Protection of animals used for scientific purposes ***I

P6_TA(2009)0343


(Codecision procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0543),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0391/2008),

— having regard to Rule 51 of its Rules of Procedure,

— having regard to the report of the Committee on Agriculture and Rural Development and the opinions of the Committee on the Environment, Public Health and Food Safety and the Committee on Industry, Research and Energy (A6-0240/2009),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and the Commission.

P6_TC1-COD(2008)0211


(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

— Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

— Having regard to the proposal from the Commission ‡,†

— Having regard to the opinion of the European Economic and Social Committee (†),

— After consulting the Committee of the Regions ‡.

— Acting in accordance with the procedure laid down in Article 251 of the Treaty (‡),

Whereas:

(1) Animal welfare is a Community value that is enshrined in the Protocol on the protection and welfare of animals annexed to the Treaty.

(2) On 23 March 1998 the Council adopted Decision 1999/575/EC concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (1). By becoming a Party to that Convention, the Community acknowledged the importance of the protection and welfare of animals used for scientific purposes at international level.

(3) On 24 November 1986 the Council adopted Directive 86/609/EEC (2) in order to eliminate disparities between laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Since the adoption of that Directive, further disparities between Member States have emerged. Certain Member States have adopted national implementing measures that ensure a high level of protection of animals used for scientific purposes while others only apply the minimum requirements laid down in Directive 86/609/EEC. Accordingly, this Directive should provide for more detailed rules in order to reduce such disparities and to ensure a proper functioning of the internal market.


(5) New scientific knowledge is available on factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm. It is therefore necessary to improve the welfare of animals used in scientific procedures by raising the minimum standards for the protection of such animals in line with the latest scientific developments.

(6) It is desirable to include specific invertebrate species within the scope of this Directive, where there is scientific evidence of the potential ability of such species to experience pain, suffering, distress and lasting harm.

(7) This Directive should also cover embryonic and foetal forms of vertebrate animals, in cases where there is scientific evidence showing that such forms in the last third of their development have an increased risk of experiencing pain, suffering and distress, which may also affect negatively their subsequent development. Scientific evidence has also shown that procedures on embryonic and foetal forms of species of mammals at an earlier stage of development could result in pain, suffering, distress or lasting harm, should the developmental forms be allowed to live beyond the first two thirds of their development.

(8) The use of live animals continues to be necessary to protect human health, animal health and the environment, within current scientific limitations. However this Directive represents an important step towards achieving the goal of the full replacement of procedures on live animals for scientific purposes as soon as it is scientifically possible to do so. To that end, this Directive seeks to facilitate and promote the advancement of alternative methods and to ensure a high level of protection for animals used in procedures. This Directive should be reviewed regularly in light of evolving scientific and animal protection measures.

(9) In light of scientific progress, the use of animal experiments remains an important means of ensuring a very high standard of research into public health.

The care and use of live animals for scientific purposes is governed by internationally established principles of replacement, reduction and refinement. To ensure that the way in which animals are bred, cared for and used in procedures in the Community is in line with that of the other international and national standards outside the Community, the replacement, reduction and refinement should be considered systematically when implementing this Directive. The Commission should ensure a high level of transparency in relation to the use of animals and in terms of reporting to the public on the implementation of animal protection measures and progress made towards replacing animal methods.

Animals have an intrinsic value in themselves which must be respected. There are also ethical concerns of the general public as regards the use of animals in procedures. Therefore, the animals should always be treated as sentient creatures and their use in scientific procedures should be restricted to areas which advance science and fundamental knowledge, since this may ultimately benefit e.g. human or animal health, or the environment. The use of animals in scientific procedures should therefore only be considered where a non-animal alternative is not available. Use of animals for scientific procedures in other areas under Community competence should be prohibited.

The principles of replacement, reduction and refinement should be implemented through a strict hierarchy of the requirement to use alternative methods. Where no alternative method is recognised by Community legislation, numbers of animals may be reduced by resorting to other methods which are reasonably and practically available, and by implementing testing strategies, such as use of in vitro and other methods that would reduce and refine the use of animals.

In accordance with the objectives of the Communication of 23 January 2006 from the Commission to the European Parliament and the Council ‘Community Action Plan on the Protection and Welfare of Animals 2006 – 2010’, the Commission should endeavour to promote the welfare of animals used for scientific purposes internationally, in particular by seeking promotion of the replacement, reduction and refinement of animal procedures through the World Organisation for Animal Health (OIE), and by seeking to add animal welfare standards to the criteria assessed in order to establish compliance with Good Laboratory Practice (GLP).

The choice of methods and the species to be used have a direct impact on both the numbers of animals used and their welfare. The choice of methods should therefore ensure the selection of the method that is able to provide most adequate results and likely to cause the minimum pain, suffering or distress. Such selected methods should use the minimum number of animals that would provide reliable results and choose the species with the lowest degree of neurophysiological sensitivity that are optimal for the extrapolation into target species.

The methods selected should avoid, as far as possible, death as an end-point due to severe suffering caused by the approaching death. Where possible, it should be substituted by more humane end-points using clinical signs that determine the impending death thereby allowing the animal to be killed by a humane method without any further suffering.

The use of inappropriate methods for killing an animal can cause significant pain, distress and suffering to the animal. The level of competence of the person carrying out this operation is equally important. Animals should therefore be killed only by a trained and authorised person using a humane method that is considered appropriate to the species.

It is necessary to ensure that the use of animals in procedures does not pose a threat to biodiversity. Therefore, the use of endangered species in procedures should be limited to a strict minimum to cover essential biomedical reasons as well as research aimed at the preservation of those species.
(18) With current scientific knowledge the use of non-human primates in scientific procedures is still necessary in biomedical research. Due to their genetic proximity to human beings and to their highly developed social skills, the use of non-human primates in scientific procedures raises specific ethical and practical problems in terms of meeting their behavioural, environmental and social needs in a laboratory environment. Furthermore, the use of non-human primates is of the highest concern to the public. Therefore the use of non-human primates should only be allowed in those essential biomedical areas for the benefit of human beings for which no other replacement alternative methods are yet available or for the preservation of the respective non-human primate species. Fundamental research in some areas of the biomedical sciences can provide important new information relevant, at some future stage, to many life-threatening and debilitating human conditions.

(19) The use of great apes, as the closest species to human beings with the most advanced social and behavioural skills, should only be allowed in research aimed at the preservation of those species and where action in relation to a life-threatening, debilitating condition endangering human beings is warranted, and no other species or alternative method could suffice for the aims of the procedure. The Member State claiming such a need should provide the necessary information for the Commission to take a decision.

(20) In order to gradually end the capturing of animals from the wild for breeding purposes, a thorough scientific study should be conducted as soon as possible on the feasibility of limiting the animals used to those from self-sustaining colonies. Establishments breeding and supplying non-human primates should therefore have a strategy in place to support and facilitate the progressive move towards that goal.

(21) There is a need for certain species of vertebrate animals used in procedures to be bred specifically for use in procedures so that their genetic, biological and behavioural background is well-known to persons undertaking the procedures. Such knowledge both increases the scientific quality and reliability of the results and decreases the variability, ultimately resulting in fewer procedures and reduced animal use. Furthermore, for reasons of animal welfare and conservation, the use of animals taken from the wild in procedures should be limited only to cases where the purpose of the procedures cannot be achieved using animals bred specifically for use in procedures.

(22) Since the background of stray and feral animals of domestic species is not known, and capture and placement into establishments increases distress for those animals, they should not be used in procedures.

(23) To enhance transparency, facilitate the project authorisation and provide tools for monitoring compliance, a severity classification of procedures should be introduced on the basis of estimated levels of pain, suffering, distress and lasting harm that is inflicted on the animals.

(24) From the ethical standpoint, there should be an upper limit of pain, suffering and distress, above which animals should not be subjected in scientific procedures. To that effect, the performance of procedures that result in severe pain, suffering or distress and which is likely to be prolonged, should not ordinarily be permitted. When developing a common format for reporting purposes, instead of the predicted severity at the time of the ethical evaluation, the actual severity experienced by the animal should be taken into account.

(25) The number of animals used in procedures could be reduced by performing procedures on animals more than once, where this does not detract from the scientific objective or result in poor animal welfare. However, the re-use of animals should be judged against minimising any adverse affects on their welfare, taking into account the lifetime experience of the individual animal. As a result of this potential conflict, the re-use of animals should be considered on a case-by-case basis and limited to only those procedures where the cumulative pain, distress and suffering are ethically justified.
At the end of an authorised procedure, the most appropriate decision should be taken with regard to the future of the animal on the basis of animal welfare and potential risks to the environment. The animals whose welfare would be compromised should be killed using a humane method. In some cases, animals should be set free or animals such as dogs and cats should be allowed to be re-homed in families as there is a high level of public concern as to the fate of such animals. Should establishments allow re-homing, it is essential that there is a scheme in place to provide the appropriate socialisation of those animals in order to promote successful re-homing as well as to avoid unnecessary distress to the animals and to guarantee public safety.

Animal tissue and organs are used for the development of in vitro methods. To implement the principle of reduction, it is desirable for Member States to establish programmes for sharing the organs and tissue of animals that are killed using humane methods.

The welfare of the animals used in procedures is highly dependent on the quality and professional competence of persons supervising procedures, as well as of those performing procedures or supervising those taking care of the animals on a daily basis. In order to secure an adequate degree of competence of persons dealing with animals and with procedures involving animals, such activities should only be performed in establishments, and by persons, authorised by the competent authorities. The main focus should be on obtaining and maintaining an adequate level of competence which should be demonstrated before authorising those persons or renewing their authorisation. Authorisation by a competent authority and proof of the successful completion of relevant training courses should be mutually recognised by all Member States.

Establishments should have adequate installations and equipment in place to meet the accommodation requirements of the animal species concerned and to allow the procedures to be performed efficiently and with the least distress both to the animals directly concerned and their animal companions. The establishments should operate only if they are authorised by the competent authorities.

To ensure the ongoing monitoring of animal welfare needs, appropriate veterinary care should be available at all times and a staff member should be made responsible for the care and welfare of animals in each establishment.

Animal welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. Each establishment should therefore have a permanent ethical review body in place with the primary task of focusing on ethical debate at establishment level, fostering a climate of care and providing tools for practical application and timely implementation of the recent technical and scientific developments in relation to the principles of replacement, reduction and refinement to enhance the life-time experience of the animals. The decisions of the permanent ethical review body should be properly documented and open to scrutiny during inspections.

In order to enable the competent authorities to monitor compliance with this Directive, each establishment should, where possible, maintain accurate records on the numbers of animals, their origins and fate.

Non-human primates with highly developed social skills, as well as dogs and cats, should have a personal history file from birth covering the duration of their lives in order to be able to receive the care, accommodation and treatment that meet their individual needs and characteristics.

The accommodation and care of the animals should be based on the specific needs and characteristics of each species.

On 15 June 2006 the Fourth Multilateral Consultation of Parties to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes adopted a revised Appendix A which sets out guidelines for accommodation and care of experimental animals. Commission Recommendation 2007/526/EC of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes (1) incorporated those guidelines.

(36) There are differences in the requirements for the accommodation and care of animals between Member States, which contribute to the distortion of the internal market. Furthermore, some of those requirements no longer reflect the most recent knowledge on the impacts of accommodation and care conditions on both the animal welfare and the scientific results of procedures. It is therefore necessary to establish in this Directive the minimum requirements on accommodation and care always to developments based on new scientific evidence.

(37) To monitor compliance with this Directive, Member States should carry out at least one inspection annually in each establishment. To ensure public confidence and promote transparency at least one inspection must be unannounced. Programmes for joint inspections by Member States should be established to foster an environment of sharing good practice and expertise.

(38) To assist the Member States in the enforcement of this Directive and on the basis of the findings in the reports on the operation of the national inspections, the Commission should, where appropriate, carry out controls of the national inspection systems. Member States should address any weaknesses identified in the findings of these controls.

(39) Comprehensive ethical evaluation of projects using animals, which forms the core of the project authorisation, should ensure implementation of principles of replacement, reduction and refinement in those projects.

(40) It is also essential to ensure both on moral and scientific grounds that each use of animals is carefully evaluated in terms of the scientific validity, usefulness and relevance of that use. The likely harm to the animals should be balanced against the expected benefits of the project. Therefore, an ethical evaluation, independent of those in charge of the study, should be carried out as part of the authorisation process of projects involving the use of live animals. Effective implementation of an ethical evaluation should also allow for an appropriate assessment of the use of any new scientific experimental techniques as they emerge.

(41) In certain cases, due to the nature of the project, the type of species used and the likelihood of achieving the desired objectives of the project, it might be necessary to carry out a retrospective assessment. Since projects may vary significantly in terms of complexity, length, as well as the delay for obtaining the results, it is necessary that the decision as to whether retrospective assessment should be carried out takes those aspects fully into account.

(42) To ensure that the public is informed, it is important that objective information on the projects using live animals is made publicly available. The format of such information should not violate proprietary rights or expose confidential information. Therefore, user establishments should provide the competent authority with data, which may be qualitative or quantitative, concerning the use of live animals and make such data publicly available.

(43) To manage risks to human and animal health and the environment, Community legislation provides that substances and products can only be marketed after appropriate safety and efficacy data have been submitted. Some of those requirements can be fulfilled only by resorting to animal testing, hereinafter referred to as ‘regulatory testing’. It is necessary to introduce specific measures in order to increase the use of alternative approaches and to eliminate unnecessary duplication of regulatory testing. For that purpose Member States should recognise the validity of test data produced using test methods provided for in Community legislation.

(44) To reduce the unnecessary administrative workload and enhance the competitiveness of Community research and industry, it should be possible to authorise multiple regulatory testing procedures under one group authorisation, albeit without exempting those procedures from ethical evaluation.
To ensure effective examination of authorisation applications and to enhance the competitiveness of Community research and industry, a time-limit should be set for the competent authorities to evaluate project proposals and take decisions on authorisation of those projects. In order not to compromise the quality of the ethical evaluation, additional time may be required for more complex project proposals due to the number of disciplines involved, the novel characteristics and more complex techniques of the proposed project. However, extension of deadlines for ethical evaluation should remain an exception.

