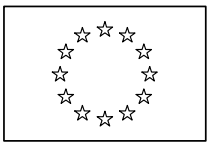

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 5.11.2008
COM(2008) 543 final

2008/0211 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of animals used for scientific purposes

(presented by the Commission)

{SEC(2008) 2410}
{SEC(2008) 2411}

EXPLANATORY MEMORANDUM

1) CONTEXT OF THE PROPOSAL

Grounds for and objectives of the proposal

Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes was adopted to harmonise practices in the area of animal experimentation in the EU. However, due to a variety of weaknesses in the current Directive, a number of Member States have established considerably more far-reaching measures in their national implementation whereas others apply only minimum rules. The present uneven situation needs to be rectified to ensure that the objectives of the internal market are re-established. The current proposal aims at ensuring a level playing field, throughout the EU, for industry and the research community, at the same time strengthening the protection of animals still used in scientific procedures in line with the EC Treaty's Protocol on Animal Welfare[1]. The proposal supports the Commission's overall strategy on animal experimentation, including enhanced promotion of the development, validation, acceptance and implementation of alternative methods and provides a solid basis for a full implementation of the principles of the Three Rs[2] - Replacement, Reduction and Refinement of animals in experiments.

General context

Around 12 million animals are used on a yearly basis in scientific procedures in the EU-27[3]. All efforts should be made to reduce the numbers of animals used in experiments to a minimum. The most pragmatic approach to reducing experiments on animals is through the introduction of alternative methods, as with current scientific knowledge, a complete phase-out of animal experimentation is not yet achievable[4]. Therefore, it is imperative to ensure that those animals that are still used for legitimate reasons receive the highest protection and welfare consistent with the aims of the experiment.

The scientific grounds on which Directive 86/609/EEC was founded dates back over 20 years. A number of provisions are out of date and the Directive therefore does not cater for modern techniques in the field of animal experimentation, nor does it incorporate the latest advancements in the field of animal welfare. Furthermore, the wording of the Directive follows that of an international Convention; the style of some provisions is thus more political than regulatory. A significant number of provisions are open to interpretation and provide guidance rather than harmonisation.

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1 OJ C 340, 10.11.1997, p. 110.

2 Three Rs Principles by Russel, Burch 1959 which today is a commonly accepted principle among scientists, academia and industry internationally when using animals in scientific procedures.

3 12.1 million animals in 2005 in EU-25, Commission Report on the statistics on the number of animals used for experimental and other scientific purposes in the Member States of the European Union - COM(2007) 675.

4 See: A. P. Worth, M. Balls (ed.), alternative (Non-animal) Methods for chemicals testing: Current status and Future Prospects – A report prepared by ECVAM and the ECVAM Working Group on chemicals. ATLA 30, Supplement 1, July 2002; and CSTEE Opinion of 8 January 2004 (Opinion on the BUAV-ECEAE report on "The way forward – action to end animal toxicity testing").

Contrary to the objectives of the Directive, the afore-mentioned factors have resulted in a distortion of the internal market, with significant differences in the level of regulation between Member States. Moreover, the current provisions contain ambiguities and inconsistencies, leading to transposition and compliance problems.

The importance attached to animal welfare is evolving in terms of ethical concerns and this has become a "cultural attitude" for European society. This is acknowledged by the EC Treaty's Protocol on Protection and Welfare of Animals which recognises animals as sentient beings. It requires the Community, and the Member States, to pay full regard to animal welfare. However, the current provisions of the Directive no longer meet this obligation.

There is an increasing awareness of and concern for animal welfare in the public arena. The participation in recent opinion polls and public consultations gives a strong indication of the public interest in this area – two of the three largest public consultations ever launched by the European Commission amongst any of its various policy activities addressed the subject of animal welfare[5]. The existing measures do not sufficiently mirror these expectations and fail to provide a sufficient level of transparency in this highly controversial field.

Other Community policies and legislative measures, such as REACH,[6] may have as a temporary negative effect an increased use of animals in regulatory testing, despite the provisions already taken to avoid unnecessary tests. In light of this and the provisions of the Cosmetics Directive,[7] the necessity to reduce our dependency on animal experimentation is compelling. The ultimate goal should be to replace the use of animal experiments all together. In addition to animal welfare benefits, alternative methods also have the potential to provide robust information through quality-controlled, state-of-the-art tests which could be faster and less cost-intensive than classical animal-based tests.

Directive 86/609/EEC has encouraged the development of alternatives to animal testing. For example, in 1991 the Commission created the European Centre for Validation of Alternative Testing Methods (ECVAM)[8] within the Commission's Joint Research Centre. To move forward to the next level, the proposal has a specific emphasis on complementing this structure by introducing a number of measures to promote alternative approaches, though recognising that the identification and setting of regulatory testing needs is done and should be done through the use of other pieces of legislation. The measures to promote alternative approaches range from a general requirement to use alternative methods as soon as they become available, to further concrete measures to promote their development, validation and acceptance, also at international level. Generally the proposal requires that the principles of the Three Rs are fully taken into account when developing Community measures to protect the health and safety of human beings, animals and the environment.

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5 The consultation on the regulation on origin marking ("made in") received 166,680 replies, the consultation on the Community Action Plan on Animal Welfare and Protection 44,514 replies and the one about the Revision of Directive 86/609/EEC received 42,655 replies.

6 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

7 Directive 76/768/EEC and its 7th Amendment through Directive 2003/15/EC.

8 SEC(91) 1794.

The use of animals in scientific procedures today, however, still remains essential for ensuring a level of safety for human beings, animals and the environment and for the advancement of knowledge which will lead to improvements in human and animal health and welfare[9],[10]. There are strong arguments for differentiating the use of animals with respect to the species, in particular in relation to their genetic proximity to human beings. Although the proximity of non-human primates makes some of these species the only suitable ones for certain types of testing, this differentiation is supported by science and should be respected.

Therefore, and in line with earlier commitments[11], specific provisions have been incorporated to reduce the use of non-human primates to an absolute minimum. A strict case-by-case scrutiny is imposed in cases where non-human primates are still the only suitable species. The proposal limits the use of non-human primates by prohibiting the use of Great Apes and restricting the use of other species of non-human primate to only specific fields of application. Furthermore, there are ambitious requirements on the origins of the animals and specific monitoring mechanisms are foreseen to ensure the effectiveness of the proposed measures, ultimately facilitating the move towards abolishing the use of non-human primates in scientific procedures. It is recognised, however, that current scientific knowledge will not allow us to achieve this goal in the near future[12].

In its role as guardian of the EC Treaties, the Commission is also responsible for ensuring that Community legislation is properly implemented and enforced. The current Directive has faced criticism linked to its enforcement, transparency and public accountability. To remedy the situation, the proposal foresees tightening of national inspections, not only to ensure compliance, but as a means to promote the exchange of best practices and implementation of the principles of the Three Rs. Furthermore, the Commission can play a constructive role in assisting where appropriate the national inspection systems in fulfilling their role.

Existing provisions in the area of the proposal

The proposal builds on the current provisions of Directive 86/609/EEC. It seeks to tighten the loopholes, remove ambiguities, make the provisions coherent and align it with the better regulation standards of the Community. The existing provisions that have had the most pronounced impact on the distortion of the internal market, namely authorisation and accommodation and care requirements, have been further developed to specifically ensure harmonised objectives and minimum standards can be applied throughout the EU.

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9 Opinion of The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the BUAV-ECEAE Report on "The way forward – Action to end animal toxicity testing", adopted on 8 January 2004 - http://ec.europa.eu/health/ph_risk/committees/sct/documents/out217_en.pdf.

10 The Scientific Committee on Health and Environmental Risks opinion on "Endocrine Disrupting Chemicals: a Non-animal Testing Approach", adopted on 25 November 2005 - http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_015.pdf.

11 Council Decision 1999/575/EC of 23 March 1998 concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes; whereas 3 and 4.

12 The Scientific Steering Committee: "The need for non-human primates in biomedical research", statement adopted 4-5 April 2002. http://europa.eu.int/comm/food/fs/sc/ssc/out253_en.pdf.

