where practicable, recognise the results of procedures carried out in the territory of another Party.

2. To that end the Parties undertake, where practicable and lawful, to render each other mutual assistance, in particular by furnishing information on their legislation and administrative practice relating to the requirements for procedures to be carried out in support of submissions for registration of products, as well as factual information on procedures carried out in their territory and on authorisation or any other administrative particulars pertaining to these procedures.

PART X

Multilateral consultations

Article 30

The Parties shall, within five years from the entry into force of this Convention and every five years thereafter, or more frequently if a majority of the Parties should so request, hold multilateral consultations within the Council of Europe to examine the application of this Convention, and the advisability of revising it or extending any of its provisions. These consultations shall take place at meetings convened by the Secretary-General of the Council of Europe. The Parties shall communicate the name of their representative to the Secretary-General of the Council of Europe at least two months before meetings.

PART XI

Final provisions

Article 31

This Convention shall be open for signature by the Member States of the Council of Europe and by the European Communities. It is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval

shall be deposited with the Secretary-General of the Council of Europe.

Article 32

1. This Convention shall enter into force on the first day of the month following the expiration of a period of six months after the date on which four Member States of the Council of Europe have expressed their consent to be bound by the Convention in accordance with the provisions of Article 31.

2. In respect of a signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of six months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 33

1. After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may invite any State not a member of the Council to accede to this Convention, by a decision taken by the majority provided for in Article 20.d of the Statute of the Council of Europe and by the unanimous vote of the representatives of the Contracting States entitled to sit on the committee.

2. In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of six months after the date of deposit of the instrument of accession with the Secretary-General of the Council of Europe.

Article 34

1. Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance, approval or accession, make one or more reservations. No reservations may, however, be made in respect of Articles 1 to 14 or Articles 18 to 20.

2. Any Party which has made a reservation under the preceding paragraph may wholly or partly withdraw it by means of a notification addressed to the Secretary-General of the Council of Europe. The withdrawal shall take effect on the date of receipt of such notification by the Secretary-General.

3. A Party which has made a reservation in respect of a provision of this Convention may not claim the application of that provision by any other Party; it may, however, if its reservation is partial or conditional, claim the application of that provision in so far as it has itself accepted it.

Article 35

1. Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance, approval or accession, specify the territory or territories to which this Convention shall apply.

2. Any Party may at any later date, by a declaration addressed to the Secretary-General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration. In respect of such territory, the Convention shall enter into force on the first day of the month following the expiration of a period of six months after the date of receipt of such declaration by the Secretary-General.

3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary-General. The withdrawal shall become effective on the first day of the month following the expiration of a period of six months after the date of receipt of such notification by the Secretary-General.

Article 36

1. Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary-General of the Council of Europe.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at Strasbourg, this 18 March 1986 in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary-General of the Council of Europe shall transmit certified copies to each Member State of the Council of Europe, to the European Communities and to any State invited to accede to this Convention.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of six months after the date of receipt of the notification by the Secretary-General.

Article 37

The Secretary-General of the Council of Europe shall notify the Member States of the Council of Europe, the European Communities and any State which has acceded to this Convention of:

- (a) any signature;
- (b) the deposit of any instrument of ratification, acceptance, approval or accession;
- (c) any date of entry into force of this Convention in accordance with Articles 32, 33 and 35;
- (d) any other act, notification or communication relating to this Convention.

ANNEX B

RESERVATION IN RESPECT OF ARTICLE 28(1) OF THE CONVENTION FOR THE PROTECTION OF VERTEBRATE ANIMALS USED FOR EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES

In application of Article 34(1) of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, the European Community states that it does not consider itself bound by the requirements to communicate statistical data laid down in Article 28(1) of the said Convention.