The availability of alternative methods is highly dependent on the progress of the research into the development of alternatives. The Community Framework Programmes for Research and Technological Development have provided increasing funding for projects which aim to replace, reduce and refine the use of animals in procedures. Therefore, in order to increase competitiveness of research and industry in the Community, the Commission and the Member States should contribute to the development and validation of alternative approaches.

The European Centre for the Validation of Alternative Methods is established within the Joint Research Centre of the Commission and coordinates the validation of alternative approaches in the Community. However, there is an increasing need for new methods to be developed and proposed for validation. To provide the necessary mechanisms at Member State level, a reference laboratory for the validation of alternative methods should be designated by each Member State. Member States should designate reference laboratories which are accredited in accordance with Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (1) in order to ensure coherent and comparable quality of the results. In addition, the remit of the European Centre for the Validation of Alternative Methods should be extended to include the co-ordination and promotion of the development and use of alternatives to animal experiments.

There is a need to ensure a coherent approach to ethical evaluation and ethical review strategies at national level. Member States should establish national animal welfare and ethics committees to give advice to the competent authorities and permanent ethical review bodies of establishments in order to promote the principles of replacement, reduction and refinement. Therefore, the network of national animal welfare and ethics committees should play a role in the exchange of best practice at Community level.

The technical and scientific advancements in biomedical research can be rapid as can the increase in knowledge of factors influencing animal welfare. It is therefore necessary to provide for a review of this Directive. Such a review, based on the results of peer-assessed scientific studies, should examine possible replacement of the use of animals, and in particular non-human primates, as a matter of priority where it is possible, taking into account the advancement of science.

The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (2).

In particular, power should be conferred on the Commission to establish the criteria for classification of procedures and to adapt Annexes II to IX to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, inter alia by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

Directive 86/609/EEC should therefore be repealed.

(1) OJ L 50, 20.2.2004, p. 44.
Benefits to animal welfare from applying project authorisation retrospectively, and the related administrative costs, can only be justified for long term ongoing projects. Therefore, it is necessary to include transitional measures for ongoing short and medium term projects to avoid the need for a retrospective authorisation with only limited benefits.

Since the objectives of this Directive, namely the harmonisation of legislation on use of animals for scientific purposes, cannot be sufficiently achieved by the Member States and can therefore, by reason of scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I
GENERAL PROVISIONS

Article 1
Subject matter

This Directive establishes measures for the protection of animals used or intended to be used for scientific purposes.

To that end, it lays down rules on the following:

(1) the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures;

(2) the origin, breeding, marking, care and accommodation of animals;

(3) the functioning of breeding, supplying or user establishments;

(4) the evaluation and authorisation of projects involving the use of animals in procedures.

Article 2
Scope

1. This Directive shall apply to the accommodation and husbandry of animals used or intended to be used in procedures or where they are bred specifically so that their organs or tissues may be used for scientific purposes, and shall cover all uses of animals in procedures that are likely to cause them pain, suffering, distress or lasting harm.

Where there is any pain, suffering, distress or lasting harm, its elimination by the successful use of anaesthesia, analgesia or other methods shall not exclude the use of an animal in procedures from the scope of this Directive.

2. This Directive shall apply to the following animals:

(a) live non-human vertebrate animals, including independently feeding larval forms and embryonic or foetal forms of species of mammals as from the last third of their normal development;

(b) live invertebrate animals of those species of orders listed in Annex I.
3. This Directive shall apply to animals used in procedures, which are at an earlier stage of development than that referred to in point (a) of paragraph 2, if the animal is to be allowed to live beyond that stage of development and is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development.

4. **Other than the general checks on breeding facilities**, this Directive shall not apply to the following:

(a) non-experimental, agricultural or clinical veterinary practices and trials;

(b) practices undertaken for the purposes of recognised animal husbandry;

(c) practices undertaken for the primary purpose of marking an animal;

(d) practices that **do not cause pain, suffering, distress or lasting harm**.


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**Article 3**

**Definitions**

For the purposes of this Directive the following definitions shall apply:

1. 'procedure' means any use of an animal for experimental or other scientific purposes, with known or unknown outcome, which **may or may not** cause the animal pain, suffering distress or lasting harm and includes any course of action intended, or liable, to result in the birth of an animal in any such condition or in the creation of a new genetically modified animal line;

2. 'project' means a programme of work having a defined scientific objective and involving one or more procedures;

3. 'establishment' means any installation, building, group of buildings or other premises and may include a place that is not wholly enclosed or covered and mobile facilities;

4. 'breeding establishment' means any establishment where animals are bred with a view to their use in procedures or for the use of their tissue or organs for scientific purposes;

5. 'supplying establishment' means any establishment, other than a breeding establishment, from which animals are supplied with a view to their use in procedures or for the use of their tissue or organs for scientific purposes;

6. 'user establishment' means any establishment where animals are used in procedures;

7. 'competent authority' means the authority or authorities designated by each Member State as being responsible for supervising the enforcement of this Directive;

8. 'ethical approach' means the approach which precedes experimentation and consists of assessing the scientific and societal grounds for using animals, with reference to humankind’s duty to respect animals as living, sentient beings;

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(9) ‘competent person’ means any person who is considered by a Member State to be competent to perform the relevant function described in this Directive;

(10) ‘husbandry’ means all those activities required to breed and maintain phenotypically normal animals, whether for scientific or other purposes, but which do not themselves constitute experiments;

(11) ‘practice’ means any non-experimental activity or any scientific activity which does not constitute an experiment;

(12) ‘properly anaesthetised’ means deprived of sensation by means of anaesthesia, whether local or general, which is as effective as those used in good veterinary practice;

(13) ‘protocol’ means a series of procedures that constitute an experiment with a defined objective;

(14) ‘regulated procedure’ means any experimental or other scientific procedure, which is likely to have the effect of causing a protected animal pain, suffering, distress or lasting harm;

(15) ‘re-use’ means the use of an animal already used in a procedure, when a different animal on which no procedure has previously been carried out could also be used;

(16) ‘confidential information’ means information, the non-consensual release of which could prejudice the legitimate commercial or other interests of its owner or a third party.

Article 4

Replacement, reduction and refinement

1. Where a method of testing, experimentation or other scientific activity not involving the use of living animals exists which, from a scientific point of view, is a satisfactory method or testing strategy for obtaining the result sought and which may be used in place of a procedure, Member States shall ensure that the alternative method is used, provided it is not prohibited in the Member State concerned. Pursuant to this Directive, testing methods which involve the use of human embryonic and foetal cells shall not be regarded as alternatives, in other words the Member States may take their own ethical decisions concerning the use of these methods of testing.

2. Member States shall ensure that the number of animals used in projects is reduced to the minimum without compromising the objectives of the project.

3. Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.

4. Member States shall ensure that funding is provided for training and research on, and development and implementation of, scientifically satisfactory methods or testing strategies that do not entail the use of animals.

5. Member States shall ensure that the aim of paragraph 1 is pursued by the competent authority when considering the authorisation of projects.

6. Member States shall ensure that training is provided on the use of scientifically satisfactory methods or testing strategies that do not entail the use of animals, to appropriate persons and establishments, and promote such methods or testing strategies.
Article 5

Purposes of procedures

Procedures may be carried out for the following purposes only:

(1) basic research for the advancement of knowledge in biological or behavioural sciences;

(2) translational or applied research with any of the following aims:

(a) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;

(b) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants;

(c) the improvement of the production conditions and welfare of animals reared for agricultural purposes;

(3) the development, manufacture or testing of the quality, effectiveness and safety of drugs, food- and feed-stuffs and other substances or products having any of the aims referred to in point (2);

(4) the protection of the natural environment in the interests of the health or welfare of human beings or animals;

(5) the protection of human health in the context of workers’ or consumers’ exposure to chemicals;

(6) research aimed at preservation, health and welfare of the species;

(7) higher education or training;

(8) forensic inquiries.

Article 6

Humane methods of killing

1. Member States shall ensure that animals are killed in an authorised establishment, by an authorised person and with a minimum of pain, suffering and distress and, in relation to the species included in Annex VI, using an appropriate humane method of killing as set out in that Annex or by such other methods as are scientifically demonstrated to be at least as humane. Where a more humane method of killing is possible and readily available, it may be used even if it is not included in Annex VI.

However, for the purposes of a field study an animal may be killed in a place other than an authorised establishment.

2. Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification that the purpose of the procedure cannot be achieved by the use of a humane method of killing or that other methods providing better animal protection have been developed. Notwithstanding any exemption, animals shall be killed with a minimum of pain, suffering and distress.

3. Paragraph 1 shall not apply where an animal has to be killed in emergency circumstances for animal welfare reasons.

Member States shall determine the emergency circumstances referred to in the first subparagraph.
Article 7

National measures

This Directive shall not prevent Member States from applying or adopting stricter national measures seeking to improve the well-being and protection of animals used for scientific purposes.

Chapter II

Provisions on the use of certain animals in procedures

Article 8

Endangered species other than non-human primates

1. Endangered species listed in Annex A to Council Regulation (EC) No 338/97 (1) shall not be used in procedures, with the exception of those procedures meeting the following conditions:

(a) the procedure has one of the purposes referred to in points (2)(a), (3) or (6) of Article 5;

(b) there is a scientific justification that the purpose of the procedure cannot be achieved by the use of species other than those listed in that Annex;

(c) as far as possible, the animals used should be bred specifically for testing purposes.

2. This article shall not apply to any species of non-human primates.

Article 9

Non-human primates

1. Given their particularly high level of neurophysiological sensitivity and cognitive development, non-human primates shall not be used in procedures, with the exception of those procedures meeting the following conditions:

(a) the procedure has one of the purposes referred to in points (1), (2)(a), (3) or (6) of Article 5;

(b) the applicant provides a scientific and ethical justification that the purpose of the procedure cannot be achieved by the use of other species than non-human primates.

2. Notwithstanding paragraph 1, great apes shall not be used in procedures, subject to the use of the safeguard clause in Article 53.

3. Every two years, and for the first time ... (*), the Commission shall, in consultation with Member States, conduct a review of the use of non-human primates in procedures and publish the results thereof. The review shall examine the impact of developments in technological, scientific and animal-welfare knowledge, and set targets for the implementation of validated replacement methods.

Article 10

Animals taken from the wild

1. Animals taken from the wild shall not be used in procedures.


(*) Two years after the entry into force of this Directive.
Tuesday 5 May 2009

2. Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification that the purpose of the procedure cannot be achieved by the use of an animal which has been bred for use in procedures.

Article 11

Animals bred for use in procedures

1. The Commission shall carry out an animal welfare assessment and a feasibility evaluation of implementation of the requirements set out in subparagraphs 2 and 3; … (*).

Member States shall ensure that animals belonging to the species listed in Annex II may only be used in procedures where those animals have been bred for use in procedures.

Where feasibility is established, as from the dates to be set in Annex III in light of the evaluation referred to in subparagraph 1, Member States shall ensure that non-human primates listed in that Annex may only be used in procedures where they are sourced from self-sustaining colonies.

2. Competent authorities may grant exemptions from subparagraphs 2 and 3 of paragraph 1 on the basis of a veterinary justification for reasons of animal welfare or on the basis of a scientific justification.

Article 12

Stray and feral animals of domestic species

Stray and feral animals of domestic species shall not be used in procedures.

Article 13

Use of cadavers, tissue and organs of animals for training purposes

For higher education and training purposes, the cadavers, tissue and organs of animals may be used only if they come from animals slaughtered in accordance with the provisions of Council Regulation (EC) No 2928/2009 of … [on the protection of animals at the time of killing] (†).

CHAPTER III

PROCEDURES

Article 14

Procedures

1. Member States shall ensure that procedures are always carried out in establishments as defined in Article 3.

The competent authority may grant an exemption from the first subparagraph on the basis of scientific justification.

2. Procedures may be carried out only within the framework of a project.

(*) Five years after the entry into force of this Directive.
(†) OJ …
Article 15

Methods used in procedures

1. Member States shall ensure that a procedure is not carried out if another scientifically satisfactory method or testing strategy of obtaining the result sought, not entailing the use of an animal, is recognised by Community legislation. In the absence of such a method, a procedure may not be carried out if a scientifically satisfactory method or testing strategy for obtaining the result sought, including computer supported, in vitro and other methodologies, not entailing the use of an animal, is reasonably and practicably available.

2. In the event of a choice between procedures, those which use the fewest animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected.

3. Death as the end-point in a procedure shall be avoided as far as possible and replaced by early and humane end-points. If death as the end-point is unavoidable, the procedure shall be designed so as to result in the deaths of as few animals as possible.

Article 16

Anaesthesia

1. Member States shall ensure that, where appropriate, all procedures are carried out under general or local anaesthesia or using other methods that may alleviate pain or minimise suffering.

2. By way of derogation from paragraph 1, procedures may be carried out without anaesthesia under the following conditions:

(a) where anaesthesia is judged to be more traumatic to the animal than the procedure itself;

(b) where analgesics are used to prevent or control potentially severe pain;

(c) where anaesthesia is incompatible with the purpose of the procedure unless the procedure involves serious injuries that may cause severe pain.

3. If the procedure is carried out without anaesthesia, analgesics or other appropriate methods shall be used wherever this would be beneficial to the animal to ensure that unavoidable pain, suffering and distress are kept to a minimum.

4. Member States shall ensure that animals are not given any drug to stop or restrict them from showing pain without an adequate level of anaesthesia or analgesia.

In such cases, a scientific justification shall be provided, accompanied by the details of the anaesthetic or analgesic regime.

5. An animal, which may suffer pain once anaesthesia has worn off, shall be treated with pre-emptive and post-operative analgesics or other appropriate pain-relieving methods, provided that it is compatible with the purpose of the procedure. Where the treatment with analgesics is not possible, the animal shall be immediately killed by a humane method.
Article 17

Classification of severity of procedures

1. Member States shall ensure that all procedures are classified as ‘up to mild’, ‘moderate’ or ‘severe’ in conformity with Annex IX.

2. Member States shall ensure that the procedures classified as ‘severe’ are scientifically justified, and ethically monitored if the pain, suffering or distress is likely to be more than transient. Such procedures must be exceptional and shall be subject to particular harm/benefit analysis and scrutiny by the competent authority.