The accommodation and care guidelines annexed to the Council of Europe Convention (ETS 123) were fully revised in June 2006, with the support of the Community. In line with the Community's international obligations to implement the revised guidelines, parts of these guidelines will be implemented as minimum standards through this proposal.

Consistency with other policies and objectives of the Union

EU context

This proposal, which aims at harmonising and levelling the practices for the breeding, keeping and use of animals in scientific procedures in the EU, is in line with the objectives of Article 95 of the EC Treaty. It is specifically designed to take account of the diversity of infrastructures in different Member States by leaving sufficient scope for implementing measures at a national level, in line with the principle of subsidiarity of the Community. Optimum implementation at the national level through the use of identified best practices will provide ample opportunity to reduce unnecessary red-tape and administrative costs.

In accordance with the Lisbon Agenda objectives, the proposal is based on an analysis of the potential benefits and costs of action or lack of action as well as the respect of the economic and social development of the Community as a whole. Moreover, specific measures have been included to allow smooth administrative procedures in support of the objectives of the Lisbon Agenda. The proposal strikes a balance in promoting European research and competitiveness while at the same time being at the forefront in ensuring that full regard is paid to animal welfare.

The proposal ensures that the necessary harmonised framework is put in place to facilitate EU wide research projects, especially in terms of the mobility of research personnel via establishment of minimum training standards. At the same time, the Community Framework Programmes for Research have put an increasing emphasis on the development and validation of alternative approaches which are echoed strongly in the proposal.

In addition, the Commission has an important responsibility to ensure that new legislation regarding animal welfare standards is based on evolving scientific knowledge and current best practice. As part of this policy, the European Food Safety Authority (EFSA),[13] established in 2002, serves as an independent scientific source of risk assessment and advice, information and risk communication to the European Commission. Scientific questions on animal welfare fall also under the remit of EFSA and these are tackled by the Panel on Animal Health and Animal Welfare (AHAW). A number of specific measures are based on the recommendations provided by AHAW. The incorporation of the latest scientific knowledge will be facilitated through requirements for regular review of these provisions.

The proposal incorporates fully the principles of the Three Rs in line with other Community policies. The requirement to replace, reduce and refine the use of animals in scientific procedures is highlighted in a number of other pieces of

[13] Council Regulation (EC) No 178/2002 establishing the European Food Safety Authority.

Community legislation such as Directive 98/8/EC on biocidal products, Directive 1999/45/EC on dangerous preparations, 7th Amendment to Directive 76/768/EEC and most recently in Regulation (EC) No 1907/2006 (REACH)[14],[15],[16],[17].

In the area of alternative methods, the proposal further facilitates the aims of the European Partnership on Alternative Approaches to Animal Testing, EPAA[18] which was launched in 2006 between the Commission and industry to promote alternative approaches to animal testing.

Finally, the proposal is fully in line with the recent Community Action Plan on Animal Welfare[19] which included this proposal as part of its specific actions. The European Parliament reiterated its call for the Commission to come forward as soon as possible with a proposal to revise Directive 86/609/EEC[20].

2) CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents

Stakeholder groups have been extensively involved in the development of this proposal from the beginning through a Technical Expert Working Group (TEWG) convened by the Commission, bilateral consultations with different stakeholder groups as well as through public internet consultations. The documents distributed for the TEWG were also widely distributed to the research community and industry to allow maximum input. In 2006, the Commission carried out a public Internet consultation directed at the general public and experts and stakeholders in the field[21].

Summary of responses and how they have been taken into account

The results of the citizens' consultation are based on the responses of citizens who were interested in the subject and took the initiative to fill in the questionnaire. Therefore, the results are not comparable to those obtained from surveys, such as Eurobarometer. However, the high level of participation gives a strong indication of the public interest in this area. A large majority of the respondents supports measures at EU level to increase the welfare of animals.

The expert consultation received over 12,000 comments on the different options for the revision. These have been analysed in detail and taken into account in the legal drafting as well as in modifying and updating the Commission Impact Assessment.

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14 OJ L 123, 24.4.1998, p. 1.
15 OJ L 200, 30.7.1999, p. 1.
16 Directive 2003/15/EC, OJ L 66, 11.3.2003, p. 26.
17 OJ L 396, 30.12.2006, p. 1.
18 http://ec.europa.eu/enterprise/epaa/index_en.htm
19 Communication from the Commission to the European Parliament and the Council on a Community Action Plan on the Protection and Welfare of Animals 2006-2010 - COM(2006) 13, 23.1.2006.
20 EP-Resolution 2006/2046(INI).
21 Published in December 2006 on the DG Environment Website under: http://ec.europa.eu/environment/chemicals/lab_animals/background_en.htm

Collection and use of expertise

Domains of scientific expertise concerned

Experts in the area of animal testing and experimentation, laboratory animal science, natural sciences (especially biology, medicine, pharmacology, toxicology and ecotoxicology), animal welfare, ethics, laboratory animal breeders, technicians and veterinarians, animal behaviourists, and experts in legal and economic affairs related to these areas were asked for and provided input.

Methodology used

The proposal is based on the best available scientific and technical knowledge. Such expertise has been gathered through the comprehensive stakeholder consultations including the TEWG, a public internet consultation and by contracting an outside study to assess the socioeconomic and animal welfare impacts of the measures proposed. In addition, specific scientific questions were addressed to the Panel on Animal Health and Animal Welfare of the European Food Safety Authority and to its predecessor Scientific Committee on Animal Health and Animal Welfare (SCAHAW).

Main organisations/experts consulted

The consultation included national administrations, industry associations, animal welfare organisations, patient organisations, science and research institutes, organisations in the field of the principles of the Three Rs and alternative methods, the European Medicines Agency, the Joint Research Centre and other Commission services, national administrations and breeders of laboratory animals in third countries as well as many other associations which had European coverage.

Summary of advice received and used

There is a broad consensus that the current Directive is outdated and has led to distortion of the internal market. The technical-scientific advice was used as the basis for a preliminary set of foreseen measures. These measures were then presented for a wide consultation during which they received clear support from stakeholders.

Among the options that were abandoned as a result of feedback received, was a requirement for publication of ethical evaluations and systematic retrospective assessments of all projects using animals. These were replaced by a requirement for non-technical summaries to be produced by the applicant and retrospective assessment based on case-by-case analysis of its necessity. Furthermore, the option to have an EU wide database as a means to combat unnecessary duplication of testing was discarded.

Throughout the consultation, stakeholders supported the approach to ensure a flexible mechanism that allows implementation to be determined at a national level.

There was a broad consensus that the current Directive should be revised to include the main elements presented establishing common objectives and principles throughout the EU, leaving to Member States the adoption of detailed measures at the appropriate administrative level.

Impact assessment

The following broad options, from less to more prescriptive, have been considered:

(1) Deregulation

(2) Maintaining status quo

(3) Strengthening the current legislation

(4) Voluntary agreements as an alternative to legislation

The Commission carried out an Impact Assessment, which sets out in more detail the findings as regards the socio-economic impacts and impacts on animal welfare linked to this proposal and the more detailed options therein.

The current situation in the European Community is characterised by a highly diversified, unequal competitive environment for industry and the research community. The main economic actors affected by the functioning of the internal market are:

- Contract research institutes performing animal tests on behalf of other companies for cost or expertise reasons.

- Companies doing product development research in-house (e.g. pharmaceutical, chemical producers). Their cost structure varies across Europe due to differences in the regulatory environment.

Universities are also affected by the functioning of the internal market in the area of animal experimentation, as they compete for industry sponsorship for research, are tendering for public procurement contracts and sometimes create their own commercial off-spring or branches.

The Impact Assessment was reviewed in March 2007 by the independent Commission Impact Assessment Board. The Board issued its Opinion on 16 March 2007 and emphasised the following positive elements: The attempt to quantify and where possible monetise benefits and costs for each specific option, the inclusion of information about third country systems of laboratory animal protection, the examination of links with other Community legislation and the inclusion of a glossary of terms. In light of the Board's recommendations, the following sections have been further improved: internal market problems, the option of self-regulation, the qualitative benefit dimension and the use of the standard model of administrative costs.