3. Procedures performed under general anaesthesia, at the end of which and without a possibility to recover consciousness the animal is killed using humane method, shall be classified as ‘non-recovery’.

4. The Commission shall, by … (*), complete the criteria for classification of procedures as referred to in Annex IX on the basis of international classifications and in line with best practices developed within the European Union. Such criteria shall include an upper limit of severity beyond which procedures on animals will be prohibited.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall by … (**) be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(4).

Article 18

Re-use

1. Member States shall ensure that an animal on which a procedure has already been carried out, when a different animal on which no preparatory or other procedure has previously been carried out could instead be used, may be re-used in subsequent unrelated new procedures only when all of the following conditions are met:

(a) the previous procedure was classified as up to ‘moderate’;

(b) it is demonstrated that its general state of health and well-being has been fully restored;

(c) the further procedure is classified as up to ‘moderate’ or ‘non-recovery’. The re-use of animals shall be accompanied by veterinary examinations.

2. By way of derogation from paragraph 1, the competent authority, on the basis of scientific justification, may allow re-use of an animal where the previous procedure performed on the animal is classified as up to ‘moderate’ and the further procedure is classified as up to ‘moderate’ or as ‘non-recovery’.

Article 19

End of the procedure

1. A procedure shall be deemed to end when no further observations are to be made for that procedure or, as regards new genetically modified animal lines, when lack of adverse effects to animals can be scientifically demonstrated.

2. At the end of a procedure, a decision shall be taken by a veterinarian or by another competent person on whether the animal shall be kept alive or killed by a humane method.

(*) 12 months after the entry into force of this Directive.
(**) 18 months after the entry into force of this Directive.
3. **At the end of a procedure** an animal shall be killed by a humane method when it is likely to remain in lasting pain or distress.

4. Where an animal is to be kept alive, it shall receive the care and accommodation appropriate to its state of health and be placed under the supervision of a veterinarian or another competent person.

**Article 20**

Sharing organs and tissues

Member States shall encourage the establishment of programmes for the sharing of organs and tissues of animals killed by a humane method.

**Article 21**

Setting free of animals and re-homing

Member States may allow animals used or intended to be used in procedures to be released into their original habitat, returned to a husbandry system appropriate to the species, or re–homed provided that the following conditions are met:

(a) the state of health of the animal allows it;

(b) there is no danger to public health or the environment;

(c) the maximum possible care has been taken to safeguard the well-being of the animal, including an assessment of the animal’s behaviour and its ability to adapt to highly variable environmental conditions;

(d) the animals concerned are not genetically modified experimental animals or non-human primates.

**CHAPTER IV**

**AUTHORISATION**

**Section 1**

Authorisation of persons

**Article 22**

Authorisation of persons

1. Member States shall ensure that persons are authorised by the competent authority or the delegated authority before they carry out any of the following functions:

(a) the carrying out of procedures on animals, including their killing by a humane method;

(b) the supervision or design of procedures and projects;

(c) the supervision of those taking care of animals.

2. Member States shall ensure that, for the purposes of the authorisation, the persons referred to in paragraph 1 have the appropriate veterinary or scientific education and training and have evidence of the requisite competence.

Persons carrying out the functions referred to in point (b) of paragraph 1 shall have received instruction in a scientific discipline relevant to the work being undertaken and shall be capable of handling and taking care of the species concerned.
3. All authorisations of persons shall be granted for a limited period, not exceeding five years. Member States shall ensure that the renewal of an authorisation of persons is only granted on the basis of evidence of the requisite competence. **Member States shall ensure the mutual recognition of education and training qualifications and authorisation to conduct designated procedures.**

4. Member States shall publish, on the basis of the elements set out in Annex VII, minimum requirements with regard to education, training and requirements for obtaining, maintaining and demonstrating requisite competence.

**Section 2**

Requirements for establishments

**Article 23**

Authorisation of establishments

1. Member States shall ensure that all breeding, supplying and user establishments are authorised by and registered with the competent authority.

An authorisation shall be given to an establishment only if it has been inspected by the competent authority and found to comply with the requirements of this Directive.

2. The authorisation shall specify the type of establishment and the person responsible for the establishment and for compliance with the provisions of this Directive.

**Article 24**

Suspension and withdrawal of authorisation

1. Where an establishment no longer complies with requirements set out in this Directive, the competent authority shall have the power to suspend or withdraw its authorisation, or take appropriate remedial action or require such action to be taken. There shall be appropriate procedures for the license-holders to appeal against any such decision.

2. Member States shall ensure that, where the authorisation is suspended or withdrawn, the welfare of the animals housed in the establishment is not adversely affected.

**Article 25**

Requirements for installations and equipment

1. Member States shall ensure that all breeding, supplying and user establishments have installations and equipment suited to the species of animals housed and, where procedures are carried out, to the performance of the procedures.

2. The design, construction and method of functioning of the installations and equipment referred to in paragraph 1 shall ensure that the procedures are carried out as effectively as possible, with the minimum number of animals and the minimum degree of pain, suffering, distress or lasting harm.

**Article 26**

Requirements for personnel in establishments

Each breeding, supplying and user establishment shall have sufficient trained staff, including as a minimum:

(1) persons responsible on site for the welfare and care of the animals bred, kept or used in the establishment, who shall ensure the following:
(a) the staff dealing with animals have access to the information specific to the species housed in the establishment;

(b) the projects are carried out in accordance with the project authorisation;

(c) any procedure in the course of which any unnecessary distress, pain or suffering is being inflicted on an animal is stopped;

(d) in the event of non-compliance with the project authorisation, the appropriate measures to rectify the non-compliance are taken, recorded and reported to the permanent ethical review body.

(2) a designated veterinarian with expertise in laboratory animal medicine charged with advisory duties in relation to the well-being and treatment of the animals.

Without prejudice to the generality of point 1, each breeding, supplying and user establishment shall ensure that there is at least one trained person available at all times to look after the animals’ welfare.

Article 27

Permanent ethical review body

1. Member States shall ensure that each breeding, supplying and user establishment sets up a permanent ethical review body.

2. The permanent ethical review body shall include as a minimum the designated veterinarian, the person(s) responsible for the welfare and care of the animals in the establishment and, in the case of a user establishment, a scientific member and a person with expertise in the application of the principles of replacement, reduction and refinement.

Article 28

Tasks of permanent ethical review body

1. Having regard to the objectives of this Directive, and in particular Article 4, the permanent ethical review body shall fulfil the following tasks:

(a) provide ethical advice to the staff dealing with animals on matters related to the welfare of animals in relation to their acquisition, accommodation, care and use;

(b) advise the staff of the establishment on the application of the requirement of replacement, reduction and refinement and keep it informed on the latest technical and scientific developments on the application of those requirements;

(c) establish and review internal operational processes as regards monitoring, reporting and follow up in relation to the welfare of animals housed or used in the establishment;

(d) review annually all projects classified as ‘severe’ or those on non-human primates, and every three years all other projects which are of more than 12 months duration, focusing in particular on:

— the numbers, species and life stages of animals used in the preceding year;

— the justification for the numbers, species and life stages of animals needed for the subsequent year;
the scientific progress of the project;

— the use of humane methods of killing and how new developments in relation to the use of animals in procedures have been taken into account;

(e) based on the review referred to in point (d) or, in the case of deviations from the project authorisation, examine whether the project authorisation needs to be submitted for amendment or renewal;

(f) advise on re-homing schemes, in particular in relation to the appropriate socialisation of the animals to be re-homed.

2. Member States shall ensure that the records of any advice given to the establishment by the permanent ethical review body and decisions taken regarding that advice are kept.

The records shall be made available to the competent authority upon request. Member States shall pay particular attention to the collection, collation and publication of records relating to projects classified as ‘severe’ or those on non-human primates in order to provide information which can improve animal welfare and further the principles of replacement, reduction and refinement.

Article 29

Breeding strategy for non-human primates

1. Member States shall ensure that EU breeding and supplying establishments of non-human primates have a strategy in place for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity. Where the use of non-human primates is authorised, the Commission and the Member States shall take all necessary measures to ensure appropriate transport conditions.

2. EU establishments acquiring non-human primates shall supply proof to the competent authority, on request, that the establishment from which animals have been acquired have a breeding strategy in place.

Article 30

Re-homing scheme

Where Member States allow re-homing as referred to in Article 21, the breeding, supplying and user establishments from which animals are intended to be re-homed shall have a re-homing scheme in place that ensures socialisation of the animals that are re-homed.

Article 31

Records on animals

1. Member States shall, where possible, ensure that all breeding, supplying and user establishments keep records of the following:

(a) the number and the species of vertebrate animals bred, acquired, supplied, released or re-homed;

(b) the origin of the animals, including whether they are bred for use in procedures;

(c) the dates on which the animals are acquired, supplied, released or re-homed;

(d) the name and address of the supplying establishment and the date of their arrival;
(e) the name and address of the the establishment receiving the animals;

(f) the number and species of animals which have died or have been killed using a humane method in the establishment.

2. The records referred to in paragraph 1 shall be kept for a minimum of three years and shall be submitted to the competent authority upon request.

Article 32
Information on dogs, cats and non-human primates

1. Member States shall ensure that all breeding, supplying and user establishments keep the following information on each dog, cat and non-human primate:

(a) identity;

(b) place of birth;

(c) whether it is bred for use in procedures;

(d) in the case of a non-human primate, whether it is the offspring of non-human primates that have been bred in captivity.

2. Each dog, cat and non-human primate shall have an individual history file, which follows the animal throughout its life. Member States shall ensure the adequate and consistent implementation of this Directive.

The file shall be established at birth and shall cover any relevant reproductive, medical and social information on the individual animal.

3. The information referred to in paragraph 1 shall be kept for a minimum of three years after the death of the animal and shall be submitted to the competent authority upon request.

Article 33
Marking

1. Each dog, cat and non-human primate in any breeding, supplying or user establishment shall, except in the cases referred to in paragraph 2, be provided, before it is weaned, with an individual identification mark in the least painful manner possible.

2. Where a dog, cat or non-human primate is transferred from one establishment 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 is so marked.

3. Where an unmarked dog, cat or non-human primate is taken into an establishment for the first time it shall be marked as soon as possible.

4. The establishment shall provide, on request by the competent authority, reasons for the animal being unmarked.
Article 34

Care and accommodation

1. Member States shall, as far as the care and accommodation of animals is concerned, ensure the following:

(a) all animals are provided with accommodation, an environment, freedom of movement, food, water and care which are appropriate to their health and well-being and which allow them to satisfy their ethological as well as physical needs;

(b) any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are limited to a minimum;

(c) the environmental conditions in which animals are bred, kept or used are checked daily;

(d) the well-being and state of health of animals are observed by a competent person at least once a day to prevent pain or avoidable suffering, distress or lasting harm;

(e) arrangements are made to ensure that any avoidable defect or suffering discovered is eliminated as quickly as possible.

2. For the purposes of points (a) and (b) of paragraph 1, Member States shall apply the care and accommodation standards set out in Annex IV as from the dates provided for in that Annex.

3. Member States may allow exemptions to paragraph 2 for justified scientific reasons, veterinary reasons or animal welfare reasons.

4. In those procedures whose purpose is described in Article 5(2)(c), the animal species of agricultural interest listed in Annex V may be housed in normal breeding conditions as defined by the current agricultural practices of the Member States and the applicable rules.

Section 3

Inspections

Article 35

National inspections

1. Member States shall ensure that all breeding, supplying and user establishments are subject to inspections on the compliance of those establishments with this Directive.

2. National inspections shall be carried out by the competent authority on average once a year, with the competent authority adapting the frequency of inspection on the basis of a risk analysis for each establishment.

At least one of the inspections shall be unannounced.

3. Member States shall ensure that the frequency and the extent of inspections are adequate to the number and species of animals housed, to the compliance record of the establishment with this Directive and, in the case of user establishments, to the number and types of projects carried out in those establishments. Member States shall take the necessary measures to ensure that the inspections do not jeopardise the scientific quality of the projects and the welfare of the animals, and do not take place under conditions that fail to comply with the other regulations in force.
4. Records of all inspections, **including details of any failure to meet the requirements of this Directive**, shall be kept by each Member State’s competent authority for at least five years.

5. Member States shall ensure that an appropriate infrastructure with sufficient numbers of trained inspectors is in place to carry out inspections.

6. Member States shall establish programmes for joint inspections by Member States.

**Article 36**

Controls of national inspections

1. The Commission **shall** undertake controls of the infrastructure and operation of national inspections as well as of the correct application of severity classifications in Member States. **To that end, the Commission shall set up a system to monitor each Member State’s inspections and enforcement of this Directive on average once every three years, ensuring harmonised practices for the use and the care of animals used or intended to be used in scientific procedures.**

2. The Member State in the territory of which the control is being carried out shall give all necessary assistance to the experts of the Commission in carrying out their duties. The Commission shall inform the competent authority of the Member State concerned of the results of the control.

3. The competent authority of the Member State concerned shall take measures to take account of the results of the control.

**Section 4**

Requirements for projects

**Article 37**

Authorisation of projects

1. Member States shall ensure that projects **classified as ‘moderate’ or ‘severe’ or any projects involving non-human primates** are not carried out without a prior authorisation by the competent authority. **All other projects shall be notified in advance to the competent authority following ethical review by the institution’s permanent ethical review body.**

2. Granting of authorisation shall be subject to favourable independent ethical and scientific evaluation by the competent authority.

**Article 38**

Application for the project authorisation

1. **When required**, the user establishment or the person scientifically responsible for the project shall submit an application for the project authorisation, which shall include the following:

   (a) project proposal;

   (b) non-technical project summary;

   (c) information on the elements set out in Annex VIII;

   (d) a scientifically justified statement that the research project is indispensable and ethically defensible and that the purposes of the project cannot be achieved using other methods or procedures.
2. Member States may waive the requirement in paragraph 1(b) and permit the user establishment to submit a reduced project proposal covering only the ethical evaluation and elements listed in Article 43(2), provided that the project involves only procedures classified as ‘up to mild’ and does not use non-human primates.

Article 39

Ethical evaluation

1. The ethical evaluation shall verify that the project meets the following criteria:

(a) the project is scientifically justified, **indispensable and ethically defensible**;

(b) the purposes of the project justify the use of animals **and cannot be achieved through other methods or procedures**;

(c) the project is designed so as to enable procedures to be carried out with **maximum respect for animal welfare** and in the most environmentally sensitive manner.

2. The ethical evaluation shall consider in particular the following:

(a) an evaluation of the objectives of the project, the predicted scientific benefits or educational value;

(b) an assessment of compliance of the project with the requirement of replacement, reduction and refinement;

(c) an assessment of the classification of the severity of procedures;

(d) a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress, and to the environment, where appropriate, is **ethically defensible in light of the expected advancement of science that may ultimately benefit human beings, animals or the environment**;

(e) an assessment of any scientific justification referred to in Articles 6, 8, 9, 10, 11, 14, 16 and 18.

3. The competent authority carrying out the ethical evaluation shall consider **corresponding expertise** in particular in the following areas:

(a) the areas of scientific use for which animals will be used;

(b) experimental design, including statistics where appropriate;

(c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;

(d) animal husbandry and care, in relation to the species that are intended to be used;

(e) practical application of the requirement of replacement, reduction and refinement;

(f) applied ethics;

(g) environmental science, where appropriate.

4. Ethical evaluation shall be performed in a transparent manner by integrating independent expertise whilst safeguarding intellectual property and confidential information as well as the safety of goods and persons.
Article 40
Retrospective assessment

1. The **competent authority carrying out the** ethical evaluation shall determine, on the basis of the harm-benefit analysis referred to in point (d) of Article 39(2), whether the project should, once it has been completed, be assessed retrospectively.

If a retrospective assessment is deemed appropriate, the ethical evaluation shall determine, in relation to the project concerned, the deadline by which the retrospective assessment is to take place.

2. Retrospective assessment shall **establish** the following:

(a) whether the objectives of the project were achieved;

(b) harm inflicted on animals including the numbers and species of animals used and the severity of the procedures;

(c) **whether there are** elements that may contribute to the further implementation of the requirement of replacement, reduction and refinement.

3. All projects using non-human primates shall undergo a retrospective assessment.

4. **All projects involving only procedures classified as up to 'moderate' shall be exempted from the requirement for a retrospective assessment.**

Article 41
Records of ethical evaluation

1. The establishment shall keep records of ethical evaluation for at least three years from the expiry date of authorisation of the project and shall submit those records to the competent authority upon request.

2. However, records of ethical evaluation for projects which have to undergo retrospective assessment shall be kept until the retrospective assessment has been completed.

Article 42
Non-technical project summaries

1. Subject to safeguarding confidential information, **establishment and personnel details**, the non-technical project summary shall provide the following:

(a) information on the objectives of the project, including the likelihood of achieving them, the potential harm, and details of the number and types of animals to be used;

(b) a demonstration that the principles of replacement, reduction and refinement have been observed where practicable.

2. On the basis of the results of the ethical evaluation, the user establishment shall specify in the non-technical project summary whether a project is to undergo a retrospective assessment and by which deadline.
3. The user establishment shall update the non-technical project summary with the results of retrospective assessment.

4. Member States shall make publicly available anonymous versions of the non-technical project summaries of authorised projects and any updates to them.

5. Subject to the safeguarding of confidential and personal information, Member States shall make publicly available non-personal information regarding infringements of this Directive, national laws and authorisations.

Article 43

Granting of project authorisation

1. The project authorisation shall be limited to the procedures which have been subject to an ethical evaluation and to the severity classifications assigned to those procedures.

2. The project authorisation shall identify the following:

(a) the persons in the establishment responsible for the overall implementation of the project;

(b) the user establishments in which the project will be undertaken;

(c) in the case of field studies, the user establishment which is responsible for the project;

(d) at least one person demonstrating species specific knowledge.

3. Project authorisations shall be granted for a period not exceeding five years.

4. Member States may allow the authorisation of multiple projects when those projects are required by law, or when standardised procedures are applied, the ethical evaluation of which has already produced a positive result.

5. User establishments shall keep records of all project authorisations for at least three years from the expiry date of the authorisation and shall submit those records to the authority upon request.

Article 44

Amendment, renewal and withdrawal of a project authorisation

1. The competent authority may amend or renew the project authorisation on the request of the user establishment or the person in charge of the project.

2. Any amendment or renewal of a project authorisation shall be subject to a further ethical evaluation.

3. Amendments to mild or moderate procedures that do not increase the severity of the procedure may be made by the permanent ethical review body but must be communicated to the competent authority within one week of such change.

4. The competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation and may cause a deterioration in animal welfare standards.

5. Where a project authorisation is withdrawn, the welfare of the animals used or intended to be used in the project shall not be adversely affected.
6. Member States shall establish and publish detailed conditions for amendment and renewal of project authorisations.

**Article 45**

**Authorisation decisions**

Member States shall ensure that the decision to grant an authorisation is taken and communicated to the user establishment at the latest within 30 days from the submission of the application. Should the Member State fail to take a decision within that period, the authorisation shall be deemed to have been granted, where the project concerned involves only procedures classified as ‘up to mild’ and non-human primates are not used. In all other cases, no such presumption shall apply.

**CHAPTER V**

**AVOIDANCE OF DUPLICATION AND ALTERNATIVE APPROACHES**

**Article 46**

**Unnecessary duplication of procedures**

1. Each Member State shall accept *from another Member State* data that are generated by procedures recognised by, or which take place under, Community legislation.

2. Subject to the safeguarding of confidential information, Member States shall ensure the sharing of data generated by procedures, including those which have taken place in the European Union prior to the coming into force of the Directive. A person seeking to rely on data owned by another shall where appropriate contribute towards the intrinsic cost of producing such data.

3. Before applying for a project authorisation, a person intending to carry out a procedure must take all reasonable steps to ascertain whether data relevant to the proposed project already exists and, if so, to access such data (including contributing towards the cost thereof), and Member States shall similarly verify whether such data exists before granting an authorisation.

4. Member States shall not authorise a procedure where a person has not taken reasonable steps to comply with paragraph 3.

5. Where relevant data is reasonably available, Member States shall only grant authorisation for a project where this is necessary for the protection of the public.

**Article 47**

**Alternative approaches**

The Commission and Member States shall contribute financially and otherwise to the development and, where appropriate, the scientific validation of alternative approaches intended to provide a comparable level of information as that obtained in procedures using animals but that do not involve the use of animals or use fewer animals or that entail less painful procedures and shall take such other steps as they consider appropriate to encourage research in this field. It is appropriate to establish large-scale veterinary biobanks to support the principles of replacement, reduction and refinement using surplus tissue taken as part of clinical procedures.
Article 48

European Centre for the Validation of Alternative Methods

The remit of the European Centre for the Validation of Alternative Methods shall be extended so that it includes the co-ordination and promotion of the development and use of alternatives to animal procedures including applied and basic biomedical research and veterinary research and regulatory testing by performing the following functions:

(a) coordinate research undertaken to facilitate the development of alternatives to animal procedures by the National Centres for Alternative Methods described in Article 49;

(b) conduct research to facilitate the development of alternatives to animal procedures;

(c) commission research in fields likely to yield information that will facilitate the replacement, reduction or refinement of animal procedures;

(d) in consultation with relevant stakeholders, create and implement strategies to replace, reduce and refine animal procedures;

(e) make available information on alternatives to animal procedures through regular reporting to the public, to stakeholders and to Member State authorities;

(f) provide databases to facilitate the exchange of relevant information including information on available alternative methods and information contributed voluntarily by researchers which would otherwise remain unpublished, but which could prevent duplication of unsuccessful animal studies;

(g) coordinate pre-validation and validation studies undertaken by the National Centres for Alternative Methods in accordance with Article 49 of this Directive;

(h) conduct validation and pre-validation studies where appropriate;

(i) in consultation with relevant regulatory bodies and stakeholders, create and implement strategies to replace, reduce and refine animal tests used for regulatory purposes;

(j) facilitate the scientific endorsement and regulatory acceptance of alternatives to animal tests used for regulatory purposes;

(k) inform relevant regulatory authorities when pre-validation and validation studies begin, and when alternative test methods achieve scientific endorsement and regulatory acceptance, and make this information available to the public and stakeholders through dedicated websites.

Article 49

National reference laboratories for alternative methods

1. Each Member State shall, by … (*) nominate a centre responsible for supporting the development, validation and promotion of alternatives to animal tests used for regulatory purposes, and facilities to develop and promote the use of alternatives to animal procedures undertaken for other purposes, such as basic and applied biomedical and veterinary research.

(*) One year after the entry into force of this Directive.
2. Member States may only designate as national reference laboratories those that are accredited in accordance with Directive 2004/10/EC.

3. The national reference laboratories shall fulfil the following requirements:

(a) they shall have suitably qualified staff with adequate training in alternative methods and validation process and techniques applied in their area of competence;

(b) they shall possess the equipment and products needed to carry out the tasks assigned to them;

(c) they shall have an appropriate administrative infrastructure;

(d) they shall ensure that their staff respect the rules on confidentiality.

4. The national reference laboratories shall perform the following functions:

(a) cooperate with the Commission in their area of competence and perform tasks to advance strategies for replacing animal procedures;

(b) participate in pre-validation and validation of alternative methods, where appropriate, under the co-ordination of the Commission;

(c) communicate information on the availability and application of alternative methods received from the Commission to the relevant authorities of the Member State;

(d) provide scientific and technical assistance to the relevant authorities and to user establishments, within and between the Member States, for the acceptance and implementation of alternative methods;

(e) provide training on the use of alternative methods to persons referred to in Article 22(1) and, if required, to user establishments;

(f) communicate developments on alternative methods and inform the public of positive and negative outcomes.

5. The national centres shall work with all relevant stakeholders to further the aim of replacing all animal procedures.

6. National reference laboratories shall declare any conflict of interest on any task being undertaken.

7. Each Member State shall communicate the name and address of their reference laboratory to the Commission. The Commission shall make publicly available the list of national reference laboratories.

8. After consulting the national reference laboratories, the Commission shall set the priorities for the validation studies and allocate the tasks between those laboratories for carrying out those studies.

Article 50

National animal welfare and ethics committee

1. Each Member State shall establish a national animal welfare and ethics committee that shall advise the competent authorities and permanent ethical review bodies in matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practices.

2. The national animal welfare and ethics committees shall exchange information on the operation of permanent ethical review bodies and ethical evaluation and share best practices within the Community.
CHAPTER VI
FINAL PROVISIONS

Article 51
Adaptation of annexes to technical progress

The Commission may adapt Annexes II to IX to technical and scientific progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(4).

Article 52
Reporting

1. Member States shall by … (*) and every five years thereafter, send the information on the implementation of this Directive and in particular Articles 11(1), 27, 29, 35, 39, 40, 42 and 46 thereof to the Commission.

2. Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures.

Member States shall make that statistical information publicly available and submit it to the Commission by … (**) and thereafter at intervals not exceeding two years.

3. The Commission shall by … (***) establish a common format for submitting the information referred to in paragraph 2 in accordance with the regulatory procedure referred to in Article 54(2).

Article 53
Safeguard clause

1. Where a Member State has justifiable grounds for believing that action is essential for the preservation of the species or in relation to an unexpected outbreak of a life-threatening or debilitating clinical condition in human beings, it may authorise the use of great apes in procedures having one of the purposes referred to in Article 5(2)(a), (3) or (6); provided that the purpose of the procedure cannot be achieved by the use of other species than great apes or by the use of alternative methods. However, the reference to Article 5(2)(a) shall not be taken to include the reference to animals or plants.

2. The Member State shall immediately inform the Commission and the other Member States thereof, giving reasons for its decision and submitting evidence of the situation as described in paragraph 1 on which the provisional measure is based.

3. The Commission shall take a decision in accordance with the regulatory procedure referred to in Article 54(2) within 60 days of receipt of the information from the Member State. This decision shall either:

(a) authorise the provisional measure for a time period defined in the decision; or

(b) require the Member State to revoke the provisional measure.

(*) Six years after the transposition date.
(**) Three years after the transposition date.
(***) 18 months after the entry into force of this Directive.
Article 54

Committee

1. The Commission shall be assisted by a Committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 55

Commission report

1. By ... (*) and every five years thereafter, the Commission shall, based on the information received from the Member States under Article 52(1), submit to the European Parliament and the Council a report on the implementation of this Directive.

2. By ... (*) and every three years thereafter the Commission shall, based on the statistical information submitted by Member States under Article 52(2), submit to the European Parliament and the Council a summary report on that information.

Article 56

Review

The Commission shall review this Directive by ... (**) taking into account advancement in development of alternative methods not entailing the use of animals, and in particular of non-human primates, and propose any amendments, where appropriate.

Article 57

Thematic review

The Commission shall, in consultation with Member States and any relevant stakeholders, conduct a thematic review of the use of animals in procedures every two years commencing ... (***) The review shall examine the impact of developments in technological, scientific and animal welfare knowledge, and set targets for the implementation of validated replacement methods.

In the periodic reviews, the Commission shall give priority to the reduction and elimination of procedures causing the greatest permissible pain, suffering, distress or lasting harm and those which are not designed to alleviate life-threatening or debilitating clinical conditions in human beings, with a view to the elimination of all procedures. The Commission shall take into account evolving public opinion about the use of animals in procedures in the periodic reviews.

Article 58

Competent authorities

1. Each Member State shall designate one or more competent authorities responsible for the implementation of this Directive.

(*) Seven years after transposition date.
(**) Five years after the date of entry into force of this Directive.
(***) Two years after the entry into force of this Directive.
Member States may designate bodies other than public authorities for the implementation of this Directive. Bodies thus designated shall be considered competent authorities for the purposes of this Directive.

2. Member States shall inform the Commission of the names and addresses of the competent authorities by ... (*) at the latest. Member States shall inform the Commission of any changes to the names and addresses of the competent authorities.

The Commission shall make publicly available the list of the competent authorities.

Article 59
Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by ... (**) at the latest and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 60
Transposition

1. Member States shall adopt and publish, by ... (***) at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from ... (****).