The increase in annual costs is estimated to be about 143.7 million € for the EU-25. This figure includes additional administrative costs of about 45 million € annually mainly from increased scrutiny of project applications, covering more animals, more inspections and improved statistics.

These costs should be mirrored against the benefits to animal welfare, innovation and science as well as society in terms of increased public accountability and transparency. Authorisation of groups of projects for regulatory testing would reduce

the average costs of this type of project at the establishment level due to economies of scale. Positive impacts would also occur at the level of authorisation bodies in Member States due to more flexible and efficient handling of the procedures. Industry and academia would benefit from deadlines for authorisation decisions.

Some simplification benefits have been taken into account, especially related to group authorisations which will greatly reduce the administrative burden. Expected savings will be about 22 million € per year. The benefits from reduced administrative costs and avoidable unnecessary testing alone were estimated to be 90 million € per year. These, however, are not reflected in the estimated annual cost.

3) LEGAL ELEMENTS OF THE PROPOSAL

Summary of the proposed action

- the proposed Directive includes requirements for:

  – the acquisition, breeding, marking and keeping of animals, including their accommodation and care requirements;

  – the authorisation and functioning of establishments breeding, supplying or using animals and inspections of these establishments;

  – the authorisation of persons using or caring for animals, supervising or responsible for designing projects using animals;

  – the evaluation and authorisation of projects using animals, including their retrospective assessment;

  – the choice of procedures and their conduct;

  – the development, validation, regulatory acceptance and implementation of alternative approaches;

  – transparency through publication of non-technical information on projects, national implementing rules and guidelines as well as reporting on implementation and statistics.

  The basis of the specific measures is anchored in the globally acknowledged principles of the Three Rs (Replacement, Reduction and Refinement). 'Replacement' means the attempt to replace procedures involving live animals by alternatives which do not use live animals; 'reduction' means the attempt to reduce the number of animals used in procedures to the minimum necessary without compromising the quality of scientific results; 'refinement' means the employment of methods to ensure that any possible pain and suffering by the animals are reduced to the minimum, as well as to improve the care, treatment and living conditions of the animals to enhance their well-being, taking into consideration the life-time experience of the animals.

  Community context

  There is Community legislation in place to evaluate and manage potential risks of products and substances for health and safety reasons. In some cases, it is necessary to resort to animal testing to evaluate these risks. The areas include pharmaceuticals, chemicals, pesticides as well as food and feed safety. It is therefore necessary that animal welfare considerations are taken into account, while being balanced against the potentially serious threats to human and animal health, and the environment which need to be tested.

Legal basis

The provisions of this Directive relate to the harmonisation of the internal market in the field of breeding, supplying and use of animals and consequently Article 95 of the EC Treaty was kept as the legal basis.

Subsidiarity principle

For the following reasons the proposal complies with the subsidiarity principle:

- The EC Treaty provides the European Community in Article 95 with a legal base to adopt measures to approximate Member State provisions laid down by law, regulation or administrative action, in order to ensure the functioning of the internal market.

- The Protocol on protection and welfare of animals annexed to the EC Treaty requires the European Community and the Member States to pay full regard to the welfare requirements of animals in formulating and implementing the Community's internal market and research policies.

- While some of the identified problems fall under a competence shared by the Community and the Member States, problems such as those resulting from diversified requirements for authorisation and ethical evaluation as well as for accommodation and care of animals, cannot be sufficiently solved by the Member States themselves because action or non-action by the Member States has created the problems of distortion of the internal market in the first place. Without regulatory action at European level, the distortion of the internal market will persist and possibly worsen.

Without Community action to underpin the efforts at national level, the current situation has created an uneven playing field for industry and the research community.

As a result there are competitive disadvantages for establishments in countries with high animal welfare standards resulting primarily from price differences, diverging regulatory and authorisation procedures and criteria in the Member States leading to variable delays and cost of projects, unsatisfactory conditions for researchers and obstacles to horizontal mobility and between academia and the private sector. Similar problems can be identified for the breeders and suppliers of experimental animals.

The proposal aims at achieving common principles, objectives and actions for all Member States to ensure a fair and level playing field in the future.

Proportionality principle

The proposal complies with the proportionality principle for the following reasons:

The proposed Directive would establish a set of measures to harmonise the practices for the use and the care of animals used or intended to be used in scientific procedures, in line with the animal welfare protocol of the EC Treaty. Much scope is left to the Member States to identify the most suitable specific measures at the most appropriate administrative level and the respective administrative infrastructure. This

will ensure that the regional and local specificities as regards socio-economic and ethical aspects can be properly taken into account.

The practical implementing measures are to be decided by Member States, allowing for an efficient use and further development of national administrative capabilities which may also be best suited to support the local industry and research community. As demonstrated by the Impact Assessment, the benefits of the proposed measures to the internal market as well as to animal welfare outweigh the costs. The final measures have been refined to secure a balance between the need for harmonisation, the costs and flexibility for local implementation.

The Member States will be entitled to take more stringent measures than those laid down in the proposed Directive, where they satisfy the requirements of Article 95(4) EC.

Choice of instrument

Proposed instrument: Directive.

Other means would not be adequate for the following reason:

A more prescriptive instrument, such as a Regulation, would be too rigid to encompass all the existing regulatory systems that have developed over the last 20 years in the Member States. Deregulation or a non-binding instrument would not address the problems identified with the current Directive and could not prevent the further distortion of the internal market.

4) BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

5) ADDITIONAL INFORMATION

Review/revision/sunset clause

The proposal includes a review clause.

Correlation table

The Member States are required to communicate to the Commission the text of national provisions transposing the Directive as well as a correlation table between those provisions and this Directive.

European Economic Area

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

2008/0211 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of animals used for scientific purposes

(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[22],

Having regard to the opinion of the European Economic and Social Committee[23],

Having regard to the opinion of the Committee of the Regions[24],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[25],

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[26]. 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[27] 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

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22 OJ C […], […], p. […].
23 OJ C […], […], p. […].
24 OJ C […], […], p. […].
25 OJ C […], […], p. […].
26 OJ L 222, 24.8.1999, p. 29.
27 OJ L 358, 18.12.1986, p. 1. Directive as amended by Directive 2003/65/EC of the European Parliament and of the Council (OJ L 230, 16.9.2003, p. 32).

rules in order to reduce such disparities and to ensure a proper functioning of the internal market.

(4) The European Parliament in its report of [5 December] 2002 on Directive 86/609/EEC called for the Commission to come forward with a proposal for a revision of that Directive with more stringent and transparent measures in the area of animal experimentation.

(5) New scientific knowledge is available on factors influencing animal welfare as well as the capacity of the 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 those animals in line with the latest scientific developments.

(6) It is necessary to include specific invertebrate species within the scope of this Directive, as 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, as 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 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) While it is desirable to replace the use of live animals in procedures by other methods not entailing the use of live animals, the use of live animals continues to be necessary to protect human and animal health and the environment.

(9) 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.

(10) 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 ultimately benefit human or animal health, or the environment. Use of animals for scientific procedures in other areas under Community competence should be prohibited.

(11) 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.

(12) 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 statistically reliable results and choose the species with the lowest degree of neurophysiological sensitivity that are optimal for the extrapolation into target species.

(13) 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.

(14) 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 an authorised person with a humane method that is considered appropriate to the species.

(15) 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.

(16) 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 and only in cases where the procedures are carried out in relation to clinical conditions having a substantial impact on patients' day-today functioning as being either life-threatening or debilitating, 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 to many life-threatening and debilitating human conditions. The reference to life-threatening or debilitating clinical conditions is established terminology in EC legislation as reflected in Regulation 141/2000/EC, in Directive 2001/20/EC, Regulation 726/2004/EC and Commission Regulation 507/2006/EC.

(17) 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.

(18) The capture of non-human primates from the wild is highly stressful for the animals and increases the risk of injury and suffering during capture and transport. In order to gradually end the capturing of animals from the wild for breeding purposes, only animals that are the offspring of an animal which has been bred in captivity should be made available for use in scientific procedures as soon as possible. Establishments breeding and supplying non-human primates should therefore have a strategy in place to support and facilitate the progressive move towards that goal.

(19) 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.

(20) 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.

(21) 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 level of pain, suffering, distress and lasting harm that is inflicted on the animals. To give precision how severity classes should be assigned, the Commission should develop criteria with stakeholder input using existing severity classification schemes in place in Member States as well as those promoted by international organisations as basis.

(22) From the ethical standpoint, there should be an upper limit of pain, suffering and distress, above which animals should never 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 be prohibited. 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.

(23) 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 only to those procedures where pain, distress and suffering are significantly reduced.

(24) At the end of the procedure, the most appropriate decision should be taken as regards 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 public concern as to the fate of those animals. Should establishments allow re-homing, it is

essential that there is a scheme in place to provide the appropriate socialisation to those animals in order to ensure successful re-homing as well as to avoid unnecessary distress to the animals and to guarantee public safety.

(25) Animal tissue and organs are used for the development of *in vitro* methods. To implement the principle of reduction, Member States should establish programmes for sharing the organs and tissue of animals that are killed using humane methods.

(26) The welfare of the animals used in procedures is highly dependent on the quality and professional competence of the personnel 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 the persons dealing with animals and with procedures involving animals, those activities should only be performed 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.

(27) 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 to the animals. The establishments should operate only if they are authorised by the competent authorities.

(28) To ensure the on-going 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.

(29) Animal welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. Each establishment should therefore have an independent 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.

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

(31) Non-human primates with highly developed social skills should have a personal history file from birth covering their lifetimes in order to be able to receive the care, accommodation and treatment that meet their individual needs and characteristics.

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

(33) 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[28] incorporated those guidelines.

(34) 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.

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

(36) 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.

(37) 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.

(38) It is also essential to ensure both on moral and scientific grounds that each use of animals is carefully evaluated on the scientific validity, usefulness and relevance of the expected result of that use. The likely harm to the animals should be balanced against the expected benefits of the project. Therefore, an independent ethical evaluation 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.

(39) 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 is 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.

(40) 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 that information should not violate proprietary rights or expose confidential information. Therefore, user establishments should provide anonymous non-technical summaries of those projects, including the results of any retrospective assessments, and make those summaries publicly available.

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[28] OJ L 197, 30.7.2007, p. 1.

(41) 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.

(42) 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.

(43) 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.

(44) The availability of alternative methods is highly dependent on the progress of the research for 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.

(45) 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[29] in order to ensure coherent and comparable quality of the results.

(46) 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

[29] OJ L 50, 20.2.2004, p. 44.

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.

(47) 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 review of this Directive. Such a review 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.

(48) 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[30].

(49) In particular, power should be conferred on the Commission to establish the criteria for classification of procedures and to adapt Annexes II to VII 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.

(50) 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.

(51) Directive 86/609/EEC should therefore be repealed.

(52) Benefits to animal welfare from applying project authorisation retrospectively, and the related administrative costs, can only be justified for long term on-going projects. Therefore, it is necessary to include transitional measures for on-going short and medium term projects to avoid the need for a retrospective authorisation with only limited benefits.

(53) Since the objectives of the action to be taken - 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.

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[30] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

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 where animals are 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.

   The elimination of pain, suffering, distress or lasting harm 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 as from the last third of their normal development;

   (b) live invertebrate animals, including independently feeding larval forms, of those species 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. 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 are not invasive

5. This Directive shall apply without prejudice to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.

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 cause the animal pain, suffering distress or lasting harm, including 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.

Article 4
Replacement, reduction and refinement

1. Where a method of testing not involving the use of animals exists and may be used in place of a procedure, Member States shall ensure that the alternative method is used.

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.

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 either 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;

(3) the development, manufacture or testing of the quality, effectiveness and safety of drugs, food- and feed-stuffs and other substances or products having either 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) research aimed at preservation of the species;

(6) higher education or training;

(7) 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 V, using the appropriate humane method of killing as set out in that Annex.

However, in case of a field study an animal may be killed outside of 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.

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.

CHAPTER II
PROVISIONS ON THE USE OF CERTAIN ANIMALS IN PROCEDURES

Article 7
Endangered species other than non-human primates

1. Endangered species listed in Annex A to Council Regulation (EC) No 338/97[31] 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 (5) 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.

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

Article 8

Non-human primates

1. 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) and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of life-threatening or debilitating clinical conditions in human beings or the purpose referred to in point (5) of Article 5;

   (b) there is a scientific 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 50.

[31] OJ L 61, 3.3.1997, p. 1.

Article 9
Animals taken from the wild

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

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 10
Animals bred for use in procedures

1. 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.

   However, as from the dates set out in Annex III, Member States shall ensure that non-human primates listed in that Annex may only be used in procedures where they are the offspring of non-human primates which have been bred in captivity.

2. Competent authorities may grant exemptions from paragraph 1 on the basis of a scientific justification.

Article 11
Stray and feral animals of domestic species

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

CHAPTER III
PROCEDURES

Article 12
Procedures

1. Member States shall ensure that procedures are always carried out in user establishments.

   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.

Article 13
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 a choice between procedures, those which use the minimum number of 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 14
Anaesthesia

1. Member States shall ensure that all procedures are carried out under general or local anaesthesia.

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

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

   (d) 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 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 those cases, a scientific justification shall be provided, accompanied by the details of the anaesthetic or analgesic regime.

5. An animal, which may suffer considerable 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 15
Classification of severity of procedures

1. Member States shall ensure that all procedures are classified as 'up to mild', 'moderate', 'severe' or 'non-recovery' on the basis of the duration and intensity of potential pain, suffering, distress and lasting harm, the frequency of intervention, the deprivation of ethological needs and the use of anaesthesia or analgesia or both.

2. Member States shall ensure that the procedures classified as "severe" are not performed if the pain, suffering or distress is likely to be prolonged.

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 establish the criteria for classification of procedures.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall by *[within 18 months from the entry into force of this Directive]* be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 51(3).

Article 16
Re-use

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

(a) the previous procedure was classified as 'up to mild';

(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 mild' or 'non-recovery'.

2. By way of derogation from paragraph 1, the competent authority, on the basis of scientific justification, may allow re-use of an animal as long as the animal is not used more than once after having undergone a procedure entailing severe pain, distress or equivalent suffering and the further procedure is classified as 'up to mild' or as 'non-recovery'.

Article 17
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.

3. 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 18
Sharing organs and tissues

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

Article 19
Setting free of animals and re-homing

Member States may allow animals used or intended to be used in procedures to be set free 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.

CHAPTER IV
AUTHORISATION

Section 1
Authorisation of persons

Article 20
Authorisation of persons

1. Member States shall ensure that persons are authorised by the competent 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 education and training and have demonstrated 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 of time, not exceeding five years. Member States shall ensure that the renewal of an authorisation of persons is only granted on the basis of demonstration of the requisite competence.

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

Section 2
Requirements for establishments

Article 21
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 22
Suspension and withdrawal of authorisation

1. Where an establishment no longer complies with requirements set out in this Directive, the competent authority shall suspend or withdraw its authorisation.

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 23
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, obtaining consistent results with the minimum number of animals and the minimum degree of pain, suffering, distress or lasting harm.

Article 24
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.

Article 25
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 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.

Article 26
Tasks of permanent ethical review body

1. 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 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 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 submitted to the competent authority upon request.

Article 27
Breeding strategy for non-human primates

1. Member States shall ensure that 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.

2. 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 28
Re-homing scheme

Where Member States allow re-homing as referred to in Article 19, 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 29
Records on animals

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

   (a) the number and the species of 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 recipient of 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 30
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 non-human primate shall have an individual history file, which follows the animal throughout its life.

The file shall be established at birth and shall cover detailed 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 31
Marking

1. Each dog, cat or 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 32
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, at least some freedom of movement, food, water and care which are appropriate to their health and well-being;

(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 to prevent pain or avoidable suffering, distress or lasting harm;

(e) arrangements are made to ensure that any 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 animal welfare reasons.

Section 3
Inspections

Article 33
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 at least twice a year.

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.