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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

Article 61
Repeal

Directive 86/609/EEC is repealed with effect from ... (*****).

References to the repealed Directive shall be construed as references to this Directive.

Article 62
Transitional provisions

1. Member States shall not apply laws, regulations and administrative provisions adopted in accordance with Articles 37 to 45 to projects which were started before ... (******) and the duration of which does not extend beyond three years after ... (******).

2. Projects which were started before ... (******) and the duration of which extends beyond ... (******) shall obtain project authorisation by three years after ... (******).

(*) Three months after the entry into force of this Directive.
(**) The date specified in first subparagraph of Article 60(1).
(***:18 months after the entry into force of this Directive.
(****) 1 January of the year following the date of transposition as specified in the first subparagraph of Article 60(1).
(******) The date referred to in the second subparagraph of Article 60(1).
Article 63
Entry into force
This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 64
Addressees
This Directive is addressed to the Member States.

Done at [blank],

For the European Parliament
The President

For the Council
The President

ANNEX I

Invertebrate Orders referred to in Article 2(2)(b)

— Cephalopods

— Decapod crustaceans of the infraorders Brachyura and Astacidea
ANNEX II

List of animals referred to in second subparagraph of Article 11(1)

1. Frog (Xenopus (laevis, tropicalis), Rana (temporaria, ppiens))
2. Mouse (Mus musculus)
3. Rat (Rattus norvegicus)
4. Guinea Pig (Cavia porcellus)
5. Syrian (Golden) Hamster (Mesocricetus auratus)
6. Chinese Hamster (Cricetulus griseus)
7. Mongolian gerbil (Meriones unguiculatus)
8. Dog (Canis familiaris)
9. Cat (Felis catus)
10. All species of non-human primate

11. Zebrafish (danio danio)

ANNEX III

List of non-human primates and dates referred to in the third subparagraph of Article 11(1)

<table>
<thead>
<tr>
<th>Species</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marmoset (Callithrix jacchus)</td>
<td>[date of application referred to in the second subparagraph of the first paragraph Article on transposition]</td>
</tr>
<tr>
<td>Cynomolgus monkey (Macaca fascicularis)</td>
<td>[10 years after transposition of Directive]</td>
</tr>
<tr>
<td>Rhesus monkey (Macaca mulatta)</td>
<td>[10 years after transposition of Directive]</td>
</tr>
<tr>
<td>Other species of non-human primates</td>
<td>[10 years after transposition of Directive]</td>
</tr>
</tbody>
</table>
ANNEX IV

Care and accommodation standards referred to in Article 34

SECTION A: GENERAL SECTION

_The care and accommodation conditions shall be tailored to the scientific objective_

1. THE PHYSICAL FACILITIES

_The accommodation conditions shall be tailored to the scientific objective._

1.1. Functions and general design

a) All facilities shall be constructed so as to provide an environment which takes into account the physiological and ethological needs of the species kept in them. Facilities shall also be designed and managed to prevent access by unauthorised persons and the ingress or escape of animals.

b) Establishments shall have an active maintenance programme to prevent and remedy any defect of buildings or equipment.

1.2. Holding rooms

a) Establishments shall have a regular and efficient cleaning schedule of the rooms and the maintenance of satisfactory hygienic standards.

b) Where the animals are allowed to run freely, walls and floors shall be surfaced with a material resistant to the heavy wear and tear caused by the animals and the cleaning process. The material shall not be detrimental to the health of the animals and shall be such that the animals cannot hurt themselves. Additional protection shall be given to any equipment or fixtures so that they are not damaged by the animals or injure the animals themselves.

c) Species that are incompatible, for example predator and prey, or animals requiring different environmental conditions, shall not be housed in the same room nor, in the case of predator and prey, within sight, smell or sound.

1.3. General and special purpose procedure rooms

a) All establishments shall have available laboratory facilities for the carrying out of simple diagnostic tests, post-mortem examinations, and/or the collection of samples that are to be subjected to more extensive laboratory investigations elsewhere.

b) Facilities shall be provided to enable newly-acquired animals to be isolated until their health status can be determined and the potential health risk to established animals assessed and minimised.

c) There shall be accommodation for separate housing of sick or injured animals.

1.4. Service rooms

a) Storerooms shall be designed, used and maintained to safeguard the quality of food and bedding. These rooms shall be vermin and insect-proof. Other materials, which may be contaminated or present a hazard to animals or staff, shall be stored separately.

b) The cleaning and washing areas shall be large enough to accommodate the installations necessary to decontaminate and clean used equipment. The cleaning process shall be arranged so as to separate the flow of clean and dirty equipment to prevent the contamination of newly-cleaned equipment.

c) Establishments shall provide for the hygienic storage and disposal of carcasses and animal waste. Establishment shall have specific measures in place to handle, store and dispose of toxic, radioactive or infectious waste.
2. THE ENVIRONMENT AND CONTROL THEREOF

2.1. Ventilation
   a) Ventilation shall be provided in the holding room and the animal enclosures to satisfy the requirements of the species housed.

   b) The air in the room shall be renewed at frequent intervals.

   c) The ventilation system shall be designed so as to avoid harmful draughts and noise disturbance.

   d) Smoking in rooms where there are animals shall be forbidden.

2.2. Temperature
   a) Temperature in the holding rooms shall be adapted to the species housed. Temperature in the holding rooms shall be measured and logged on a daily basis.

   b) Animals shall not be restricted to outdoor areas under climatic conditions which may cause them distress.

2.3. Humidity
   Humidity levels in the holding rooms shall be adapted to the species housed.

2.4. Lighting
   a) Where natural light does not provide an appropriate light/dark cycle, controlled lighting shall be provided to satisfy the biological requirements of the animals and to provide a satisfactory working environment.

   b) Illumination shall satisfy the needs for the performance of husbandry procedures and inspection of the animals.

   c) Regular photoperiods and intensity of light adapted to the species shall be provided.

   d) When keeping albino animals, the lighting shall be adjusted to take into account their sensitivity to light.

2.5. Noise
   a) Noise levels within the hearing ranges of animals, including ultrasound, shall be minimised particularly during their resting phase.

   b) Establishments shall have alarm systems that sound outside the sensitive hearing range of the animals, where this does not conflict with their audibility to human beings.

   c) Holding rooms shall be provided with noise insulation and absorption materials.

2.6. Alarm systems
   a) Establishments relying on electrical or mechanical equipment for environmental control and protection, shall have a stand-by system to maintain essential services and emergency lighting systems as well as to ensure that alarm systems themselves do not fail to operate;

   b) Heating and ventilation systems shall be equipped with monitoring devices and alarms;

   c) Clear instructions on emergency procedures shall be prominently displayed.
3. CARE

The care shall be tailored to the scientific objective.

3.1. Health

a) Establishments shall have a strategy in place to ensure that a health status of the animals is maintained that safeguards animal welfare and meets scientific requirements. This strategy shall include a microbiological surveillance programme, plans for dealing with health breakdowns and shall define health parameters and procedures for the introduction of new animals.

b) Inspections of the animals shall be made at least daily by the person responsible on site for the welfare and care of the animals. Inspections shall include the health monitoring of the animals and ensure that all sick or injured animals are identified and appropriate action taken.

3.2. Capture from the wild

a) When animals need to be captured from the wild, it shall be done by humane methods and by persons competent to apply them. The impact of the capturing procedures on the remaining wildlife and habitats shall be minimised.

b) Any animal found, at or after capture, to be injured or in poor health shall be examined by a competent person as soon as possible and action taken to minimise the suffering of the animals, having as first priority to restore the health of the animal.

c) Transport containers and means of transport adapted to the species concerned shall be available at capture sites, in case animals need to be moved for examination or treatment.

d) Special measures shall be taken for the acclimatisation, quarantine, housing, husbandry and care of wild caught animals.

3.3. Housing and enrichment

a) Housing

Animals, except those which are naturally solitary, shall be socially housed in stable groups of compatible individuals. In cases where single housing is allowed on the basis of exceptional scientific and/or welfare justification supported by a favourable ethical evaluation, the duration shall be limited to the minimum period necessary and visual, auditory, olfactory and/or tactile contact shall be maintained. The introduction or re-introduction of animals to established groups shall be carefully monitored to avoid problems of incompatibility and disrupted social relationships.

b) Enrichment

All animals shall be provided with space of sufficient complexity to allow expression of a wide range of normal behaviour. They shall be given a degree of control and choice over their environment to reduce stress-induced behaviour. Establishments shall have appropriate enrichment techniques in place, to extend the range of activities available to the animal and increase their coping activities including physical exercise, foraging, manipulative and cognitive activities, as appropriate to the species. Environmental enrichment in animal enclosures shall be adapted to the species and individual needs of the animals concerned. The enrichment strategies in establishments shall be regularly reviewed and updated.

c) Animal enclosures

Animal enclosures shall not be made out of materials detrimental to the health of the animals. Their design and construction shall be such that no injury to the animals is caused. Unless they are disposable, they shall be made from materials that will withstand cleaning and decontamination techniques. The design of animal enclosure floors shall be adapted to the species and age of the animals and be designed to facilitate the removal of excreta.

3.4. Feeding

a) The form, content and presentation of the diet shall meet the nutritional and behavioural needs of the animal.
b) The animals' diet shall be palatable and non-contaminated. In the selection of raw materials, production, preparation and presentation of feed, establishments shall take measures to minimise chemical, physical and microbiological contamination.

c) Packing, transport and storage shall be such as to avoid contamination, deterioration or destruction. All feed hoppers, troughs or other utensils used for feeding shall be regularly cleaned and, if necessary, sterilised.

d) Each animal shall be able to access the food, with sufficient feeding space provided to limit competition.

3.5. Watering

a) Uncontaminated drinking water shall always be available to all animals.

b) When automatic watering systems are used, their functioning shall be regularly checked, serviced and flushed to avoid accidents. If solid-bottomed cages are used, care shall be taken to minimise the risk of flooding.

c) Provision shall be made to adapt the water supply for aquaria and tanks to the needs and tolerance limits of the individual fish, amphibian and reptile species.

3.6. Flooring, substrate, litter, bedding and nesting material

a) Bedding materials or sleeping structures adapted to the species shall always be provided, including nesting materials or structures for breeding animals.

b) Within the animal enclosure, the flooring shall provide a solid, comfortable resting area for all animals. All sleeping areas shall be kept clean and dry.

3.7. Handling

Establishments shall set up training programmes for co-operation of animals during procedures. The training programmes shall be adapted to the species and their origin, the procedures and length of the project. Social contact with human beings shall be made a priority and adapted to the species and their origin, the procedures and length of the project.

SECTION B: SPECIES-SPECIFIC SECTION

1. Mice, rats, gerbils, hamsters and guinea pigs

In this and subsequent tables for mice, rats, gerbils, hamsters and guinea pigs, 'enclosure height' means the vertical distance between the enclosure floor and the top of the enclosure and this height applies over more than 50 % of the minimum enclosure floor area prior to the addition of enrichment devices.

When designing procedures, consideration shall be given to the potential growth of the animals to ensure adequate space is provided (as detailed in Tables 1.1. to 1.5) for the duration of the study.

Table 1.1. Mice

<table>
<thead>
<tr>
<th>In stock and during procedures</th>
<th>Body weight (g)</th>
<th>Minimum enclosure size (cm²)</th>
<th>Floor area per animal (cm²)</th>
<th>Minimum enclosure height (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 20</td>
<td></td>
<td>330</td>
<td>60</td>
<td>12</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>over 20 to 25</td>
<td></td>
<td>330</td>
<td>70</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>over 25 to 30</td>
<td></td>
<td>330</td>
<td>80</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>over 30</td>
<td></td>
<td>330</td>
<td>100</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Body weight (g)</td>
<td>Minimum enclosure size (cm²)</td>
<td>Floor area per animal (cm²)</td>
<td>Minimum enclosure height (cm)</td>
<td>Date referred to in Article 34(2)</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------</td>
<td>-----------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Breeding</td>
<td></td>
<td>330</td>
<td></td>
<td>12</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>For a monogamous pair (outbred/inbred) or a trio (inbred). For each additional female plus litter 180 cm² shall be added.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock at breeders (*)</td>
<td>Enclosure size 950 cm²</td>
<td>less than 20</td>
<td>950</td>
<td>40</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Enclosure size 1 500 cm²</td>
<td>less than 20</td>
<td>1 500</td>
<td>30</td>
<td>12</td>
</tr>
</tbody>
</table>

(*) Post-weaned mice may be kept at these higher stocking densities, for the short period after weaning until issue, provided that the animals are housed in larger enclosures with adequate enrichment. These housing conditions shall not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes and other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

Table 1.2. Rats

<table>
<thead>
<tr>
<th></th>
<th>Body weight (g)</th>
<th>Minimum enclosure size (cm²)</th>
<th>Floor area per animal (cm²)</th>
<th>Minimum enclosure height (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In stock and during procedures (*)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>up to 200</td>
<td>800</td>
<td>200</td>
<td>18</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td></td>
<td>over 200 to 300</td>
<td>800</td>
<td>250</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>over 300 to 400</td>
<td>800</td>
<td>350</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>over 400 to 600</td>
<td>800</td>
<td>450</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>over 600</td>
<td>1 500</td>
<td>600</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Breeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>800</td>
<td>Mother and litter. For each additional adult animal permanently added to the enclosure add 400 cm²</td>
<td></td>
<td></td>
<td>18</td>
</tr>
<tr>
<td>Stock at breeders (**)</td>
<td>Enclosure size 1 500 cm²</td>
<td>up to 50</td>
<td>1 500</td>
<td>100</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>over 50 to 100</td>
<td>1 500</td>
<td>125</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>over 100 to 150</td>
<td>1 500</td>
<td>150</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>over 150 to 200</td>
<td>1 500</td>
<td>175</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Stock at breeders (**)</td>
<td>Enclosure size 2 500 cm²</td>
<td>up to 100</td>
<td>2 500</td>
<td>100</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>over 100 to 150</td>
<td>2 500</td>
<td>125</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>over 150 to 200</td>
<td>2 500</td>
<td>150</td>
<td>18</td>
<td></td>
</tr>
</tbody>
</table>

(*) In lifetime studies, animals shall be provided with enclosures of a suitable size to enable the animals to be socially housed. Where space allowances per individual animal fall below those indicated above, priority shall be given to maintaining stable social structures.