4. Records of all inspections shall be kept 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 34
Controls of national inspections

1. The Commission may undertake controls of the infrastructure and operation of national inspections in Member States.

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 35
Authorisation of projects

1. Member States shall ensure that projects are not carried out without a prior authorisation by the competent authority.

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

Article 36
Application for the project authorisation

1. The user establishment 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 VII.

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 41(2), provided that the project involves only procedures classified as "up to mild" and does not use non-human primates.

Article 37
Ethical evaluation

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

   (a) the project is scientifically justified or required by law;

   (b) the purposes of the project justify the use of animals;

   (c) the project is designed so as to enable procedures to be carried out in the most humane and 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 justified by the expected advancement of science that ultimately benefits human beings, animals or the environment;

(e) an assessment of any scientific justification referred to in Articles 6, 7, 8, 9, 10, 12, 14 and 16.

3. The competent authority carrying out the ethical evaluation shall consider experts 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 the opinion of independent parties.

Article 38
Retrospective assessment

1. The ethical evaluation shall determine, on the basis of the harm-benefit analysis referred to in point (d) of Article 37(2), whether the project should, once it has been completed, be assessed retrospectively by the competent authority.

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 evaluate 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) 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. Without prejudice to paragraph 3, all projects involving only procedures classified as "up to mild" shall be exempted from the requirement for a retrospective assessment.

Article 39
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 40
Non-technical project summaries

1. Subject to safeguarding confidential information, 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 of compliance with the requirement of replacement, reduction and refinement.

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 the non-technical project summaries of authorised projects and any updates to them.

Article 41
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 four years.

4. Member States may allow the authorisation of multiple projects when those projects are required by law.

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 42
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.

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

3. The competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation.

4. 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.

5. Member States shall establish and publish detailed conditions for amendment and renewal of project authorisations.

Article 43
Authorisation decisions

1. 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.

2. Notwithstanding paragraph 1, in exceptional circumstances and where the project is non-routine, multi-disciplinary and innovative, the decision to grant an authorisation shall be taken and communicated to the user establishment within 60 days from the submission of the application.

CHAPTER V
AVOIDANCE OF DUPLICATION AND ALTERNATIVE APPROACHES

Article 44
Unnecessary duplication of procedures

1. Each Member State shall accept data that are required by law and generated by procedures recognised by Community legislation from another Member State, unless further procedures need to be carried out regarding that data for the protection of public health, safety or the environment.

2. Outside the area of testing required by law, subject to safeguarding confidential information, the Member States shall ensure the sharing of data generated by procedures.

Article 45
Alternative approaches

The Commission and Member States shall contribute to the development and validation of alternative approaches that could provide the same or higher 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.

Article 46
National reference laboratories for alternative methods

1. Each Member State shall, by *[one year after entry into force of this Directive],* designate a national reference laboratory for the validation of alternative methods replacing, reducing and refining the use of animals.

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;

   (b) participate in pre-validation and validation of alternative methods 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 of 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 20(1).

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

6. 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.

7. 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 47
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 48
Adaptation of annexes to technical progress

The Commission may adapt Annexes II to VII 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 51(4).

Article 49
Reporting

1. Member States shall by *[within six years from transposition date]*, and every five years thereafter, send the information on the implementation of this Directive and in particular Articles 10(1), 25 , 27, 33, 37, 38, 40 and 44 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 submit that statistical information to the Commission by [three years from transposition date] and every year thereafter.

3. The Commission shall by *[within 18 months from the entry into force of this Directive]* establish a common format for submitting the information referred to in paragraph 2 in accordance with the regulatory procedure referred to in Article 51(2).

Article 50
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 5; 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 procedure referred to in Article 51(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.

Article 51
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 52
Commission report

1. By *[seven years after transposition date]* *and* every five years thereafter , the Commission shall, based on the information received from the Member States under Article 49(1), submit to the European Parliament and the Council a report on the implementation of this Directive.

2. By *[seven years after transposition date]* *and* every three years thereafter the Commission shall, based on the statistical information submitted by Member States under Article 49(2), submit to the European Parliament and the Council a summary report on that information.

Article 53
Review

The Commission shall review this Directive by *[10 years after the date of entry into force]* 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 54
Competent authorities

1. Each Member State shall designate one or more competent authorities responsible for the implementation 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 *[three months after Entry into Force of this Directive]*, 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 55
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 *[(the date specified in Article 56)]* at the latest and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 56
Transposition

1. Member States shall adopt and publish, by [*18 months from the Entry into Force of this Directive*] 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 [*1 January of the year following the date of transposition as specified in the first subparagraph*].

   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 57
Repeal

Directive 86/609/EEC is repealed with effect from [the date referred to in the second subparagraph of Article [56(1)].

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

Article 58
Transitional provisions

1. Member States shall not apply laws; regulations and administrative provisions adopted in accordance with Articles 35 to 43 to projects which have been started before [the date referred to in the second subparagraph of Article [56(1)] and the duration of which does not extend beyond [three years after the date referred to in the second subparagraph of Article [56(1)].

2. Projects which have been started before [the date referred to in the second subparagraph of Article [56(1)] and the duration of which extends beyond [three years after the date referred to in the second subparagraph of Article [56(1)] shall obtain project authorisation by [three years after the date referred to in the second subparagraph of Article [56(1)].

Article 59
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 60
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

Invertebrate Species referred to in Article 2(2)

- Cyclostomes
- Cephalopods
- Decapod crustaceans

ANNEX II

List of animals referred to in Article 10

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

ANNEX III

list of non-human primates and dates referred to in the second subparagraph of Article 10(1)

Species	Dates
Marmoset (*Callithrix jacchus*)	*[date of application referred to in the second subparagraph of the first paragraph Article on transposition]*
Cynomolgus monkey (*Macaca fascicularis*)	*[7 years after transposition of Directive]*
Rhesus monkey (*Macace mulatta*)	*[7 years after transposition of Directive]*
Other species of non-human primates	*[10 years after transposition of Directive]*

ANNEX IV

Care and accomodation standards referred to in Article 32

SECTION A: GENERAL SECTION

1. THE PHYSICAL FACILITIES

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 ITS CONTROL

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

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

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 32(2)
In stock and during procedures	up to 20 over 20 to 25 over 25 to 30 over 30	330 330 330 330	60 70 80 100	12 12 12 12	*[Jan 2012*]
Breeding		330 For a monogamous pair (outbred/inbred) or a trio (inbred). For each additional female plus litter 180 cm^2 shall be added.		12	
Stock at breeders* Enclosure size 950 cm²	less than 20	950	40	12	
Enclosure size 1500 cm²	less than 20	1500	30	12	

* 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

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 32(2)
In stock and during procedures*****	up to 200	800	200	18	*[Jan 2012]*
	over 200 to 300	800	250	18	
	over 300 to 400	800	350	18	
	over 400 to 600	800	450	18	
	over 600	1500	600	18	
Breeding		800 Mother and litter. For each additional adult animal permanently added to the enclosure add 400 cm^2		18	
Stock at breeders* Enclosure size 1500 cm²	up to 50	1500	100	18	
	over 50 to 100	1500	125	18	
	over 100 to 150	1500	150	18	
	over 150 to 200	1500	175	18	
Stock at breeders****** Enclosure size 2500 cm²	up to 100	2500	100	18	
	over 100 to 150	2500	125	18	
	over 150 to 200	2500	150	18	

* 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

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 32(2)

In stock and during procedures	up to 40 over 40	1200 1200	150 250	18 18	*[Jan 2012*]
Breeding		1200 Monogamous pair or trio with offspring		18	

Table 1.4. Hamsters

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 32(2)
In stock and during procedures	up to 60 over 60 to 100 over 100	800 800 800	150 200 250	14 14 14	*[Jan 2012*]
Breeding		800 Mother or monogamous pair with litter		14	
Stock at breeders*	less than 60	1500	100	14	

* 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

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 32(2)
In stock and during procedures	up to 200 over 200 to 300 over 300 to 450 over 450 to 700 over 700	1800 1800 1800 2500 2500	200 350 500 700 900	23 23 23 23 23	*[Jan 2012*]
Breeding		2500 Pair with litter. For each additional breeding female add 1000 cm^2		23	

2. <u>Rabbits</u>

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 3000 cm^2 per rabbit for the third, the fourth, the fifth and the sixth rabbit, while 2500 cm^2 as a minimum shall be added for each additional rabbit above a number of six.