(**) Post-weaned rats may be kept at these stocking densities, for the short period after weaning until issue, provided that the animals are housed in larger enclosures with adequate enrichment. These housing conditions shall not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes and other behavioural deficits, weight loss, or other physiological or behavioural stress responses.
### Table 1.3. Gerbils

<table>
<thead>
<tr>
<th>Body weight (g)</th>
<th>Minimum enclosure size (cm²)</th>
<th>Floor area per animal (cm²)</th>
<th>Minimum enclosure height (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In stock and during procedures</td>
<td>up to 40</td>
<td>1 200</td>
<td>150</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>over 40</td>
<td>1 200</td>
<td>250</td>
<td>18</td>
</tr>
<tr>
<td>Breeding</td>
<td>1 200 Monogamous pair or trio with offspring</td>
<td></td>
<td>18</td>
<td></td>
</tr>
</tbody>
</table>

### Table 1.4. Hamsters

<table>
<thead>
<tr>
<th>Body weight (g)</th>
<th>Minimum enclosure size (cm²)</th>
<th>Floor area per animal (cm²)</th>
<th>Minimum enclosure height (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In stock and during procedures</td>
<td>up to 60</td>
<td>800</td>
<td>150</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>over 60 to 100</td>
<td>800</td>
<td>200</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>over 100</td>
<td>800</td>
<td>250</td>
<td>14</td>
</tr>
<tr>
<td>Breeding</td>
<td>800 Mother or monogamous pair with litter</td>
<td></td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Stock at breeders (*)</td>
<td>less than 60</td>
<td>1 500</td>
<td>100</td>
<td>14</td>
</tr>
</tbody>
</table>

(*) Post-weaned hamsters may be kept at these stocking densities, for the short period after weaning until issue, provided that the animals are housed in larger enclosures with adequate enrichment. These housing conditions shall not cause any welfare deficit such as: increased levels of aggression, morbidity or mortality, stereotypes and other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

### Table 1.5. Guinea pigs

<table>
<thead>
<tr>
<th>Body weight (g)</th>
<th>Minimum enclosure size (cm²)</th>
<th>Floor area per animal (cm²)</th>
<th>Minimum enclosure height (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In stock and during procedures</td>
<td>up to 200</td>
<td>1 800</td>
<td>200</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>over 200 to 300</td>
<td>1 800</td>
<td>350</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>over 300 to 450</td>
<td>1 800</td>
<td>500</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>over 450 to 700</td>
<td>2 500</td>
<td>700</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>over 700</td>
<td>2 500</td>
<td>900</td>
<td>23</td>
</tr>
</tbody>
</table>
2. Rabbits

A raised area shall be provided within the enclosure. This raised area must allow the animal to lie and sit and easily move underneath, and shall not cover more than 40 % of the floor space. When for exceptional scientific or veterinary reasons a shelf cannot be used, the enclosure shall be 33 % larger for a single rabbit and 60 % larger for two rabbits. Where a raised area is provided for rabbits of less than 10 weeks of age, the size of the raised area shall be at least of 55x25 cm and the height above the floor shall be such that the animals can make use of it.

Table 2.1. Rabbits over 10 weeks of age

Table 2.1 is to be used for both cages and pens. The additional floor area is as a minimum 3 000 cm² per rabbit for the third, the fourth, the fifth and the sixth rabbit, while 2 500 cm² as a minimum shall be added for each additional rabbit above a number of six.

<table>
<thead>
<tr>
<th>Final body weight (kg)</th>
<th>Minimum floor area for one or two socially harmonious animals (cm²)</th>
<th>Minimum height (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 3</td>
<td>3 500</td>
<td>45</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>from 3 to 5</td>
<td>4 200</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>over 5</td>
<td>5 400</td>
<td>60</td>
<td></td>
</tr>
</tbody>
</table>

Table 2.2. Doe plus litter

<table>
<thead>
<tr>
<th>Doe weight (kg)</th>
<th>Minimum enclosure size (cm²)</th>
<th>Addition for nestboxes (cm²)</th>
<th>Minimum height (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 3</td>
<td>3 500</td>
<td>1 000</td>
<td>45</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>from 3 to 5</td>
<td>4 200</td>
<td>1 200</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>over 5</td>
<td>5 400</td>
<td>1 400</td>
<td>60</td>
<td></td>
</tr>
</tbody>
</table>

Table 2.3. Rabbits less than 10 weeks of age

Table 2.3 is to be used for both cages and pens.

<table>
<thead>
<tr>
<th>Age</th>
<th>Minimum enclosure size (cm²)</th>
<th>Minimum floor area per animal (cm²)</th>
<th>Minimum height (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weaning to 7 weeks</td>
<td>4 000</td>
<td>800</td>
<td>40</td>
</tr>
<tr>
<td>From 7 to 10 weeks</td>
<td>4 000</td>
<td>1 200</td>
<td>40</td>
</tr>
</tbody>
</table>
Table 2.4. Rabbits: Optima dimensions for raised areas for enclosures having the dimensions indicated in Table 2.1.

<table>
<thead>
<tr>
<th>Age in Weeks</th>
<th>Final body weight (kg)</th>
<th>Optimum size (cm × cm)</th>
<th>Optimum height from the enclosure floor (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>over 10</td>
<td>less than 3</td>
<td>55 × 25</td>
<td>25</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td></td>
<td>from 3 to 5</td>
<td>55 × 30</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>over 5</td>
<td>60 × 35</td>
<td>30</td>
<td></td>
</tr>
</tbody>
</table>

3. Cats

Table 3.1. Cats

The minimum space in which a queen and litter may be held is the space for a single cat, which shall be gradually increased so that by four months of age litters have been re-housed to follow the space requirements for adults.

Areas for feeding and for litter trays shall not be less than 0.5 metres apart and shall not be interchanged.

<table>
<thead>
<tr>
<th>Floor (*) (m²)</th>
<th>Shelves (m²)</th>
<th>Height (m)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum for one adult animal</td>
<td>1.5</td>
<td>0.5</td>
<td>2</td>
</tr>
<tr>
<td>For each additional animal add</td>
<td>0.75</td>
<td>0.25</td>
<td>–</td>
</tr>
</tbody>
</table>

(*) Note: Floor area excluding shelves.

4. Dogs

The internal enclosure shall represent at least 50 % of the minimum space to be made available to the dogs, as detailed in Table 4.1.

The space allowances detailed below are based on the requirements of beagles, but giant breeds such as St Bernards or Irish wolfhounds shall be provided with allowances significantly in excess of those detailed in Table 4.1. For breeds other than the laboratory beagle, space allowances shall be decided in consultation with veterinary staff.

Table 4.1. Dogs

Dogs that are pair or group housed may each be constrained to half the total space provided (2 m² for a dog under 20 kg, 4 m² for a dog over 20 kg) while they are undergoing procedures as defined in this Directive, if this separation is essential for scientific purposes.

A nursing bitch and litter shall have the same space allowance as a single bitch of equivalent weight. The whelping pen shall be designed so that the bitch can move to an additional compartment or raised area away from the puppies.

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Minimum enclosure size (m²)</th>
<th>Minimum floor area for one or two animals (m²)</th>
<th>For each additional animal add a minimum of (m²)</th>
<th>Minimum height (m)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 20</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>[Jan 2017]</td>
</tr>
<tr>
<td>over 20</td>
<td>8</td>
<td>8</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
### Table 4.2. Dogs - post-weaned stock

<table>
<thead>
<tr>
<th>Weight of dog (kg)</th>
<th>Minimum enclosure size (m²)</th>
<th>Minimum floor area/animal (m²)</th>
<th>Minimum height (m)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 5</td>
<td>4</td>
<td>0,5</td>
<td>2</td>
<td>[Jan 2017]</td>
</tr>
<tr>
<td>over 5 to 10</td>
<td>4</td>
<td>1,0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>over 10 to 15</td>
<td>4</td>
<td>1,5</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>over 15 to 20</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>over 20</td>
<td>8</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

5. Ferrets

### Table 5. Ferrets

<table>
<thead>
<tr>
<th>Animals</th>
<th>Minimum enclosure size (cm²)</th>
<th>Minimum floor area per animal (cm²)</th>
<th>Minimum height (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animals up to 600 g</td>
<td>4 500</td>
<td>1 500</td>
<td>50</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>Animals over 600 g</td>
<td>4 500</td>
<td>3 000</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Adult males</td>
<td>6 000</td>
<td>6 000</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Jill and litter</td>
<td>5 400</td>
<td>5 400</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

6. Non-human primates

### Table 6.1. Marmosets and tamarins

<table>
<thead>
<tr>
<th>Animals</th>
<th>Minimum floor area of enclosures for 1 (*) or 2 animals plus offspring up to 5 months old (m²)</th>
<th>Minimum volume per additional animal over 5 months (m³)</th>
<th>Minimum enclosure height (m) (***)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marmosets</td>
<td>0,5</td>
<td>0,2</td>
<td>1,5</td>
<td>[Jan 2017]</td>
</tr>
<tr>
<td>Tamarins</td>
<td>1,5</td>
<td>0,2</td>
<td>1,5</td>
<td></td>
</tr>
</tbody>
</table>

(*) Animals shall only be kept singly in exceptional circumstances.  
(***) The top of the enclosure shall be at least 1.8m from the floor.

### Table 6.2. Squirrel monkeys

<table>
<thead>
<tr>
<th>Minimum floor area for 1 (*) or 2 animals (m²)</th>
<th>Minimum volume per additional animal over 6 months of age (m³)</th>
<th>Minimum enclosure height (m)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,0</td>
<td>0,5</td>
<td>1,8</td>
<td>[Jan 2017]</td>
</tr>
</tbody>
</table>

(*) Animals shall only be kept singly in exceptional circumstances.
Table 6.3. Macaques and vervets (*)

<table>
<thead>
<tr>
<th>Minimum enclosure size (m²)</th>
<th>Minimum enclosure volume (m³)</th>
<th>Minimum volume per animal (m³)</th>
<th>Minimum enclosure height (m)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Animals less than 3 yrs of age (</strong>)**</td>
<td>2,0</td>
<td>3,6</td>
<td>1,0</td>
<td>1,8</td>
</tr>
<tr>
<td><strong>Animals from 3 yrs of age (</strong>*)**</td>
<td>2,0</td>
<td>3,6</td>
<td>1,8</td>
<td>1,8</td>
</tr>
<tr>
<td><strong>Animals held for breeding purposes (****)</strong></td>
<td></td>
<td></td>
<td>3,5</td>
<td>2,0</td>
</tr>
</tbody>
</table>

(*) Animals shall only be kept singly in exceptional circumstances.
(**) An enclosure of minimum dimensions may hold up to three animals.
(***) An enclosure of minimum dimensions may hold up to two animals.
(****) In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mother.

Table 6.4. Baboons (*)

<table>
<thead>
<tr>
<th>Minimum enclosure size (m²)</th>
<th>Minimum enclosure volume (m³)</th>
<th>Minimum volume per animal (m³)</th>
<th>Minimum enclosure height (m)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Animals (</strong>) less than 4 yrs of age**</td>
<td>4,0</td>
<td>7,2</td>
<td>3,0</td>
<td>1,8</td>
</tr>
<tr>
<td><strong>Animals (</strong>) from 4 yrs of age**</td>
<td>7,0</td>
<td>12,6</td>
<td>6,0</td>
<td>1,8</td>
</tr>
<tr>
<td><strong>Animals held for breeding purposes (</strong>*)**</td>
<td></td>
<td></td>
<td>12,0</td>
<td>2,0</td>
</tr>
</tbody>
</table>

(+) Animals shall only be kept singly in exceptional circumstances.
(++) An enclosure of minimum dimensions may hold up to 2 animals.
(*** In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mother.

7. Farm animals

Table 7.1. Cattle

<table>
<thead>
<tr>
<th>Body weight (kg)</th>
<th>Minimum enclosure size (m²)</th>
<th>Minimum floor area/animal (m²/animal)</th>
<th>Trough space for ad libitum feeding of polled cattle (m/animal)</th>
<th>Trough space for restricted feeding of polled cattle (m/animal)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 100</td>
<td>2,50</td>
<td>2,30</td>
<td>0,10</td>
<td>0,30</td>
<td>[Jan 2017]</td>
</tr>
<tr>
<td>over 100 to 200</td>
<td>4,25</td>
<td>3,40</td>
<td>0,15</td>
<td>0,50</td>
<td></td>
</tr>
<tr>
<td>over 200 to 400</td>
<td>6,00</td>
<td>4,80</td>
<td>0,18</td>
<td>0,60</td>
<td></td>
</tr>
<tr>
<td>over 400 to 600</td>
<td>9,00</td>
<td>7,50</td>
<td>0,21</td>
<td>0,70</td>
<td></td>
</tr>
<tr>
<td>over 600 to 800</td>
<td>11,00</td>
<td>8,75</td>
<td>0,24</td>
<td>0,80</td>
<td></td>
</tr>
<tr>
<td>over 800</td>
<td>16,00</td>
<td>10,00</td>
<td>0,30</td>
<td>1,00</td>
<td></td>
</tr>
</tbody>
</table>
### Table 7.2. Sheep and goats

<table>
<thead>
<tr>
<th>Body weight (kg)</th>
<th>Minimum enclosure size (m²)</th>
<th>Minimum floor area/animal (m²/animal)</th>
<th>Minimum partition height (m)</th>
<th>Trough space for ad-libitum feeding (m/animal)</th>
<th>Trough space for restricted feeding (m/animal)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 20</td>
<td>1.0</td>
<td>0.7</td>
<td>1.0</td>
<td>0.10</td>
<td>0.25</td>
<td>[Jan 2017]</td>
</tr>
<tr>
<td>over 20 to 35</td>
<td>1.5</td>
<td>1.0</td>
<td>1.2</td>
<td>0.10</td>
<td>0.30</td>
<td></td>
</tr>
<tr>
<td>over 35 to 60</td>
<td>2.0</td>
<td>1.5</td>
<td>1.2</td>
<td>0.12</td>
<td>0.40</td>
<td></td>
</tr>
<tr>
<td>over 60</td>
<td>3.0</td>
<td>1.8</td>
<td>1.5</td>
<td>0.12</td>
<td>0.50</td>
<td></td>
</tr>
</tbody>
</table>

### Table 7.3. Pigs and minipigs

<table>
<thead>
<tr>
<th>Liveweight (kg)</th>
<th>Minimum enclosure size (*) (m²)</th>
<th>Minimum floor area per animal (m²/animal)</th>
<th>Minimum lying space per animal (in thermoneutral conditions) (m²/animal)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 5</td>
<td>2.0</td>
<td>0.20</td>
<td>0.10</td>
<td>[Jan 2017]</td>
</tr>
<tr>
<td>over 5 to 10</td>
<td>2.0</td>
<td>0.25</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>over 10 to 20</td>
<td>2.0</td>
<td>0.35</td>
<td>0.18</td>
<td></td>
</tr>
<tr>
<td>over 20 to 30</td>
<td>2.0</td>
<td>0.50</td>
<td>0.24</td>
<td></td>
</tr>
<tr>
<td>over 30 to 50</td>
<td>2.0</td>
<td>0.70</td>
<td>0.33</td>
<td></td>
</tr>
<tr>
<td>over 50 to 70</td>
<td>3.0</td>
<td>0.80</td>
<td>0.41</td>
<td></td>
</tr>
<tr>
<td>over 70 to 100</td>
<td>3.0</td>
<td>1.00</td>
<td>0.53</td>
<td></td>
</tr>
<tr>
<td>over 100 to 150</td>
<td>4.0</td>
<td>1.35</td>
<td>0.70</td>
<td></td>
</tr>
<tr>
<td>over 150</td>
<td>5.0</td>
<td>2.50</td>
<td>0.95</td>
<td></td>
</tr>
<tr>
<td>Adult (conventional) boars</td>
<td>7.5</td>
<td>1.30</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Pigs may be confined in smaller enclosures for short periods of time, for example by partitioning the main enclosure using dividers, when justified on veterinary or experimental grounds, for example where individual food consumption is required.