Final body weight (kg)	Minimum floor area for one or two socially harmonious animals (cm^2)	Minimum height (cm)	Date referred to in Article 32(2)
less than 3	3500	45	*[Jan 2012*]
from 3 to 5	4200	45	
over 5	5400	60	

Table 2.2. Doe plus litter

Doe weight (kg)	Minimum enclosure size (cm2)	Addition for nestboxes (cm2)	Minimum height (cm)	Date referred to in Article 32(2)
less than 3	3500	1000	45	*[Jan 2012*]
from 3 to 5	4200	1200	45	
over 5	5400	1400	60	

Table 2.3. Rabbits less than 10 weeks of age

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

Age	Minimum enclosure size (cm^2)	Minimum floor area per animal (cm^2)	Minimum height (cm)	
Weaning to 7 weeks	4000	800	40	
From 7 to 10 weeks	4000	1200	40	

Table 2.4. Rabbits: Optima dimensions for raised areas for enclosures having the dimensions indicated in Table 2.1.

Age in Weeks	Final body weight (kg)	Optimum size (cm x cm)	Optimum height from the enclosure floor (cm)	Date referred to in Article 32(2)
over 10	less than 3	55 x 25	25	*[Jan 2012*]
	from 3 to 5	55 x 30	25	
	over 5	60 x 35	30	

3. <u>Cats</u>

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.

	Floor* (m²)	Shelves (m²)	Height (m)	Date referred to in Article 32(2)
Minimum for one adult animal	1.5	0. 5	2	*[Jan 2017*]
For each additional animal add	0.75	0.25	–	

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.

Weight (kg)	Minimum enclosure size (m²)	Minimum floor area for one or two animals (m²)	For each additional animal add a minimum of (m²)	Minimum height (m)	Date referred to in Article 32(2)
up to 20 over 20	4 8	4 8	2 4	2 2	*[Jan 2017*]

Table 4.2. Dogs - post-weaned stock

Weight of dog (kg)	Minimum enclosure size (m^2)	Minimum floor area/animal (m^2)	Minimum height (m)	Date referred to in Article 32(2)
up to 5	4	0.5	2	*[Jan 2017]*
over 5 to 10	4	1.0	2	
over 10 to 15	4	1.5	2	
over 15 to 20	4	2	2	
over 20	8	4	2	

5. Ferrets

Table 5. Ferrets

	Minimum enclosure size (cm^2)	Minimum floor area per animal (cm^2)	Minimum height (cm)	Date referred to in Article 32(2)
Animals up to 600g	4500	1500	50	*[Jan 2012]*
Animals over 600g	4500	3000	50	
Adult males	6000	6000	50	
Jill and litter	5400	5400	50	

6. Non-human primates

Table 6.1. Marmosets and Tamarins

	Minimum floor area of enclosures for 1* or 2 animals plus offspring up to 5 months old (m^2)	Minimum volume per additional animal over 5 months (m^3)	Minimum enclosure height (m) **	Date referred to in Article 32(2)
Marmosets	0.5	0.2	1.5	*[Jan 2017]*
Tamarins	1.5	0.2	1.5	

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

Table 6.2. Squirrel Monkeys

Minimum floor area for 1* or 2 animals (m^2)	Minimum volume per additional animal over 6 months of age (m^3)	Minimum enclosure height (m)	Date referred to in Article 32(2)
2.0	0.5	1.8	*[Jan 2017*]

* Animals shall only be kept singly under exceptional circumstances.

Table 6.3. Macaques and vervets *

	Minimum enclosure size (m^2)	Minimum enclosure volume (m^3)	Minimum volume per animal (m^3)	Minimum enclosure height (m)	Date referred to in Article 32(2)
*Animals less than 3 yrs of age ***	2.0	3.6	1.0	1.8	*[Jan 2017*]
*Animals from 3 yrs of age ****	2.0	3.6	1.8	1.8	
*Animals held for breeding purposes*****			3.5	2.0	

* Animals shall only be kept singly under 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*

	Minimum enclosure size (m^2)	Minimum enclosure volume (m^3)	Minimum volume per animal (m^3)	Minimum enclosure height (m)	Date referred to in Article 32(2)
Animals** less than 4 yrs of age	4.0	7.2	3.0	1.8	*[Jan 2017*]
Animals** from 4 yrs of age	7.0	12.6	6.0	1.8	
Animals held for breeding purposes***			12.0	2.0	

* Animals shall only be kept singly under 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

Body weight (kg)	Minimum enclosure size (m^2)	Minimum floor area/animal (m^2/animal)	Trough space for ad-libitum feeding of polled cattle (m/animal)	Trough space for restricted feeding of polled cattle (m/animal)	Date referred to in Article 32(2)
up to 100	2.50	2.30	0.10	0.30	*[Jan 2017*]
over 100 to 200	4.25	3.40	0.15	0.50	
over 200 to 400	6.00	4.80	0.18	0.60	
over 400 to 600	9.00	7.50	0.21	0.70	
over 600 to 800	11.00	8.75	0.24	0.80	
over 800	16.00	10.00	0.30	1.00	

Table 7.2. Sheep and Goats

Body weight (kg)	Minimum enclosure size (m^2)	Minimum floor area/animal (m^2/ animal)	Minimum partition height (m)	Trough space for ad-libitum feeding (m/animal)	Trough space for restricted feeding (m/animal)	Date referred to in Article 32(2)
less than 20	1.0	0.7	1.0	0.10	0.25	*[Jan 2017*]
over 20 to 35	1.5	1.0	1.2	0.10	0.30	
over 35 to 60	2.0	1.5	1.2	0.12	0.40	
over 60	3.0	1.8	1.5	0.12	0.50	

Table 7.3. Pigs and Minipigs

Liveweight (kg)	Minimum enclosure size* (m^2)	Minimum floor area per animal (m^2/animal)	Minimum lying space per animal (in, thermoneutral conditions) (m^2/animal)	Date referred to in Article 32(2)
Up to 5	2.0	0.20	0.10	*[Jan 2017*]
over 5 to 10	2.0	0.25	0.11	

over 10 to 20	2.0	0.35	0.18	
over 20 to 30	2.0	0.50	0.24	
over 30 to 50	2.0	0.70	0.33	
over 50 to 70	3.0	0.80	0.41	
over 70 to 100	3.0	1.00	0.53	
over 100 to 150	4.0	1.35	0.70	
over 150	5.0	2.50	0.95	
Adult (conventional) boars	7.5		1.30	

* 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 x the wither height of the animal. The height of indoor enclosures shall allow animals to rear to their full height.

Wither height (m)	Minimum floor area/animal (m^2/animal)			Minimum enclosure height (m)	Date referred to in Article 32(2)
	For each animal held singly or in groups of up to 3 animals	For each animal held in groups of 4 or more animals	Foaling box / mare with foal		*[Jan 2017*]
1.00 to 1.40	9.0	6.0	16	3.00	
over 1.40 to 1.60	12.0	9.0	20	3.00	
over 1.60	16.0	$(2 \times WH)^2$ *	20	3.00	

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

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 m^2.

Body mass (g)	Minimum enclosure size (m^2)	Minimum area per bird (m^2)	Minimum height (cm)	Minimum length of feed trough per bird (cm)	Date referred to in Article 32(2)

Up to 200	1.00	0.025	30	3	*[Jan 2012*]
over 200 to 300	1.00	0.03	30	3	
over 300 to 600	1.00	0.05	40	7	
over 600 to 1200	2.00	0.09	50	15	
over 1200 to 1800	2.00	0.11	75	15	
over 1800 to 2400	2.00	0.13	75	15	
over 2400	2.00	0.21	75	15	

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 m^2 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.