### Table 7.4. Equines

The shortest side shall be a minimum of 1.5 × the wither height of the animal. The height of indoor enclosures shall allow animals to rear to their full height.

<table>
<thead>
<tr>
<th>Withers height (m)</th>
<th>Minimum floor area/animal (m²/animal)</th>
<th>Minimum enclosure height (m)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.00 to 1.40</td>
<td>9.0</td>
<td>6.0</td>
<td>16</td>
</tr>
<tr>
<td>over 1.40 to 1.60</td>
<td>12.0</td>
<td>9.0</td>
<td>20</td>
</tr>
<tr>
<td>over 1.60</td>
<td>16.0</td>
<td>(2 × WH)² (*)</td>
<td>20</td>
</tr>
</tbody>
</table>

(*) To ensure adequate space is provided, space allowances for each individual animal shall be based on height to withers (WH)

---


Tuesday 5 May 2009
8. Birds

Table 8.1. Domestic fowl

Where these minimum enclosures sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0.75 m².

<table>
<thead>
<tr>
<th>Body mass (g)</th>
<th>Minimum enclosure size (m²)</th>
<th>Minimum area per bird (m²)</th>
<th>Minimum height (cm)</th>
<th>Minimum length of feed trough per bird (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 200</td>
<td>1.00</td>
<td>0.025</td>
<td>30</td>
<td>3</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>over 200 to 300</td>
<td>1.00</td>
<td>0.03</td>
<td>30</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>over 300 to 600</td>
<td>1.00</td>
<td>0.05</td>
<td>40</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>over 600 to 1 200</td>
<td>2.00</td>
<td>0.09</td>
<td>50</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>over 1 200 to 1 800</td>
<td>2.00</td>
<td>0.11</td>
<td>75</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>over 1 800 to 2 400</td>
<td>2.00</td>
<td>0.13</td>
<td>75</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>over 2 400</td>
<td>2.00</td>
<td>0.21</td>
<td>75</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

Table 8.2. Domestic turkey

All enclosure sides shall be at least 1.5 m long. Where these minimum enclosures sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0.75 m² and a minimum height of 50 cm for birds below 0.6 kg, 75 cm for birds below 4 kg, and 100 cm for birds over 4 kg. These can be used to house small groups of birds in accordance with the space allowances given in table 8.2.

<table>
<thead>
<tr>
<th>Body mass (kg)</th>
<th>Minimum enclosure size (m²)</th>
<th>Minimum area per bird (m²)</th>
<th>Minimum height (cm)</th>
<th>Minimum length of feed trough per bird (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 0.3</td>
<td>2.00</td>
<td>0.13</td>
<td>50</td>
<td>3</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>over 0.3 to 0.6</td>
<td>2.00</td>
<td>0.17</td>
<td>50</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>over 0.6 to 1</td>
<td>2.00</td>
<td>0.30</td>
<td>100</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>over 1 to 4</td>
<td>2.00</td>
<td>0.35</td>
<td>100</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>over 4 to 8</td>
<td>2.00</td>
<td>0.40</td>
<td>100</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>over 8 to 12</td>
<td>2.00</td>
<td>0.50</td>
<td>150</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>over 12 to 16</td>
<td>2.00</td>
<td>0.55</td>
<td>150</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>over 16 to 20</td>
<td>2.00</td>
<td>0.60</td>
<td>150</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>over 20</td>
<td>3.00</td>
<td>1.00</td>
<td>150</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>
### Table 8.3. Quail

<table>
<thead>
<tr>
<th>Body mass (g)</th>
<th>Minimum enclosure size (m²)</th>
<th>Area per bird pair-housed (m²)</th>
<th>Area per additional bird group-housed (m²)</th>
<th>Minimum height (cm)</th>
<th>Minimum length of trough per bird (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 150</td>
<td>1,00</td>
<td>0,5</td>
<td>0,10</td>
<td>20</td>
<td>4</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>Over 150</td>
<td>1,00</td>
<td>0,6</td>
<td>0,15</td>
<td>30</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

### Table 8.4. Ducks and geese

Where these minimum enclosures sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0,75 m². These can be used to house small groups of birds in accordance with the space allowances given in table 8.4.

<table>
<thead>
<tr>
<th>Body mass (g)</th>
<th>Minimum enclosure size (m²)</th>
<th>Area per bird (m²) (*)</th>
<th>Minimum height (cm)</th>
<th>Minimum length of feed trough per bird (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
</table>

#### Ducks

|               |                             |                        |                     |                                            |                                  |
|---------------|-----------------------------|------------------------|---------------------|--------------------------------------------|                                  |
| Up to 300     | 2,00                        | 0,10                   | 50                  | 10                                         | [Jan 2012]                       |
| Over 300 to 1 200 (***) | 2,00                        | 0,20                   | 200                 | 10                                         |                                  |
| Over 1 200 to 3 500 | 2,00                        | 0,25                   | 200                 | 15                                         |                                  |
| Over 3 500    | 2,00                        | 0,50                   | 200                 | 15                                         |                                  |

#### Geese

|                         |                             |                        |                     |                                            |                                  |
|-------------------------|-----------------------------|------------------------|---------------------|--------------------------------------------|                                  |
| Up to 500               | 2,00                        | 0,20                   | 200                 | 10                                         |                                  |
| Over 500 to 2 000       | 2,00                        | 0,33                   | 200                 | 15                                         |                                  |
| Over 2 000              | 2,00                        | 0,50                   | 200                 | 15                                         |                                  |

(*) This shall include a pond of minimum area 0,5 m² per 2 m² enclosure with a minimum depth of 30 cm. The pond may contribute up to 50% of the minimum enclosure size.

(**) Pre-fledged birds may be held in enclosures with a minimum height of 75 cm.

### Table 8.5. Ducks and geese: Minimum pond sizes (*)

<table>
<thead>
<tr>
<th></th>
<th>Area (m²)</th>
<th>Depth (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ducks</td>
<td>0,5</td>
<td>30</td>
</tr>
<tr>
<td>Geese</td>
<td>0,5</td>
<td>from 10 to 30</td>
</tr>
</tbody>
</table>

(*) Pond sizes are per 2 m² enclosure. The pond may contribute up to 50% of the minimum enclosure size.
Table 8.6. Pigeons

Enclosures shall be long and narrow (for example 2 m by 1 m) rather than square to allow birds to perform short flights.

<table>
<thead>
<tr>
<th>Group size</th>
<th>Minimum enclosure size (m²)</th>
<th>Minimum height (cm)</th>
<th>Minimum length of food trough per bird (cm)</th>
<th>Minimum length of perch per bird (cm)</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 6</td>
<td>2</td>
<td>200</td>
<td>5</td>
<td>30</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>from 7 to 12</td>
<td>3</td>
<td>200</td>
<td>5</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>For each additional bird above 12</td>
<td>0,15</td>
<td></td>
<td>5</td>
<td>30</td>
<td></td>
</tr>
</tbody>
</table>

Table 8.7. Zebra finch

Enclosures shall be long and narrow (for example, 2 m by 1 m) to enable birds to perform short flights. For breeding studies, pairs may be housed in smaller enclosures containing appropriate enrichment with a minimum floor area of 0.5 m² and a minimum height of 40 cm. The duration of the confinement shall be justified by the experimenter in consultation with veterinary staff.

<table>
<thead>
<tr>
<th>Group size</th>
<th>Minimum enclosure size (m²)</th>
<th>Minimum height (cm)</th>
<th>Minimum number of feeders</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 6</td>
<td>1,0</td>
<td>100</td>
<td>2</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>7 to 12</td>
<td>1,5</td>
<td>200</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>13 to 20</td>
<td>2,0</td>
<td>200</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>for each additional bird above 20</td>
<td>0,05</td>
<td></td>
<td>1 per 6 birds</td>
<td></td>
</tr>
</tbody>
</table>

9. Amphibians

Table 9.1. Aquatic urodele

<table>
<thead>
<tr>
<th>Body length (*) (cm)</th>
<th>Minimum water surface area (cm²)</th>
<th>Minimum water surface area for each additional animal in group-holding (cm²)</th>
<th>Minimum water depth (cm)</th>
<th>Optimal temperature</th>
<th>Relative humidity</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 10</td>
<td>262,5</td>
<td>50</td>
<td>13</td>
<td>15°C-22°C</td>
<td>100 %</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>over 10 to 15</td>
<td>525</td>
<td>110</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>over 15 to 20</td>
<td>875</td>
<td>200</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>over 20 to 30</td>
<td>1 837,5</td>
<td>440</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>over 30</td>
<td>3 150</td>
<td>800</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Measured from snout to vent
### Table 9.2. Aquatic anurans (*)

<table>
<thead>
<tr>
<th>Body length (**)(cm)</th>
<th>Minimum water surface area (cm²)</th>
<th>Minimum water surface area for each additional animal in group-holding (cm²)</th>
<th>Minimum water depth (cm)</th>
<th>Optimal temperature</th>
<th>Relative humidity</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 6</td>
<td>160</td>
<td>40</td>
<td>6</td>
<td>18°C-22°C</td>
<td>100 %</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>from 6 to 9</td>
<td>300</td>
<td>75</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>over 9 to 12</td>
<td>600</td>
<td>150</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>over 12</td>
<td>920</td>
<td>230</td>
<td>12.5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) These conditions apply to holding (i.e. husbandry) tanks but not to those tanks used for natural mating and super-ovulation for reasons of efficiency, as the latter procedures require smaller individual tanks. Space requirements determined for adults in the indicated size categories; juveniles and tadpoles shall either be excluded, or dimensions altered according to the scaling principle.

(**) Measured from snout to vent

### Table 9.3. Semi-aquatic anurans

<table>
<thead>
<tr>
<th>Body length (**)(cm)</th>
<th>Minimum enclosure size (**)(cm²)</th>
<th>Minimum area for each additional animal in group-holding (cm²)</th>
<th>Minimum enclosure height (***)(cm)</th>
<th>Minimum water depth (cm)</th>
<th>Optimal temperature</th>
<th>Relative humidity</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 5.0</td>
<td>1 500</td>
<td>200</td>
<td>20</td>
<td>10</td>
<td>10°C-15°C</td>
<td>50-80 %</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>over 5.0 to 7.5</td>
<td>3 500</td>
<td>500</td>
<td>30</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>over 7.5</td>
<td>4 000</td>
<td>700</td>
<td>30</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Measured from snout to vent

(**) One third land division, two thirds water division sufficient for animals to submerge

(***) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosures shall be adapted to the interior design

### Table 9.4. Semi-terrestrial anurans

<table>
<thead>
<tr>
<th>Body length (**)(cm)</th>
<th>Minimum enclosure size (**)(cm²)</th>
<th>Minimum area for each additional animal in group-holding (cm²)</th>
<th>Minimum enclosure height (***)(cm)</th>
<th>Minimum water depth (cm)</th>
<th>Optimal temperature</th>
<th>Relative humidity</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 5.0</td>
<td>1 500</td>
<td>200</td>
<td>20</td>
<td>10</td>
<td>23°C-27°C</td>
<td>50-80 %</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>over 5.0 to 7.5</td>
<td>3 500</td>
<td>500</td>
<td>30</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>over 7.5</td>
<td>4 000</td>
<td>700</td>
<td>30</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Measured from snout to vent

(**) Two-thirds land division, one-third water division sufficient for animals to submerge

(***) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosures shall be adapted to the interior design
### Table 9.5. Arboreal anurans

<table>
<thead>
<tr>
<th>Body length (*) (cm)</th>
<th>Minimum enclosure size (**)(cm²)</th>
<th>Minimum area for each additional animal in group-holding (cm²)</th>
<th>Minimum enclosure height (***) (cm)</th>
<th>Optimal temperature</th>
<th>Relative humidity</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 3</td>
<td>900</td>
<td>100</td>
<td>30</td>
<td>18°C-25°C</td>
<td>50-70 %</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>over 3</td>
<td>1 500</td>
<td>200</td>
<td>30</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Measured from snout to vent  
(**) Two-thirds land division, one-third pool division sufficient for animals to submerge  
(***) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosures shall be adapted to the interior design.