Body mass (kg)	Minimum enclosure size (m^2)	Minimum area per bird (m^2)	Minimum height (cm)	Minimum length of feed trough per bird (cm)	Date referred to in Article 32(2)
Up to 0.3	2.00	0.13	50	3	*[Jan 2012*]
over 0.3 to 0.6	2.00	0.17	50	7	
over 0.6 to 1	2.00	0.30	100	15	
over 1 to 4	2.00	0.35	100	15	
over 4 to 8	2.00	0.40	100	15	
over 8 to 12	2.00	0.50	150	20	
over 12 to 16	2.00	0.55	150	20	
over 16 to 20	2.00	0.60	150	20	
over 20	3.00	1.00	150	20	

Table 8.3. Quail

Body mass (g)	Minimum enclosure size	Area per bird pair-housed (m^2)	Area per additional bird group-housed (m^2)	Minimum height (cm)	Minimum length of trough per bird (cm)	Date referred to in Article 32(2)

	(m^2)					
Up to 150	1.00	0.5	0.10	20	4	*[Jan 2012*]
Over 150	1.00	0.6	0.15	30	4	

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 m^2. These can be used to house small groups of birds in accordance with the space allowances given in table 8.4.

Body mass (g)	Minimum enclosure size (m^2)	Area per bird (m^2)*	Minimum height (cm)	Minimum length of feed trough per bird (cm)	Date referred to in Article 32(2)
Ducks					*[Jan 2012*]
Up to 300	2.00	0.10	50	10	
Over 300 to 1200**	2.00	0.20	200	10	
Over 1200 to 3500	2.00	0.25	200	15	
Over 3500	2.00	0.50	200	15	
Geese					
Up to 500	2.00	0.20	200	10	
Over 500 to 2000	2.00	0.33	200	15	
Over 2000	2.00	0.50	200	15	

* This shall include a pond of minimum area 0.5 m^2 per 2m^2 enclosure with a minimum depth of 30cm. 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*

	Area (m^2)	Depth (cm)
Ducks	0.5	30
Geese	0.5	from 10 to 30

* 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.

Group size	Minimum enclosure size (m^2)	Minimum height (cm)	Minimum length of food trough per bird (cm)	Minimum length of perch per bird (cm)	Date referred to in Article 32(2)
Up to 6	2	200	5	30	*[Jan 2012*]
from 7 to 12	3	200	5	30	
For each additional bird above 12	0.15		5	30	

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 m^2 and a minimum height of 40 cm. The duration of the confinement shall be justified by the experimenter in consultation with veterinary staff.

Group size	Minimum enclosure size (m^2)	Minimum height (cm)	Minimum number of feeders	Date referred to in Article 32(2)
Up to 6	1.0	100	2	*[Jan 2012*]
7 to 12	1.5	200	2	
13 to 20	2.0	200	3	
for each additional bird above 20	0.05		1 per 6 birds	

9. Amphibians

Table 9.1. Aquatic urodele

Body length*(cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group-holding (cm^2)	Minimum water depth (cm)	Optimal temperature	Relative humidity	Date referred to in Article 32(2)
Up to 10	262.5	50	13	15ºC-22∘C	100%	*[Jan 2012*]
over 10 to 15	525	110	13			
over 15 to 20	875	200	15			
over 20 to 30	1837.5	440	15			
Over 30	3150	800	20			

* measured from snout to vent

Table 9.2. Aquatic anurans*

Body length**(cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group-holding (cm^2)	Minimum water depth (cm)	Optimal temperature	Relative humidity	Date referred to in Article 32(2)
Less than 6	160	40	6	18ºC-22ºC	100%	*[Jan 2012*]
from 6 to 9	300	75	8			
over 9 to 12	600	150	10			
over 12	920	230	12.5			

* 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

Body length* (cm)	Minimum enclosure size** (cm^2)	Minimum area for each additional animal in group holding (cm^2)	Minimum enclosure height*** (cm)	Minimum water depth (cm)	Optimal temperature	Relative humidity	Date referred to in Article 32(2)
up to 5.0	1500	200	20	10	10ºC-15ºC	50-80%	*[Jan 2012*]
over 5.0 to 7.5	3500	500	30	10			
Over 7.5	4000	700	30	15			

* 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

Body length* (cm)	Minimum enclosure size** (cm^2)	Minimum area for each additional animal in group-holding (cm^2)	Minimum enclosure height*** (cm)	Minimum water depth (cm)	Optimal temperature	Relative humidity	Date referred to in Article 32(2)
Up to 5.0	1500	200	20	10	23ºC-27ºC	50-80%	*[Jan 2012*]
over 5.0 to 7.5	3500	500	30	10			

over 7.5	4000	700	30	15			

* 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

Body length* (cm)	Minimum enclosure size** (cm^2)	Minimum area for each additional animal in group-holding (cm^2)	Minimum enclosure height*** (cm)	Optimal temperature	Relative humidity	Date referred to in Article 32(2)
up to 3.0	900	100	30	18ºC-25ºC	50-70%	*[Jan 2012*]
Over 3.0	1500	200	30			

* 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. <u>Reptiles</u>

Table 10.1. Aquatic chelonians

Body length*) (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group holding (cm^2)	Minimum water depth (cm)	Optimal temperature	Relative humidity	Date referred to in Article 32(2)
up to 5	600	100	10	20ºC-25ºC	80-70%	*[Jan 2012*]
Over 5 to 10	1600	300	15			
Over 10 to 15	3500	600	20			
Over 15 to 20	6000	1200	30			
Over 20 to 30	10000	2000	35			
Over 30	20000	5000	40			

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

Table 10.2. Terrestrial snakes

Body length*) (cm)	Minimum floor area (cm^2)	Minimum area for each additional animal in group-holding (cm^2)	Minimum enclosure height **) (cm)	Optimal temperature	Relative humidity	Date referred to in Article 32(2)
up to30	300	150	10	22ºC-27ºC	60-80%	*[Jan 2012*]
Over 30 to 40	400	200	12			

Over 40 to 50	600	300	15			
Over 50 to 75	1200	600	20			
Over 75	2500	1200	28			

*) 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

Humane Methods of Killing animals

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

Agent	Rapidity	Efficacy	Ease of use	Operator safety	Aesthetic value	Overall rating (1-5)	Remarks
Anaesthetic overdose	++	++	++	+ to ++	++	4 to 5*	May be used with prior sedation of the animal. *Some anaesthetics may cause skin irritation when used on fish.
Electrical stunning	++	+	+	+	++	4	Specialised equipment required. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Maceration	++	++	++	++	+	4	Only for fish less than 2 cm in length
Concussion	++	+	+	++	-	3	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Cervical dislocation	++	++	+	++	-	2 - if animal conscious 5 - if animal unconscious	Not used in fish >500g. To be followed by destruction of the brain.

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

Rapidity: ++ very rapid, + rapid, - slow. **Efficacy**: ++ very effective, + effective, - not effective. **Ease of use**: ++ easy to use, + requires expertise, - requires specialist training.

Operator safety: ++ no danger, + little danger, - dangerous. **Aesthetic value**: ++ good aesthetically, + acceptable for most people, - unacceptable for many people. **Rating**: 1-5 with 5 as most satisfactory.

Table 2 - Humane methods of killing amphibians

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

*) Neuromuscular blocking agent, NMB

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

Rapidity: ++ very rapid, + rapid, - slow. **Efficacy**: ++ very effective, + effective, - not effective. **Ease of use**: ++ easy to use, + requires expertise, - requires specialist training. **Operator safety**: ++ no danger, + little danger, - dangerous. **Aesthetic value**: ++ good aesthetically, + acceptable for most people, - unacceptable for many people. **Rating**: 1-5 with 5 as most satisfactory.

Table 3 - Humane methods of killing reptiles

Agent	Rapidity	Efficacy	Ease of use	Operator safety	Aesthetic value	Overall rating (1-5)	Remarks
Anaesthetic overdose	++	++	++	+	++	5	May be used with prior sedation of the animal.
Captive bolt	++	++	++	+	+	5	For large reptiles. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Shooting	++	++	++	-	+	4	To be used by experienced marksman. May need a method to ensure death. To be used in field conditions.
Concussion	+	+	+	++	-	3	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.