### 10. Reptiles

#### Table 10.1. Aquatic chelions

<table>
<thead>
<tr>
<th>Body length (*) (cm)</th>
<th>Minimum water surface area (cm²)</th>
<th>Minimum water surface area for each additional animal in group holding (cm²)</th>
<th>Minimum water depth (cm)</th>
<th>Optimal temperature</th>
<th>Relative humidity</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 5</td>
<td>600</td>
<td>100</td>
<td>10</td>
<td>20°C-25°C</td>
<td>80-70 %</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>Over 5 to 10</td>
<td>1 600</td>
<td>300</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 10 to 15</td>
<td>3 500</td>
<td>600</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 15 to 20</td>
<td>6 000</td>
<td>1 200</td>
<td>30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 20 to 30</td>
<td>10 000</td>
<td>2 000</td>
<td>35</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 30</td>
<td>20 000</td>
<td>5 000</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Measured in a straight line from the front edge to the back edge of the shell

#### Table 10.2. Terrestrial snakes

<table>
<thead>
<tr>
<th>Body length (*) (cm)</th>
<th>Minimum floor area (cm²)</th>
<th>Minimum area for each additional animal in group-holding (cm²)</th>
<th>Minimum enclosure height (***) (cm)</th>
<th>Optimal temperature</th>
<th>Relative humidity</th>
<th>Date referred to in Article 34(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 30</td>
<td>300</td>
<td>150</td>
<td>10</td>
<td>22°C-27°C</td>
<td>60-80 %</td>
<td>[Jan 2012]</td>
</tr>
<tr>
<td>Over 30 to 40</td>
<td>400</td>
<td>200</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 40 to 50</td>
<td>600</td>
<td>300</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 50 to 75</td>
<td>1 200</td>
<td>600</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 75</td>
<td>2 500</td>
<td>1 200</td>
<td>28</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Measured from snout to tail  
(***) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosure shall be adapted to the interior design.
ANNEX V

List of animals referred to in Article 34(4)

1) Cattle (Bos taurus and Bos indicus);
2) Sheep and goats (Ovis aries and Capra hircus);
3) Swine (Sus scrofa);
4) Equine animals (Equus caballus and Equus asinus);
5) Domestic fowl (Gallus gallus domesticus);
6) Domestic turkey (Meleagris gallopavo);
7) Ducks and geese (Anas platyrhynchos, Anser anser domesticus, Cairina moschata);
8) Domestic quail (Coturnix spp);
9) Pigeons (Colombia livia);
10) Rabbits (Oryctolagus cuniculus).

ANNEX VI

Humane methods of killing animals

Table 1 – Humane methods of killing fish, including gnathostomes and cyclostomes

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of use</th>
<th>Operator safety</th>
<th>Aesthetic value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetic overdose</td>
<td>++</td>
<td>++</td>
<td>+ to ++</td>
<td>++</td>
<td>++</td>
<td>4 to 5 (*)</td>
<td>May be used with prior sedation of the animal.</td>
</tr>
<tr>
<td>Electrical stunning</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>4</td>
<td>Specialised equipment required. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Maceration</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>4</td>
<td>Only for fish less than 2 cm in length</td>
</tr>
<tr>
<td>Concussion</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>3</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Cervical dislocation</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>2 - if animal conscious 5 - if animal unconscious</td>
<td>Not used in fish &gt; 500 g. To be followed by destruction of the brain.</td>
</tr>
</tbody>
</table>

(*) Some anaesthetics may cause skin irritation when used on fish.

Other methods may be used on unconscious fish, providing the animal does not regain consciousness before death.

### Table 2 - Humane methods of killing amphibians

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of use</th>
<th>Operator safety</th>
<th>Aesthetic value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetic overdose</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>5</td>
<td>May be used with prior sedation of the animal.</td>
</tr>
<tr>
<td>Concussion</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>3</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>NMB/anaesthetic mixtures (*)</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>3</td>
<td>To be injected intravenously, therefore requires expertise.</td>
</tr>
<tr>
<td>Microwave irradiation</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>++</td>
<td>3</td>
<td>Specialised equipment required. For small amphibians.</td>
</tr>
<tr>
<td>Electrical stunning</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>Specialised equipment required. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
</tbody>
</table>

(*) Neuromuscular blocking agent, NMB

Other methods may be used on unconscious amphibians, providing the animal does not regain consciousness before death.


### Table 3 - Humane methods of killing reptiles

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of use</th>
<th>Operator safety</th>
<th>Aesthetic value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetic overdose</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>5</td>
<td>May be used with prior sedation of the animal.</td>
</tr>
<tr>
<td>Captive bolt</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>5</td>
<td>For large reptiles. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Shooting</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>4</td>
<td>To be used by experienced marksman. May need a method to ensure death. To be used in field conditions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of Use</th>
<th>Operator Safety</th>
<th>Aesthetic Value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concussion</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>3</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
</tbody>
</table>

Other methods may be used on unconscious reptiles, providing the animal does not regain consciousness before death.


Table 4 - Humane methods of killing birds

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of Use</th>
<th>Operator Safety</th>
<th>Aesthetic Value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>NMB/anaesthetic mixtures</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>4</td>
<td>To be injected intravenously, therefore requires expertise.</td>
</tr>
<tr>
<td>Inert gases (Ar, N₂)</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>4</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Maceration</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>4</td>
<td>For chicks up to 72 h old</td>
</tr>
<tr>
<td>Cervical dislocation</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>1/3 - if animal conscious 5 - if animal unconscious</td>
<td>For small and young birds (&lt; 250 g). To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Microwave irradiation</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>++</td>
<td>+</td>
<td>3</td>
<td>Specialised equipment required.</td>
</tr>
<tr>
<td>Concussion</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>3</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Electrical stunning</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>Specialised equipment required. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Carbon monoxide</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>Danger to operator.</td>
</tr>
</tbody>
</table>

Other methods may be used on unconscious birds, providing the animal does not regain consciousness before death.

Table 5 - Humane methods of killing rodents

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of use</th>
<th>Operator safety</th>
<th>Aesthetic value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetic overdose</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>5</td>
<td>May be used with prior sedation of the animal.</td>
</tr>
<tr>
<td>NMB/anaesthetic mixtures</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>++</td>
<td>4</td>
<td>To be injected intravenously, therefore requires expertise.</td>
</tr>
<tr>
<td>Inert gases (Ar)</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>4</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another listed method.</td>
</tr>
<tr>
<td>Concussion</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>3</td>
<td>For rodents under 1 kg. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Cervical dislocation</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>2/3 - if animal conscious 5 - if animal unconscious</td>
<td>For rodents under 150 g. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Microwave irradiation</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>++</td>
<td>+</td>
<td>3</td>
<td>Specialised equipment required.</td>
</tr>
<tr>
<td>Decapitation</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>1/2 - if animal conscious 5 - if animal unconscious</td>
<td></td>
</tr>
<tr>
<td>Carbon dioxide</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>5</td>
<td>To be used in gradual fill only.</td>
</tr>
<tr>
<td>Carbon monoxide</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>++</td>
<td>1</td>
<td>Danger to operator</td>
</tr>
</tbody>
</table>

Other methods may be used on unconscious rodents, providing the animal does not regain consciousness before death.


Table 6 - Humane methods of killing rabbits

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of use</th>
<th>Operator safety</th>
<th>Aesthetic value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetic overdose</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>5</td>
<td>May be used with prior sedation of the animal.</td>
</tr>
<tr>
<td>NMB/anaesthetic mixtures</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>++</td>
<td>4</td>
<td>To be injected intravenously, therefore requires expertise.</td>
</tr>
</tbody>
</table>
### Table 7 - Humane methods of killing dogs, cats, ferrets and foxes

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of use</th>
<th>Operator safety</th>
<th>Aesthetic value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Captive bolt</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>4</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Cervical dislocation</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>3</td>
<td>Acceptable for rabbits under 1 kg. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Concussion</td>
<td>++</td>
<td>+</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>3</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Electrical stunning</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>3</td>
<td>Specialised equipment required. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Microwave irradiation</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>++</td>
<td>+</td>
<td>3</td>
<td>Specialised equipment required.</td>
</tr>
<tr>
<td>Decapitation</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>1 - if animal conscious 5 - if animal unconscious For rabbits under 1 kg.</td>
</tr>
<tr>
<td>Carbon monoxide</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>++</td>
<td>1</td>
<td>Danger to operator.</td>
</tr>
<tr>
<td>Rapid freezing</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>1</td>
<td>To be used with foetuses under 4g</td>
</tr>
</tbody>
</table>

Other methods may be used on unconscious rodents, providing the animal does not regain consciousness before death.

**Table 8 - Humane methods of killing large mammals**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of use</th>
<th>Operator safety</th>
<th>Aesthetic value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetic overdose</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>++</td>
<td>5</td>
<td>May be used with prior sedation of the animal.</td>
</tr>
<tr>
<td>Captive bolt</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>5</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Shooting with a free bullet with appropriate rifles, guns and ammunition</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>4</td>
<td>To be used by experienced marksman. May need a method to ensure death.</td>
</tr>
<tr>
<td>NMB/anaesthetic mixtures</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>++</td>
<td>4</td>
<td>To be injected intravenously, therefore requires expertise.</td>
</tr>
<tr>
<td>Inert gases (Ar)</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>4</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method. Acceptable for pigs.</td>
</tr>
</tbody>
</table>

Other methods may be used on unconscious dogs, cats, ferrets or foxes, providing the animal does not regain consciousness before death.

Table 9 - Humane methods of killing non-human primates

<table>
<thead>
<tr>
<th>Agent</th>
<th>Rapidity</th>
<th>Efficacy</th>
<th>Ease of use</th>
<th>Operator safety</th>
<th>Aesthetic value</th>
<th>Overall rating (1-5)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical stunning</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>Specialised equipment required. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
<tr>
<td>Concussion</td>
<td>++</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>3 - if animal conscious 5 - if animal unconscious</td>
<td>To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.</td>
</tr>
</tbody>
</table>

Other methods may be used on other large unconscious mammals, providing the animal does not regain consciousness before death.


Other methods may be used on unconscious non-human primates, providing the animal does not regain consciousness before death.

ANNEX VII

List of elements referred to in Article 22(4)

1. National legislation in force relevant to the acquisition, husbandry, care and use of animals in scientific procedures.

2. Ethics in relation to human animal relationship, intrinsic value of life and arguments for and against the use of animals in scientific procedures.

3. Basic biology in relation to anatomy, physiological features, breeding, genetics and genetic alteration.

4. Animal behaviour, husbandry and enrichment.

5. Animal health management and hygiene.

6. Recognition of species specific distress, pain and suffering of most common laboratory species.

7. Anaesthesia, pain relieving methods and euthanasia.

8. Use of humane end-points.


ANNEX VIII

List of elements referred to in Article 38(1)(c)

1. Relevance and justification of the following:
   (a) use of animals including their origin, estimated numbers, species and life stages;
   (b) procedures.

2. Demonstration that existing methods to replace, reduce and refine the use of animals in procedures have been applied.

3. Demonstration of competence of persons involved in the project.

4. The planned use of anaesthesia, analgesia and other pain relieving methods.

5. Reduction, avoidance and alleviation of any form of animal suffering from birth to death.

6. Housing, husbandry and care conditions of the animals.

7. Use of early and humane end-points.

8. Experimental or observational strategy and statistical design to minimise animal numbers, suffering and environmental impact.

9. Life time experience and re-use of animals.

10. Avoidance of unnecessary duplication of procedures.
ANNEX IX

General Definitions of Degrees of Severity referred to in Article 17(1)

In general:

Unless the contrary is known or established, it should be assumed that procedures that cause pain in humans also cause pain in animals.

No pain or mild pain: Severity Grade 1

Interventions and manipulations in animals for experimental purposes as a result of which the animals experience no pain or short term mild pain, suffering, injury, or mild distress with no significant impairment of their general condition.

Examples:

— studies with differing feed compositions or with unphysiological diet, with minor clinical signs or symptoms.

— withdrawal of blood samples or injection (s.c., i.m., i.p., i.v.) of a drug.

— superficial tissue biopsy under anaesthesia

— non-invasive scanning techniques, with or without sedation or anaesthesia of the animals

— tolerability studies which give cause to expect short term, minor, local or systemic reactions

— Electrocardiogram (ECG) recordings in conscious animals

— observational studies such as open-field test, labyrinth tests, or staircase test

— experiments under general anaesthesia without recovery

Moderate: Severity Grade 2

Interventions and manipulations in animals for experimental purposes which subject the animals to short term moderate distress, or a moderately long to long-lasting episode of mild distress, pain, suffering, or injury, or significant impairment of general condition.

Examples:

— surgery under anaesthesia and appropriate analgesia

— implantation of devices such as catheters, telemetry transmitters, minipumps under general anaesthesia

— studies with unphysiological diet, with clinical signs or symptoms of untreated diabetes mellitus

— frequent repeated blood sampling or administration of substances

— induction of anxiety in animal models

— acute toxicity tests, acute tolerability studies, range-finding studies, chronic toxicity/carcinogenicity tests with non-lethal endpoints

— seizure models e.g. epilepsy studies

— non-lethal animal models of cancer e.g. xenograft studies
Severe: Severity Grade 3

Interventions and manipulations in animals for experimental purposes which cause the animals severe to very severe distress, or subject them to a moderately long to long-lasting episode of moderate distress, severe pain, prolonged suffering or severe injury, or significant and persistent impairment of general condition.

Examples:

— bacterial or viral lethal infections
— chronic models of rheumatoid arthritis
— genetically modified animals with lethal phenotypes (e.g. oncogenes), without early termination of the experiment
— organ transplantation (e.g. kidney, pancreas)
— chronic models of severe neurological diseases, e.g. Parkinsons disease

Ship-source pollution and penalties for infringements ***I

P6_TA(2009)0344


(2010/C 212 E/32)

(Codecision procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0134),

— having regard to Article 251(2) and Article 80(2) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0142/2008),

— having regard to Rule 51 of its Rules of Procedure,

— having regard to the report of the Committee on Transport and Tourism and the opinions of the Committee on the Environment, Public Health and Food Safety and the Committee on Legal Affairs (A6-0080/2009),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and to the Commission.