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

Rapidity: ++ very rapid, + rapid, - slow. **Efficacy**: ++ very effective, + effective, - not effective. **Ease of use**: ++ easy to use, + requires expertise, - requires specialist training. **Operator safety**: ++ no danger, + little danger, - dangerous. **Aesthetic value**: ++ good aesthetically, + acceptable for most people, - unacceptable for many people. **Rating**: 1-5 with 5 as most satisfactory.

Table 4 - Humane methods of killing birds

Agent	Rapidity	Efficacy	Ease of Use	Operator safety	Aesthetic value	Overall rating (1-5)	Remarks
NMB/ anaesthetic mixtures	++	++	+	+	++	4	To be injected intravenously, therefore requires expertise.
Inert gases (Ar, N2)	++	++	++	++	+	4	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Maceration	++	++	++	++	-	4	For chicks up to 72 h old
Cervical dislocation	++	++	-	++	-	1/3 - if animal conscious 5 - if animal unconscious	For small and young birds (<250 g). To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Microwave irradiation	++	++	-	++	+	3	Specialised equipment required.
Concussion	++	++	-	++	-	3	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.

Electrical stunning	++	++	+	-	-	3	Specialised equipment required. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Carbon monoxide	+	+	++	-	-	1	Danger to operator.

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

Rapidity: ++ very rapid, + rapid, - slow. **Efficacy**: ++ very effective, + effective, - not effective. **Ease of use**: ++ easy to use, + requires expertise, - requires specialist training. **Operator safety**: ++ no danger, + little danger, - dangerous. **Aesthetic value**: ++ good aesthetically, + acceptable for most people, - unacceptable for many people. **Rating**: 1-5 with 5 as most satisfactory.

Table 5 - Humane methods of killing rodents

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

Carbon dioxide	+	++	++	+	++	1 - if sole agent 5 - if animal unconscious	To be used in gradual fill only.
Carbon monoxide	+	+	+	-	++	1	Danger to operator

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

Rapidity: ++ very rapid, + rapid, - slow. **Efficacy**: ++ very effective, + effective, - not effective. **Ease of use**: ++ easy to use, + requires expertise, - requires specialist training. **Operator safety**: ++ no danger, + little danger, - dangerous. **Aesthetic value**: ++ good aesthetically, + acceptable for most people, - unacceptable for many people. **Rating**: 1-5 with 5 as most satisfactory.

Table 6 - Humane methods of killing rabbits

Agent	Rapidity	Efficacy	Ease of use	Operator safety	Aesthetic value	Overall rating (1-5)	Remarks
Anaesthetic overdose	++	++	++	+	++	5	May be used with prior sedation of the animal.
NMB/ anaesthetic mixtures	++	++	-	+	++	4	To be injected intravenously, therefore requires expertise.
Captive bolt	++	++	-	+	+	4	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Cervical dislocation	++	++	-	++	-	3 - if animal conscious 5 - if animal unconscious	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.
Concussion	++	+	-	++	-	3	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Electrical stunning	++	+	++	-	+	3	Specialised equipment required. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Microwave	++	++	-	++	+	3	Specialised equipment

irradiation							required.
Decapitation	+	+	+	-	-	1 - if animal conscious 5 - if animal unconscious	For rabbits under 1 kg.
Carbon monoxide	+	+	++	-	++	1	Danger to operator.
Rapid freezing	+	+	++	++	+	1	To be used with foetuses under 4g

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

Rapidity: ++ very rapid, + rapid, - slow. **Efficacy**: ++ very effective, + effective, - not effective. **Ease of use**: ++ easy to use, + requires expertise, - requires specialist training. **Operator safety**: ++ no danger, + little danger, - dangerous. **Aesthetic value**: ++ good aesthetically, + acceptable for most people, - unacceptable for many people. **Rating**: 1-5 with 5 as most satisfactory.

Table 7 - Humane methods of killing dogs, cats, ferrets and foxes

Agent	Rapidity	Efficacy	Ease of use	Operator safety	Aesthetic value	Overall rating (1-5)	Remarks
Anaesthetic overdose	++	++	-	+	++	5	May be used with prior sedation of the animal.
NMB/ anaesthetic mixtures	++	++	-	+	+	4	To be injected intravenously, therefore requires expertise.
Shooting with a free bullet with appropriate rifles, guns and ammunition	++	++	-	-	-	4	To be used by experienced marksman. May need a method to ensure death.
Captive bolt	++	++	-	++	+	3	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Electrical stunning	++	++	-	-	-	3	Specialised equipment required. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Concussion	++	++	+	++	-	2	To be used on neonates. To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by

							another method.

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

Rapidity: ++ very rapid, + rapid, - slow. **Efficacy**: ++ very effective, + effective, - not effective. **Ease of use**: ++ easy to use, + requires expertise, - requires specialist training. **Operator safety**: ++ no danger, + little danger, - dangerous. **Aesthetic value**: ++ good aesthetically, + acceptable for most people, - unacceptable for many people. **Rating**: 1-5 with 5 as most satisfactory.

Table 8 - Humane methods of killing large mammals

Agent	Rapidity	Efficacy	Ease of use	Operator safety	Aesthetic value	Overall rating (1-5)	Remarks
Anaesthetic overdose	++	++	-	+	++	5	May be used with prior sedation of the animal.
Captive bolt	++	++	+	+	+	5	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Shooting with a free bullet with appropriate rifles, guns and ammunition.	++	++	+	-	+	4	To be used by experienced marksman. May need a method to ensure death. To be used in field conditions.
NMB/ anaesthetic mixtures	++	++	-	+	++	4	To be injected intravenously, therefore requires expertise.
Inert gases (Ar)	++	++	+	+	+	4	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method. Acceptable for pigs.
Electrical stunning	++	++	+	-	-	3	Specialised equipment required. To be followed

							by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.
Concussion	++	+	-	+	+	3 - if animal conscious 5 - if animal unconscious	To be followed by immediate exsanguination, or immediate destruction of the brain, or death to be ensured by another method.

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

Rapidity: ++ very rapid, + rapid, - slow. **Efficacy**: ++ very effective, + effective, - not effective. **Ease of use**: ++ easy to use, + requires expertise, - requires specialist training. **Operator safety**: ++ no danger, + little danger, - dangerous. **Aesthetic value**: ++ good aesthetically, + acceptable for most people, - unacceptable for many people. **Rating**: 1-5 with 5 as most satisfactory.

Table 9 - Humane methods of killing non-human primates

Agent	Rapidity	Efficacy	Ease of use	Operator safety	Aesthetic value	Overall rating (1-5)	Remarks
Anaesthetic overdose	++	++	-	+	++	5	May be used with prior sedation of the animal.

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

Rapidity: ++ very rapid, + rapid, - slow. **Efficacy**: ++ very effective, + effective, - not effective. **Ease of use**: ++ easy to use, + requires expertise, - requires specialist training. **Operator safety**: ++ no danger, + little danger, - dangerous. **Aesthetic value**: ++ good aesthetically, + acceptable for most people, - unacceptable for many people. **Rating**: 1-5 with 5 as most satisfactory.

ANNEX VI

List of elements referred to in Article 20(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.

9. Requirement of replacement, reduction and refinement.

ANNEX VII
List of elements referred to in Point (3) of Article 36

1. Relevance and justification of the following:

   (a) use of animals including their origin, estimated numbers, species and life stages;

   (f) 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.

LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS HAVING A BUDGETARY IMPACT EXCLUSIVELY LIMITED TO THE REVENUE SIDE

1. NAME OF THE PROPOSAL:

Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes and repealing Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes

2. BUDGET LINES:

Chapter and Article:

Amount budgeted for the year concerned:

3. FINANCIAL IMPACT

X Proposal has no financial implications

☐ Proposal has no financial impact on expenditure but has a financial impact on revenue – the effect is as follows:

(€ million to one decimal place)

Budget line	Revenue[32]	12 month period, starting dd/mm/yyyy	[Year n]
Article …	*Impact on own resources*		
Article …	*Impact on own resources*		

Situation following action					
	[n+1]	[n+2]	[n+3]	[n+4]	[n+5]

[32] Regarding traditional own resources (agricultural duties, sugar levies, customs duties) the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25 % of collection costs.

Article …					
Article …					

4. ANTI-FRAUD MEASURES

5. OTHER REMARKS